ID Cover Page

Tissue Structure Developer (TSD): Jellyfish-based Collagen as an Innovative Wound Healing Treatment

Group constitution:

Student Name	Program	Individual Title
Martin Christoph Gartmann	Management	TSD: Jellyfish-based Collagen as an Innovative Wound Healing Treatment – Business Development & Financial Structure

Work project carried out under the supervision of:

Advisor: Nuno Arantes-Oliveira

A Work Project, presented as part of the requirements for the Award of a Master's degree in Management from the Nova School of Business and Economics.

Abstract

TSD, a novel biotech venture, aims to revolutionise the wound healing market by utilising jellyfish, a new source of collagen. Its product, the CollaPatch™, harnesses the benefits of jellyfish collagen across social, environmental, and ecological dimensions, offering a superior alternative to bovine- and porcine-based collagen products for wound healing. TSD strives to capture significant market share in the treatment of both acute and chronic wounds by presenting a comprehensive business model, covering the diverse user and customer needs, existing and potential competitors, the optimal path to commercialisation, the required steps in the development roadmap and valuable funding and exit opportunities.

Keywords

Biotechnology, Biomedical Innovation, Business Strategy, Intellectual Property, Pharmaceutical, Competitive Analysis, Funding, Ulcers, Wound Healing, Chronical Wounds, Jellyfish, Marine Collagen, Venture Capital, Intrapreneurship, Entrepreneurship, Science-Based Entrepreneurship, Research and Development, Clinical Trials, Innovation

This work used infrastructure and resources funded by Fundação para a Ciência e a Tecnologia (UID/ECO/00124/2013, UID/ECO/00124/2019 and Social Sciences DataLab, Project 22209), POR Lisboa (LISBOA-01-0145-FEDER-007722 and Social Sciences DataLab, Project 22209) and POR Norte (Social Sciences DataLab, Project 22209).

Table of Contents

Executive Summary

We, Tissue Structure Developer (TSD), are pleased to introduce the CollaPatch™. Our innovative wound care product is based on the revolutionary scientific breakthrough of type 0 collagen, a unique universal collagen type that integrates the various features of multiple collagen types, all required for an optimal wound healing process, in just one molecule. Making use of this breakthrough, we have developed a wound patch that not only incorporates all state-of-the-art technologies in wound care, but also utilises type 0 collagen to significantly accelerate the wound healing process.

With the global wound care market currently being valued at $21.5 billion, at a compound annual growth rate (CAGR) of 5.9% projected, the market is expected to grow to $28.6 billion by 2032, creating an attractive opportunity for our CollaPatch™. This trend is consistent with chronic wound management becoming increasingly challenging, driven by an ageing population and rising diabetes prevalence. These conditions result in prolonged and costly care, placing a significant burden on healthcare systems. CollaPatch™ addresses these challenges with a highly biocompatible and ethically sourced formulation that accelerates healing and reduces overall healthcare costs.

Our strategy at TSD is to advance the CollaPatch™ through research and development (R&D) to the completion of clinical trial phase II. We estimate the cost of reaching this milestone at approximately €20 million. To achieve a return on investment, we aim to prepare our company for a strategic exit after phase II, targeting a valuation of approximately €250 million. We plan to achieve this by selling to a large pharmaceutical company that can fully commercialise the product. This approach is designed not only to demonstrate the efficacy of our CollaPatch™, but also to increase the likelihood of subsequent commercialisation to drive the wound care market forward in the long term.

1. Problem

The complex and dynamic process of wound healing exemplifies the body's remarkable ability to repair itself, yet significant hurdles often disrupt this intricate process, resulting in chronic wounds that refuse to heal (Schilrreff & Alexiev, 2022). From the moment an injury occurs, a carefully orchestrated sequence of events aims to restore skin integrity (Ibrahim et al., 2018). Collagen, a key protein in wound healing, provides structural support and facilitates cellular processes (Mathew-Steiner et al., 2021). Despite its importance, current collagen-based products face limitations such as biocompatibility issues, variable efficacy and ethical concerns due to their mammalian origin, which increases the risk of immunogenic reactions and disease transmission (Lee & Lee, 2016).

1.1. The Wound Healing Process

According to Ibrahim et al. (2018), the process of wound healing consists of a sequence of precisely organised steps that restore the structural integrity and functional capability of the injured tissue. The body's largest organ, the skin has complex reparative mechanisms that enable rapid and effective healing (Wilkinson & Hardman, 2020). According to a classical analysis, the wound healing response can be divided into four main phases: haemostasis, inflammation, proliferation, and dermal remodelling. Each of these processes are essential for completing tissue restoration (Wilkinson & Hardman, 2020). Haemostasis, which aims to stop bleeding by blood vessel constriction and clot formation, starts shortly after injury during the early phase of wound healing (Guo & DiPietro, 2010). This step prepares the body for the inflammatory phase, which is when infection is avoided, and the immune system is triggered to get rid of dead cells. During this stage, neutrophils, macrophages, and lymphocytes are important participants because they invade the wound site and release growth factors and cytokines that control the succeeding stages of healing (Ibrahim et al., 2018; Wang et al., 2022). Nevertheless, excessive inflammation can result in chronic wounds that never heal, which

emphasises the significance of a balanced inflammatory response (Wang et al., 2022). After inflammation, several cell types, including keratinocytes, fibroblasts, and endothelial cells, migrate and proliferate to restore the damaged tissue during the proliferative phase. This phase is characterised by the creation of collagen by fibroblasts and the generation of new blood vessels, or angiogenesis, which lays the groundwork for the growth of new tissue (Álvarez & Zuñiga, 2023; Mathew-Steiner et al., 2021). The maturation and reshaping of the newly created tissue and collagen occur during the remodelling phase, which is the last step of wound healing. This process might take many months to years, and it ultimately determines the strength and look of the healed area (Álvarez & Zuñiga, 2023).

Wounds can be classified based on their healing duration into acute and chronic wounds. Acute wounds usually heal in a matter of days to weeks, following the prompt, organised healing process mentioned above (Ibrahim et al., 2018). In contrast, chronic wounds are characterised by a failure to progress through the normal healing stages, leading to a state of prolonged inflammation, persistent infection, and necrosis (Schilrreff & Alexiev, 2022). They have higher protease levels, which lead to a persistent, self-reinforcing inflammatory environment (Gould, 2016). Such wounds are a significant burden on healthcare systems globally, primarily affecting the elderly and individuals with diabetes, and are associated with an increased risk of morbidity (Wilkinson & Hardman, 2020).

Infections and other wound complications can have a major effect on the healing process. Chronic wound problems can arise due to phase andfection, which can prolong inflammation, delay the initiation of the proliferation phase, and interfere with the regular healing phases (Schilrreff & Alexiev, 2022). The development of biofilms by pathogenic bacteria further complicates the treatment of infected wounds, as they are resistant to antibiotics and the host's immune response (Schilrreff & Alexiev, 2022).

1.2. The Role of Collagen in the Process of Wound Healing

The most prevalent protein in the body, collagen, is essential to the control of several biological processes that are involved in the healing of wounds. Collagen is produced in the healing wound by cells called fibroblasts, which then modify it into complex morphologies. Collagen serves as a natural substrate for cellular adhesion, proliferation, and differentiation in addition to giving tissues their mechanical strength and flexibility (Mathew-Steiner et al., 2021). The tensile strength of the repaired skin is dependent on the kind, quantity, and arrangement of collagen in the wound. Collagen type III is initially produced during the initial phases of wound healing and aids in cell adhesion and migration. Collagen I, the dominant collagen in the skin, eventually replaces this collagen, which is primarily involved in early repair and forms the granulation tissue. Collagen type I is induced by the oxidase enzyme to form covalent cross-links that allow it to mature into complex structures that are reoriented for the restoration of tensile strength. After the wound closes, the collagen continues to remodel for several months, during which time the healed tissue's tensile strength reaches 80–85% of that of normal tissue. In the skin, the fibrillar collagen types I, III and V are the most common, followed by fibril-associated collagens type XII, XIV, XVI, and VI. The non-fibrillar collagens type IV, XVIII are found in the basement membrane of the skin (Mathew-Steiner et al., 2021).

Notable is collagen's function in inflammation during wound healing. When injury exposes collagen to the bloodstream, the clotting cascade is triggered, resulting in a fibrin clot that halts the bleeding. Fragments of collagen types I and IV can function as strong chemo attractants for neutrophils, boosting phagocytosis and immunological responses and influencing gene expression (Mathew-Steiner et al., 2021).

When a wound heals, scarring is a normal by-product since the newly created tissue is not the same as the original in terms of texture or quality. Scars are a sign of effective healing, however extensive or hypertrophic scarring can cause functional limitations and aesthetic issues (Shen

et al., 2021). Factors contributing to impaired wound healing and excessive scarring include systemic conditions such as diabetes, poor nutrition, and specific medications, alongside local factors like infection and repeated trauma to the wound site (Guo & DiPietro, 2010).

Chronic wounds, on the other hand, typically heal slowly, incompletely, and uncoordinatedly, with poor anatomic and functional outcomes. A clinical expression of this phenomena is chronic, non-healing ulcers, which emphasises the significance of the wound cytokine profile and the essential balance required for normal healing to happen (Schultz et al., 2011). For instance, in diabetics, collagen is glycosylated, and even if the gene encoding collagen is highly expressed, there is less collagen deposited in wounds. This results in a net breakdown of the extracellular matrix and extended inflammation. It is accompanied by increased matrix metalloproteinase (MMP) and elastase activity, whereas tissue-derived inhibitors of metalloproteinases (TIMPs) are diminished (Gould, 2016).

1.3. Current Solutions & Their Limitations

Collagen-based wound healing remains one of the most intricate processes within the domain of healthcare. The journey to find effective wound healing products has been both diverse and challenging, reflecting the complexity of human physiology and the varying nature of wounds (Nguyen et al., 2023). Initially, this chapter delves into the broad spectrum of wound healing products, outlining their development from traditional remedies to advanced biomedical inventions. This exploration provides a foundation to understand the critical aspects of wound healing, including factors like speed, infection control, and tissue regeneration (Mirhaj et al., 2022).

As the narrative progresses, it is examined why certain materials excel in facilitating wound healing. Here, the focus sharpens on the characteristics necessary for ideal wound healing products, such as biocompatibility, efficacy, and safety (Nguyen et al., 2023). The discussion naturally leads to collagen, a standout material in the realm of wound care. Unlike dressings

that primarily function to protect the wound (like gauze or hydrocolloid dressings), maintain moisture (like hydrogels), or absorb exudate (like alginates or foam dressings), collagen dressings are actively involved in the healing process at a biochemical level (Shen et al., 2021; Zhang & Zhao, 2020). While other dressings might create an optimal healing environment, collagen directly interacts with the cell structure to stimulate and support the healing process (Ying et al., 2019).

A variety of such products, each designed with distinct functionalities, has been formulated to target various facets of the wound healing cascade (Lee & Lee, 2016). Collagen dressings, used in chronic wounds, act as substrates to assist in forming new tissue, but may be less effective in highly exudative wounds or those needing frequent dressing changes (Ying et al., 2019). Collagen sponges, improved with hyaluronic acid and fibronectin, enhance cell attraction and collagen deposition, yet might lack mechanical strength for diverse wound types (Sawaragi et al., 2023). Collagen hydrogels, with impressive structural properties, notably improve wound closure but can struggle to maintain consistent moisture over time (Jridi et al., 2015). Collagen-based scaffolds, critical for dermal substitution, provide a platform for cell growth but may not fully mimic the natural skin matrix's complexity and function (Ruszczak, 2003). Finally, collagen powder, aiding in chronic wound healing by stimulating cells, faces challenges in maintaining its stability and biological activity both in storage and upon application (Qureshi et al., 2019). In the context of wound healing, a diversity of collagen types is requisite for optimal tissue repair. However, the predominant composition of commercially available products is centred around collagen types I and III (Clore et al., 1979). This prevalence is attributed to several factors: their extensive applicability in various healing scenarios, the relative simplicity of their extraction process, and their abundant presence in typical mammalian sources. In contrast, the inclusion of other collagen types needed in a later stage

during the healing process, such as types V, VI and VII, is markedly limited in these products (Mathew-Steiner et al., 2021).

In conclusion, while collagen-based products play a critical role in wound healing, their application is met with considerable challenges that necessitate a nuanced, stage-specific approach. The reliance on mammalian collagen, particularly of bovine origin, introduces complexities including immunogenic reactions, variable efficacy, and the risk of disease transmission, which significantly impairs its practicality in clinical settings (Lee & Lee, 2016; Mathew-Steiner et al., 2021). These limitations, along with the high costs and partial resolution of complications associated with these products, underscore a critical need for continued innovation and improvement in wound healing methodologies (Harding & Queen, 2017). There is a clear imperative for advancing wound healing methodologies by exploring alternative sources like marine collagen and refining existing collagen-based strategies (Salvatore et al., 2020). This evolution in wound healing practices is essential not only for enhancing the efficacy of treatments but also for reducing potential risks, thereby contributing to more effective and safer healthcare solutions (Mathew-Steiner et al., 2021).

2. Opportunity

Recent research has identified a collagen source that provides multiple collagen types in one, significantly expanding the possibilities for innovative medical applications. Jellagen, the laboratory behind this breakthrough, extract the so-called “type 0 collagen” from the *Rhizostoma pulmo* jellyfish off the coast of the UK. Collagen type 0, or "stem collagen", integrates the functionalities of several collagen types essential for different stages of wound healing into a single, versatile biomaterial, and works as a generalist source (Spragg et al., 2020).

Although jellyfish collagen has been known as an alternative to conventional collagen sources since the 2000s, it has never been a truly viable option, partly because previous extraction

methods were inefficient and costly, and partly because the added value of jellyfish collagen had not been explored at the time. This made it unattractive for commercial usage. With recent research presenting more efficient extraction methods and the advanced benefits, this opens the door to multiple medical applications (Khong et al., 2018).

This development not only opens a new chapter in the field of sustainable and ethically sourced biomaterials, but also presents a unique opportunity to address and mitigate several pressing concerns associated with conventional collagen sources. Through the lens of emerging potential in biomedical applications, jellyfish type 0 collagen provides an opportunity that holds advanced medical benefits over conventional collagen sources (Alkildani et al., 2021).

2.1. Jellyfish Collagen

Traditional collagen sources, such as bovine and porcine collagens, have long been used in various biomedical applications due to their structural and functional compatibility with human tissues. However, concerns about the transmission of zoonotic diseases, ethical dilemmas regarding animal welfare and the potential allergenicity of mammalian collagen have driven the search for alternatives. Such challenges have catalysed the need for safer, more sustainable, and ethically sourced biomaterials, with jellyfish collagen emerging as a prominent candidate due to its distinctive advantages (Addad et al., 2011).

Offering several advantages over mammalian collagens, such as being less dependent on religious restrictions, getting cheaper with advanced extraction methods, as well as offering an addition to existing sources with the increasing demand of a growing population, jellyfish collagen identifies as an attractive alternative (Addad et al., 2011; Alkildani et al., 2021; Khong et al., 2018).

Recent research conducted by Jellagen classifies jellyfish collagen as a generalist collagen with a higher degree of molecular simplicity that results into greater flexibility in tissue structure and multifunctionality. The fact that jellyfish collagen combines the properties of several different

types of collagens in a single molecule indicates jellyfish collagen as a generalist. Consequently, Jellagen uses the name “type 0 collagen” to refer to jellyfish-derived collagen (Spragg et al., 2020).

Characterised by its biocompatibility, minimal risk of disease transmission and unique biochemical properties, type 0 collagen has attracted attention for its potential in medical applications, particularly in tissue engineering (Addad et al., 2011; Pesterau et al., 2023).

Type 0 collagen has demonstrated its ability to serve as an ideal scaffold material in tissue engineering and regeneration due to its generalist collagen properties. These scaffolds support the growth and maturation of cells into functional tissues, which is essential for the advancement of regenerative medicine strategies. Biocompatibility and bioactivity of jellyfish collagen, demonstrate its supportive role in cell adhesion, proliferation, and differentiation. Furthermore, the hypoallergenic nature and safety profile of jellyfish collagen, combined with its sustainability and ethical sourcing, underscore its attractiveness amongst other for medical applications, potentially enhancing the functional integration of engineered tissues into the human body (Alkildani et al., 2021; Pesterau et al., 2023).

The work of Khong et al. (2018) represents a pivotal moment in the exploitation of jellyfish collagen through the introduction of a physically induced solubilisation process, which significantly increased the yield of collagen extraction beyond conventional methods (Khong et al., 2018). These innovative methods have streamlined the process, making jellyfish collagen more accessible, while also improving its purity (James et al., 2023). By maintaining the integrity and biocompatibility of the extracted collagen, this method paves the way for its wider application in the biomedical industry, thus providing a tangible opportunity to utilise jellyfish collagen as a competitive and sustainable biomaterial, opening the door to the commercial scalability of jellyfish collagen (Addad et al., 2011; Pesterau et al., 2023).

2.2. Benefits of Type 0 Collagen in the Wound Healing Process

Jellyfish derived type 0 collagen has a unique mode of activity that significantly enhances the wound healing process. Its structure closely mimics the human extracellular matrix (ECM), providing a more favourable environment for cell attachment, migration, and proliferation - key processes in tissue regeneration. This compatibility facilitates the early stages of wound healing when rapid cellular activity is critical for wound closure (Khong et al., 2018).

In addition, type 0 collagen has an enhanced ability to modulate the MMP activity. This modulation is critical for the remodelling phase of wound healing, where the balance between collagen deposition and degradation determines the functional and aesthetic quality of the healed tissue. By fine-tuning MMP activity, jellyfish collagen ensures a more controlled remodelling process, reducing the risk of hypertrophic scarring and improving the overall healing outcome (Felician et al., 2019; Salvatore et al., 2020).

The incorporation of type 0 collagen into the ECM not only supports structural repair, but also actively participates in signalling pathways that promote healing. It has been shown to enhance the recruitment and proliferation of fibroblasts, which are essential for the synthesis of new collagen fibres, and to support angiogenesis, ensuring adequate blood supply to the healing tissue. This multifaceted support accelerates the proliferation phase and smoothly transitions to remodelling (Felician et al., 2019). In addition, collagen type 0 stimulates tissue regeneration by modulating macrophage activity. It increases M2 macrophages, which encourage tissue repair and regeneration, and decreases M1 macrophages, which are known to cause inflammation, thereby preventing a prolonged inflammation phase, and enhancing the overall healing efficacy. As a result, a recent study by Jellagen showed that wounds treated with collagen type 0 reached 80% of closure nearly twice as quickly as those untreated. Additionally, collagen type 0 demonstrated superior uniformity, ensuring complete and consistent closure of

the final 20% of the wounds, compared to wounds treated with mammalian collagen sources (see Appendix A) (Spragg et al., 2020).

The role of type 0 collagen as a generalist is particularly beneficial in the wound healing process, where different types of collagens are required at different stages. For example, while type I collagen is crucial for strength and structure, type III collagen plays a key role in the early stages of wound repair, and type IV collagen supports basement membrane repair. Type 0 collagen, with its versatile nature, can effectively fulfil the roles of these specific collagen types, acting as a universal scaffold to support all phases of wound healing, from haemostasis to remodelling (Flaig et al., 2020). This versatility extends to its application in tissue engineering, where the need for different collagen types can complicate scaffold design. By using type 0 collagen, researchers and clinicians can simplify the development of regenerative therapies, making them more efficient and widely applicable (Song et al., 2006).

Overall, the utilisation of jellyfish-derived type 0 collagen introduces an innovative breakthrough in wound healing and tissue engineering. Its improved mode of action, superior ECM integration, and role as a generalist collagen offer significant advantages over conventional collagen sources. This breakthrough not only enhances the physiological wound healing process but also opens new avenues for the development of advanced biomedical applications, promising better outcomes for patients worldwide (Felician et al., 2019).

2.3. Economic, Ecologic, and Social Benefits of the Use of Jellyfish-Collagen

Jellyfish collagen emerges as a promising and multifaceted alternative to traditional sources of collagen, offering a unique blend of economic, ecological, and social benefits.

In the economic realm, the use of jellyfish as a source of collagen presents a highly cost-effective solution. The cultivation and maintenance of jellyfish for collagen extraction are significantly less resource-intensive compared to traditional livestock farming, which involves high costs associated with feeding, land use, and animal welfare management. Furthermore,

jellyfish offer a higher yield of collagen per individual compared to common livestock, making the process more efficient and sustainable (Khong et al., 2018). Additionally, the burgeoning interest in marine-derived bioproducts positions jellyfish collagen as a high-value commodity in the global market, enhancing its potential for generating substantial economic returns. This aspect is particularly vital considering the growing demand for alternative and sustainable sources of collagen in various industries, including pharmaceuticals, cosmetics, and food production (Pesterau et al., 2023).

From an ecological standpoint, harvesting jellyfish for collagen is inherently sustainable and contributes positively to the health of marine ecosystems. Unlike the extraction of collagen from traditional marine sources, such as fish, which often disrupts marine biodiversity and leads to overfishing, the utilisation of jellyfish is less likely to cause such ecological imbalances. This practice is partly due to the abundance and rapid reproduction rates of jellyfish, which ensure a steady and sustainable supply without the risk of overharvesting (Coppola et al., 2020). In addition, the controlled harvesting of jellyfish can aid in managing their populations, which is crucial in regions where jellyfish blooms pose environmental and economic threats to marine systems and fisheries. This management can inadvertently lead to the preservation and restoration of affected marine habitats and species, thereby enhancing overall marine biodiversity (Edelist et al., 2021).

Moreover, jellyfish collagen stands out due to its substantial social and health benefits. It notably differs from mammalian collagen, often linked to allergies and ethical issues, by exhibiting higher biocompatibility and reduced allergenicity (Alkildani et al., 2021). These characteristics not only diminish the risk of allergic reactions but also address ethical and religious concerns associated with animal-derived products, making it a favourable option for those with specific dietary, ethical, or religious considerations (Chiarelli et al., 2023). Furthermore, the extraction and processing of jellyfish collagen can stimulate socio-economic

growth in coastal communities by creating jobs, especially where traditional fisheries are in decline. This encompasses roles in harvesting, processing, and sustainable jellyfish farming, enhancing economic resilience (Coppola et al., 2020). Moreover, the burgeoning jellyfish collagen industry may drive research and innovation, notably in medical fields like wound healing and tissue engineering, promising significant healthcare advancements, especially in resource-limited areas (Geahchan et al., 2022).

In conclusion, jellyfish collagen emerges as a groundbreaking, sustainable, and ethically sourced alternative to traditional mammalian collagen. Technological advancements have enhanced its commercial viability, particularly in medical fields like tissue engineering and wound healing. Jellyfish collagen's biocompatibility, hypoallergenic nature, and structural similarity to human ECM address the limitations of mammalian collagens. It effectively modulates MMP activity, supporting various stages of healing. Economically, it offers cost-effectiveness and higher yields, while benefiting marine ecosystems and coastal communities. This makes jellyfish collagen a superior choice in the collagen market, aligning with global trends towards sustainable, ethically responsible resources and promising further innovations in healthcare and biomaterials.

3. Solution

In today´s rapidly evolving healthcare landscape, TSD, as an innovative, cutting-edge venture is poised to revolutionise wound healing concepts. Therefore, we aim to disrupt the traditional approaches of wound healing treatment by pioneering the development of the CollaPatch^{TM}, an advanced medical product tailored for enhanced wound healing. Our CollaPatch^{TM}, an innovative wound patch, is integrating the breakthroughs in biotechnology with type 0 collagen to accelerate tissue regeneration, while simultaneously combating infection effectively. The company´s overarching goal is to maximise both the market and therapeutic value of the CollaPatch^{TM} by strategically navigating through the early stages of development with a view

to divestment at the completion of Phase 2 of the clinical trials and consequently de-risking further commercialisation approaches.

TSD is committed to address the urgent needs of patients for quicker healing processes and of healthcare providers for reliable, effective treatments. By focusing on innovative, patient-centred solutions, TSD aims to significantly advance current standards in wound care. At the core of its vision is the positioning of the CollaPatch^{TM} as a transformative force in wound care, using advanced biotechnology to redefine standards of treatment efficacy and patient comfort worldwide.

3.1. Target Product

As type 0 collagen from jellyfish provides the highest added value in tissue regeneration, the focus will henceforth be on the treatment of acute wounds, such as abrasions, incisions or burns, as well as chronical wounds. In the treatment of such wounds, both healthcare professionals and patients prioritise different features, either to speed up healing, reduce complications, or favour comfort. The ideal wound dressing should balance clinical efficacy with patients valued attributes.

Extensive inputs from Dr. Till Ossenkop (Pharmacist), Dr. Hans Peter Weinschenk (Pharmacist) and Dr. Sabine Coulon (Doctor of Medicine) underline the exceptional efficacy of closed wound dressings for wound management and identifies these as most widely adopted. Further, the interviewed healthcare professionals outlined, that an optimal wound dressing should provide a comprehensive approach to wound management, effectively preventing infection and creating an environment conducive to healing (Coulon, 2024; Ossenkop, 2024; Weinschenk, 2024). Key features include:

- **Barrier function against micro-organisms**: This critical feature prevents the ingress of bacteria and pathogens, significantly reducing the risk of infection.

- **Antimicrobial properties**: The integration of antimicrobial substances actively fights infections.
- **Sterility**: Sterile packaging is essential to prevent the introduction of new pathogens.
- **Moisture retention**: A moist environment is promoted, facilitating faster and more efficient healing.
- **Exudate management**: Maintains optimal moisture levels, preventing wound dryness or damage to surrounding skin.
- **Gas permeability**: Essential for healing, this feature allows for the necessary gas exchange.
- **Durability and Resilience**: The dressing withstands physical stress, reducing the need for frequent changes.
- **Compatibility with medical procedures**: Ensures the dressing does not interfere with diagnostic tests or treatments.
- **Bioactivity and tissue regeneration**: The incorporation of type 0 collagen significantly enhances this aspect. It supports cellular healing processes and tissue regeneration by providing a scaffold for new tissue growth, making it a key advancement in wound care.

Information on customer prioritised attributes of an optimal wound dressing was obtained from a comprehensive open survey conducted by 33 participants (see Appendix B).

Users prioritise:

- **Comfort**: A high level of comfort provided by the dressing's ability to conform to body contours was highlighted as critical. A dressing that fits the body seamlessly is perceived as less intrusive and more comfortable for daily activities.
- **Handling** (application/replacement): Ease of use, especially when applying and changing the dressing, was identified as a key factor. Consumers prefer dressings that are easy to apply and change without causing pain or interfering with wound healing. A

- self-adhesive design that provides secure adhesion without causing pain when removed is highly valued.
- **Water resistance**: Another important feature is water resistance. Consumers appreciate a dressing that retains its functionality and protects the wound when exposed to water, such as showering, without the need for immediate replacement.
- **Appearance**: The aesthetic appearance of the dressing is also important. Consumers prefer a discreet design that blends in with their appearance and does not draw attention to itself.

Other attributes highlighted include breathability to prevent moisture build-up under the dressing and flexibility to allow unrestricted movement. These findings emphasise the importance of a holistic approach to wound dressing development, going beyond wound healing to improve user comfort and ease of use.

The introduction of type 0 collagen into closed wound dressings represents a significant advancement in wound care. This innovative addition will significantly enhance tissue regeneration capabilities and set new standards for clinical efficacy. The proposed target product combines the best features of closed wound dressings with the regenerative benefits of type 0 collagen. This advanced dressing should not only deliver high efficacy, pioneering a new approach to healing that promises faster and more extensive tissue regeneration, but also incorporate the highest standards of comfort. With this product, the aim is to redefine excellence in wound care, ensuring superior healing outcomes and an improved patient experience.

3.2. Patients Journey

Within the figure shown below, the potential journey of Michael Thompson is demonstrated and all stages he might have to go through to find an effective treatment.

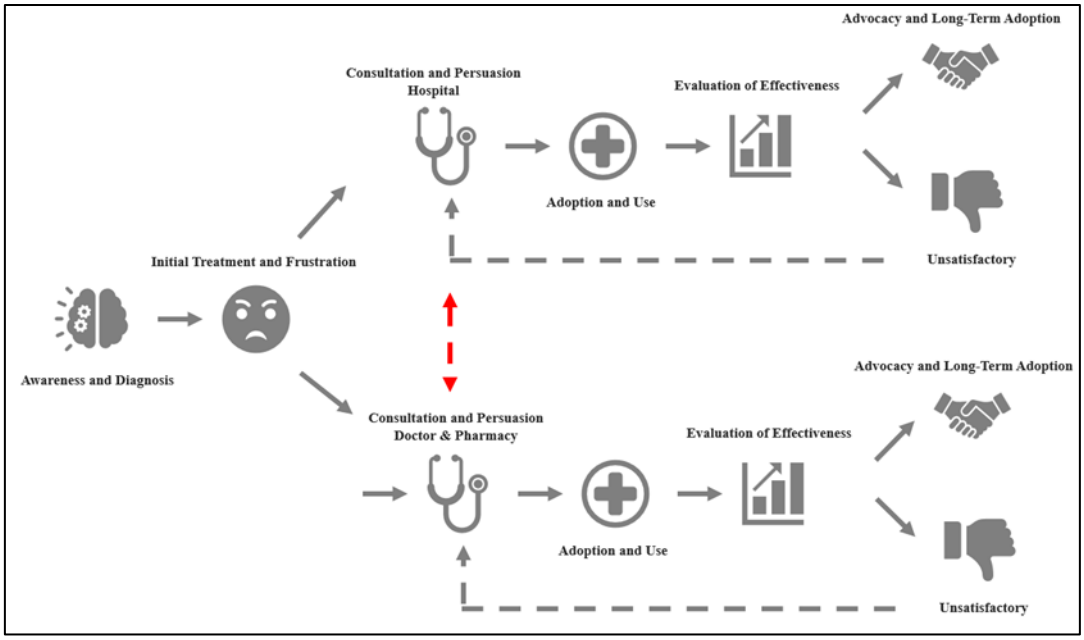


Figure 1: User Journey

Awareness and Diagnosis: Michael's journey starts when he recognises the symptoms of his condition - persistent pain and non-healing wounds - which leads to a diagnosis of chronic diabetic foot ulcers. This is the "Awareness and Diagnosis" stage, represented by the brain with gears (a problem is identified).

Initial Treatment and Frustration: Michael begins with standard treatments, such as traditional dressings or topical medications. However, he encounters "Initial Treatment and Frustration," symbolised by the sad face, as these conventional treatments do not lead to significant improvement, causing him distress.

Consultation and Persuasion: Michael is then exposed to two possible routes that are typical for the German healthcare market in particular: **Doctor & Pharmacy:** He consults with his primary care physician or a pharmacist who might recommend the CollaPatch^{TM} to him.

Hospital: Alternatively, during a more severe episode that requires hospital attention, he might be introduced to the CollaPatch^{TM} as a new treatment option within the hospital setting.

Adoption and Use: After consultations, Michael decides to adopt the new treatment, symbolised by the pill icon. He begins using our product with guidance from his healthcare providers.

Evaluation of Effectiveness: Over time, the effectiveness of the CollaPatch™ in healing his foot ulcers is evaluated, represented by the chart icon. Michael and his doctor monitor the wound for signs of improvement.

Advocacy and Long-Term Adoption: If Michael's treatment is successful, leading to faster healing and improved quality of life, he reaches the "Advocacy and Long-Term Adoption" stage. Here, the handshake icon indicates his likely recommendation of the product to others with similar conditions and his continued use of the CollaPatch™ for any future wounds.

Unsatisfactory: If the treatment doesn't yield the desired results or if Michael experiences any side effects, the thumbs-down icon indicates his dissatisfaction. This may lead him to consult his doctor’s office again or be likely to switch to another doctor, hospital, or pharmacy.

The outlined patient journey, combined with the detailed persona of Michael Thompson, illustrates how a patient might progress through the stages of treatment for a chronic medical condition. It also demonstrates potential decision-making points and outcomes, offering insight into the patient experience from initial problem recognition to the adoption and advocacy or rejection of any medical product.

3.3. Doctors, Hospitals, and Insurances

Understanding the interplay between doctors, hospital management, and insurance companies is crucial for successfully introducing our product into the German healthcare market. This complexity stems from the distinct, yet interconnected roles each party plays in the healthcare system. Starting off with the journey of our previously descripted persona, Dr. Ford:

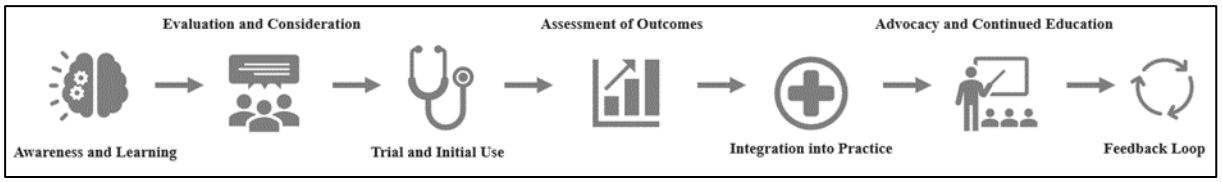


Figure 2: Dr. Fords Journey

Awareness and Learning: The journey begins as Dr. Ford encounters new product information through medical journals, conferences, or by current hospital suppliers, which is the most likely scenario. This initial awareness might also come from professional networks or continuing education.

Evaluation and Consideration: Dr. Ford evaluates new products by reviewing clinical data, safety profiles, and efficacy reports, consulting with peers who have used the product and participating in online medical communities.

Trial and Initial Use: Dr. Ford trials the CollaPatch^{TM} on a selected group of patients with chronic, non-healing wounds, closely monitoring effectiveness and any side effects, while also training the medical team on its application.

Assessment of Outcomes: Dr. Ford assesses patient outcomes focusing on wound closure rate, pain management, and patient satisfaction, comparing these results to those achieved with traditional treatments.

Integration into Practice: If trial results are favourable, the CollaPatch^{TM} is integrated into regular practice for appropriate cases, with the doctor developing specific protocols for its use.

Advocacy and Continued Education: If convinced of its benefits, Dr. Ford may advocate for our products broader use, sharing results through case studies at conferences, workshops, or in medical publications.

Feedback Loop: Dr. Ford continues to collect data and feedback, refining treatment protocols and providing feedback to the hospital's supplier for potential improvements.

In Germany, doctors are the primary influencers of medical product adoption, relying on both clinical efficacy and regulatory approval to recommend new treatments. However, their decisions are heavily influenced by hospital management policies and the procurement strategies that dictate available medical products and technologies. Hospital management must balance clinical needs with budgetary constraints and compliance with health policies, which often necessitates a careful selection process involving tenders and negotiations with suppliers. Furthermore, insurance companies wield significant power through their reimbursement policies, which determine whether a treatment can be affordably accessed by patients. These companies require rigorous evidence of a product's cost-effectiveness and long-term benefits to include it in their coverage schemes. The German system, with its emphasis on cost containment and quality care, often necessitates that new treatments like TSDs CollaPatch™ demonstrate clear clinical and economic advantages over existing solutions.

To effectively introduce the CollaPatch™ into German hospitals, a comprehensive strategy is necessary. This starts with developing educational marketing materials to highlight the scientific and clinical benefits of the product, targeting key decision-makers like chief medical officers and department heads in dermatology or wound care. Furthermore, partnering up with well-known suppliers and producers is crucial since well-established supply chains do not have to be interrupted and the hospital does not have to switch any of its producers. Additionally, our product can be shown at medical conferences and enhance its credibility through key opinion leaders. Publishing in peer-reviewed journals is also crucial for scientific validation. Partnering with hospitals for pilot studies is essential to evaluate CollaPatch™'s efficacy and user satisfaction compared to existing treatments, including rigorous data collection and feedback integration. Understanding hospital tender processes and articulating a clear value proposition that emphasises clinical and economic benefits, such as reduced treatment times, is critical for procurement. Compliance with quality standards reassures procurement committees

of the product's safety. For insurance reimbursement, navigating the Diagnoses Related Groups (DRG) system, possibly applying for New Examination and Treatment Method (NUB) status, and preparing economic data to demonstrate cost-effectiveness are vital. Direct engagement with insurance companies and preparing for health technology assessments, supported by

endorsements from clinical champions, are key for securing coverage. This strategic approach navigates the complex interactions between hospital adoption and insurance processes in Germany.

4. Competitors

In this chapter, we focus on identifying competitors in the wound care market, categorising them into direct, indirect, and potential competitors. Direct competitors include those offering similar collagen-based wound care products, crucial for understanding our market position and strategy. Indirect competitors encompass a range of alternative wound care solutions like foam dressings and Negative Pressure Wound Therapy (NPWT), serving similar patient needs (Pollak, 2008). Additionally, we must consider potential competitors, who may operate outside the wound care market or perhaps have products under development and will have the capability to become direct competitors. This comprehensive analysis is essential for strategic planning and maintaining a competitive edge in the evolving wound care market.

4.1. Direct Competitors

Within the chapter of direct competitors in the wound care market, we delve into the analysis of companies that directly parallel our product offerings in terms of technology and market approach. This section aims to dissect the strategies, product offerings, and market positions of firms specialising in collagen-based wound care solutions. By closely examining these competitors, we can better understand the market dynamics, identify key areas for

differentiation, and sharpen our competitive edge. This analysis is crucial in framing our strategic responses and aligning our product development to effectively meet market demands.

Human BioSciences is recognised for its pioneering work in collagen-based wound care products, notably through their first FDA-cleared product, Kollagen™. Their product range includes various forms such as SkinTemp® II and Collatek® Gel, emphasising innovation in biocompatible and advanced healing solutions. Kollagen™ stands out for its proprietary technology that preserves the native triple helix structure of collagen, ensuring stability and effectiveness throughout all wound healing phases (Human BioSciences, 2024).

Covalon, another key player in this market, offers products like ColActive® Plus and ColActive® Plus-AG, which combine collagen with antimicrobial silver. Their focus is on infection control and promoting faster healing while minimising scarring. Covalon is recognised for its innovative solutions in wound care, emphasising the incorporation of antimicrobials to prevent wound infections (Covalon, 2024).

3M Health Care contributes to the market with its 3M™ Promogran™ Collagen Matrix with ORC, a unique blend of 45% oxidised regenerated cellulose and 55% collagen. This product, designed for sterile, freeze-dried application, aids in creating a moist wound healing environment. 3M's reputation in healthcare innovation is reflected in their approach to wound healing, which combines different materials for optimal outcomes (3M Health Care, 2024).

L&R, Inc. offers BIOCOL™, a bovine collagen powder that forms a gel to provide a moist wound healing environment. This product focuses on reducing inflammation and promoting cellular regeneration, highlighting L&R's emphasis on natural healing processes and the use of bovine collagen (L&R USA, 2024).

Smith+Nephew, Inc. distinguishes itself with the BIOSTEP* Collagen Matrix, targeting excess Matrix Metalloproteinases in chronic wounds to optimise wound closure. Known for its high conformability and ease of application, Smith+Nephew focuses on managing chronic

wounds and optimising the healing process through biochemical interventions (Smith+Nephew, 2024)

Lastly, **HARTMANN, Inc**. brings to the market ColActive® Plus Collagen Sheets and Powder, featuring fish-derived collagen and Ethylenediaminetetraacetic Acid to target elevated MMP activity. These products also incorporate alginate and carboxymethyl cellulose to maintain an optimal moisture balance, reflecting HARTMANN's commitment to advanced wound care solutions that combine collagen with other materials for enhanced healing environments (HARTMANN, 2024).

4.2. Indirect Competitors

In the German wound care market, several non-collagen-based products emerge as potential substitutes for collagen-based dressings in the treatment of chronic wounds. Foam dressings are highly absorbent, ideal for wounds with heavy exudation, while hydrocolloid dressings support moist healing environments for ulcers and pressure sores (Dumville JC & Speak, 2013; Trucillo & Di Maio, 2021). Alginate dressings, made from seaweed, excel in absorbing excess fluid from heavily exuding wounds (Zhang & Zhao, 2020). Antimicrobial dressings, which may contain silver, iodine, or honey, help prevent or treat infections in chronic wounds (Lin et al., 2019). NPWT uses suction to enhance healing in complex wounds, and skin substitutes or regenerative products facilitate skin regeneration in severe cases like burns and ulcers (Pollak, 2008). Each product type offers specific advantages for different wound conditions, underscoring the importance of tailored wound care management. As our target market is mainly focused on chronic wounds such as ulcers this should be taken into consideration while analysing indirect competitors:

While **3M and Smith + Nephew** have been mentioned already, it is important to note that both companies account as direct and indirect competitors, since both companies have a wide range of products focusing on the wound care market in its entirety. 3M is a multifaceted industry

corporation with a strong presence in healthcare and advanced wound care, offering a variety of high-quality wound dressings and a reputation for merging innovation with practical healthcare solutions (3M Health Care, 2024). Smith + Nephew, meanwhile, is a medical technology leader focused on advanced wound management, delivering a wide range of clinically tested products, with a strong commitment to research and development to stay at the cutting edge of the field (Smith+Nephew, 2024).

ConvaTec presents a diverse array of wound care solutions, catering to a wide spectrum of wound types and stages. Their innovative approach is evident in products like unique foam dressings and hydrocolloids. With a strong global market presence, ConvaTec is backed by extensive research and is renowned for its patient-centered products (ConvaTec, 2024).

Mölnlycke Health Care specialises in providing medical solutions, with a strong emphasis on wound care. They offer a range of products, including foam and antimicrobial dressings, tailored for effective wound management. Mölnlycke is particularly valued for its focus on quality and patient comfort, ensuring their products are both effective and gentle for wound care (Mölnlycke Health Care, 2024).

Coloplast focuses on developing user-friendly and efficient wound care products. Their range, including hydrocolloid and foam dressings, is designed with patient comfort and ease of use in mind. Coloplast's products are widely used and trusted in healthcare settings around the world, reflecting their commitment to quality and innovation (Coloplast, 2024).

B. Braun offers a wide range of healthcare solutions, with wound care being a significant part of their portfolio. Their offerings include various types of dressings and skin care products, known for their quality and efficacy. The company is committed to patient care and safety, focusing on providing reliable and effective wound management options (B. Braun, 2024).

4.3. Potential Competitors

In the evolving landscape of advanced wound care, identifying the most formidable competitors for our product requires a focus on companies that are pioneering in biocompatible materials and regenerative properties. While there are lot of ideas and companies forming around advanced wound care, it is important to note that many are focusing on other elements such as new technologies for early-stage diagnosis, innovative therapies to find the right treatment for every stage, surgical aids, and wound protection. Determining the top five closest competitors to our CollaPatch^{TM} involves considering companies that are innovating in the area of advanced wound dressings, particularly those focusing on biocompatible materials and regenerative properties. Leading the charge is **Organogenesis**, a company known for its innovative use of living cells and naturally occurring materials in products such as Apligraf and Dermagraft. Their dedication to regenerative medicine aligns closely with the biocompatible aspect of jellyfish collagen (Organogenesis, 2024).

Another notable player is **MiMedx**, which specialises in regenerative biomaterials. Their product, EpiCord Expandable, derived from the umbilical cord, mirrors the natural and regenerative properties of a collagen wound patch. Their focus on biologically active wound care solutions earmarks them as another potential competitor (MiMedx, 2024).

Fibroheal Woundcare's use of silk proteins as biomaterials for active wound management, including dressings and gels that promote tissue regeneration, draws a parallel to the natural and healing-oriented approach of jellyfish collagen. This focus on biomaterials for tissue regeneration places them in the realm of direct competition (Fibroheal, 2024).

Similarly, **RenovoDerm's** approach, particularly with their Phoenix Wound Matrix that leverages 3D scaffold technology for in-situ tissue regeneration, reflects the regenerative aspect of jellyfish collagen patches (RenovoDerm, 2024). Lastly, **Gel4Med**'s development of advanced biomaterials, such as G4Derm and G4Derm Plus, which aim to mimic the

extracellular matrix and provide antibacterial barriers, is akin to the natural healing facilitation offered by jellyfish collagen. Their emphasis on biomimicry and wound healing efficacy aligns them closely as a competitor (Gel4Med, 2024).

4.4. Competitive Advantage

Based on the perceptual map shown in figure 5, direct-, indirect- and potential- competitors are visualised on the following parameters, firstly, the breadth of application in terms of wound healing stages (x-axis) and the volume of product usage (y-axis). This mapping aids in visualising the competitive landscape, direct- and indirect- competitors, and potential market entrants in order to understand where to position ourselves relative to others in terms of product versatility and usage frequency.

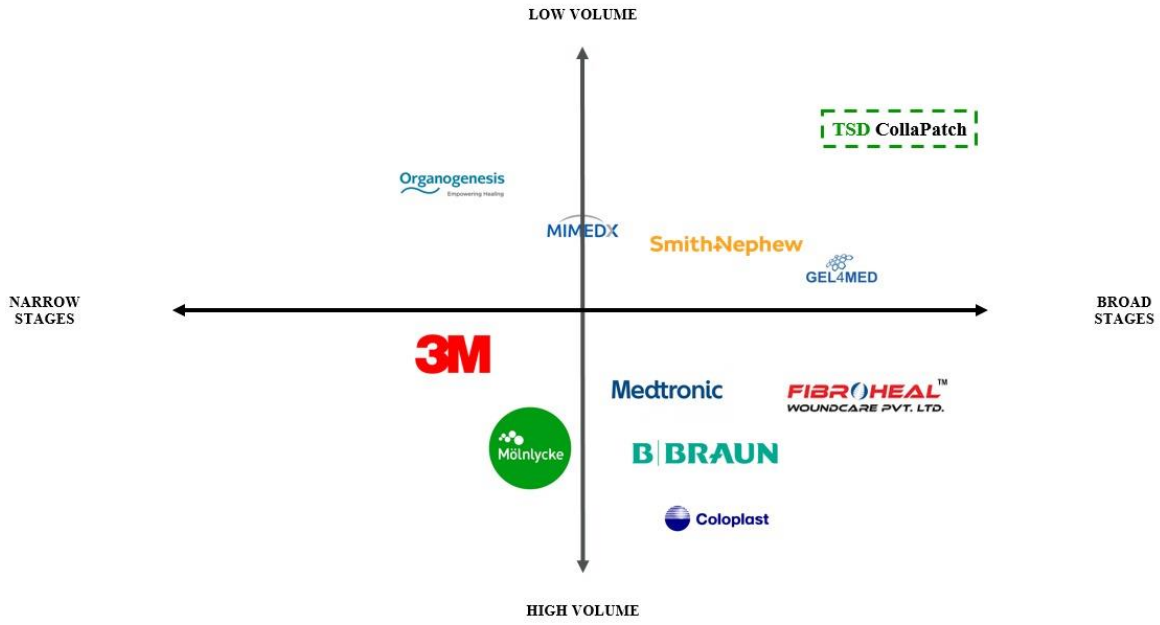


Figure 3: Perceptual Map

On the x-axis, we have "Narrow Stages" on the left and "Broad Stages" on the right, which indicates whether the companies' products are specialised for specific stages of wound healing or can be used across multiple stages. For instance, companies placed towards the "Narrow Stages" end would have products designed for a particular phase of wound healing, whereas those towards "Broad Stages" provide solutions that cover a range of healing stages. On the y-

axis, "Low Volume" at the top indicates companies whose products require a smaller amount or less frequent application. "High Volume" at the bottom signifies companies whose products are used in larger quantities or more frequently. Quick breakdown of the competition:

- **Mölnlycke:** Positioned centrally on the x-axis but lower on the y-axis, suggesting that their products have a moderate range of applications in wound healing stages and require a high volume of product usage.
- **Medtronic, B. Braun, and Coloplast:** These companies are centred on the x-axis, which means their products are likely versatile across different wound healing stages. They are placed variably on the y-axis, with Coloplast notably lower, implying higher volume use.
- **3M:** Located at the origin, suggesting an average application range and volume usage.
- **Organogenesis and MiMedx**: These companies are towards the "Low Volume" and "Narrow Stages" quadrant, indicating specialised, infrequently used products.
- **Smith&Nephew and GEL4MED:** These are positioned towards the "Broad Stages" but still closer to the centre on the y-axis, suggesting a wide range of application with moderate volume usage.
- **FIBRHEAL**: Found on the far right, close to the "High Volume" on the y-axis, indicating that their products are used across all stages and in higher quantities.

TSDs CollaPatch^{TM} is strategically positioning itself in the market with its type 0 collagen solution, which is versatile enough to be used across all stages of wound healing without requiring modification for different phases. Wound patches can be worn for a duration of 5-8 days, as the CollaPatch^{TM} effectively shortens the healing time for chronic wounds, this can significantly reduce the frequency of application. The following attributes provide a competitive advantage over other existing products within the Market:

- **Enhanced Tissue Regeneration – Effectiveness**: Unlike our direct competitors whose products are mainly based on mammalian collagens sources, that often induce inflammation, the CollaPatch™ promotes tissue regeneration. This is attributed to its ability to modulate macrophage responses—decreasing the M1 macrophages which are pro-inflammatory and increasing the M2 macrophages which aid in tissue repair. Utilising this technology, it has been reported that the healing process in chronic wounds can be accelerated by up to 80% compared to untreated wounds and much better chances of closing chronic wounds compared to those treated with products derived from bovine collagen sources (Spragg et al., 2020). This finding was underlined by another study that focused on the physiological mechanisms of healing in chronic diabetic wounds (Sumiyoshi et al., 2021).
- **Biocompatibility and Ancestral Simplicity:** The CollaPatch™ is inherently biocompatible with human tissues due to its simpler chemical structure, which is ancestrally more ancient than any other collagen source. Resulting in far less adverse reactions such as inflammation. This simplicity allows for better integration and less complexity in interaction with human tissues (Khong et al., 2018).
- **Safety & Allergy free:** The CollaPatch™ does not cause allergic reactions, offering an advantage over most mammalian collagens which can induce such responses, furthermore it lacks the risk of transmitting diseases such as bovine spongiform encephalopathy, which are typical concerns with mammalian collagen sources (Spragg et al., 2020).
- **Multi-phase Efficacy:** The CollaPatch™ acts as a universal scaffold, effectively fulfilling the roles of various collagen types needed across different healing phases, from hemostasis to remodelling. It supports essential processes like fibroblast recruitment and angiogenesis, key to tissue regeneration (Khong et al., 2018).

- **Modulation of MMP Activity:** The CollaPatch™ modulates MMP activity. This is crucial during the remodelling phase of healing, thus improving the aesthetic and functional quality of healed tissue and reducing scarring (Salvatore et al., 2020).

As TSD we offer a revolutionary approach to chronic wound management. Unlike traditional treatments that may induce inflammation or fail to integrate seamlessly with human tissues, our CollaPatch™ minimises inflammation and enhance natural healing processes through a favourable macrophage response. This leads to much faster, safer, and more reliable healing outcomes with reduced scarring. Moreover, our sourcing from sustainably managed jellyfish

opulations ensures an environmentally responsible choice, aligning with modern healthcare's move towards sustainable medical products. This combination of clinical efficacy, patient comfort, and environmental sustainability sets our jellyfish collagen patches apart in the competitive landscape of wound care products.

5. Development Roadmap

The initial step in launching our business roadmap following the successful approval of an exclusive partnership with Jellagen involves assembling the necessary resources. This phase encompasses hiring specialised laboratory staff and establishing collaborations with local biolabs to facilitate the development of our prototype. Given the complexity of the prototype's components, as described within chapter 3, the precise balance of ingredients requires professional expertise. This stage sets the groundwork for a streamlined transition into the actual prototype development, ensuring all necessary materials and human resources are aligned for the commencement of the design and engineering phase.

5.1. Development Phase

Design and Engineering Phase (3-4 months): As shown within our Development Roadmap (see Appendix E), due to leveraging outcomes from prior in vitro and in vivo studies and raw materials provided by Jellagen, the design and engineering phase focuses on the composition of a prototype that meets specified healing and application criteria (mentioned within Chapter 3). This involves utilising advanced tools like Computer-Aided Design (CAD) software to create initial designs and conduct small-scale fabrications. The timelines for developing similar biomedical products, such as other types of collagen-based wound patches, generally align with this 3–6-month window, reflecting an industry-standard approach to prototype development (Callegari et al., 2007). **Biomaterial Selection and Composite Formulation:** A critical component in the prototype development is selecting the right biomaterials. The choice of jellyfish collagen is informed by its superior biocompatibility, minimal disease transmission risk, and unique properties that facilitate healing. To optimise the prototype, the jellyfish collagen will be combined with several ingredients as mentioned within the chapter 3.2., to create a composite that maximises elasticity, strength, and biological interaction with human tissue. This formulation process is guided by established research and aims to produce a patch

that closely mimics the natural extracellular matrix, supporting optimal cellular infiltration and tissue growth (Zhao et al., 2023).

Small-Scale Manufacturing and Initial Testing (2-3 months): Upon finalising the design, the project moves into small-scale manufacturing to produce prototype samples for laboratory testing. This phase is crucial for verifying that the prototype adheres to design specifications and meets expected performance metrics under controlled conditions. It also provides an opportunity to identify and rectify any immediate deficiencies, ensuring the prototype's efficacy and biocompatibility before proceeding to more extensive testing (Parsons et al., 2002).

Feedback Integration and Redesign (1-2 months): Feedback from initial testing phases plays an integral role in the iterative process of prototype refinement. This stage involves making necessary modifications to enhance functionality and address any issues identified during the testing. Such iterative redesign is commonplace in medical device development, where prototypes often undergo multiple revisions to achieve the ideal configuration that meets all clinical and regulatory requirements before advancing to pre-clinical testing.

5.2. Preclinical Phase – Intellectual Property

Once the prototype has undergone thorough refinement and meets all preliminary criteria, it progresses to pre-clinical testing. This stage tests the prototype in a controlled, clinically relevant environment to ensure it is safe and effective for eventual human use. Pre-clinical tests are critical for gaining regulatory approvals and moving forward to clinical trials, marking the final step in validating the prototype's readiness for market introduction.

Leveraging the existing data from Jellagen's in vitro and in vivo studies plays a critical role in streamlining the pre-clinical testing process. Since the studies are comprehensive and align well with the specifications of the prototype (main part of the product is raw material from Jellagen), their data can be utilised either as part of the regulatory submissions or to inform the specific tests required for the prototype. This approach can significantly reduce redundant testing

efforts, allowing for a focused examination of the unique aspects or enhancements introduced by the new prototype, such as innovative formulations, structural designs, and integration with other materials. By concentrating pre-clinical testing on these novel attributes, the scope and consequently the timeline of this phase can be notably reduced. Although estimating exact time savings without a detailed analysis during the prototype production it is reasonable to assume that there will be saved time during the typical pre-clinical phase. Standard pre-clinical testing which typically spans 3-6 months could potentially be shortened by several weeks to a month, contingent on the extent to which Jellagen's data can be effectively leveraged (Rahmani & Dahaghin, 2023).

However, several strategic considerations must be addressed to ensure the success of this approach. Due diligence is essential to verify that Jellagen's previous studies are applicable and meet the specific safety and efficacy requirements of the new prototype. Furthermore, maintaining early and ongoing communication with regulatory bodies is crucial. This dialogue helps clarify the acceptability of utilising existing data and outlines any additional data that might be required, thus averting potential delays associated with regulatory concerns.

Intellectual Property (IP): In the highly competitive biomedical device sector, obtaining a patent for our CollaPatch^{TM} provides essential exclusive rights to manufacture, use, sell, and distribute the product within Germany. This exclusivity is pivotal for deterring competitors, enabling the patent holder to establish a robust market position and recoup investments made in research and development. Moreover, patents are indicators of novelty and potential market value, significantly boosting the attractiveness of startups and new companies to investors and venture capitalists who prefer to fund businesses with protected intellectual property that promises a competitive advantage and potential long-term profitability (Heus et al., 2017). Additionally, holding a patent would allow TSD to license the technology to other manufacturers, fostering revenue generation and partnerships that facilitate further

development and distribution both domestically and internationally. Patents also enhance a company's valuation and reputation, bolstering its credibility as an innovator in the medical field (Nunnally et al., 2005).

Regarding the costs of patenting without in-house expertise in Germany, the initial expenses include conducting a comprehensive patent search to ensure the uniqueness of the invention, typically necessitating the services of a patent attorney or a professional search firm, with costs ranging from €1,000 to €3,000. Drafting and filing fees, especially given the complexity of biotechnological inventions like CollaPatch™, can vary between €7,000 and €15,000, in addition to the relatively lower but still significant filing fees with the German Patent and Trademark Office (DPMA). The patent prosecution phase may incur further costs from €1,000 to €5,000 due to DPMA reviews, objections, or amendment requests. Additionally, once the patent is granted, issue fees and periodic maintenance fees are necessary to maintain the patent's activity, with these fees increasing over time. If international protection is sought through mechanisms like the Patent Cooperation Treaty (PCT), this can substantially increase costs, with PCT filing fees ranging from €2,000 to €4,000, excluding the significant translation and national phase entry fees in each designated country. Without in-house expertise, the total cost of obtaining and maintaining a patent in Germany could range from €20,000 to €30,000 over the life of the patent, with costs potentially exceeding €100,000 if international protection is pursued (van Pottelsberghe de la Potterie & Mejer, 2010).

The Initial Patent Research and Pre-Filing Preparation phase generally spans 1-3 months and entails a thorough patent search to establish the novelty of the invention. This preliminary phase also involves the creation of detailed descriptions, claims, and, where applicable, schematic illustrations of the invention. Furthermore, this stage includes consultations with patent attorneys to refine the patent application. As documented in Appendix F, there has been a notable increase in patent filings related to collagen and marine collagen since 2015, indicating

sustained interest and activity in this field. This trend supports the hypothesis that, following initial research and external consultation, it is feasible to proceed with filing a patent. The patent examination process typically spans 1 to 3 years. During this phase, examiners evaluate the claims for their novelty, inventiveness, and industrial applicability. Applicants may be required to address requests for clarification or objections, which can extend the duration of this phase. As illustrated in our Appendix F, the average duration for filing a patent related to collagen applications in the pharmaceutical sector is approximately 3.2 years. Despite these substantial costs, the strategic benefits of patent protection, such as market exclusivity, attracting investment, and enhancing company valuation, justify these expenditures as vital investments in securing the commercial and competitive future of our innovative product.

5.3. Clinical Phase

For a burgeoning medical device company like ours, clinical trials are crucial for ensuring the safety, efficacy, and market viability of innovative solutions such as the CollaPatch™. These trials are essential for meeting regulatory standards and establishing the therapeutic value of new devices. Despite their significant costs and resource demands, clinical trials provide indispensable insights into product performance, optimise treatment protocols, and are necessary for regulatory approval and market acceptance. This rigorous testing is vital for us as we aim to revolutionise wound care market with the CollaPatch™.

Phase I: Safety Trial

Objective: The primary focus of phase I is to evaluate the safety and biocompatibility of the CollaPatch™. This initial phase is critical for determining the device's behaviour in human subjects, identifying any immediate adverse reactions, and understanding the primary physiological responses to the device (Wright, 2017).

Duration: Typically, phase I trials, which have a success rate of 63.6%, last from several months up to two years, averaging approximately 1.79 years. The duration is dependent on

initial outcomes and may require adjustments based on early feedback from participants (Thomas et al., 2021).

Cost: Financial outlays for phase I are estimated between €1 million and €3 million, encompassing expenses related to regulatory submissions, trial protocol development, participant recruitment, and administrative overhead (Di Tonno et al., 2022).

Participants: This phase usually engages a small cohort of 20-100 individuals, possibly including healthy volunteers or specific patient groups, depending on the device's nature and the study design sanctioned by regulatory authorities (Fisher et al., 2021).

Key Personnel Involved: Essential personnel include a clinical trial manager, principal investigators specialised in wound care, clinical research coordinators, and data analysts. Regulatory specialists play a pivotal role in ensuring adherence to the guidelines set forth by the EMA (Lazar, 2017).

Phase II: Efficacy Trial

Objective: This phase aims to ascertain the therapeutic efficacy of the CollaPatch^{TM} in enhancing wound healing. Secondary aims focus on optimising the dosage and administration protocol, such as the frequency and method of the patch application (Wright, 2017).

Duration: phase II of the trial, which typically lasts between one to four years, with an average duration of 3.5 years, focuses on refining the treatment protocol and gathering adequate data for a comprehensive statistical analysis. The success rate for this phase is 38.6% (Thomas et al., 2021).

Cost: The costs associated with phase II generally range from €5 million to €20 million, driven by an increased number of participants, more intricate data collection needs, and extended trial periods (Bennett et al., 2001).

Participants: The trial involves 100-300 patients, selected based on precise inclusion criteria that align with the specific wound conditions targeted by the patch (Torres-Saavedra & Winter, 2022).

Key Personnel Involved: The team expands to include more clinical investigators, additional trial sites across Europe, biostatisticians for advanced data analysis, and continued regulatory oversight (Cameron, 1997).

Phase III: Comparative Trial

Objective: Phase III is designed to confirm CollaPatch™'s efficacy relative to standard treatments, monitor any long-term adverse effects, and finalise usage recommendations. It represents the conclusive step prior to seeking market approval in Europe (Wright, 2017).

Duration: This phase, which is the longest in the process, typically spans two to four years, averaging 3.2 years. It requires extensive data collection to demonstrate the patch's effectiveness and safety relative to existing treatments, achieving a success rate of 60% (Thomas et al., 2021).

Cost: Often exceeding €20 million, phase III expenses are substantial due to the scale of operations, encompassing multiple sites across different European nations, extensive data collection, and significant administrative and operational costs (Mullard, 2018).

Participants: The participant pool ranges from several hundred to thousands, providing the statistical robustness needed to draw definitive conclusions regarding the patch's effectiveness (Herledan et al., 2020).

Key Personnel Involved: The team includes a broad array of international investigators, project managers, regulatory compliance officers, data management experts, and potentially marketing strategists to prepare for the product's market introduction (Pinheiro et al., 2021).

After completing clinical trials, the approval process for our CollaPatch™ in the European Union hinges on the device's characteristics, data quality, and the selected regulatory path,

boasting an 88.4% success rate of approval (Thomas et al., 2021). Typically classified as Class IIa or IIb, these products undergo a conformity assessment that includes quality system audits and technical reviews by a Notified Body. If these evaluations are successful, the product is granted a CE mark, indicating compliance with EU standards. Continuous performance monitoring is ensured through post-market surveillance. The approval process can span from 3 to 9 months for just the assessment phase, and potentially several years from concept to market. Although our strategy involves exiting after phase II trials, it is crucial to detail the remaining steps leading to final approval to fully illustrate the development process of our CollaPatch™ as a new product (European Medicines Agency, 2022).

6. Financials

For TSD to know how much money will be needed along the journey, this chapter takes a closer look on the cost structure and provides a detailed breakdown on how much money is needed and when the money will be needed. By starting with analysing the costs that arise within the first six years upon completion of the clinical trial phase II.

6.1. Cost Structure

To accurately assess the total costs involved in developing our inaugural product – CollaPatch™, the figure below provides a comprehensive visualisation of all expenses incurred over the six-year development period. For an itemised annual analysis of each cost category, see Appendix K & L. It is crucial to note that the cost projections presented are based on a baseline scenario, incorporating worst-case, base-case, and best-case estimates. These estimates have been derived from averages found in scientific literature and supplementary research. It is important to note that these costs are subject to significant volatility and may fluctuate during the development process.

Item / Task Description	Amount Y1 - Y6
Prototype Development	50,000.00 €
Pre-Clinical Testing (3-6 months)	100,000.00 €
Intellectual Property	25,000.00 €
Clinical Phase I & II	14,500,000.00 €
Labour Costs	2,529,000.00 €
PPE / Facility (third party laboratory)	1,080,000.00 €
General and Administrative	490,000.00 €
Total Costs	18,774,000.00 €

Figure 4: Cost Summary

Prototype Development: The financial planning for prototype development focuses primarily on direct costs associated with the necessary raw materials—such as jellyfish collagen, hydrogels, and alginates (detailed in Chapter 3). These materials are essential for testing and formulating the prototype. However, there are additional expenses related to the prototype development, such as personnel and laboratory equipment, which will be addressed in subsequent sections. The allocated budget of €45,000 will be split into the design and engineering phase (€20,000), small scale manufacturing (€15,000) and integration of feedback (€15,000). Furthermore, the allocation of €15,000 for integrating feedback highlights a strong commitment to iterative design. This is a critical component of product development, emphasising the incorporation of user and stakeholder feedback into refining the product, ensuring that it meets their needs and expectations effectively.

Pre-Clinical Trials: As mentioned within chapter 8, even though we have detailed studies provide by Jellagen (in vitro and in vivo), it is important to note that we do have a short period of time for our own pre-clinical trials, due to the time and resource savings it is estimated that the pre-clinical phase will amount up to €100,000.

Intellectual Property: We've allocated €25,000 of our budget to protect our proprietary technologies. This sum covers initial patent searches and filing fees—€11,000 for national and

€3,000 for international filings via the PCT, reflecting global ambitions. Additionally, €3,000 is reserved for 'Other' expenses, which includes unexpected costs or extra-legal advice, illustrating the unpredictable nature of patent prosecution. It's important to note that the €25,000 only applies to filings in Germany; expenses can increase substantially with filings in multiple countries, potentially multiplying costs tenfold. The fee variation depends on the IP portfolio's complexity, the scope of patent filings, and the law firm's reputation and expertise.

Clinical Trial Phases I & II: The substantial funds allocated to clinical trials (€14,500,000 in total) underscore the significant financial burden these phases impose. The allocation specifically earmarks €2,000,000 for phase I safety trials and €12,500,000 for phase II efficacy trials, reflecting the escalating costs as the product moves closer to potential market approval. This progression aligns with the regulatory requirements and the critical need to establish both safety and efficacy to regulatory bodies.

Labor / Team: The investment in human resources is a critical strategy for advancing the intricate processes involved in biotechnological development. The initial recruitment is particularly pivotal, encompassing roles such as the Product Development Manager (€59,000 p.a.) (Schade, 2022), Biochemist (€63,000 p.a.) (Thießen & Marx, 2022), Laboratory Assistant (€37,500 p.a.) (Stollberg, 2024), and the Chief Scientific Officer (€117,000 p.a.) (StepStone, 2023). These roles are essential for the development of the product prototype. The salaries for these positions reflect the median compensation within their respective fields, based on data from the German labour agency, ensuring competitive remuneration aligned with industry standards. Given the diverse compensation strategies available for advisory boards—such as equity stakes, per-meeting fees, reimbursement— TSD has opted for an annual retainer model (and a later stage option to gain equity, see chapter 11). This approach is designed to remunerate members for their significant insights and consultancy services. Each board member is awarded an annual payment of €5,000 p.a.

Facility / PPE (Third-Party Laboratory): The budgetary allocation for facility-related expenses, which includes €120,000 p.a. for rent and €60,000 p.a. for machinery usage, is derived from average rates offered by the top three third-party laboratory providers in Germany (Bio-Security, 2024). This strategic investment ensures access to state-of-the-art laboratory spaces equipped with cutting-edge technologies. The cost structure encompasses both the leasing of the laboratory space and a usage fee for each piece of equipment within the facility. The equipment provided, ranging from Biological Safety Cabinets and Centrifuges to Spectrophotometers, Polymerase Chain Reaction (PCR) Machines, and Incubators, constitutes a substantial portion of the facility costs. These resources are crucial for upholding the stringent standards demanded in biotechnological research and development, ensuring that each phase of product testing and development is conducted within advanced environments that promote innovation and adhere to regulatory norms.

G&A Expenses: These expenses cover a broad range of day-to-day operational costs that are not directly tied to production but are essential for running the business. Our G&A expenses are categorised into two main areas: equipment costs (€20,000 p.a.), which provide employees with the essential tools needed for efficient performance (further raw materials, Gloves, Lab Coats, PCR Tubes and Plates, Petri Dishes, Microcentrifuge Tubes, and other necessary laboratory materials), and administrative costs (€45,000 p.a.). The latter includes crucial services such as insurance, IT, and accounting, which offer necessary support and safeguard the company's operations. Additionally, travel expenses, which can involve plane tickets, hotel rooms, and meals, particularly dinners with investors, are crucial for fostering relationships and securing funding. Once clinical trials have started, costs for laboratory equipment are expected to double, since feedback must be considered for further adjustments to the product.

6.2. P&L Statement

The Profit and Loss (P&L) statement provided below offers a detailed summary of the company's financial activities over a period from 2025 to 2030. This summary is vital for projecting and monitoring the financial health of our business, giving stakeholders insight into how effectively TSD manages its costs during its development phase.

P&L - Key Positions						
Item	**2025**	**2026**	**2027**	**2028**	**2029**	**2030**
Revenue	-	-	-	-	-	-
Operating Costs	-841,500.00 €	-2,686,500.00 €	-686,500.00 €	-13,186,500.00 €	-686,500.00 €	-686,500.00 €
Gross Profit	-	-	-	-	-	-
EBITDA	-841,500.00 €	-2,686,500.00 €	-686,500.00 €	-13,186,500.00 €	-686,500.00 €	-686,500.00 €
Net Loss	**-841,500.00 €**	**-2,686,500.00 €**	**-686,500.00 €**	**-13,186,500.00 €**	**-686,500.00 €**	**-686,500.00 €**
Forward Losses	-841,500.00 €	-3,528,000.00 €	-4,214,500.00 €	-17,401,000.00 €	-18,087,500.00 €	-18,774,000.00 €

*Costs of goods sold are excluded within this P&L summary, only the operating costs are listed, since they reflect all costs associated with the development.

Figure 5: P&L Statement

Key line items essential for assessing the financial performance include Revenue (no items can be recorded, as government grands nor any form of funding can be recorded as revenue), Operating Costs, Gross Profit, EBITDA (Earnings Before Interest, Taxes, Depreciation, and Amortisation), Net Loss, and accumulated Forward Losses (tax beneficiary once first revenues are generated) (Accounting Standard (AS) 12, 2012). Notably, the table indicates no revenue generation throughout the six-year period, reflecting TSD's focus on the development of the CollaPatch™. Operating Costs vary significantly, with a peak in 2028, due to the start of clinical trials phase II, leading to substantial negative EBITDA and Net Loss figures. The cumulative Forward Losses highlight the growing financial impact of these investments, emphasising the need for effective cost management and strategic planning to sustain operations. This P&L statement underscores our commitment to the development process of the CollaPatch™, a common scenario for BioTech startups in the early stages of growth, necessitating careful financial oversight and strategic funding to achieve long-term success

Bibliography

3M Health Care. (2024). *3M Health Care*. https://www.3m.com/3M/en_US/health-care-us/

Accounting Standard (AS) 12. (2012). *Accounting for Government Grants*.

Addad, S., Exposito, J. Y., Faye, C., Ricard-Blum, S., & Lethias, C. (2011). Isolation, characterization and biological evaluation of jellyfish collagen for use in biomedical applications. *Marine Drugs*, *9*(6), 967–983. https://doi.org/10.3390/md9060967

Alkildani, S., Jung, O., & Barbeck, M. (2021). In vitro investigation of jellyfish collagen as a tool in cell culture and (Bone) tissue engineering. *Anticancer Research*, *41*(2), 707–717. https://doi.org/10.21873/ANTICANRES.14822

Álvarez, J. A. P., & Zuñiga, C. C. (2023). Wound Care and Healing. *International Journal of Medical Science and Clinical Research Studies*, *03*(05), 951–953. https://ijmscr.org/

B. Braun. (2024). *B. Braun* . B. Braun

Baur, J. O., Rahmanian-Schwarz, A., Held, M., Schiefer, J., Daigeler, A., & Eisler, W. (2021). Evaluation of a cross-linked versus non-cross-linked collagen matrix in full-thickness skin defects. *Burns*, *47*(1), 150–156. https://doi.org/10.1016/J.BURNS.2020.03.018

Bennett, C. L., Adams, J. R., Knox, K. S., Kelahan, A. M., Silver, S. M., & Bailes, J. S. (2001). Clinical Trials: Are They a Good Buy? *Journal of Clinical Oncology*, *19*(23), 4330–4339. https://doi.org/10.1200/JCO.2001.19.23.4330

Bhavyasri, D., Manikandan, K., & Kamaraj, R. (2019). Marketing Approval for Medical Devices in European Union. *Research Journal of Pharmacy and Technology*, *12*(1), 391. https://doi.org/10.5958/0974-360X.2019.00071.4

Bigus, J. (2006). Staging of Venture Financing, Investor Opportunism and Patent Law. *Journal of Business Finance & Accounting*, *33*(7–8), 939–960. https://doi.org/10.1111/J.1468-5957.2006.00005.X

Bio-Security. (2024). *Bio-Security - Kompetenzzentrum für Biologische Sicherheit*. https://www.bio-security.de/s1-s2-labore-bueros-mieten/

BIVF. (2024). *Boehringer Ingelheim Venture Fund | About us*. https://www.boehringer-ingelheim-venture.com/about-us

Callegari, A., Bollini, S., Iop, L., Chiavegato, A., Torregrossa, G., Pozzobon, M., Gerosa, G., De Coppi, P., Elvassore, N., & Sartore, S. (2007). Neovascularization induced by porous collagen scaffold implanted on intact and cryoinjured rat hearts. *Biomaterials*, *28*(36), 5449–5461. https://doi.org/10.1016/J.BIOMATERIALS.2007.07.022

Cameron, C. (1997). The clinical research unit: a nurse-led unit for patients undergoing early anti-cancer drug trials. *Journal of Cancer Nursing*, *1*(1), 32–36. https://doi.org/10.1016/S1364-9825(97)80420-8

CBINSIGHT. (2018, September 6). *The venture capital funnel highlights the natural selection inherent in the venture capital process.* https://www.cbinsights.com/research/venture-capital-funnel-2/

Chiarelli, P. G., Suh, J. H., Pegg, R. B., Chen, J., & Mis Solval, K. (2023). The emergence of jellyfish collagen: A comprehensive review on research progress, industrial applications, and future opportunities. In *Trends in Food Science and Technology* (Vol. 141). Elsevier Ltd. https://doi.org/10.1016/j.tifs.2023.104206

Clore, J. N., Cohen, I. K., & Diegelmann, R. F. (1979). Quantitation of Collagen Types I and III during Wound Healing in Rat Skin. *Proceedings of the Society for Experimental Biology and Medicine*, *161*(3), 337–340. https://doi.org/10.3181/00379727-161-40548

Coloplast. (2024). *Coloplast*. https://www.coloplast.com/products/wound/

ConvaTec. (2024). *ConvaTec*. https://www.convatec.com/de-de/wundversorgung/versorgung-und-pflege/

Coppola, D., Oliviero, M., Vitale, G. A., Lauritano, C., D'Ambra, I., Iannace, S., & de Pascale, D. (2020). Marine collagen from alternative and sustainable sources: Extraction, processing and applications. In *Marine Drugs* (Vol. 18, Issue 4). MDPI AG. https://doi.org/10.3390/md18040214

Coulon, Dr. med, S. (2024). *Medical Doctor, Specialist in General Medicine, Bonn, Interviewed by Lückenbach. 20.03.2024*.

Covalon. (2024). *Covalon*. https://covalon.com/product/

Di Tonno, D., Perlin, C., Loiacono, A. C., Giordano, L., Martena, L., Lagravinese, S., Rossi, F., Marsigliante, S., Maffia, M., Falco, A., Piscitelli, P., Miani, A., Esposito, S., Distante, A., & Argentiero, A. (2022). Trends of Phase I Clinical Trials in the Latest Ten Years across Five European Countries. *International Journal of Environmental Research and Public Health*, *19*(21). https://doi.org/10.3390/ijerph192114023

Dumville JC, D. S. O. S., & Speak, K. (2013). Hydrocolloid dressings for healing diabetic foot ulcers. *Cochrane Database of Systematic Reviews*, *8*. https://doi.org/10.1002/14651858.CD009099.pub3

Earlybird. (2024). *Earlybird | About us*. https://earlybird.com/#about

Edelist, D., Angel, D. L., Canning-clode, J., Gueroun, S. K. M., Aberle, N., Javidpour, J., & Andrade, C. (2021). Jellyfishing in europe: Current status, knowledge gaps, and future directions towards a sustainable practice. In *Sustainability (Switzerland)* (Vol. 13, Issue 22). MDPI. https://doi.org/10.3390/su132212445

European Medicines Agency. (2022). The 'Blue Guide' on the implementation of EU product rules 2022. *Official Journal of the European Union*, 64–70.

EXIST. (2024). *Gründungsförderung - EXIST*. https://www.exist.de/EXIST/Navigation/DE/Ueber_EXIST/ueber_exist.html

Felician, F. F., Yu, R. H., Li, M. Z., Li, C. J., Chen, H. Q., Jiang, Y., Tang, T., Qi, W. Y., & Xu, H. M. (2019). The wound healing potential of collagen peptides derived from the jellyfish Rhopilema esculentum. *Chinese Journal of Traumatology - English Edition*, *22*(1), 12–20. https://doi.org/10.1016/j.cjtee.2018.10.004

Fernald, K., Pennings, E., & Claassen, E. (2015). Biotechnology Commercialization Strategies: Risk and Return in Interfirm Cooperation. *Journal of Product Innovation Management*, *32*(6), 971–996. https://doi.org/10.1111/JPIM.12218

Fernandez, D., & Chow, M. (2005). Intellectual property strategy in bioinformatics and biochips. *Biosensors and Bioelectronics*, *21*(1), 197–200. https://doi.org/10.1016/J.BIOS.2004.09.014

Fibroheal. (2024). *Fibroheal* . https://fibroheal.com/wound-care/

Fisher, J. A., McManus, L., Kalbaugh, J. M., & Walker, R. L. (2021). Phase I trial compensation: How much do healthy volunteers actually earn from clinical trial enrollment? *Clinical Trials*, *18*(4), 477–487. https://doi.org/10.1177/17407745211011069

Flaig, I., Radenković, M., Najman, S., Pröhl, A., Jung, O., & Barbeck, M. (2020). In vivo analysis of the biocompatibility and immune response of jellyfish collagen scaffolds and its suitability for bone regeneration. *International Journal of Molecular Sciences*, *21*(12), 1–25. https://doi.org/10.3390/ijms21124518

Fortune Business Insights. (2023). *Wound Care Market*.

Fujiwara, T. (2014). Real options analysis on strategic partnerships of biotechnological start-ups. *Technology Analysis & Strategic Management*, *26*(6), 617–638. https://doi.org/10.1080/09537325.2014.923834

Fung, W., Hsieh, D. A., Naik, N. Y., & Teo, M. (2017). Hedge Fund Franchises. *SSRN Electronic Journal*. https://doi.org/10.2139/SSRN.2542476

Geahchan, S., Baharlouei, P., & Rahman, M. A. (2022). Marine Collagen: A Promising Biomaterial for Wound Healing, Skin Anti-Aging, and Bone Regeneration. In *Marine Drugs* (Vol. 20, Issue 1). MDPI. https://doi.org/10.3390/md20010061

Gel4Med. (2024). *Gel4Med*. https://www.gelformed.com/

Giakoumelou, A., Salvi, A., Kvasova, O., & Rizomyliotis, I. (2023). The start-up's roadmap to private equity financing: substituting discounts with a premium in valuation for growth. *International Journal of Entrepreneurial Behaviour and Research, ahead-of-print*(ahead-of-print). https://doi.org/10.1108/IJEBR-02-2022-0197/FULL/XML

Global Market Insights. (2023, November). *Wound Care Market - Product (Advanced Wound Dressing, Surgical Wound Care, Traditional Wound Care, Wound Therapy Devices, Wound Care Biologics), Application (Chronic, Acute), End use – Global Forecast, 2023-2032*.

Gompers, P., & Lerner, J. (2001). The Venture Capital Revolution. *Journal of Economic Perspectives*, *15*(2), 145–168. https://doi.org/10.1257/JEP.15.2.145

Gould, L. J. (2016). Topical Collagen-Based Biomaterials for Chronic Wounds: Rationale and Clinical Application. In *Advances in Wound Care* (Vol. 5, pp. 19–31). Mary Ann Liebert Inc. https://doi.org/10.1089/wound.2014.0595

Grand View Research. (2023). *Wound Care Market Size, Share & Trends Analysis By Product (Advanced, Traditional), By Application (Chronic Wounds), By End-use (Hospitals, Nursing Homes), By Mode Of Purchase, By Distribution Channel, By Region, And Segment Forecasts, 2024 - 2030*.

GTAI. (2023). *The Pharmaceutical Industry in Germany*. https://www.gtai.de/en/invest/industries/healthcare-market-germany/pharmaceutical-industry

Guo, S., & DiPietro, L. A. (2010). Critical review in oral biology & medicine: Factors Affecting Wound Healing. *Journal of Dental Research*, *89*(3), 219–229. https://doi.org/10.1177/0022034509359125

Harding, K., & Queen, D. (2017). Innovation in wound healing. In *International Wound Journal (IWJ)* (Vol. 14, Issue 1, p. 5). Blackwell Publishing Ltd. https://doi.org/10.1111/iwj.12718

HARTMANN, I. (2024). *HARTMANN, Inc*. https://www.hartmann.info/en-us/our-products/wound-management

Healy, E. M., & Kaitin, K. I. (1999). The European Agency for the Evaluation of Medicinal Products' Centralized Procedure for Product Approval: Current Status. *Drug Information Journal : DIJ / Drug Information Association*, *33*(4), 969–978. https://doi.org/10.1177/009286159903300401

Herledan, C., Ranchon, F., Schwiertz, V., Baudouin, A., Karlin, L., Ghesquières, H., Salles, G., & Rioufol, C. (2020). Drug cost savings in phase III hematological oncology clinical trials in a university hospital. *Hematological Oncology*, *38*(4), 576–583. https://doi.org/10.1002/hon.2753

Heus, J. J., de Pauw, E. S., Mirjam, L., Margherita, M., R, H. M., & Michal, H. (2017). Importance of intellectual property generated by biomedical research at universities and academic hospitals. *Journal of Clinical and Translational Research*, *3*, 250–259. https://api.semanticscholar.org/CorpusID:4732297

Human BioSciences. (2024). *Human BioSciences*. https://humanbiosciences.com/aboutus/

Ibrahim, N. 'Izzah, Wong, S. K., Mohamed, I. N., Mohamed, N., Chin, K. Y., Ima-Nirwana, S., & Shuid, A. N. (2018). Wound healing properties of selected natural products. In *International Journal of Environmental Research and Public Health* (Vol. 15, Issue 11). MDPI AG. https://doi.org/10.3390/ijerph15112360

IMAA. (2023). *Mean Enterprise Value to EBITDA and Revenue Multiples*. https://imaa-institute.org/blog/mean-enterprise-value-to-ebitda-and-revenue-multiples/#:~:text=As%20of%20October%202023%2C%20the%20average%20EV%2FRevenue%20multiple%20for,deal%20valuations%20within%20these%20industries.

James, S., Tilvi, S., Khandeparker, R., Sreepada, R. A., Thakur, N., & Gauthankar, M. (2023). Jellyfish Rhizostoma pulmo Collected Off Goa Coast (India) as a rich source of Tryptophan Containing Collagen and its Enhanced Antioxidant Potential. In *Jellyfish Rhizostoma pulmo Collected Off Goa Coast* (Vol. 60, Issue 11). https://www.globenewswire.com

Jridi, M., Bardaa, S., Moalla, D., Rebaii, T., Souissi, N., Sahnoun, Z., & Nasri, M. (2015). Microstructure, rheological and wound healing properties of collagen-based gel from cuttlefish skin. *International Journal of Biological Macromolecules*, *77*, 369–374. https://doi.org/10.1016/J.IJBIOMAC.2015.03.020

Kang, H. D. (2018). Pharmaceutical Start-ups' Technology and Financing Strategy. *Journal of Pharmaceutical Innovation*, *13*(4), 301–312. https://doi.org/10.1007/S12247-018-9326-0/TABLES/5

Khong, N. M. H., Yusoff, F. M., Jamilah, B., Basri, M., Maznah, I., Chan, K. W., Armania, N., & Nishikawa, J. (2018). Improved collagen extraction from jellyfish (Acromitus hardenbergi) with increased physical-induced solubilization processes. *Food Chemistry*, *251*, 41–50. https://doi.org/10.1016/j.foodchem.2017.12.083

KMU. (2024). *KMU - innovativ - BMBF*. https://www.bmbf.de/bmbf/de/forschung/innovativer-mittelstand/kmu-innovativ/kmu-innovativ_node

Lao, Y., & Zhou, L. (2023). Analysis of the Medical Device Industry in German & US: Evidence from Medtronic and Siemens. *Advances in Economics, Management and Political Sciences*, *35*(1), 1–6. https://doi.org/10.54254/2754-1169/35/20231771

Lazar, E. L. (2017). Budgeting for a Clinical Trial. In K. M. F. Itani & D. J. Reda (Eds.), *Clinical Trials Design in Operative and Non Operative Invasive Procedures* (pp. 435–440). Springer International Publishing. https://doi.org/10.1007/978-3-319-53877-8_50

Lee, C. H., & Lee, Y. (2016). Collagen-based formulations for wound healing applications. *Wound Healing Biomaterials*, *2*, 135–149. https://doi.org/10.1016/B978-1-78242-456-7.00007-6

Lin, Z., Wu, T., Wang, W., Li, B., Wang, M., Chen, L., Xia, H., & Zhang, T. (2019). Biofunctions of antimicrobial peptide-conjugated alginate/hyaluronic acid/collagen wound dressings promote wound healing of a mixed-bacteria-infected wound. *International Journal of Biological Macromolecules*, *140*, 330–342. https://doi.org/10.1016/J.IJBIOMAC.2019.08.087

L&R USA, Inc. (2024). *L&R, Inc.* https://www.lohmann-rauscher.com/us-en/products/wound-care/special-wound-dressings/vliwasorb/

Mach, M., & Baruch, Y. (2015). *Team Performance in Cross Cultural Project Teams: The Moderated Mediation role of Consensus, Heterogeneity, Faultlines and Trust Author Details*. https://doi.org/10.1108/CCM-10-2014-0114

Markan, S. (2021). Strategic Intellectual Property Management and spin offs during Medical Device Innovation and commercialisation. *International Journal of Drug Regulatory Affairs*, *9*(2), 43–51. https://doi.org/10.22270/IJDRA.V9I2.469

Markets and Markets. (2023, October). *Wound Care Market by Product (Dressings (Foam, Hydrocolloid, Collagen), Devices (NPWT, Debridement), Biological Skin Substitutes,*

Sutures, Staplers), Wounds (Traumatic, Surgical, Burns), End User (Hospitals, Clinics), and Region - Global Forecast to 2028.

Marshall, J., Morrill, K., Gobbe, M., & Blanchard, L. (2021). The Difference between Approval Processes for Medicinal Products and Medical Devices in Europe. *Ophthalmologica*, *244*(5), 368–378. https://doi.org/10.1159/000517522

Mathew-Steiner, S. S., Roy, S., & Sen, C. K. (2021). Collagen in Wound Healing. In *Bioengineering* (Vol. 8, Issue 63). MDPI AG. https://doi.org/10.3390/bioengineering8050063

MiMedx. (2024). *MiMedx*. https://www.mimedx.com/epicord/

Mirhaj, M., Labbaf, S., Tavakoli, M., & Seifalian, A. M. (2022). Emerging treatment strategies in wound care. In *International Wound Journal (IWJ)* (Vol. 19, Issue 7, pp. 1934–1954). John Wiley and Sons Inc. https://doi.org/10.1111/iwj.13786

Mölnlycke Health Care. (2024). *Mölnlycke Health Care*. https://www.molnlycke.com/about-us/business-areas/wound-care/

Mullard, A. (2018). How much do phase III trials cost? *Nature Reviews Drug Discovery*, *17*(11), 777. https://doi.org/10.1038/nrd.2018.198

Nguyen, H. M., Ngoc Le, T. T., Nguyen, A. T., Thien Le, H. N., & Pham, T. T. (2023). Biomedical materials for wound dressing: recent advances and applications. In *Royal Society Of Chemistry (RSC) Advances* (Vol. 13, Issue 8, pp. 5509–5528). Royal Society of Chemistry. https://doi.org/10.1039/d2ra07673j

Nunnally, A. C., Webster, C. J., Brown, S. A., & Cohen, G. A. (2005). Genetic Patent Protection in the Pharmaceutical and Biotechnology Industries. *Community Genetics*, *8*(4), 209–216. https://doi.org/10.1159/000087957

Organogenesis. (2024). *Organogenesis*. https://organogenesis.com/advanced-wound-care/

Ossenkop, Dr. , T. (2024). *Pharmacist, Schiller Apotheke, Iserlohn, Interviewed by Gartmann/Lückenbach. 01.04.2024*.

Parsons, I. D., White, S., Therriault, D., & Bignell, J. L. (2002). Manufacture and Testing of a Filament Wound Composite Bridge Superstructure. *NCHRP-IDEA Program Project Final Report*. https://api.semanticscholar.org/CorpusID:107134410

Pesterau, A.-M., Sirbu, R., & Cadar, E. (2023). Biomedical Applications Based on Marine Collagen Obtained from the Jellyfish Species Rhizostoma Pulmo Extracted from the Black Sea European Journal of Natural Sciences and Medicine. *European Journal of Natural Sciences and Medicine*.

Pinheiro, K., Ribeiro, M., Gadotti, L. L., Marson, F., Lopes, C. D. H., Saddi, R., Alessi, J. V. M., & Katz, A. (2021). Phase III randomized clinical trials global distribution and funding: Trends and disparities. *Journal of Clinical Oncology*, *39*(15_suppl), e18563–e18563. https://doi.org/10.1200/JCO.2021.39.15_suppl.e18563

Pollak, A. N. (2008). Use of Negative Pressure Wound Therapy With Reticulated Open Cell Foam for Lower Extremity Trauma. *Journal of Orthopaedic Trauma*, *22*. https://journals.lww.com/jorthotrauma/fulltext/2008/11101/use_of_negative_pressure_wound_therapy_with.5.aspx

Power, N. (2018). *Extreme Teams: Towards a Greater Understanding of Multi-Agency Teamwork During Major Emergencies and Disasters*. https://doi.org/10.1037/amp0000248

Qureshi, A., Murphy, E., Milando, R., Rengifo-Pardo, M., Clayton, C., & Friedman, A. (2019). A head to head comparison of topical collagen powder to primary closure for acute full-thickness punch biopsy-induced human wounds: An internally controlled pilot study. *Journal of the American Academy of Dermatology*, *81*(4), AB6. https://doi.org/10.1016/J.JAAD.2019.06.064

Raappana, M., & Horila, T. (2020). Team communication in the workplace. In *Workplace Communication* (pp. 28–40). Taylor and Francis. https://doi.org/10.4324/9780429196881-3

Rahmani, A., & Dahaghin, M. (2023). Accelerating Drug Development: Regulatory and Operational Strategies for Shortening Clinical Trials. In *Int J Cancer Res Ther* (Vol. 8, Issue 3).

RenovoDerm. (2024). *RenovoDerm*. https://www.renovoderm.tech/Phoenix-Wound-Matrix/Learn-More/

Rick, N. (2008). Drugs: From Discovery to Approval (2nd ed.). By Rick Ng. *John Wiley & Sons*, *2*, 217–220. https://doi.org/10.1002/cmdc.200900232

Ruszczak, Z. (2003). Effect of collagen matrices on dermal wound healing. *Advanced Drug Delivery Reviews*, *55*(12), 1595–1611. https://doi.org/10.1016/J.ADDR.2003.08.003

Salvatore, L., Gallo, N., Natali, M. L., Campa, L., Lunetti, P., Madaghiele, M., Blasi, F. S., Corallo, A., Capobianco, L., & Sannino, A. (2020). Marine collagen and its derivatives: Versatile and sustainable bio-resources for healthcare. In *Materials Science and Engineering C* (Vol. 113). Elsevier Ltd. https://doi.org/10.1016/j.msec.2020.110963

Sawaragi, E., Yamanaka, H., Li, Y., Unzai, T., Kawabata, S., Nakano, T., Katayama, Y., Sakamoto, M., Tabata, Y., & Morimoto, N. (2023). Comparisons of the effects of silk elastin and collagen sponges on wound healing in murine models. *Regenerative Therapy*, *24*, 385–397. https://doi.org/10.1016/J.RETH.2023.09.001

Schade, M. (2022). *Arbeiten in der Produktentwicklung: Aufgaben, Voraussetzungen und Gehalt*. https://www.academics.de/ratgeber/aufgaben-produktentwicklung

Schilrreff, P., & Alexiev, U. (2022). Chronic Inflammation in Non-Healing Skin Wounds and Promising Natural Bioactive Compounds Treatment. In *International Journal of Molecular Sciences* (Vol. 23, Issue 9). MDPI. https://doi.org/10.3390/ijms23094928

Schultz, G. S., Chin, G. A., Moldawer, L., & Diegelmann, R. F. (2011). Principles of wound healing. In *Mechanisms of Vascular Disease: A Reference Book for Vascular Specialists* (Vol. 23). University of Adelaide Press. https://doi.org/10.1017/UPO9781922064004.024

Schwander, B., Krone, F. A., & Walzer, S. (2013). Clinical and Health Economic Evidence Requirements for Obtaining Health Insurance Coverage for Innovative Medical Devices in Germany. *Value in Health*, *16*(7), A474. https://doi.org/10.1016/j.jval.2013.08.877

Shen, Y., Xu, G., Huang, H., Wang, K., Wang, H., Lang, M., Gao, H., & Zhao, S. (2021). Sequential Release of Small Extracellular Vesicles from Bilayered Thiolated Alginate/Polyethylene Glycol Diacrylate Hydrogels for Scarless Wound Healing. *ACS Nano*, *15*(4), 6352–6368. https://doi.org/10.1021/acsnano.0c07714

SHS. (2018). *Venture Capital Journal: "SHS Fund V giving digital health a financial shot in the arm" – SHS Gesellschaft für Beteiligungsmanagement mbH*. https://www.shs-capital.eu/venture-capital-journal-shs-fund-v-giving-digital-health-a-financial-shot-in-the-arm-2/

Siddiqui, K. A., Al-Shaikh, M. E., Bajwa, I. A., & Alenzi, O. (2020). Venture capital challenges in Saudi Arabia. *Entrepreneurship and Sustainability Issues*, *8*(3), 291–302. https://doi.org/10.9770/JESI.2021.8.3(17)

Slowinski, G., Farris, G. F., & Jones, D. (1993). Strategic Partnering: Process Instead of Event. *Research-Technology Management*, *36*(3), 22–25. https://doi.org/10.1080/08956308.1993.11670898

Smith+Nephew, Inc. (2024). *Smith+Nephew, Inc.* https://www.smith-nephew.com/health-care-professionals/products

Song, E., Yeon Kim, S., Chun, T., Byun, H. J., & Lee, Y. M. (2006). Collagen scaffolds derived from a marine source and their biocompatibility. *Biomaterials*, *27*(15), 2951–2961. https://doi.org/10.1016/j.biomaterials.2006.01.015

Spragg, A., Weymann, A., & Jellagen. (2020). *Collagen Type 0*. www.jellagen.co.uk

Statista. (2024, March). *Wound Care - Worldwide*.

StepStone. (2023). *CSO Gehälter in Deutschland*. https://www.stepstone.de/gehalt/CSO.html

Stollberg, S. (2024). *Laborassistent/in – Gehalt und Verdienst 2024*. https://www.medi-karriere.at/medizinische-berufe/laborassistent-gehalt/?gad_source=1&gclid=Cj0KCQjwltKxBhDMARIsAG8KnqXZ0lSfCr1xocIGOIU-ZSIXVfT_XBavixpBo5JZ3Eld0Gt-3su9LKAaAs9MEALw_wcB

Sullivan, T. (n.d.). *Biotech Valuation Methods (Explained)*. Retrieved May 14, 2024, from https://exitwise.com/blog/biotech-valuation

Sumiyoshi, H., Okamura, Y., Kawaguchi, A. T., Kubota, T., Endo, H., Yanagawa, T., Yasuda, J., Matsuki, Y., Nakao, S., & Inagaki, Y. (2021). External administration of moon jellyfish collagen solution accelerates physiological wound healing and improves delayed wound closure in diabetic model mice. *Regenerative Therapy*, *18*, 223–230. https://doi.org/10.1016/J.RETH.2021.06.008

Thießen, L., & Marx, A. (2022). *Das Gehalt von Medizintechnikern: Was können Ingenieure verdienen?* https://www.academics.de/ratgeber/gehalt-medizintechniker

Thomas, D., Chancellor, D., Micklus, A., LaFever, S., Hay, M., Chaudhuri, S., Bowden, R., & Lo, A. (2021). Clinical Development Success Rates and Contributing Factors 2011 - 2020. *Biotechnology Innovation Organization, PharmaIntelligence Informa, Quantitative Life Sciences*.

Torres-Saavedra, P. A., & Winter, K. A. (2022). An Overview of Phase 2 Clinical Trial Designs. *International Journal of Radiation Oncology*Biology*Physics*, *112*(1), 22–29. https://doi.org/10.1016/J.IJROBP.2021.07.1700

Trucillo, P., & Di Maio, E. (2021). Classification and Production of Polymeric Foams among the Systems for Wound Treatment. *Polymers*, *13*(10). https://doi.org/10.3390/polym13101608

van Pottelsberghe de la Potterie, B., & Mejer, M. (2010). The London Agreement and the cost of patenting in Europe. *European Journal of Law and Economics*, *29*(2), 211–237. https://doi.org/10.1007/s10657-009-9118-6

Villiger, R., & Bogdan, B. (2005). Pitfalls of valuation in biotech. *JOURNAL OF COMMERCIAL BIOTECHNOLOGY*, *12*(3), 175–181.

Walter, Dr. , M. (2024). *Head of Patient Engagement, Access & Healthcare Affairs, Boehringer Ingelheim, Interviewed by Yusofi/Gartmann/Lückenbach. 01.05.2024*.

Wang, Z., Qi, F., Luo, H., Xu, G., & Wang, D. (2022). Inflammatory Microenvironment of Skin Wounds. In *Frontiers in Immunology* (Vol. 13). Frontiers Media S.A. https://doi.org/10.3389/fimmu.2022.789274

Weinschenk, Dr. , H. P. (2024). *Pharmacist, Königlich Privilegierte Apotheke, Satrup/Mittelangeln, Interviewed by Yusofi/Gartman/Lückenbach. 27.03.2024.*

Wilkinson, H. N., & Hardman, M. J. (2020). Wound healing: Cellular mechanisms and pathological outcomes. In *Open Biology* (pp. 341–370). Taylor and Francis. https://doi.org/10.1098/rsob.200223

Woo, J., Kim, E., Sung, T. E., Lee, J., Shin, K., & Lee, J. (2019). Developing an improved risk-adjusted net present value technology valuation model for the biopharmaceutical industry. *Journal of Open Innovation: Technology, Market, and Complexity*, *5*(3). https://doi.org/10.3390/joitmc5030045

World Health Organization. (2023, October 13). *Burns*.

Wright, B. (2017). Clinical Trial Phases. *A Comprehensive and Practical Guide to Clinical Trials*, 11–15. https://doi.org/10.1016/B978-0-12-804729-3.00002-X

Ying, H., Zhou, J., Wang, M., Su, D., Ma, Q., Lv, G., & Chen, J. (2019). In situ formed collagen-hyaluronic acid hydrogel as biomimetic dressing for promoting spontaneous wound healing. *Materials Science and Engineering: C*, *101*, 487–498. https://doi.org/10.1016/J.MSEC.2019.03.093

Zhang, M., & Zhao, X. (2020). Alginate hydrogel dressings for advanced wound management. *International Journal of Biological Macromolecules*, *162*, 1414–1428. https://doi.org/10.1016/J.IJBIOMAC.2020.07.311

Zhao, J., Yu, W., Zhang, Q., Li, X., Huang, Y., Zhao, S., Li, T., Liu, S., Li, Y., & Shan, H. (2023). Structural and biofunctional evaluation of decellularized jellyfish matrices. *Journal of Materials Chemistry B*, *11*(16), 3740–3751. https://doi.org/10.1039/d3tb00428g

ZIM. (2024). *Zentrales Innovationsprogramm Mittelstand (ZIM) - Förderung für den Mittelstand*. https://zim.de/ZIM/Navigation/DE/Home/home.html

Limitations & Assumptions

Our startup, TSD, aims to provide innovative jellyfish collagen wound patches. However, our research and business plan are based on several assumptions and face significant limitations inherent in the biotech industry. This industry is characterised by high uncertainty, with rapid technological advancements, regulatory changes, and volatile market dynamics potentially affecting our project's trajectory. Our business model relies heavily on strategic partnerships, particularly with Jellagen for high-quality jellyfish collagen and other research institutions for clinical trials. The success of TSD is contingent on the stability and effectiveness of these partnerships, which can be influenced by changes in our partners' priorities or external conditions. The pathway to market approval for our CollaPatch^{TM} involves multiple stages of clinical trials, each fraught with high risks and uncertainties. Delays or failures at any stage could significantly impact our timelines and costs. Even with successful trials, market adoption and profitability are not guaranteed. Our estimated timeframes, costs, and development periods, though meticulously researched, are subject to variability due to potential regulatory delays, unforeseen scientific challenges, and shifting market conditions. Similarly, market size estimates and penetration rates are based on current healthcare trends and market research but can fluctuate due to changes in demand, competitive landscape, and healthcare policies. Valuations of biotech startups like TSD can vary widely among investors due to differing risk appetites and market conditions. Our financial projections, though based on comprehensive models, may not align with investor perceptions at the time of fundraising.

Despite reaching out to various companies through LinkedIn, websites, emails, and referrals from friends and family, we encountered numerous denials and non-responses, which hindered the validation of our assumptions. Nevertheless, we made every effort to build the strongest case possible with the resources available to us.

Acknowledgments

While working on this project, we gained a lot of knowledge and insights through conversations with professionals and experts in the pharmaceutical and medical field. The following people deserve our sincere gratitude for their insightful comments and efforts, which have greatly enhanced our thesis:

- Dr. Hans Peter Weinschenk - Pharmacist
- Dr. Susanne Roeb - Managing Director at APOSAN, a Medical Care Service Company
- Dr. Sabine Coulon - Medical Doctor, Specialist in General Medicine
- Ulrich Lückenbach - Health Economist, Expert for German Market
- Dr. Martin Walter - Head of Patient Engagement, Access & Healthcare Affairs at Boehringer Ingelheim
- Dr. Till Ossenkop – Pharmacist
- Karin Lückenbach - Pharmacist
- Dr. Gonçalo Costa - Chief Scientific Officer of BioMimetx & PhD Biochemist from University of Lisbon.
- Nuno Arantes-Oliveira - Founder and Partner of Clinical Research Ventures & Invited Associate Professor at Nova School of Business and Economics
- Richard Gartmann – Biochemist, Bruker Corporation, Analytical Solutions
- Dr. Karin Wertz, Head of Global Research, DSM

Thank you very much for your valuable inputs into this venture project.

List of Figures

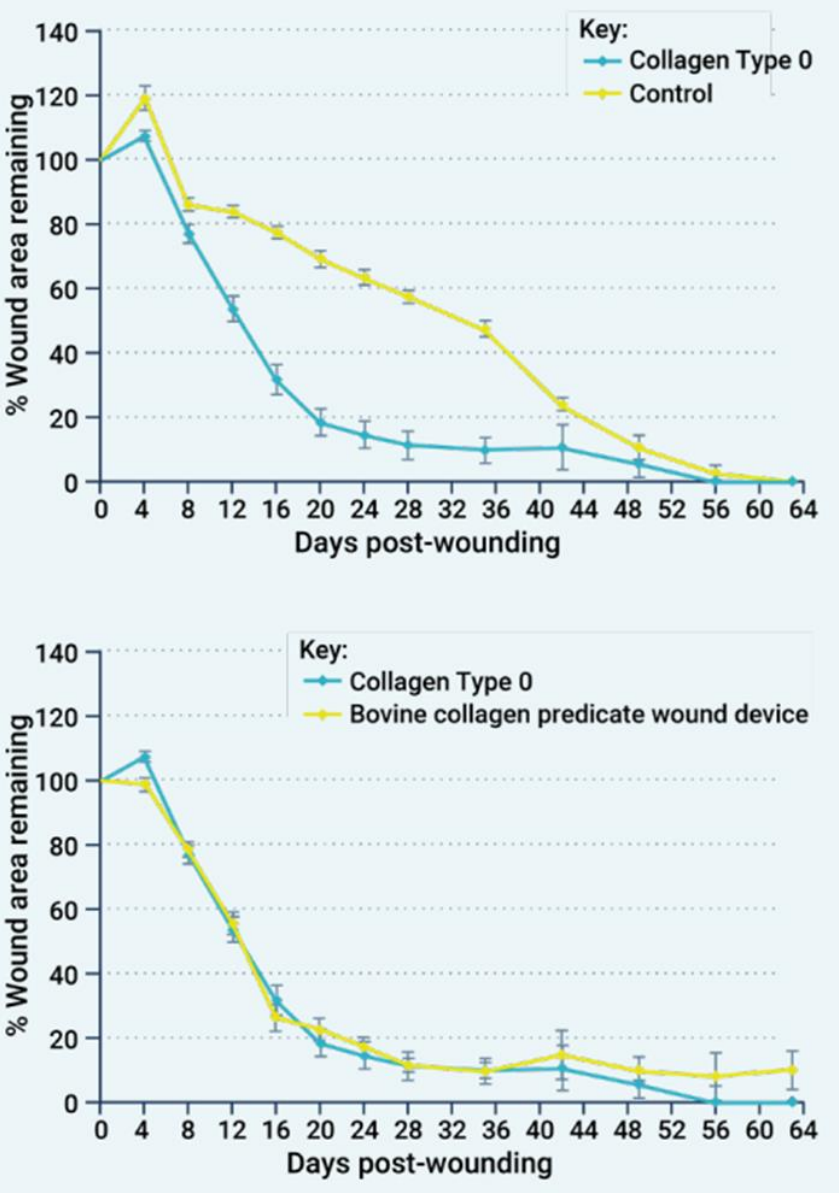
List of Abbreviations

AdvaMed	Advanced Medical Technology Association
API	Application Programming Interface
BIVF	Boehringer Ingelheim Venture Fund
BSOP	Board Share Option Pool
CAGR	Compound Annual Growth Rate
CAD	Computer-Aided Design
CEO	Chief Executive Officer
CFO	Chief Financial Officer
COO	Chief Operating Officer
CROs	Contract Research Organisations
CSO	Chief Scientific Officer
DCF	Discounted Cash Flow
DPMA	German Patent and Trademark Office
DRG	Diagnoses Related Groups
EBITDA	Earnings Before Interest, Taxes, Depreciation, and Amortisation
ECM	Extracellular Matrix
EMA	European Medicines Agency
EPO	European Patent Office
ESOP	Employee Share Option Pool
EV	Enterprise Value
FDA	Food and Drug Administration
GMP	Good Manufacturing Practices
IMAA	Institute for Mergers, Acquisitions, and Alliances
IP	Intellectual Property

IPMA	Instituto Português do Mar e da Atmosfera
IPO	Initial Public Offering
LOA	Likelihood of Approval
LPS	Lipopolysaccharide
M&A	Mergers and Acquisitions
MMP	Matrix Metalloproteinase
NPWT	Negative Pressure Wound Therapy
NUB	New Examination and Treatment Method
P&L	Profit and Loss
PCT	Patent Cooperation Treaty
PEG	Polyethylene Glycol
PCR	Polymerase Chain Reaction
P/E	Price-to-Earnings
PPC	Porcine Pericardium Collagen
POS	Probability of Success
rNPV	Risk-Adjusted Net Present Value
R&D	Research & Development
SMEs	Small and Medium-Sized Businesses
TIMPs	Tissue-Derived Inhibitors of Metalloproteinases
VC	Venture Capital
WACC	Weighted Average Cost of Capital

Appendix

Appendix A: Key Results In Vitro – In Vivo Studies Jellagen



Wound closure

Wounds treated with collagen type 0 achieved 80% closure more rapidly than those untreated, taking less than 20 days compared to 44 days. The bovine collagen predicates wound device produced similar initial outcomes. However, it exhibited considerable variability and suboptimal performance during the final 20% of closure, with numerous wounds failing to close entirely. In contrast, collagen type 0 demonstrated superior uniformity and achieved complete wound closure.

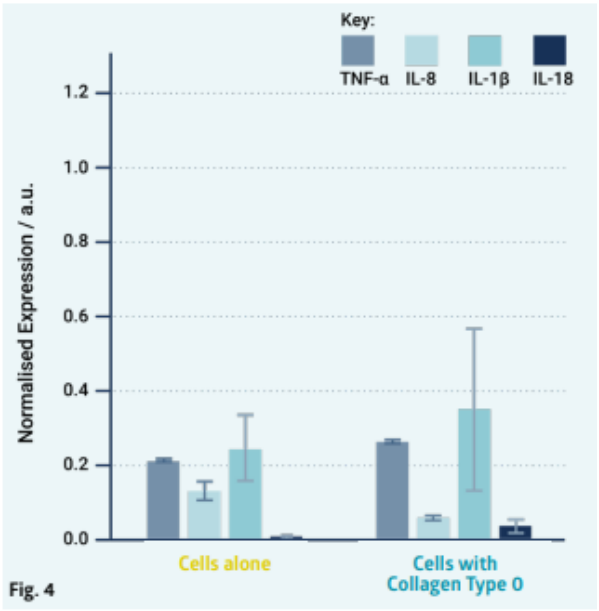


Fig. 4

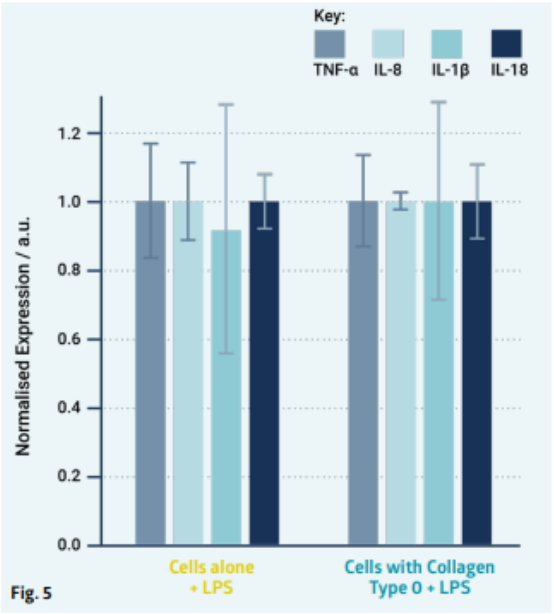


Fig. 5

This in vitro study evaluated the effect of jellyfish collagen type 0 on differentiated THP-1 cells, which are associated with wound development. Previous research indicated that collagen extracted from another jellyfish species (Nemopilema nomurai) may stimulate the secretion of pro-inflammatory cytokines (TNF-α and IL-6). Consequently, we aimed to determine whether collagen type 0 from R. pulmo would elicit a similar or different response.

Inflammatory cytokine secretion: The secretion of TNF-α, along with other inflammation-associated cytokines (IL-8, IL-1β, and IL-18), was assessed in differentiated THP-1 cells both alone and in the presence of collagen type 0. The results showed that collagen type 0 did not induce significant changes in the secretion of pro-inflammatory cytokines (Fig. 4).

Additionally, differentiated THP-1 cells, both alone and with collagen type 0, were exposed to lipopolysaccharide (LPS), a major component of gram-negative bacteria known to trigger an inflammatory immune response. LPS exposure resulted in a pronounced inflammatory response; however, the presence of collagen type 0 did not modify this response in any way (Fig. 5).

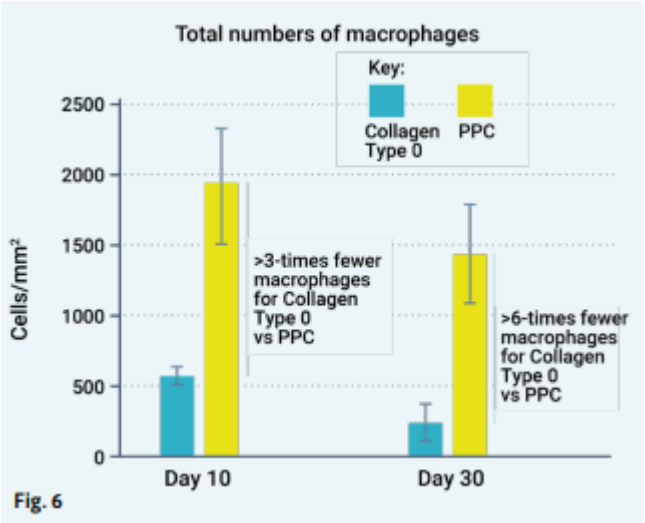


Fig. 6

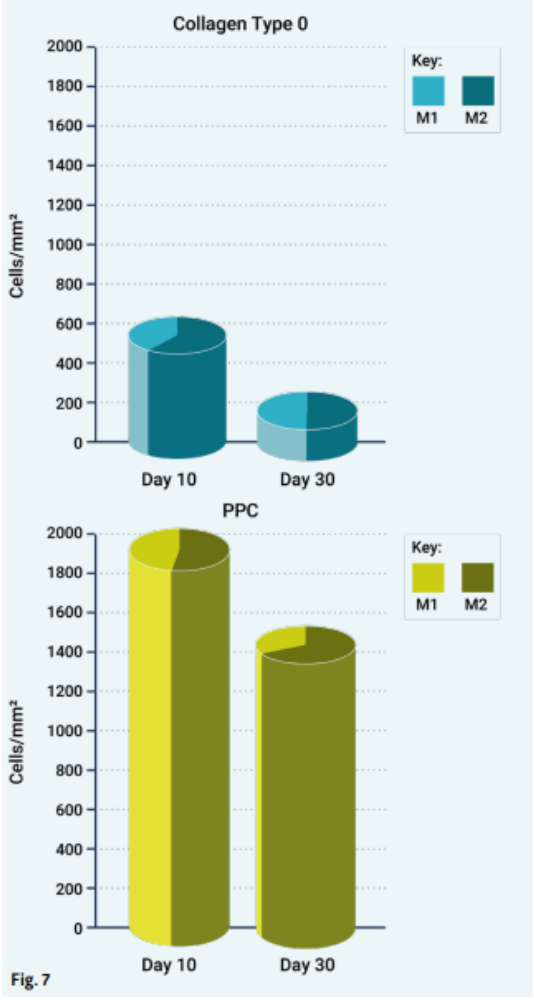


Fig. 7

collagen type 0 elicits a weaker immune tissue response compared to porcine pericardium collagen (PPC), indicating its biocompatibility. The macrophage balance reveals that collagen type 0 promotes tissue repair, characterised by M2 macrophages, early in the wound healing process, rather than inflammation, characterised by M1 macrophages. In contrast, tissue repair is only stimulated by PPC at later stages of wound healing.

Source: (Spragg et al., 2020)

Appendix B: Evaluation of Open Customer Preference Survey

Participant	Age	Most Important Feature of Wound Dressing	Category
P1	22	-Conforms to body contours - Comfortable	Comfort
P2	27	- Easy to change - Minimal irritation	Ease of Use
P3	24	- Effective in wet conditions	Durability
P4	26	- Subtle appearance	Aesthetic
P5	23	- Seamless fit - Enhances mobility	Comfort
P6	25	- Easy applicationy - Painless removal	Ease of Use
P7	28	- Breathable - Prevents moisture buildup	Others
P8	21	- Maintains flexibility	Comfort
P9	29	- Water resistant	Durability
P10	20	- Discreet design	Aesthetic
P11	27	- Prioritizes comfort	Comfort
P12	24	- Simple to handle	Ease of Use
P13	30	- Allows skin to breathe	Others
P14	28	- Adapts to body movements	Comfort
P15	26	- Waterproof	Durability
P16	38	- Aesthetic doesn't attract attention	Aesthetic
P17	42	- Gentle on skin	Others
P18	45	- Conforms closely to body	Comfort
P19	50	- Keeps wound dry	Others
P20	54	- Blends with appearance	Aesthetic
P21	58	- Sticks well without discomfort	Ease of Use
P22	62	- No skin irritation	Others
P23	65	- Flexible without constraint	Comfort
P24	67	- Avoids moisture under dressing	Others
P25	29	- Secure adhesive - No pain when removing	Ease of Use
P26	28	- Matches skin tone	Aesthetic
P27	26	- Durable in moist environments	Durability
P28	30	- Stays functional in showers	Durability
P29	24	- Low profile and effective	Aesthetic
P30	22	- Adapts well to body contours	Comfort
P31	25	- Invisible but functional	Aesthetic
P32	23	- Practical and discreet	Aesthetic
P33	27	- Promotes breathability	Others

Appendix C: Market Size Wound Healing – avg. Market Share and Penetration of TSD

Market Size Wound Healing in Germany - average Market Share TSD in Estimated Revenues

CAGR: 5,90% (in billion $) Years on Market	2023	2036	2037	2038	2039	2040	2041	2042	2043	2044	2045
Global Wound Healing Market	21,5	45,30	47,97	50,80	53,80	56,97	60,33	63,89	67,66	71,66	75,88
Market Share US	8	16,86	17,85	18,90	20,02	21,20	22,45	23,77	25,18	26,66	28,24
Rest Market Share	13,5	28,44	30,12	31,90	33,78	35,77	37,88	40,12	42,49	44,99	47,65
Europe*	5,38	11,32	11,99	12,70	13,45	14,24	15,08	15,97	16,92	17,91	18,97
Germany	1,61	3,40	3,60	3,81	4,03	4,27	4,53	4,79	5,07	5,37	5,69
Chronic Wounds	1,13	2,38	2,52	2,67	2,82	2,99	3,17	3,35	3,55	3,76	3,98
Acute Wounds	0,48	1,02	1,08	1,14	1,21	1,28	1,36	1,44	1,52	1,61	1,71
		Year 1-3			Year 4-7				Year 8-10		
(in million $)	Pre-Development Phase	Best Case	Base Case	Worst Case	Best Case	Base Case	Worst Case		Best Case	Base Case	Worst Case
Penetration Rate		**7%**	**4%**	**1%**	**10%**	**8%**	**6%**		**15%**	**12%**	**8%**
Europe*		**840,42**	**480,24**	**120,06**	**1.468,75**	**1.175,00**	**881,25**		**2.690,05**	**2.152,04**	**1.434,69**
Germany		**252,13**	**144,07**	**36,02**	**440,63**	**352,50**	**264,38**		**807,02**	**645,61**	**430,41**
Chronic Wounds		176,49	100,85	25,21	308,44	246,75	185,06		564,91	451,93	301,29
Acute Wounds		75,64	43,22	10,81	132,19	105,75	79,31		242,10	193,68	129,12

Appendix D: Personas of Dr. Ford and Mr. Thompson

Dr. Alexandra M. Ford

Age: 45
Work: Dermatologist and Wound Care Specialist
Family: Married, kids
Location: Urban Medical Center

Goals

- **Short-term Goal**: To reduce the healing time of chronic wounds in patients, thereby improving their quality of life.
- **Long-term Objective**: To be a leader in her field by adopting and advocating for innovative, effective wound care treatments; to contribute to research in wound healing.

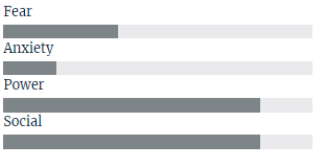
Challenges & Needs

- **Primary Challenges**: Finding effective treatments for patients with slow-healing or non-healing chronic wounds; managing patient discomfort and infection risks; reducing healing time to prevent hospital readmissions.
- **Needs**: Advanced wound care products that are clinically proven to expedite healing, reduce infection rates, and are easy to apply and remove. Interest in sustainable and biocompatible materials due to increasing awareness and demand for environmentally friendly medical products.

Pain Points

- **Limited Treatment Options:** Encountering a lack of effective treatment modalities for chronic wounds, which can lead to patient frustration and decreased trust in medical advice.
- **Time Constraints:** Facing time pressure in her practice, with the need to see a high volume of patients, which limits the time available for each individual's comprehensive care.
- **Patient Compliance Issues:** Dealing with patients who struggle to adhere to treatment regimens due to complexity, discomfort, or lack of understanding, leading to slower healing and repeated consultations.
- **Resource Management:** Balancing the need for cost-effective treatments with the desire to provide the best possible care, especially in a setting with limited healthcare resources.
- **Infection Control and Management:** Constant concern about infection risks in chronic wounds, necessitating vigilant monitoring and intervention.

Motivation



Bio

- **Key Role**: Managing a wound care clinic within a large hospital.
- **Responsibilities**: Diagnosing and treating patients with chronic wounds, including diabetic ulcers, venous ulcers, and pressure sores; staying updated with the latest treatments and innovations in wound care; conducting minor wound-related surgeries; training medical staff on wound care best practices.

Michael Thompson

Age: 58
Work: Early retired
Family: Married, kids
Location: Suburban area

Goals

- **Short-term Goal**: To find a more effective treatment for his chronic wounds to reduce pain and accelerate healing.
- **Long-term Objective**: To improve his quality of life by managing his diabetes more effectively and returning to a more active lifestyle.

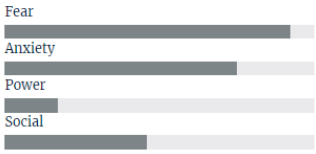
Challenges & Needs

- **Primary Challenges**: Managing pain and discomfort from chronic wounds: slow healing of foot ulcers leading to reduced mobility and quality of life
- **Needs**: Effective and affordable wound care that accelerates healing, is easy to apply and comfortable to wear, and reduces the risk of infection.

Pain Points

- **Financial Burden:** Worry about the ongoing costs associated with wound treatment, including medical appointments, dressings, and any additional therapies.
- **Risk of Complications:** Concern about the potential for serious complications, such as infections that can lead to hospitalization or, in severe cases, amputation.
- **Mental and Emotional Stress:** Experiencing anxiety and depression due to the chronic nature of his condition, and the impact it has on his daily life and independence.
- **Limitations in Daily Activities:** Frustration over not being able to perform simple tasks without discomfort or pain. For example, difficulty in standing for long periods, which affects his ability to engage in activities like cooking or attending social events.

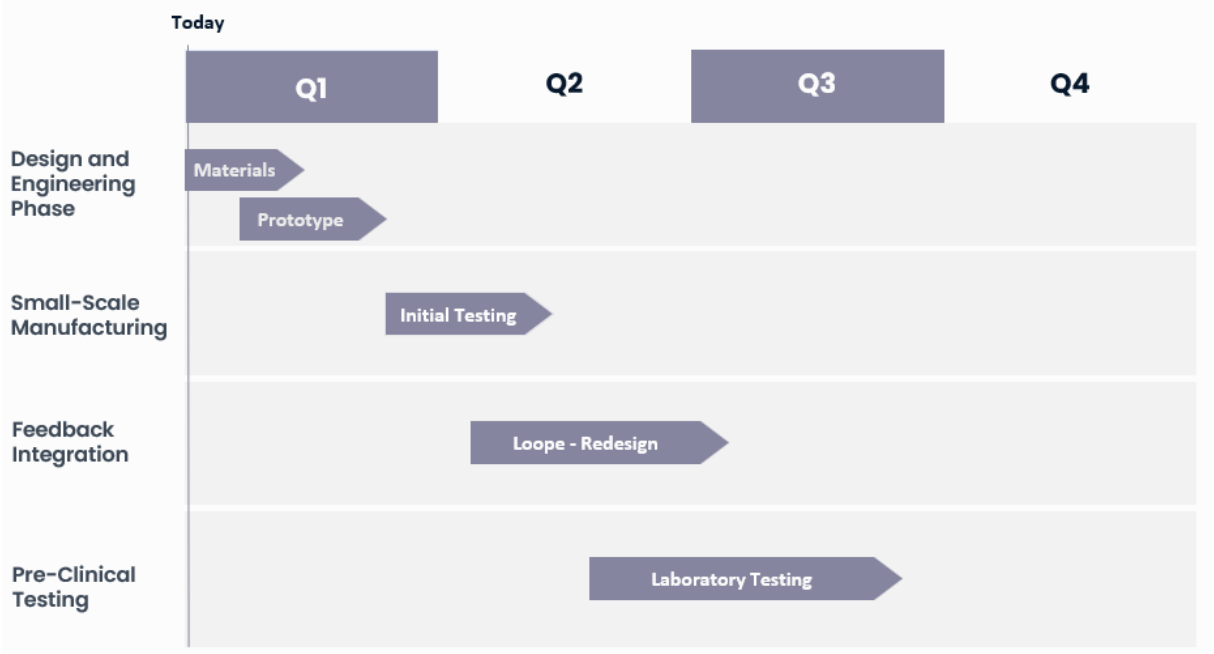
Motivation



Bio

- **Health Conditions:** Type 2 Diabetes diagnosed 10 years ago; experiences chronic diabetic foot ulcers.
- **Lifestyle:** Limited mobility due to discomfort from foot ulcers; had to reduce activities he enjoys like gardening and walking his dog
- **Healthcare Access:** Regular visits to a local clinic for diabetes management and wound care; has health insurance but is conscious of out-of-pocket costs

Appendix E: Development Phase

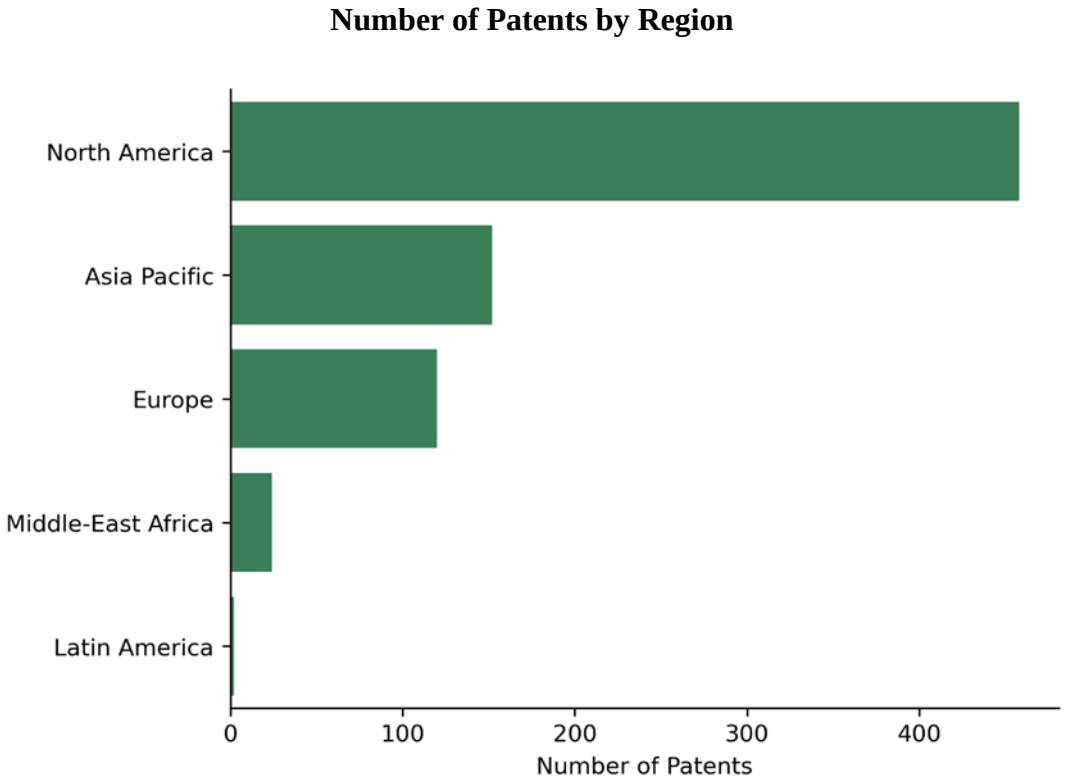


Appendix F: Panda Library (Python) – Analysis of Patent Landscape

In the realm of applied research, patents not only offer a wealth of technical details but also provide insights into competitive landscapes and emerging market trends. For companies in the health and beauty sectors, patent analysis is an essential activity that supports strategic planning and innovation management. It enables businesses to safeguard their innovations, steer clear of potential infringements, carve out niches, and spot early threats or partnership opportunities. Moreover, by understanding the state of the art through patent landscapes, companies can enhance product offerings and align their research and development efforts with market demands. However, conducting a comprehensive patent analysis often involves substantial financial and human resources, which can be prohibitive for smaller entities or academic researchers. Thus, providing accessible tools like Python scripts for patent data extraction and analysis democratises the ability to engage in this sophisticated work. Using the Python Pandas library, for instance, researchers and entrepreneurs can efficiently parse, analyse, and visualise patent data related to collagen and marine collagen. This approach not only saves time and money but also levels the playing field, fostering innovation across various sizes of enterprises engaged in the collagen market.

Solution approach: By employing simple, yet powerful, Python tools for analysing patent data, companies and researchers can maintain a competitive edge, develop informed innovation strategies, and stay abreast of the latest advancements within the collagen industry. Such tools also aid in avoiding patent infringement and in making strategic decisions that are critical to success in the fast-evolving biotech and cosmetic industries. The underlying patent data was obtained through an API (application programming interface) query at Patents View. The Patents View database is compiled under the auspices of the US Patent Office, as well as the European Patent Office (EPO), and is updated on an ongoing basis. The source can therefore be considered trustworthy. The data query was made from combined search terms. Different

variants of the spellings of "marine collagen, jellyfish collagen, collagen etc." were used in patent titles and abstracts. Since API query functionality was limited at the time the search was created, no further narrowing or expansion was done. The data obtained was converted to lowercase to avoid duplication in follow-up analyses. No duplicates had to be removed from the data set.

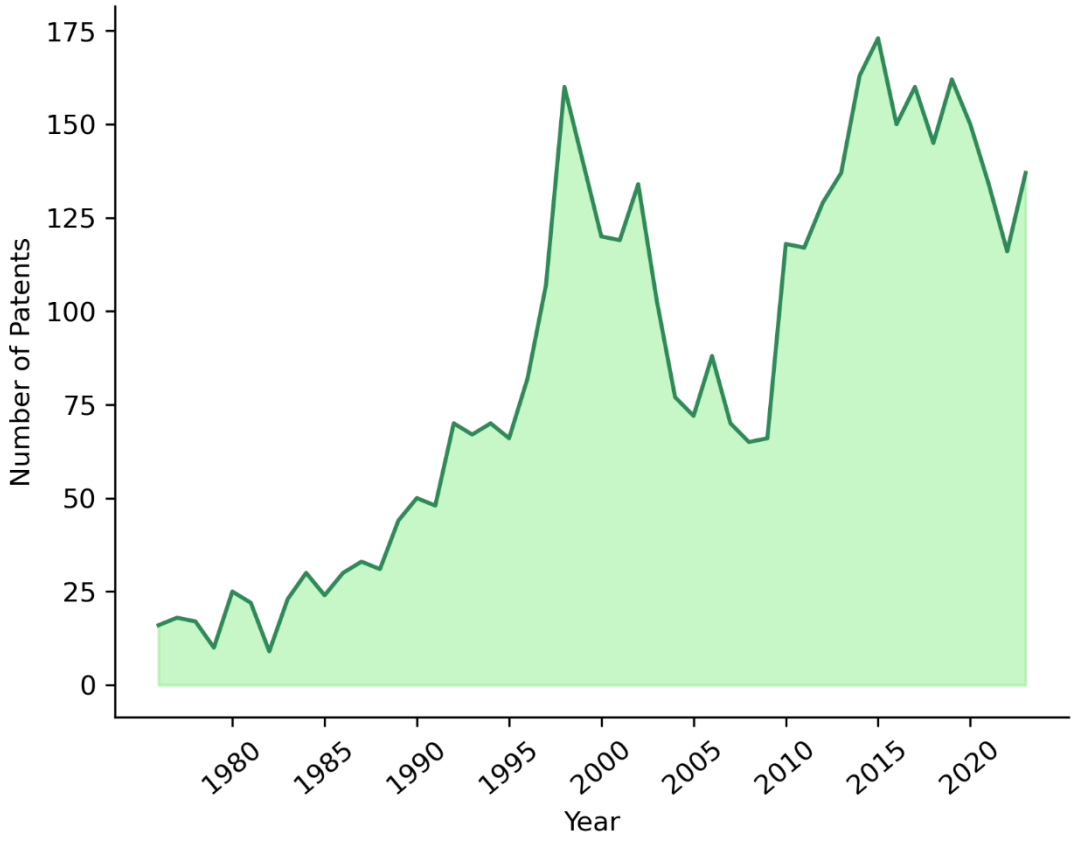


The first graph shows the distribution of patents across various regions: North America, Asia Pacific, Europe, Middle East-Africa, and Latin America. It indicates North America as having the highest number of patents, followed by Asia Pacific, Europe, Middle East-Africa, and Latin America with the fewest.

This kind of data visualisation is helpful for understanding the regional distribution of patent filings, which can reflect the innovation landscape and the investment in R&D within different areas. For instance, the high number of patents in North America could suggest a robust infrastructure for research and innovation within the field of collagen and marine collagen,

while the lower numbers in Latin America and Middle East-Africa might indicate either a smaller market or different focuses within their respective biotech industries.

Total Filing of Patents

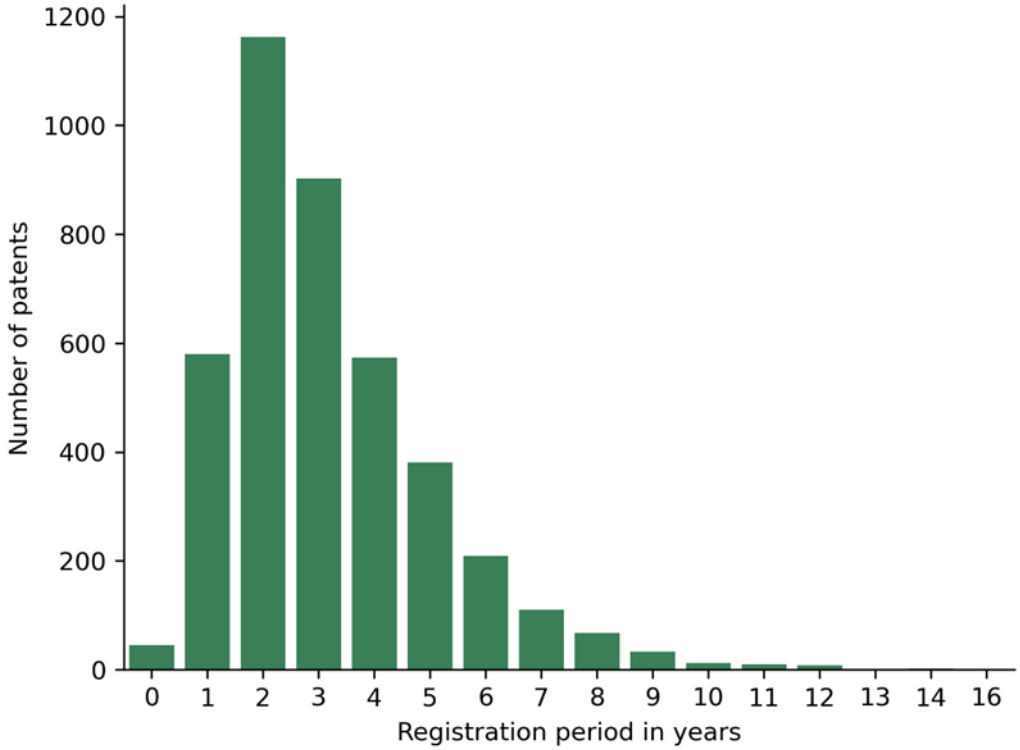


The second graph is a time series plot, showing the trend of patent filings over years from around 1980 (where the first patents have started to show up within the field of collagen) to 2022. The graph exhibits a general upward trend in the number of patents over time with some fluctuations, including what appears to be a peak in patent activity followed by a decline and then a resurgence.

This type of visualisation can be very telling in the context of collagen and marine collagen research and development. The increasing trend could be indicative of growing interest and investment in this sector, with particular surges potentially corresponding to key technological breakthroughs or increased market demand. Peaks and troughs could also correspond to changes in regulatory environments, availability of funding, or shifts in public or scientific

interest. For example, an increase in patent filings might coincide with the discovery of new extraction methods or identification of novel applications of collagen in medical treatments.

Average Time to Approval



The third graph displays a right-skewed distribution, with a large number of patents being granted within the first couple of years, and progressively fewer patents taking longer times to be approved. This pattern is typical in patent registration processes, where a majority of applications are resolved in the initial years following their filing. The diminishing number for longer durations likely reflects a combination of more complex cases, possible legal challenges, requests for additional information, or other complications that can delay the approval process. For patents in the field of collagen and marine collagen, this graph could indicate that while many patents are granted relatively quickly, which could be due to well-established protocols for evaluation and a clear scope of innovation, there remains a subset of patent applications that encounter challenges that require more time for a thorough review.

Understanding the distribution of approval times can be crucial for businesses and researchers in planning their R&D timelines and managing the patent application process strategically. For instance, if a company in the collagen industry knows that patents typically take 1-2 years to be granted, they might align their product development and go-to-market strategies accordingly. However, they also need to be prepared for potential delays, which could impact their competitive advantage and time-sensitive opportunities in the marketplace.

Appendix G: Phase Transition Success Rates by Disease Area

Phase Success	Phase I to II		Phase II to III		Phase III to NDA/BLA		NDA/BLA to Approval	
	n	Phase POS	n	Phase POS	n	Phase POS	n	Phase POS
Hematology	92	69.6%	106	48.1%	82	76.8%	72	93.1%
Metabolic	136	61.8%	149	45.0%	66	63.6%	48	87.5%
Infectious disease	403	57.8%	414	38.4%	197	64.0%	156	92.9%
Others	154	63.6%	228	38.6%	90	60.0%	69	88.4%
Ophthalmology	88	71.6%	200	35.5%	82	51.2%	45	91.1%
Autoimmune	413	55.2%	471	31.4%	219	65.3%	202	94.1%
Allergy	55	56.4%	92	28.3%	34	64.7%	20	100.0%
Gastroenterology	45	46.7%	73	34.2%	35	57.1%	33	90.9%
All indications	4414	52.0%	4933	28.9%	1928	57.8%	1453	90.6%
Respiratory	179	55.9%	215	21.9%	62	64.5%	45	95.6%
Psychiatry	150	52.7%	164	26.8%	71	56.3%	57	91.2%
Endocrine	319	43.3%	293	26.6%	151	66.2%	124	86.3%
Neurology	516	47.7%	504	26.8%	226	53.1%	165	86.7%
Oncology	1628	48.8%	1732	24.6%	495	47.7%	324	92.0%
Cardiovascular	214	50.0%	252	21.0%	105	55.2%	80	82.5%
Urology	22	40.9%	40	15.0%	13	69.2%	13	84.6%

For disease area-level reporting, we analysed 14 major groupings in the Figures: Allergy, Autoimmune, Cardiovascular, Endocrine, Gastroenterology (non-IBD), Hematology, Infectious Disease, Metabolic, Neurology, Oncology, Ophthalmology, Psychiatry, Respiratory, and Urology. The remaining disease areas were categorised as "Other," which includes Dermatology, Renal, Obstetrics, Rheumatology (for non-autoimmune indications),

ENT/Dental, and Orthopedics. These major disease areas encompass 573 indications, which will be analysed and discussed in subsequent reports.

Moving Forward, every aspect of the profitability of success, likelihood of approval rates and the average time to approval, TSD will be ranked within the category “Others”, as wound healing is part of Dermatology.

Appendix H: Likelihood of Approval Rates

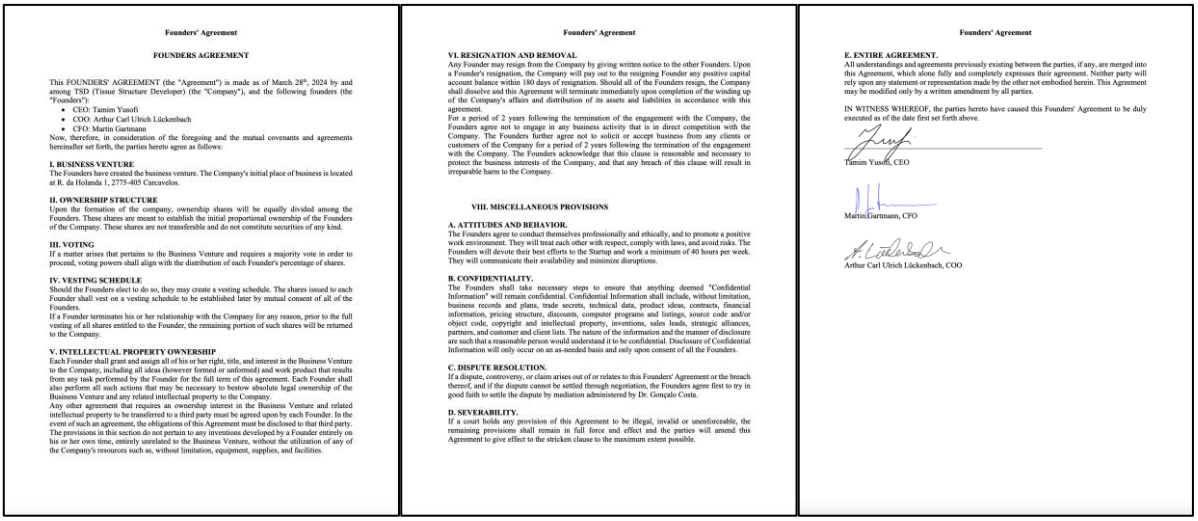
Likelihood of Approval	Phase I to Approval		Phase II to Approval		Phase III to Approval		NDA/BLA to Approval	
	LOA n	Phase LOA	LOA n	Phase LOA	LOA n	Phase LOA	LOA n	Phase LOA
Hematology	352	23.9%	260	34.4%	154	71.5%	72	93.1%
Metabolic	399	15.5%	263	25.0%	114	55.7%	48	87.5%
Infectious disease	1170	13.2%	767	22.8%	353	59.4%	156	92.9%
Others	541	13.0%	387	20.5%	159	53.0%	69	88.4%
Ophthalmology	415	11.9%	327	16.6%	127	46.7%	45	91.1%
Autoimmune	1305	10.7%	892	19.3%	421	61.4%	202	94.1%
Allergy	201	10.3%	146	18.3%	54	64.7%	20	100.0%
Gastroenterology*	186	8.3%	141	17.8%	68	51.9%	33	90.9%
All indications	12728	7.9%	8314	15.1%	3381	52.4%	1453	90.6%
Respiratory	501	7.5%	322	13.5%	107	61.6%	45	95.6%
Psychiatry	442	7.3%	292	13.8%	128	51.4%	57	91.2%
Endocrine	887	6.6%	568	15.2%	275	57.1%	124	86.3%
Neurology	1411	5.9%	895	12.3%	391	46.0%	165	86.7%
Oncology	4179	5.3%	2551	10.8%	819	43.9%	324	92.0%
Cardiovascular	651	4.8%	437	9.6%	185	45.6%	80	82.5%
Urology	88	3.6%	66	8.8%	26	58.6%	13	84.6%

Appendix I: Average Time to Approval

Phase Duration	Phase I to II		Phase II to III		Phase III to NDA/BLA		NDA/BLA to Approval	
	Advanced	Duration	Advanced	Duration	Advanced	Duration	Advanced	Duration
Allergy	31	1.5	26	3.8	22	2.9	20	1.1
Metabolic	84	2.0	67	3.2	42	3.1	42	1.2
Infectious disease	233	2.0	159	3.5	126	3.1	145	1.2
Ophthalmology	63	2.1	71	2.9	42	3.4	41	1.3
Autoimmune	228	2.1	148	3.6	143	3.2	190	1.1
Oncology	795	2.7	426	3.7	236	3.1	298	0.8
Respiratory	100	2.1	47	3.5	40	3.3	43	1.5
Psychiatry	79	2.3	44	3.4	40	2.8	52	1.8
Others	98	1.9	88	3.5	54	3.2	61	1.8
All indications	2296	2.3	1424	3.6	1115	3.3	1316	1.3
Endocrine	138	1.8	78	3.4	100	3.7	107	1.8
Hematology	64	2.2	51	3.4	63	3.6	67	1.5
Gastroenterology	21	1.6	25	3.9	20	3.9	30	1.4
Neurology	246	2.1	135	3.7	120	3.7	143	1.6
Cardiovascular	107	2.4	53	3.8	58	4.2	66	1.2
Urology	9	2.7	6	5.0	9	2.9	11	1.6

Source: (Thomas et al., 2021)

Appendix J: Signed Founder´s Agreement



Founders' Agreement

FOUNDERS AGREEMENT

This FOUNDERS' AGREEMENT (the "Agreement") is made as of March 28th, 2024 by and among TSD (Tissue Structure Developer) (the "Company"), and the following founders (the "Founders"):

- CEO: Tamim Yusofi
- COO: Arthur Carl Ulrich Lückenbach
- CFO: Martin Gartmann

Now, therefore, in consideration of the foregoing and the mutual covenants and agreements hereinafter set forth, the parties hereto agree as follows:

I. BUSINESS VENTURE
The Founders have created the business venture. The Company's initial place of business is located at R. da Holanda 1, 2775-405 Carcavelos.

II. OWNERSHIP STRUCTURE
Upon the formation of the company, ownership shares will be equally divided among the Founders. These shares are meant to establish the initial proportional ownership of the Founders of the Company. These shares are not transferable and do not constitute securities of any kind.

III. VOTING
If a matter arises that pertains to the Business Venture and requires a majority vote in order to proceed, voting powers shall align with the distribution of each Founder's percentage of shares.

IV. VESTING SCHEDULE
Should the Founders elect to do so, they may create a vesting schedule. The shares issued to each Founder shall vest on a vesting schedule to be established later by mutual consent of all of the Founders.
If a Founder terminates his or her relationship with the Company for any reason, prior to the full vesting of all shares entitled to the Founder, the remaining portion of such shares will be returned to the Company.

V. INTELLECTUAL PROPERTY OWNERSHIP
Each Founder shall grant and assign all of his or her right, title, and interest in the Business Venture to the Company, including all ideas (however formed or unformed) and work product that results from any task performed by the Founder for the full term of this agreement. Each Founder shall also perform all such actions that may be necessary to bestow absolute legal ownership of the Business Venture and any related intellectual property to the Company.
Any other agreement that requires an ownership interest in the Business Venture and related intellectual property to be transferred to a third party must be agreed upon by each Founder. In the event of such an agreement, the obligations of this Agreement must be disclosed to that third party. The provisions in this section do not pertain to any inventions developed by a Founder entirely on his or her own time, entirely unrelated to the Business Venture, without the utilization of any of the Company's resources such as, without limitation, equipment, supplies, and facilities.

Founders' Agreement

VI. RESIGNATION AND REMOVAL
Any Founder may resign from the Company by giving written notice to the other Founders. Upon a Founder's resignation, the Company will pay out to the resigning Founder any positive capital account balance within 180 days of resignation. Should all of the Founders resign, the Company shall dissolve and this Agreement will terminate immediately upon completion of the winding up of the Company's affairs and distribution of its assets and liabilities in accordance with this agreement.
For a period of 2 years following the termination of the engagement with the Company, the Founders agree not to engage in any business activity that is in direct competition with the Company. The Founders further agree not to solicit or accept business from any clients or customers of the Company for a period of 2 years following the termination of the engagement with the Company. The Founders acknowledge that this clause is reasonable and necessary to protect the business interests of the Company, and that any breach of this clause will result in irreparable harm to the Company.

VIII. MISCELLANEOUS PROVISIONS

A. ATTITUDES AND BEHAVIOR.
The Founders agree to conduct themselves professionally and ethically, and to promote a positive work environment. They will treat each other with respect, comply with laws, and avoid risks. The Founders will devote their best efforts to the Startup and work a minimum of 40 hours per week. They will communicate their availability and minimize disruptions.

B. CONFIDENTIALITY.
The Founders shall take necessary steps to ensure that anything deemed "Confidential Information" will remain confidential. Confidential Information shall include, without limitation, business records and plans, trade secrets, technical data, product ideas, contracts, financial information, pricing structure, discounts, computer programs and listings, source code and/or object code, copyright and intellectual property, inventions, sales leads, strategic alliances, partners, and customer and client lists. The nature of the information and the manner of disclosure are such that a reasonable person would understand it to be confidential. Disclosure of Confidential Information will only occur on an as-needed basis and only upon consent of all the Founders.

C. DISPUTE RESOLUTION.
If a dispute, controversy, or claim arises out of or relates to this Founders' Agreement or the breach thereof, and if the dispute cannot be settled through negotiation, the Founders agree first to try in good faith to settle the dispute by mediation administered by Dr. Gonçalo Costa.

D. SEVERABILITY.
If a court holds any provision of this Agreement to be illegal, invalid or unenforceable, the remaining provisions shall remain in full force and effect and the parties will amend this Agreement to give effect to the stricken clause to the maximum extent possible.

Founders' Agreement

E. ENTIRE AGREEMENT.
All understandings and agreements previously existing between the parties, if any, are merged into this Agreement, which alone fully and completely expresses their agreement. Neither party will rely upon any statement or representation made by the other not embodied herein. This Agreement may be modified only by a written amendment by all parties.

IN WITNESS WHEREOF, the parties hereto have caused this Founders' Agreement to be duly executed as of the date first set forth above.

Tamim Yusofi, CEO

Martin Gartmann, CFO

Arthur Carl Ulrich Lückenbach, COO

Appendix K: Detailed Cost Summary

	Amount
Item / Task Description	**Total**
Prototype Development	**50,000.00 €**
Design and Engineering Phase (3-6 months)	20,000.00 €
Small-Scale Manufacturing (2-3 months)	15,000.00 €
Feedback Integration (1-2 months)	15,000.00 €
Pre-Clinical Testing (3-6 months)	**100,000.00 €**
Intellectual Property	**25,000.00 €**
Patent Search	2,000.00 €
Filing Fees	11,000.00 €
German Patent and Trademark Fees	3,000.00 €
Patent Prosecution Phase	3,000.00 €
PCT Filing Fees	3,000.00 €
Other	3,000.00 €
Clinical Phase I & II	**14,500,000.00 €**
Phase 1: Safety Trial (1 - 2 year)	2,000,000.00 €
Phase 2: Efficacy Trial (3 - 4 years)	12,500,000.00 €
Labour Costs	**2,529,000.00 €**
CEO	240,000.00 €
COO	240,000.00 €
CFO	240,000.00 €
CSO	702,000.00 €
Product Development Manager (Bio-Tech)	354,000.00 €
Biochemists	378,000.00 €
Laboratory Assistant	225,000.00 €
Advisory Board	150,000.00 €
PPE / Facility (third party laboratory)	**1,080,000.00 €**
Rent	720,000.00 €
Machinery usage / Equipment	360,000.00 €
General and Administrative	**490,000.00 €**
Day to day laboratory Equipment	220,000.00 €
Administrative Costs	270,000.00 €
Total Costs	**18,774,000.00 €**

Appendix L: Detailed Annual Cost Structure

	Years					
Item / Task Description	**2025**	**2026**	**2027**	**2028**	**2029**	**2030**
Development Phase	**150,000.00 €**					
Design and Engineering Phase (3-6 months)	20,000.00 €	-	-	-	-	-
Small-Scale Manufacturing (2-3 months)	15,000.00 €	-	-	-	-	-
Feedback Integration (1-2 months)	15,000.00 €	-	-	-	-	-
Pre-Clinical Testing (3-6 months)	**100,000.00 €**	-	-	-	-	-
Intelecutal Property	**25,000.00 €**	-	-	-	-	-
Patent Search	2,000.00 €	-	-	-	-	-
Filing Fees	11,000.00 €	-	-	-	-	-
German Patent and Trademark Fees	3,000.00 €					
Patent Prosecution Phase	3,000.00 €	-	-	-	-	-
PCT Filing Fees	3,000.00 €	-	-	-	-	-
Other	3,000.00 €	-	-	-	-	-
Clinical Phase I & II	-	**2,000,000.00 €**	-	**12,500,000.00 €**	-	-
Phase 1: Safety Trial (1 - 2 years)	-	2,000,000.00 €	-	-	-	-
Phase 2: Efficacy Trial (3 - 4 years)	-	-	-	12,500,000.00 €	-	-
Labour Costs	**421,500.00 €**	**421,500.00 €**	**421,500.00 €**	**421,500.00 €**	**421,500.00 €**	**421,500.00 €**
CEO	40,000.00 €	40,000.00 €	40,000.00 €	40,000.00 €	40,000.00 €	40,000.00 €
COO	40,000.00 €	40,000.00 €	40,000.00 €	40,000.00 €	40,000.00 €	40,000.00 €
CFO	40,000.00 €	40,000.00 €	40,000.00 €	40,000.00 €	40,000.00 €	40,000.00 €
CSO	117,000.00 €	117,000.00 €	117,000.00 €	117,000.00 €	117,000.00 €	117,000.00 €
Product Development Manager (Bio-Tech)	59,000.00 €	59,000.00 €	59,000.00 €	59,000.00 €	59,000.00 €	59,000.00 €
Biochemists	63,000.00 €	63,000.00 €	63,000.00 €	63,000.00 €	63,000.00 €	63,000.00 €
Laboratory Assistant	37,500.00 €	37,500.00 €	37,500.00 €	37,500.00 €	37,500.00 €	37,500.00 €
Advisory Board	25,000.00 €	25,000.00 €	25,000.00 €	25,000.00 €	25,000.00 €	25,000.00 €
PPE / Facility (third party laboratory)	**180,000.00 €**	**180,000.00 €**	**180,000.00 €**	**180,000.00 €**	**180,000.00 €**	**180,000.00 €**
Rent	120,000.00 €	120,000.00 €	120,000.00 €	120,000.00 €	120,000.00 €	120,000.00 €
Machinery usage / Equipment	60,000.00 €	60,000.00 €	60,000.00 €	60,000.00 €	60,000.00 €	60,000.00 €
General and Administrative	**65,000.00 €**	**85,000.00 €**	**85,000.00 €**	**85,000.00 €**	**85,000.00 €**	**85,000.00 €**
Day to day laboratory Equipment	20,000.00 €	40,000.00 €	40,000.00 €	40,000.00 €	40,000.00 €	40,000.00 €
Administrative Costs	45,000.00 €	45,000.00 €	45,000.00 €	45,000.00 €	45,000.00 €	45,000.00 €
Total Costs	**841,500.00 €**	**2,686,500.00 €**	**686,500.00 €**	**13,186,500.00 €**	**686,500.00 €**	**686,500.00 €**

*Cost projections are laid out on the "base case" scenario analysis, due to changes within the process costs can be highly volatile.

Appendix M: Cash Flow Calculation for rNPV

in million €	Comments	1 2025	2 2026	3 2027	4 2028	5 2029	6 2030	7 2031	8 2032	9 2033	10 2034	11 2035	12 2036	13 2037	14 2038	15 2039	16 2040	17 2041	18 2042	19 2043	20 2044	21 2045
		Preclinical Phase	Phase 1		Phase 2			Phase 3			NDA/BLA		Commercialization Phase									
POS (Probability of Success)		100,00%	63,60%		38,60%			60,00%			88,40%											
LOA (Likelihood of Approval)	Cumulative probability		63,60%		24,55%			14,73%			13,02%						13,02%					
Revenue:	starting in year 12	€ -	€ -	€ -	€ -	€ -	€ -	€ -	€ -	€ -	€ -	€ -	€ 480,2	€ 480,2	€ 480,2	€ 1.175,0	€ 1.175,0	€ 1.175,0	€ 1.175,0	€ 2.152,0	€ 2.152,0	€ 2.152,0
Operating Income (EBIT):		(0,8)	(2,7)	(0,7)	(13,2)	(0,7)	(0,7)	(20,7)	(0,7)	(0,7)	(3,7)	(0,7)	48,0	48,0	48,0	235,0	235,0	235,0	235,0	645,6	645,6	645,6
Operating Margin:													10,0%	10,0%	10,0%	20,0%	20,0%	20,0%	20,0%	30,0%	30,0%	30,0%
(-) Taxes, Excluding Effect of Interest:		0,2	0,7	0,2	3,3	0,2	0,2	5,2	0,2	0,2	0,9	0,2	(12,0)	(12,0)	(12,0)	(58,8)	(58,8)	(58,8)	(58,8)	(161,4)	(161,4)	(161,4)
Tax Rate (25%)		0,25	0,25	0,25	0,25	0,25	0,25	0,25	0,25	0,25	0,25	0,25	0,25	0,25	0,25	0,25	0,25	0,25	0,25	0,25	0,25	0,25
Net Operating Profit After Taxes (NOPAT):		**(0,6)**	**(2,0)**	**(0,5)**	**(9,9)**	**(0,5)**	**(0,5)**	**(15,5)**	**(0,5)**	**(0,5)**	**(2,8)**	**(0,5)**	**36,0**	**36,0**	**36,0**	**176,3**	**176,3**	**176,3**	**176,3**	**484,2**	**484,2**	**484,2**
Adjustments for Non-Cash Charges:																						
(+) Depreciation & Amortization:		-	-	-	-	-	-	-	-	-	-	-	24,0	24,0	24,0	58,8	58,8	58,8	58,8	107,6	107,6	107,6
% Revenue:		5,0%	5,0%	5,0%	5,0%	5,0%	5,0%	5,0%	5,0%	5,0%	5,0%	5,0%	5,0%	5,0%	5,0%	5,0%	5,0%	5,0%	5,0%	5,0%	5,0%	5,0%
Net Change in Working Capital:		-	-	-	-	-	-	-	-	-	-	-	3,6	3,6	3,6	23,5	23,5	23,5	23,5	43,0	43,0	43,0
% Change in Revenue:		(5,0%)	(5,0%)	(5,0%)	(5,0%)	(5,0%)	(5,0%)	(5,0%)	(5,0%)	(5,0%)	(5,0%)	(5,0%)	(2,0%)	(2,0%)	(2,0%)	(2,0%)	(2,0%)	(2,0%)	(2,0%)	(2,0%)	(2,0%)	(2,0%)
% Revenue:		*2,0%*	*2,0%*	*2,0%*	*2,0%*	*2,0%*	*2,0%*	*2,0%*	*2,0%*	*2,0%*	*2,0%*	*2,0%*	*2,0%*	*2,0%*	*2,0%*	*2,0%*	*2,0%*	*2,0%*	*2,0%*	*2,0%*	*2,0%*	*2,0%*
(-) Capital Expenditures:		-	-	-	-	-	-	-	-	-	-	-	(9,6)	(9,6)	(9,6)	(23,5)	(23,5)	(23,5)	(23,5)	(43,0)	(43,0)	(43,0)
% Revenue:													(2,0%)	(2,0%)	(2,0%)	(2,0%)	(2,0%)	(2,0%)	(2,0%)	(2,0%)	(2,0%)	(2,0%)
Unlevered Free Cash Flow:		**(0,6)**	**(2,0)**	**(0,5)**	**(9,9)**	**(0,5)**	**(0,5)**	**(15,5)**	**(0,5)**	**(0,5)**	**(2,8)**	**(0,5)**	**60,0**	**60,0**	**60,0**	**235,0**	**235,0**	**235,0**	**235,0**	**591,8**	**591,8**	**591,8**
Discount Period:		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Discount Rate (WACC):		12,00%	12,00%	12,00%	12,00%	12,00%	12,00%	12,00%	12,00%	12,00%	12,00%	12,00%	12,00%	12,00%	12,00%	12,00%	12,00%	12,00%	12,00%	12,00%	12,00%	12,00%
Cumulative Discount Factor:		0,893	0,797	0,712	0,636	0,567	0,507	0,452	0,404	0,361	0,322	0,287	0,257	0,229	0,205	0,183	0,163	0,146	0,130	0,116	0,104	0,093
PV of Unlevered FCF:		**(0,6)**	**(1,6)**	**(0,4)**	**(6,3)**	**(0,3)**	**(0,3)**	**(7,0)**	**(0,2)**	**(0,2)**	**(0,9)**	**(0,1)**	**15,4**	**13,8**	**12,3**	**42,9**	**38,3**	**34,2**	**30,6**	**68,7**	**61,4**	**54,8**
EBITDA:		**(0,8)**	**(2,7)**	**(0,7)**	**(13,2)**	**(0,7)**	**(0,7)**	**(20,7)**	**(0,7)**	**(0,7)**	**(3,7)**	**(0,7)**	**72,0**	**72,0**	**72,0**	**293,8**	**293,8**	**293,8**	**293,8**	**753,2**	**753,2**	**753,2**

Appendix N: rNPV Formula

$$rNPVtotal = LOANPVrev - proNPVdev = \Sigma \frac{r_{LOA} CF_t}{(1+a)^t} - \Sigma \frac{Pro_{pt} C_{pt}}{(1+a)^{pt}}$$

Description of variables in the r-NPV formula,

pt: Development period in each phase,
r_{LOA}: LOA (Likelihood of Approval),
Pro_{pt}: Entry POS (Pro: Probability) in each phase,
a: Discount rate,
CF_t: Cash flow after release,
C_{pt}: Development cost in each phase,
t: Period until the expiration of the patent.

Appendix O: rNPV – 2025 Calculations for all Scenarios

Worst Case Valuation	
rNPV total	**25,71 €**
LOAN PV rev	31,66 €
pro NPV dev	(4,0)
Base Case Valuation	
rNPV total	**41,36 €**
LOAN PV rev	48,48 €
pro NPV dev	(4,0)
Best Case Valuation	
rNPV total	**55,14 €**
LOAN PV rev	63,30 €
pro NPV dev	(4,0)

Appendix P: EV to EBITDA and Revenue Multiples Valuation

Multiples 2023 - Biotech and Pharma

LOA	13,02%
EV/EBITDA	22,38X
EV/Revenue	9,71X

in million $	Best Case	Base Case	Worst Case
TSD EBITDA for strongest market penetration year	$ 66,71	$ 47,40	$ 28,09
TSD Revenue for strongest market penetration year	$ 341,17	$ 236,92	$ 132,67
Estimated Enterprise Value (EV) - EBITDA	$ 1.492,97	$ 1.060,82	$ 628,66
Estimated Enterprise Value (EV) - Revenue	$ 3.312,79	$ 2.300,50	$ 1.288,20
Average EV (in €)	**2.234,68 €**	**1.563,01 €**	**891,34 €**
Risk Adjusted EV - multiplied by LOA of 13.02% (in €)	**270,59 €**	**189,26 €**	**107,93 €**

Appendix Q: rNPV – 2030 Calculations for all Scenarios

rNPV - 2030 (in millions)

Worst Case Valuation	
rNPV total	**233,16 €**
LOAN PV rev	254,54 €
pro NPV dev	(3,8)
Base Case Valuation	
rNPV total	**358,96 €**
LOAN PV rev	389,81 €
pro NPV dev	(3,8)
Best Case Valuation	
rNPV total	**469,77 €**
LOAN PV rev	508,96 €
pro NPV dev	(3,8)

Appendix R: Sensitivity Analysis – Base Case

Sensitivity Analysis

	Weighted Average Cost of Capital - WACC		
	10,00%	**12,00%**	14,00%
rNPV (LOAN PV rev - pro NPV dev)	58,05 €	**41,36 €**	29,56 €

Appendix S: Funding Need per Stage

Funding Need	Years					
	2025	2026	2027	2028	2029	2030
Total Costs	841.500 €	2.686.500 €	686.500 €	13.186.500 €	686.500 €	686.500 €

Assumption on Funding Need	Projected Costs	with MarkUp (~30%)
Seed (2025)	841.500 €	1.200.000 €
Series A (2026)	3.373.000 €	4.600.000 €
Series B (2028)	14.559.500 €	19.700.000 €
Sum	18.774.000 €	25.500.000 €

**Seed before Grant Subsidy Recognition*

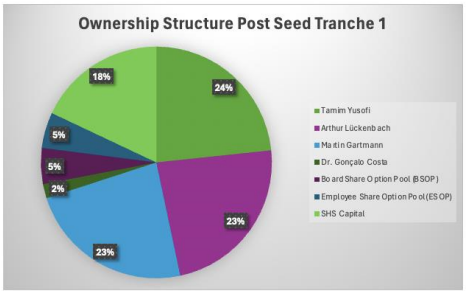
Appendix T: Target Funding Venture Capital Partners

Investor Name	Fund Manager Size (in million €)	Fundraising Stage	Latest Fund Generation	Latest Fund Size (in million	Time latest FR (Month, Year)	Ticket Size (in million €)	Target Sector	Success Rate (%)	Preferred Development Stage	Website
Wellington Partners	265	Investment	Fund V	210	April, 2022	2 - 20	Healthcare, Life Sciences	42.86%	Pre-clinical, Phase 1, Phase 2	https://www.wellington-partners.com/
Earlybird Health Tech	250	Investment	Fund III	250	October, 2022	2 - 15	Healthcare, Life Sciences	50.00%	Pre-clinical, Phase 1, Phase 2	https://earlybird.com/
Forbion	350	Investment	Fund VI	460	October, 2022	2 - 20	Healthcare, Life Sciences	50,00%	Phase 1, Phase 2	https://www.forbion.com/
LSP (Life Sciences Partners)	850	Investment	Fund VII	850	June, 2022	2 - 25	Life Sciences, MedTech	40,00%	Phase 1, Phase 2	https://www.lspvc.com/
Gilde Healthcare	450	Investment	Fund V	517	October, 2022	2 - 15	Healthcare, Life Sciences	42,86%	Phase 1, Phase 2	https://gildehealthcare.com/
BioGeneration Ventures	85	Investment	Fund V	140	March, 2022	2 - 10	Life Sciences	44.44%	Pre-clinical, Phase 1, Phase 2	https://www.biogenerationventures.com/
Inventures	300	Investment	Fund III	300	July, 2022	2 - 10	Healthcare, Life Sciences	42.86%	Seed, Pre-clinical, Phase 1, Phase 2	https://www.inventures.vc/
Heal Capital	150	Investment	Fund II	150	January, 2023	2 - 15	Healthcare, Digital Health	40.00%	Pre-clinical, Phase 1, Phase 2	https://healcapital.com/
SHS Capital	650	Investment	Fund VI	250	June, 2022	1 - 20	Healthcare, Life Sciences	42.86%	Seed, Pre-clinical, Phase 1, Phase 2	https://www.shs-capital.eu/
MTIP	100	Investment	Fund II	250	September, 2023	2 - 15	Healthcare, MedTech	50.00%	Pre-clinical, Phase 1, Phase 2	https://mtip.ch/
EQT Life Sciences	900	Investment	Fund I	1.000	November, 2022	5 - 50	Healthcare, Life Sciences	45.45%	Pre-clinical, Phase 1, Phase 2	https://eqtgroup.com/
Elytra Ventures	70	Raising	Fund I	70	February, 2024	2 - 7	Healthcare, Life Sciences	50.00%	Pre-clinical, Phase 1, Phase 2	https://elytraventures.com/
Ysios Capital	150	Investment	Fund III	300	December, 2022	5 - 20	Healthcare, Life Sciences	40.00%	Pre-clinical, Phase 1, Phase 2	https://ysioscapital.com/
Boehringer Ingelheim Venture Fund	300	Investment	Fund V	300	October, 2022	5 - 15	Healthcare, Life Sciences	41.67%	Pre-clinical, Phase 1, Phase 2	https://www.boehringer-ingelheim-venture.com/
Medicxi	400	Investment	Fund IV	400	June, 2022	2 - 20	Healthcare, Life Sciences	37.50%	Pre-clinical, Phase 1, Phase 2	https://www.medicxi.com/
Kurma Partners	300	Investment	Fund IV	300	December, 2022	5 - 15	Healthcare, Life Sciences	44.44%	Pre-clinical, Phase 1, Phase 2	https://www.kurmapartners.com/
Omnes Capital	500	Investment	Fund V	500	July, 2022	5 - 20	Healthcare, Life Sciences	42.86%	Pre-clinical, Phase 1, Phase 2	https://www.omnescapital.com/
Seventure Partners	500	Investment	Fund V	500	February, 2023	5 - 20	Healthcare, Life Sciences	38.46%	Pre-clinical, Phase 1, Phase 2	https://www.seventure.fr/
TVM Capital Life Science	900	Investment	Fund VII	476	September, 2023	2 - 20	Healthcare, Life Sciences	46.67%	Pre-clinical, Phase 1, Phase 2	https://www.tvm-lifescience.com/
Partech	750	Investment	Fund IV	750	January, 2023	0.5 - 2	Healthcare, Digital Health	41.7%	Seed, Pre-clinical, Phase 1, Phase 2	https://partechpartners.com/
Atlantic Labs	100	Investment	Fund II	150	March, 2023	0.5 - 2	Digital Health	50.0%	Seed, Pre-clinical, Phase 1, Phase 2	https://atlanticlabs.de/
HV Capital	500	Investment	Fund VIII	710	July, 2022	0.5 - 2	Healthcare, Digital Health	47.1%	Seed, Pre-clinical, Phase 1	https://hvcapital.com/
Speedinvest	450	Investment	Fund IV	450	November, 2022	0.5 - 2	Digital Health, MedTech	42.9%	Seed, Pre-clinical, Phase 1, Phase 2	https://www.speedinvest.com/
Cherry Ventures	300	Investment	Fund IV	300	October, 2022	0.5 - 2	Digital Health, MedTech	44.4%	Seed, Pre-clinical, Phase 1, Phase 2	https://www.cherry.vc/

Appendix U: Capitalisation Table Seed (Tranche 1) Funding

Seed Valuation 2025 (Tranche 1)	
Government Grants	200.000
SHS Capital (Seed Financing VC)	500.000
Total Seed Tranche 1 Finaning	700.000
Implied post-money Valuation	2.777.778
Equity Ownership	18%
Price per share	1,00 €

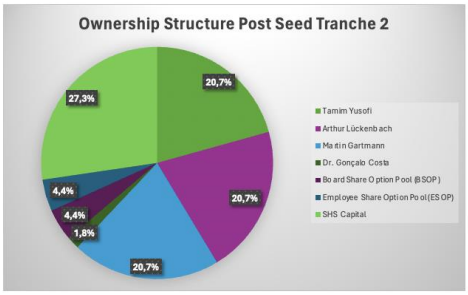
Shareholder	Investment	Share Value	Shares	% of Ownership
Tamim Yusofi	- €	648.148,15 €	648.148	23,3%
Arthur Lückenbach	- €	648.148,15 €	648.148	23,3%
Martin Gartmann	- €	648.148,15 €	648.148	23,3%
Dr. Gonçalo Costa	- €	55.555,56 €	55.556	2,0%
Board Share Option Pool (BSOP)	- €	138.888,89 €	138.889	5,0%
Employee Share Option Pool (ESOP)	- €	138.888,89 €	138.889	5,0%
SHS Capital	500.000,00 €	500.000,00 €	500.000	18,0%
Total	500.000,00 €	2.777.777,78 €	2.777.778	100%



Appendix V: Capitalisation Table Seed (Tranche 2) Funding

Seed Valuation 2025 (Tranche 2)	
Pre-money Valuation	3.400.000
SHS Capital (Seed Financing VC)	500.000
Total Seed Tranche 2 Finaning	500.000
Implied post-money Valuation	3.900.000
Pre-money share price	1,40 €
Value Step-up	1,15

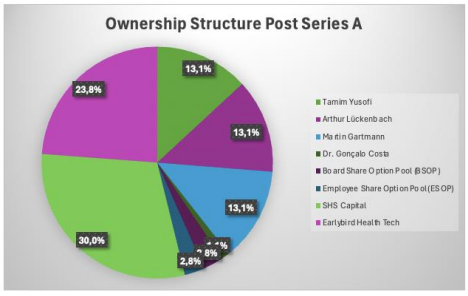
Shareholder	Investment	Share Value	Shares	% of Ownership
Tamim Yusofi	- €	806.590,91 €	648.148	20,7%
Arthur Lückenbach	- €	806.590,91 €	648.148	20,7%
Martin Gartmann	- €	806.590,91 €	648.148	20,7%
Dr. Gonçalo Costa	- €	69.136,36 €	55.556	1,8%
Board Share Option Pool (BSOP)	- €	172.840,91 €	138.889	4,4%
Employee Share Option Pool (ESOP)	- €	172.840,91 €	138.889	4,4%
SHS Capital	500.000,00 €	1.065.409,09 €	856.125	27,3%
Total	500.000,00 €	3.900.000,00 €	3.133.903	100%



Appendix W: Capitalisation Table Series A Funding

Series A Valuation 2026	
Pre-money Valuation	8.000.000
SHS Capital (Refinancing)	1.600.000
Earlybird Health Tech (Series A Financing VC)	3.000.000
Total Series A Finaning	4.600.000
Implied post-money Valuation	12.600.000
Pre-money share price	2,55 €
Value Step-up	1,58

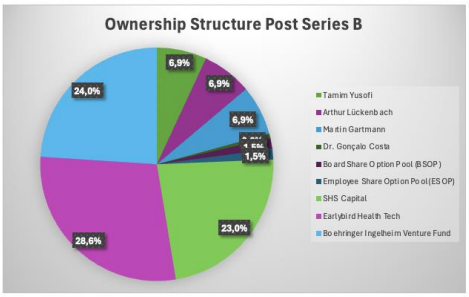
Shareholder	Investment	Share Value	Shares	% of Ownership
Tamim Yusofi	- €	1.654.545,45 €	648.148	13,1%
Arthur Lückenbach	- €	1.654.545,45 €	648.148	13,1%
Martin Gartmann	- €	1.654.545,45 €	648.148	13,1%
Dr. Gonçalo Costa	- €	141.818,18 €	55.556	1,1%
Board Share Option Pool (BSOP)	- €	354.545,45 €	138.889	2,8%
Employee Share Option Pool (ESOP)	- €	354.545,45 €	138.889	2,8%
SHS Capital	1.600.000,00 €	3.785.454,55 €	1.482.906	30,0%
Earlybird Health Tech	3.000.000,00 €	3.000.000,00 €	1.175.214	23,8%
Total	4.600.000,00 €	12.600.000,00 €	4.935.897	100%



Appendix X: Capitalisation Table Series B Funding

Series B Valuation 2028	
Pre-money Valuation	22.000.000
SHS Capital (Refinancing)	3.000.000
Earlybird Health Tech (Refinancing)	6.700.000
Boehringer Ingelheim Venture Fund	10.000.000
Total Series A Finaning	19.700.000
Implied post-money Valuation	41.700.000
Pre-money share price	4,46 €
Value Step-up	1,90

Shareholder	Investment	Share Value	Shares	% of Ownership
Tamim Yusofi	- €	2.888.888,89 €	648.148	6,9%
Arthur Lückenbach	- €	2.888.888,89 €	648.148	6,9%
Martin Gartmann	- €	2.888.888,89 €	648.148	6,9%
Dr. Gonçalo Costa	- €	247.619,05 €	55.556	0,6%
Board Share Option Pool (BSOP)	- €	619.047,62 €	138.889	1,5%
Employee Share Option Pool (ESOP)	- €	619.047,62 €	138.889	1,5%
SHS Capital	3.000.000,00 €	9.609.523,81 €	2.155.983	23,0%
Earlybird Health Tech	6.700.000,00 €	11.938.095,24 €	2.678.419	28,6%
Boehringer Ingelheim Venture Fund	10.000.000,00 €	10.000.000,00 €	2.243.590	24,0%
Total	19.700.000,00 €	41.700.000,00 €	9.355.769	100%



Appendix Y: Capitalisation Table Summary

Summary: Cap Table TSD	Seed Round (Tranche 1) - 01/2025				Seed Round (Tranche 2) - 07/2025				Series A - 01/2026				Series B - 01/2028			
Price per share (€)	1,00 €				1,40 €				2,55 €				4,46 €			
Pre-money valuation (€)	0 €				3.900.000 €				8.000.000 €				22.000.000 €			
Post-money valuation (€)	2.777.778 €				4.400.000 €				12.600.000 €				41.700.000 €			
	Investment (€)	Newshares	Total shares	%	Investment (€)	Newshares	Total shares	%	Investment (€)	Newshares	Total shares	%	Investment (€)	Newshares	Total shares	%
Tamim Yusofi	- €	0	648.148	23,3%	- €	0	648.148	20,7%	- €	0	648.148	13,1%	- €	0	648.148	6,9%
Arthur Lückenbach	- €	0	648.148	23,3%	- €	0	648.148	20,7%	- €	0	648.148	13,1%	- €	0	648.148	6,9%
Martin Gartmann	- €	0	648.148	23,3%	- €	0	648.148	20,7%	- €	0	648.148	13,1%	- €	0	648.148	6,9%
Dr. Gonçalo Costa	- €	0	55.556	2,0%	- €	0	55.556	1,8%	- €	0	55.556	1,1%	- €	0	55.556	0,6%
Board Share Option Pool (BSOP)	- €	0	138.889	5,0%	- €	0	138.889	4,4%	- €	0	138.889	2,8%	- €	0	138.889	1,5%
Employee Share Option Pool (ESOP)	- €	0	138.889	5,0%	- €	0	138.889	4,4%	- €	0	138.889	2,8%	- €	0	138.889	1,5%
SHS Capital	500.000 €	500.000	500.000	18,0%	500.000 €	356.125	856.125	27,3%	1.600.000 €	626.781	1.482.906	30,0%	3.000.000 €	673.077	2.155.983	23,0%
Earlybird Health Tech	- €	0	0	0,0%	- €	0	0	0,0%	3.000.000 €	1.175.214	1.175.214	23,8%	6.700.000 €	1.503.205	2.678.419	28,6%
Boehringer Ingelheim Venture Fund	- €	0	0	0,0%	- €	0	0	0,0%	- €	0	0	0,0%	10.000.000 €	2.243.590	2.243.590	24,0%
	500.000 €	500.000	2.777.778	100,0%	500.000 €	356.125	3.133.903	100,0%	4.600.000 €	1.801.994	4.935.897	100,0%	19.700.000 €	4.419.872	9.355.769	100,0%

Appendix Z: Target Exit Options and their Strategic Fit

Company	Headquarters	Description	Market Cap (bln $)	Type	Public	Strategic Fit	Evaluation of Fit	Link
Johnson & Johnson	USA	A global healthcare leader manufacturing a broad range of medical devices, pharmaceutical, and consumer health products.	428.5	Healthcare	Yes	10	Perfect complement to their surgical and wound closure products, TSD would introduce a new advanced wound care technology, enhancing their portfolio and leveraging their strong market presence in healthcare. This aligns perfectly with their strategic focus on	www.jnj.com
Medtronic	Ireland	Specializes in medical technologies for various health conditions, particularly in cardiac and vascular health, diabetes, and minimally invasive therapies.	133.6	Medical Technology	Yes	8	Medtronic's existing focus on broad medical technologies provides a good, but less direct, synergy for integrating TSD's collagen-based innovations into their surgical and wound management portfolio.	www.medtronic.com
3M	USA	A diversified technology company heavily invested in health care, particularly known for its products in infection prevention and wound healing.	102.6	Diversified	Yes	8	3M's broad healthcare portfolio would benefit from the addition of TSD, adding advanced collagen-based technology to their offerings and enhancing their wound care segment, though their diversified focus may dilute the strategic impact of this addition.	www.3m.com
Coloplast	Denmark	Develops and markets medical devices for wound care, ostomy, continence, and urology, focusing on improving patient comfort and clinical outcomes.	28.6	Medical Technology	Yes	10	TSD would strategically expand Coloplast's wound care capabilities with cutting-edge collagen-based technology, offering significant advancements in patient care and treatment outcomes. This acquisition perfectly matches their core mission of enhancing	www.coloplast.com
ConvaTec	UK	Manufactures innovative medical products for the management of chronic conditions, including a wide range of wound care therapies.	1.9	Healthcare	Yes	7	TSD could provide ConvaTec a novel product in the collagen-based wound care segment, enhancing their offerings but with a lesser impact compared to others due to their broader focus on chronic conditions.	www.convatec.com
Stryker	USA	A medical technology company focused on surgical equipment and neurotechnology, with a growing presence in the medical products market.	79.2	Medical Technology	Yes	7	Stryker would gain a new foothold in the wound care market with TSD, complementing its surgical solutions; however, their primary focus remains on broader surgical technologies and equipment.	www.stryker.com
Zimmer Biomet	USA	Specialized in musculoskeletal healthcare, interested in expanding into related medical sectors to complement their orthopedic and surgical solutions.	33.1	Medical Technology	Yes	7	While Zimmer Biomet could benefit from entering the wound care market with TSD, their core focus on orthopedics makes the strategic fit slightly less compelling compared to firms with a direct stake in wound care technologies.	www.zimmerbiomet.com
Cardinal Health	USA	A global healthcare services and products company, providing a comprehensive range of customized solutions for healthcare systems, including distribution and product supply for various medical needs.	16.0	Healthcare	Yes	6	Cardinal Health could expand into direct product manufacture with TSD, but as a distributor primarily, the strategic impact and alignment might be less direct compared to firms focused on manufacturing and product innovation.	www.cardinalhealth.com
Baxter International	USA	Provides essential healthcare products, including dialysis therapies, sterile IV solutions, and infusion systems, but lacks a presence in the wound care sector.	38.9	Healthcare	Yes	6	Baxter's entry into wound care with TSD would diversify their portfolio; however, their primary focus on critical care and infusion systems may not align as closely with wound care technologies, making the strategic fit moderate.	www.baxter.com
Becton Dickinson	USA	A leading medical technology company that produces medical devices, instrument systems, and reagents, with a strong focus on infection prevention and biosciences but limited involvement in wound care.	74.0	Medical Technology	Yes	6	Adding TSD would expand Becton Dickinson's product range but may not fully align with their core activities focused on biosciences and infection prevention, making the strategic fit less compelling.	www.bd.com
Boehringer Ingelheim	Germany	A global research-driven pharmaceutical company with significant expertise in animal health and prescription medicines, focusing on respiratory, cardiovascular, metabolic, and central nervous system diseases.	N/A	Pharmaceutical	No	8	The acquisition of TSD would complement Boehringer Ingelheim's strong presence in pharmaceuticals, allowing them to expand strategically into the wound care market. The advanced wound healing technology aligns well with their innovation goals and expands their global portfolio.	www.boehringer-ingelheim.com