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

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Business Strategy, Market Analysis & Architecture

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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

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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 remodeling 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 infection, 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.

4. Market

The global wound care market, a dynamic and rapidly evolving sector, was valued at $21.5 billion in 2023. It is predicted to increase significantly, reaching $28.6 billion by 2032 and growing at a compound annual growth rate (CAGR) of 5.9%. The wound care industry in the United States reached a noteworthy milestone in 2022 when its revenue size reached $8 billion,

capturing a market share of around 35%. It is anticipated that this market would increase significantly during the next five to ten years. The European wound care market has the second-largest share globally, right behind the U.S. market. The Asia Pacific region follows with the rest of the world (Global Market Insights, 2023; Markets and Markets, 2023).

4.1. Market Dynamics

The increase in illnesses and ailments that have a negative impact on wound healing capacity is one of the main factors propelling this market. This includes an aging population, an increase in serious injuries, and a rise in the quantity of surgeries performed. Furthermore, the prevalence of increasingly common illnesses like diabetes and obesity increases the frequency and complexity of wounds including ulcerations, infections, and chronic wounds (Markets and Markets, 2023). The demand is fuelled in part by the rising incidence of diabetes worldwide, which frequently causes wounds to heal more slowly. Interestingly, foot ulcers are difficult to cure and affect 15–25% of people with diabetes at some time. Major causes of hospital admissions are primarily caused by diabetic foot ulcers and pressure ulcers, which are typical complications in individuals with diabetes. Another significant driver of this market's growth is the increasing incidence of burn injuries. According to the World Health Organization (2023), burns cause over 180,000 deaths each year, most of which occur in low- and middle-income nations. These injuries require sophisticated wound care, which raises the cost of healthcare (Global Market Insights, 2023).

The market is, however, severely constrained by the high price of advanced wound care products. These expenses influence these items' accessibility and affordability, which may restrict their uptake and use, particularly among patients and in less affluent healthcare settings. Moreover, a lack of knowledge regarding appropriate wound care, especially in underdeveloped nations. This information gap may result in wounds that are ignored or managed incorrectly, which can lead to problems and longer healing times. Campaigns for healthcare education are

crucial to raising public awareness and promoting better outcomes for people with a range of wound types.

Despite these obstacles, growing economies like South Korea, Malaysia, Vietnam, India, various African nations, and Middle Eastern countries including Saudi Arabia, Israel, and the United Arab Emirates offer significant prospects. The need for wound care services and products is growing in these areas due to factors like expanding urbanisation, improving healthcare infrastructure, and raising public awareness of healthcare demands. Government programs designed to improve healthcare affordability and accessibility support these markets even more (Markets and Markets, 2023).

Regulatory frameworks are crucial in determining the direction of the wound care industry. They have an impact on areas such as marketing, patient safety, product development, and standard industry procedures. Wound care product certification and approval are handled by regulatory agencies and standards like the FDA in the US and the EMA in the EU for CE marking. Compliance to these regulatory requirements is essential for product commercialisation and market access. Strict quality and safety requirements are imposed on wound care products by these rules, which also require producers to follow Good Manufacturing Practices (GMP) and fulfil certain requirements in order to guarantee the efficacy and safety of their products (Grand View Research, 2023; Statista, 2024). These strict regulations, meanwhile, may provide challenges, especially for startups or smaller businesses. It is frequently necessary to make large investments in testing, documentation, and research to comply with these rules. Although meeting these requirements can be difficult, doing so is essential to fostering confidence among patients, healthcare professionals, and regulatory bodies as well as enhancing the general integrity and dependability of the wound care sector (Grand View Research, 2023).

4.2. Market Segmentation

The wound care industry is undergoing a period of unprecedented innovation, mostly due to the swift progress of technology and the growing use of sophisticated products, particularly in home care environments. The market segment in question has experienced notable growth due to a combination of factors including population aging, technological advancements, cost-effectiveness, and an increasing focus on patient-centric care. The development of wound care solutions that are not only efficient but also prioritise patient comfort, convenience of use, and the ability for patients to manage some parts of their treatment independently is essential to this shift towards patient-centric care (Grand View Research, 2023).

The market's product portfolio for wound care comprises advanced dressings, surgical wound care, traditional wound care, wound treatment devices, and biologics. With $6 billion in revenue, the advanced wound dressing segment was amongst the most profitable ones in 2022. The popularity of this market is due to the efficiency and adaptability of items such as foam dressings, which are very absorbent and necessary for controlling wound exudate. While preventing harmful moisture build-up, these dressings aid in maintaining a moist environment that promotes healing. Their softness, elasticity, and cushioning are other reasons why they are preferred. In addition, the market is divided into two segments according to application: acute and chronic wounds. Acute wounds include surgical wounds, trauma wounds, and burns; chronic wounds are further classified as diabetic foot ulcers, pressure ulcers, venous leg ulcers, and others. The acute wounds sector generated $11.9 billion in sales in 2022. Moist wound dressings are a typical treatment for diabetic foot ulcers; by the end of 2032, the market is expected to reach $7.2 billion. These dressings are especially helpful for treating ulcers in diabetics, who frequently have slow healing and are more vulnerable to infection because of weakened immune systems and poor circulation (Fortune Business Insights, 2023; Global Market Insights, 2023).

End-user segments such as hospitals, specialty clinics, home care settings, and others can be identified when analysing the market based on end-use. In 2022, revenues from the hospital division alone were $8 billion. Because they have access to a wide variety of cutting-edge wound care products and have specialised teams, hospitals play a major role in wound care (Global Market Insights, 2023). Over the course of the projected period, a higher CAGR is anticipated for the homecare settings sector. This is because older adults are more likely to have chronic wounds, and more patients are choosing to get their care at home. The increased investment in small and medium-sized clinics by public and private entities is expected to result in a considerable CAGR for the clinics and other categories. To enhance healthcare infrastructure, long-term care facilities are becoming more widespread worldwide, which is contributing to the segment's growth (Fortune Business Insights, 2023).

4.3. Our Market

TSDs first go-to-market will be Germany. Germany is the fourth-biggest pharmaceutical market in the world and the largest in Europe. Changes in the population, a rise in chronic illnesses, and a greater focus on self-medication and preventative treatment are driving the industry. Sales in the German pharmaceutical sector increased by 5.4% in 2022 to reach €56.5 billion, above the growth of the country's economy. It is a leading pharmaceutical innovation leader in Europe and a top site for clinical trials, as demonstrated by significant investments in R&D and patent applications. Pharmaceutical businesses in Germany spent €8.7 billion on research and development in 2021; in 2020, R&D expenses accounted for 11.1% of total revenue, and overall research intensity was 16.5% (GTAI, 2023).

Germany, the world's largest exporter of pharmaceuticals, recorded pharmaceutical exports of €101.6 billion in 2021, with a production value of €34.6 billion, indicating a 6.9% annual rise. Along with Belgium and Italy, the nation is one of the leading hubs for pharmaceutical manufacture in the European Union and a major supplier of innovative biopharmaceuticals. In

Germany, there are over 600 pharmaceutical companies, and the majority of these are small and medium-sized businesses (SMEs), with over 90% of them employing fewer than 500 people. SMEs are the backbone of the sector. There are about 140,000 workers in this industry. With 589 clinical trials conducted in 2021, Germany ranked second in the EU and sixth worldwide and with 613 patents registered with the European Patent Office in 2022, the nation also led Europe in pharmaceutical patent applications. More than 30 biotechnology clusters are located in Germany, combining local scientific knowledge with business and academic cooperation to create an internationally recognised innovation environment and considerably boost pharmaceutical innovation. Germany is the second-largest producer of EU-approved biopharmaceuticals, behind the USA. Global giants like GSK, Pfizer, Roche, Sanofi, and Takeda are among the multinational corporations operating there, along with major local companies like Bayer and Boehringer Ingelheim. Strong industrial infrastructure, the resilience of the chemical sector, and a highly skilled labour base all contribute to this importance (GTAI, 2023).

Advantageous reimbursement arrangements that guarantee widespread access to cutting-edge therapies further enhance the market's attractiveness (Schwander et al., 2013). Germany's regulatory environment prioritises patient safety and fosters medical innovation. Clear regulatory standards from Germany ease the process of getting CE marking, which is necessary to reach the EU market (Bhavyasri et al., 2019). This is critical for TSDs new product launch, as Germany's strategic stance provides a doorway to the larger European market (Lao & Zhou, 2023). Germany's competitive environment is characterised by a culture of innovation, with many organisations advancing medical technology. This dynamic promotes competitiveness as well as teamwork, which pushes for ongoing development. Germany provides a wealth of partnership options and access to cutting edge technologies for businesses that specialise in goods such as jellyfish collagen-based wound dressings. Furthermore, Germany's consumer

behaviour and demographic trends underscore the market's potential for wound care products. The aging population highlights the increasing need for advanced wound care treatments due to its increased prevalence of chronic wounds and illnesses like diabetes that hinder healing (Schwander et al., 2013).

In the beginning of this chapter, we mentioned that the overall wound healing market was valued at $21.5 billion in 2023, growing with a CAGR of 5.9%. The US claimed more than 35% market share, representing around $8 billion in revenue, followed by Europe, Asia and the rest of the world. We estimate that Europe covers a market share of around 25% consequently, led by the strongest European location Germany with respectively 7.5% global market share and 30% European market share. Hence, we expect the German wound healing market, to be at around $1.61 billion. This market is segmented in chronic and acute wounds representing 70% and 30% of the markets. Although, the number of acute wounds is higher, chronic wounds are characterised by higher costs, therefore accounting for a higher share of the market. Prospecting these numbers for our potential start of commercialisation while considering the CAGR, we conclude with a market size of $3.40 billion in 2036 (see Figure 2 below).

Market Size Wound Healing

CAGR: 5,90%	Market Share 2023 in billion $	2036 in billion $	in %
Global Wound Healing Market	21,5	45,30	100%
Market Share US	8,00	16,86	37,2%
Rest Market Share	13,50	28,44	62,8%
Europe*	5,38	11,34	25,0%
Germany	**1,61**	**3,40**	**7,5%**
Chronic Wounds (70%)	**1,13**	**2,38**	**5,3%**
Acute Wounds (30%)	**0,48**	**1,02**	**2,3%**

**based on estimations from that point on*

Figure 1: Market Size Wound Healing

When it comes to the possible penetration rates, we forecasted different scenarios for the first ten years of commercialisation in Germany; Best Case, Base Case and Worst Case. In addition, we expect the market penetration rate to increase in all the three scenarios, resulting with a maximum rate of 15%, 12% and 8% for each scenario at year ten of commercialisation. Please refer to Appendix C for the detailed market penetration forecast. A successful penetration of the German market offers the possibility for further expansion within Europe, increasing the market share in Europe, as well as intercontinental expansion.

5. Stakeholders

As we delve into the chapter ‘Stakeholders’ we will first discuss 'Segmentation,' examining the broad categories of our target market, followed by 'Patients and Doctors,' which will provide a more detailed and nuanced understanding of individuals and their characteristics such as patients and doctors. Lastly, we will look at the composition of hospitals and insurances to get a better understanding of TSD’s involvement within the process of the German healthcare reimbursement standards. This approach ensures a comprehensive understanding of our

audience, aligning our product development with the specific needs and preferences of those we aim to serve, thereby ensuring more impactful and successful engagement with our market.

5.1. Segmentation

In the realm of advanced wound care, the CollaPatch™ represent a groundbreaking innovation, offering significant benefits over traditional treatments. This chapter delves into the primary segmentations for this product: patients with chronic wounds and specialised staff, working within hospitals such as physicians and nurses. Understanding the distinct characteristics and needs of both parties is fundamental for a successful development and utilisation of our product. Patients with chronic wounds, such as diabetic ulcers, venous ulcers, and pressure ulcers, constitute a significant demographic in need of effective, painless, and conducive wound care solutions. The CollaPatch™, with its inherent biocompatibility and potential for accelerated wound healing, cater perfectly to this group. Its hypoallergenic nature and superior healing properties are ideal for patients prone to allergic reactions or with compromised healing capabilities. Addressing potential patient concerns regarding the novel use of jellyfish collagen, through educational initiatives and demonstrable evidence of efficacy, is crucial. Additionally, ensuring accessibility through insurance coverage and affordability are key factors for this segment's adoption of the product.

In the context of healthcare institutions, hospitals and clinics are continuously in pursuit of advanced wound care products that offer better outcomes, ease of use, and cost-effectiveness. The advantages of the CollaPatch™ in a clinical setting are manifold. These include enhanced healing, reduced risk of infection, and ease of application, which align well with the needs of healthcare providers. These benefits can lead to shorter hospital stays, improved wound management and significant metrics in healthcare quality assessments. The introduction of a new product in a clinical setting necessitates training and integration into existing wound care protocols. Collaborations with healthcare professionals for pilot studies and training programs

are essential for the adoption of our product. Furthermore, conducting economic analyses, including cost-benefit comparisons with existing wound care products, is crucial for adoption in hospitals. Demonstrating the long-term economic advantages, such as reduced recurrence of wounds and lesser need for additional treatments, can position the CollaPatch™ as a preferred choice for these institutions.

5.2. Patients and Doctors

In the development of the CollaPatch™, understanding and addressing the needs of our customers is crucial. This chapter focuses on two primary personas: Michael Thompson, a patient suffering from chronic diabetic foot ulcers and Dr. Alexandra M. Ford, a dermatologist and wound care specialist (see Appendix D). The juxtaposition of these personas provides a comprehensive view of patient and doctor.

Michael Thompson is a patient persona that encapsulates the experiences and challenges faced by individuals with chronic wounds. Michael's journey with diabetic foot ulcers highlights the direct impact of our product on the patient's quality of life. The CollaPatch™ addresses his key needs by offering an effective, comfortable, and easy-to-use solution to accelerate wound healing. Emphasising the product's ease of application and pain-relieving properties caters to his desire for a treatment that fits seamlessly into his daily routine, enhancing adherence and, consequently, clinical outcomes. Furthermore, the aspect of cost-effectiveness and insurance coverage is crucial in appealing to patients like Michael, who are often burdened by the financial implications of long-term wound management. Marketing strategies targeting this demographic should focus on patient education through simplified and accessible materials, along with endorsements from healthcare professionals they trust (e.g. Dr. M. Ford).

On the other end of the spectrum is Dr. Alexandra M. Ford, who represents a critical segment in the medical field: healthcare professionals specialising in wound care. Her extensive experience and commitment to integrating advanced treatment methods into her practice make

her an ideal early adopter and advocate for the CollaPatch™. By addressing Dr. Ford's pain points, such as the need for effective, time-efficient, and sustainable wound care solutions, CollaPatch™ is positioned as an innovative addition to her wound care arsenal. The products unique properties, including enhanced healing effects and biocompatibility, align with her clinical objectives of reducing healing time and infection risks. Moreover, the environmentally sustainable aspect of jellyfish collagen resonates with her inclination towards eco-friendly medical practices. Strategically, engaging with Dr. Ford through clinical trials, educational materials, and product demonstrations will not only provide her with the evidence-based confidence to use our product but also facilitate peer-to-peer marketing within her professional network, leveraging her influence and expertise.

The synergy between healthcare providers' professional needs and patients' personal needs, like Michael's, is the cornerstone of our market positioning. Our product, using jellyfish collagen, offers scientific innovation and a practical, patient-centred solution. By aligning our product's unique properties with these specific needs, we create a compelling, empathetic, and scientifically sound value proposition. This approach ensures that CollaPatch™ is both groundbreaking and resonant with patients.

6. 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.

6.1. 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).

6.2. 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).

6.3. 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).

6.4. 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.

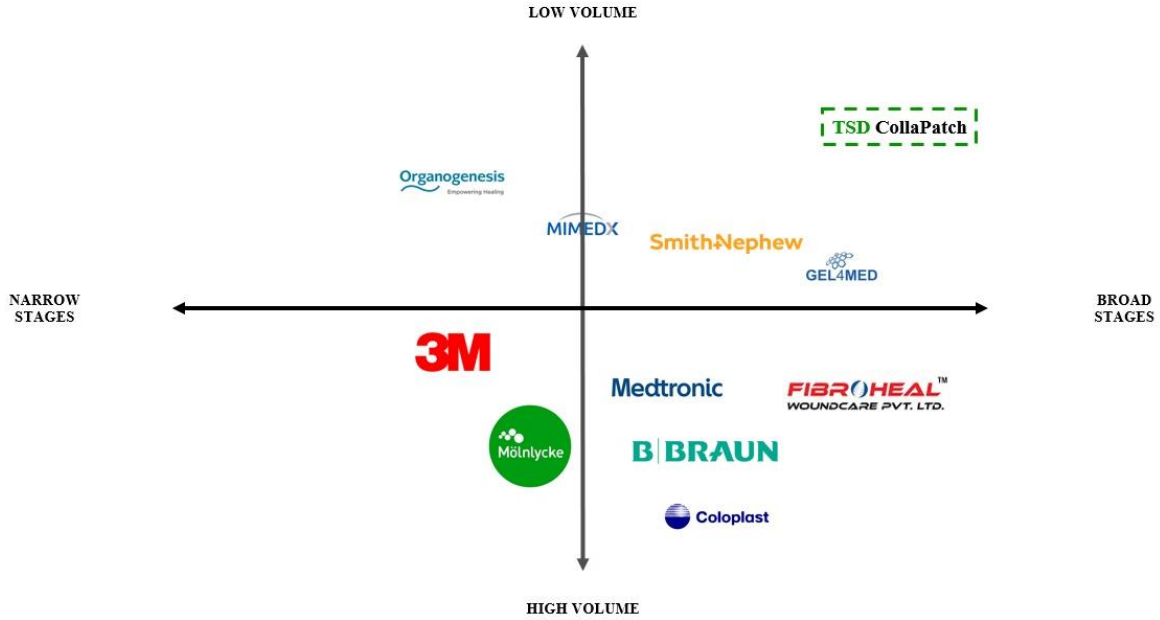

Figure 2: Perceptual Map

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™ 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™ 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

populations 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.

7. Team

TSD's composition and cooperation are critical for the development and commercialisation of the CollaPatch™. This cutting-edge endeavour, which combines biotechnology and business, calls for an interdisciplinary workforce with a high degree of synergy. Because of the strong business sense, we understand that in order to successfully negotiate the intricate pathways of product development, regulatory compliance, and market penetration, incorporating scientific competence into the core team is of high importance.

7.1. Management Structure and Key Positions

TSD's strategic orientation is guided by both commercial viability and scientific integrity thanks to the management structure's design (see Figure 6), which strikes a balance between business experience and scientific acumen. The CEO (Chief Executive Officer), who brings a strong business background and focuses on strategy and growth, the COO (Chief Operating Officer), who oversees daily operations, supply chain management, and production scaling up once product development matures, the CFO (Chief Financial Officer), who oversees the venture's financial strategy, including investments, budgeting, and financial planning, and the CSO (Chief Scientific Officer), who is in charge of overseeing the scientific and technological aspects of product development, are important positions within this structure (Raappana & Horila, 2020). The comprehensive founder's agreement further entails information about the synergy and tasks of these positions (Appendix J).

Initially, the CEO sets the company's vision and strategic direction, crafting a mission statement and establishing long-term goals that align with both the product's scientific potential and

market needs. Key early responsibilities include securing funding from sources like venture capital and managing resource allocation across departments such as R&D and marketing. The CEO also engages with stakeholders and acts as the company's primary spokesperson. As the product moves through development, the CEO focuses on risk management and strategic adjustments in response to technological, market, and regulatory challenges. Preparations for market entry involve developing marketing strategies and forming strategic alliances to enhance market penetration. Post-development, the CEO shifts focus towards driving growth by expanding operations, extending market reach, and potentially diversifying product offerings.

The COO is pivotal in ensuring the startup operates efficiently and aligns with strategic goals. Initially, the COO establishes essential operational infrastructure, including research laboratories and production facilities, and sets up crucial processes like research protocols and supply chain logistics to maintain high standards of quality and efficiency. As the product transitions from research to development, the COO manages the scaling of operations, enhancing production capabilities and streamlining processes to ensure sustainability and compliance with regulatory standards. In the commercialisation and growth phases, the COO drives operational excellence, refines processes, and integrates technology to boost productivity. The COO also develops and manages a robust supply chain and distribution network to support increased production demands and assists with strategic logistics for market entry and expansion.

In the early stages, the CFO, alongside the CEO, is crucial for securing the funding needed for research and development, identifying sources such as venture capital, angel investors, and grants. The CFO implements financial strategies to carefully manage cash flow through budgeting, forecasting, and expense management, ensuring the company can sustain operations and support essential R&D activities. As the company moves into the development phase, the CFO's role evolves to focus on strategic financial management, optimising resource allocation

and spending across R&D, marketing, and production. This includes adhering to strict financial reporting and compliance, especially crucial for companies preparing for Initial Public Offerings (IPOs) or seeking further funding rounds. During commercialisation, the CFO manages the capital structure to facilitate expansion while ensuring financial stability, which involves negotiating better financing terms and managing shareholder relations. As the company grows, controlling costs and enhancing profitability become paramount.

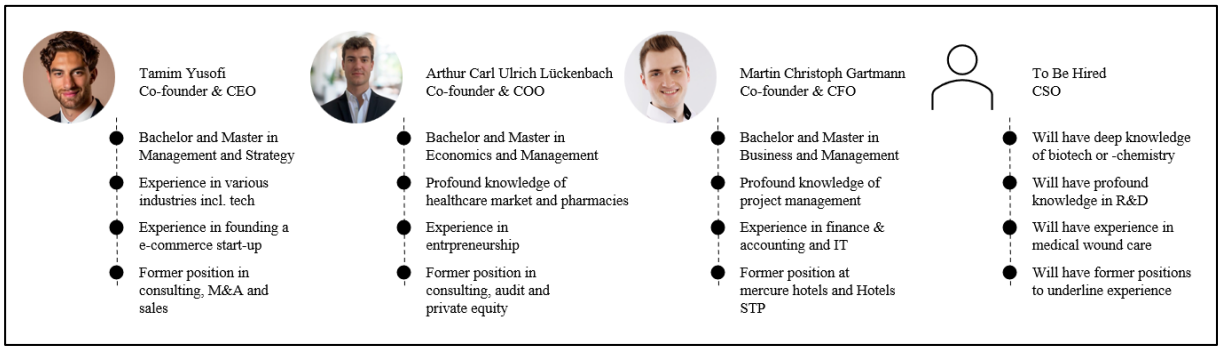

Figure 3: Top Management Positions

The role of the CSO, marked as "to be hired," is pivotal throughout the development of a biotechnology startup focusing on jellyfish collagen-based wound dressings. This position demands extensive expertise in biotechnology, biomaterials, or a related field. Initially, the CSO sets the scientific agenda, outlines key research goals, and establishes protocols essential for product development, while building and leading a knowledgeable scientific team. During the development phase, the CSO is responsible for translating research into a viable product, managing clinical trials, conducting validation studies, and driving innovation, including pursuing patents. In the commercialisation phase, the CSO navigates the regulatory landscape to secure product approvals and works closely with experts to ensure compliance with health and safety standards. Additionally, the CSO communicates the scientific merits of the product to stakeholders and regulatory bodies, a crucial step for gaining market acceptance. In addition, there are further positions that are to be hired or will be outsourced first and later integrated

with progressive maturity. These positions cover Operations, Business Development, Administration, Legal, Finance & Accounting and IT**.**

Operations:

1. **Product Development Manager (Biotech)**: This role manages the day-to-day activities related to the development of the pharmaceutical product, coordinating between different teams, and ensuring that project milestones are met and is supported by outsourced laboratory staff. The expertise needed is strongly connected to related fields such as biochemistry, pharmacology, and material science.
2. **Biochemist**: Manages the operational aspects of clinical trials, including protocol design, site selection, and data management. This role ensures that trials run smoothly and comply with regulatory standards.
3. **Laboratory Assistant:** Supports the operations team and, amongst other, ensures seamless lab operations by maintaining equipment, preparing samples, and managing inventory.

Outsourced positions that will be integrated in the future:

1. **Administration:** As the company grows, hiring professionals specialising in organisational development and human resources will be critical to manage scaling, maintain company culture, improve employee retention, and enhance team efficiency.
4. **Legal Counsel:** Legal complexities related to intellectual property, patents, and compliance can be effectively managed by specialised legal firms. Outsourcing these tasks ensures that patent filings are handled correctly and timely, protecting the company's innovations.
5. **Finance & Accounting:** Financial functions, including accounting, payroll, and even some aspects of financial planning, can be outsourced to professional firms. This allows

the startup to focus on core activities without compromising financial oversight and compliance.

6. **IT Support & Data Management:** Managing IT infrastructure and ensuring data security can be outsourced to firms specialising in IT services and data management, particularly those with experience in handling sensitive clinical and patient data.

7.2. Board of Directors

The members of the Board of Directors come from a variety of backgrounds, including biotechnology, medicine, finance, and entrepreneurship. This board ensures that TSD's goals are in line with the interests of shareholders and market demands by providing governance, strategic oversight, and resources. A strategic asset, the diversity within the team configurations allows for a range of viewpoints and talents that improve the team's capacity for innovation and problem-solving (Mach & Baruch, 2015).

The following will be part of of the board of directors:

1. The founders, Tamim Yusofi (CEO), Arthur Carl Ulrich Lückenbach (COO) and Martin Christoph Gartmann (CFO).
2. Gonçalo Costa – Chief Scientific Officer of BioMimetx, a biochemist with a PhD from University of Lisbon.
3. Representatives of future investors.

7.3. Advisory Board

Furthermore, the creation of an Advisory Board is essential for manoeuvring through the specialised fields of market trends, scientific breakthroughs, and regulatory environments. This board consists of medical professionals, regulatory specialists, and scientists with firsthand knowledge of wound care and biomaterials. The development process—from lab research to clinical trials and, eventually, market launch—is greatly influenced by their advice. The team's abilities are enhanced by the Advisory Board's experience, which offers vital insights that can

quicken product development and reduce risks related to market acceptance and regulatory compliance (Power, 2018).

The following will be part of the advisory board:

1. Dr. Hans Peter Weinschenk – Pharmacist
2. Dr. Sabine Coulon – Medical Doctor, Specialist in General Medicine
3. Ulrich Lückenbach – Health Economist, Expert for German Market
4. Dr. Martin Walter – Head of Patient Engagement, Access & Healthcare Affairs at Boehringer Ingelheim

8. Exit

This chapter provides a comprehensive analysis of the forecasted valuation and exit strategies for our biotechnology product. However, as there remains an inherent risk at that time, we include a proposal for a final sales price. While our preferred exit strategy still stays an acquisition by a strategic buyer, we also analyse alternatives such as an IPO, licensing agreements or strategic partnerships to maximise shareholder value and ensure a successful market entry of the CollaPatch™.

8.1. Valuation

The inherent risks and high stakes associated with medication development and commercialisation make biotech company valuation a unique challenge. When applied to the biotech industry, traditional valuation techniques frequently fall short, requiring a more sophisticated strategy that can account for the unique risks and large potential rewards of this sector.

Biotech companies frequently encounter noteworthy valuation obstacles at different phases, such as capital raising, license agreements, IPOs, and mergers and acquisitions (M&A). The main challenges come from the high degree of uncertainty and binary outcomes that are specific to drug development processes, which are challenging for typical discounted cash flow (DCF)

methodologies to reflect. These approaches fall short of capturing the dynamic decision-making climate of biotech companies, where project outcomes might change dramatically at every stage of the drug development process (Villiger & Bogdan, 2005; Woo et al., 2019).

Value generation in the biotech industry is predominantly driven by the de-risking process, as opposed to other industries where growth promotes value development. Through meticulous clinical research or scientific tests, businesses de-risk their science, and the value of their findings can be greatly increased. This is due to the binary nature of the risk involved, which can drastically change a company's worth overnight if study results are disclosed all at once at the conclusion of blinded studies to avoid bias. Fundraising is frequently sparked by the positive outcomes of such binary events. Since drug development takes a long time and much of the value is realised in the later years, biotech valuations are also quite sensitive to the discount rate. The cost of capital becomes a critical component in the total cost of developing new pharmaceuticals because of the high stakes, significant money required, and high-risk profile of the industry. The delicate balance of risk, capital, and time in biotechnology valuations is further highlighted by this sensitivity to financial measures (Sullivan, n.d.).

A highly customised methodology is frequently required for valuation because of the distinct qualities and stages of growth of biotech companies. Important variables that affect valuation include the particular therapeutic emphasis, pipeline maturity, and chance of regulatory approval. Additionally, we included our calculated forecast for European penetration since approval in Germany makes it easier to proceed in whole Europe. For the sake of high uncertainty and the challenging nature of a valuation of TSD, we used two approaches: the risk-adjusted Net Present Value (rNPV) and the risk-adjusted multiples approach.

The rNPV accounts for the risks associated with medication development. Considering the likelihood of failure at every step of clinical trials, this method computes the cumulative worth of projected future drug revenues. At each stage of clinical trials there is a risk of failure and

not making it into the next round (probability of success – POS) which will be multiplied with the potential cash flows of the respective phase. In the case of TSD we looked at a best-, base- and worst-case scenario to come up with a range of possible valuation outcomes (Woo et al., 2019). Following up on the market penetration rates from chapter 4, we derived a valuation range from €25.71 million to €55.14 million (Figure 10). Please refer to Appendix M-O for the calculations and formulas.

Traditional financial multiples like the price-to-earnings (P/E) ratio are not suitable for most biotech companies due to their pre-revenue nature. However, we used our average forecasted cashflows and revenues and adjusted them with the risk to account for the high uncertainty. We calculated the average of two multiples, Enterprise Value (EV) to EBITDA and EV to revenue, which relate a company´s total valuation (Market cap plus net debt) to its EBITDA and revenue. According to the institute for mergers, acquisitions, and alliances (IMAA) the EV/EBITDA multiple in the biotech and pharma industry stands at 22.4, while the EV/revenue multiple stands at 9.7 (IMAA, 2023). Finally, we multiplied the value by the likelihood of approval (LOA) of 13.02% (Appendix H) and derived to a value ranged between €107.93 and €270.59 million (Appendix P).

TSD Valuation in million €	**Best Case**	**Base Case**	**Worst Case**
rNPV	55,14 €	41,36 €	25,71 €
Risk Adjusted EV - multiplied by LOA of 13.02% (in €)	270,59 €	189,26 €	107,93 €

Figure 4: TSD Valuation

This valuation, however, doesn´t depict the whole picture. Due to many uncertainties like other expansion markets, further product developments etc. and the absence of a realistic terminal value that would display cashflows after year 10 of commercialisation, the upward potential

worth of TSD is not reached. Therefore, our final valuation lies in the upper percentile of the named range: **$50 million - $250 million.**

Considering our exit in 2030 with a successful clinical trial phase II, the valuation of the company increased significantly due to the de-risking by the success of earlier uncertain trial phases. Considering a new valuation at the end of clinical trial phase II, including a new LOA of 53%, the valuation ranges from **€233.16 million to €469.77 million.** Referring to a possible sales price, we estimate, that investors will settle towards the lower end of the valuation due to the high uncertainties, resulting in a approx. 30% discount based of the base case scenario leading to price of around €250 million (Appendix Q). However, this valuation faces similar limitations and potential for upward adjustments as seen in the earlier assessment. An additional example for that can be seen in the sensitivity analysis for the weighted average cost of capital (WACC) in Appendix R, demonstrating the variety of different outcomes.

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™ 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:

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- 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

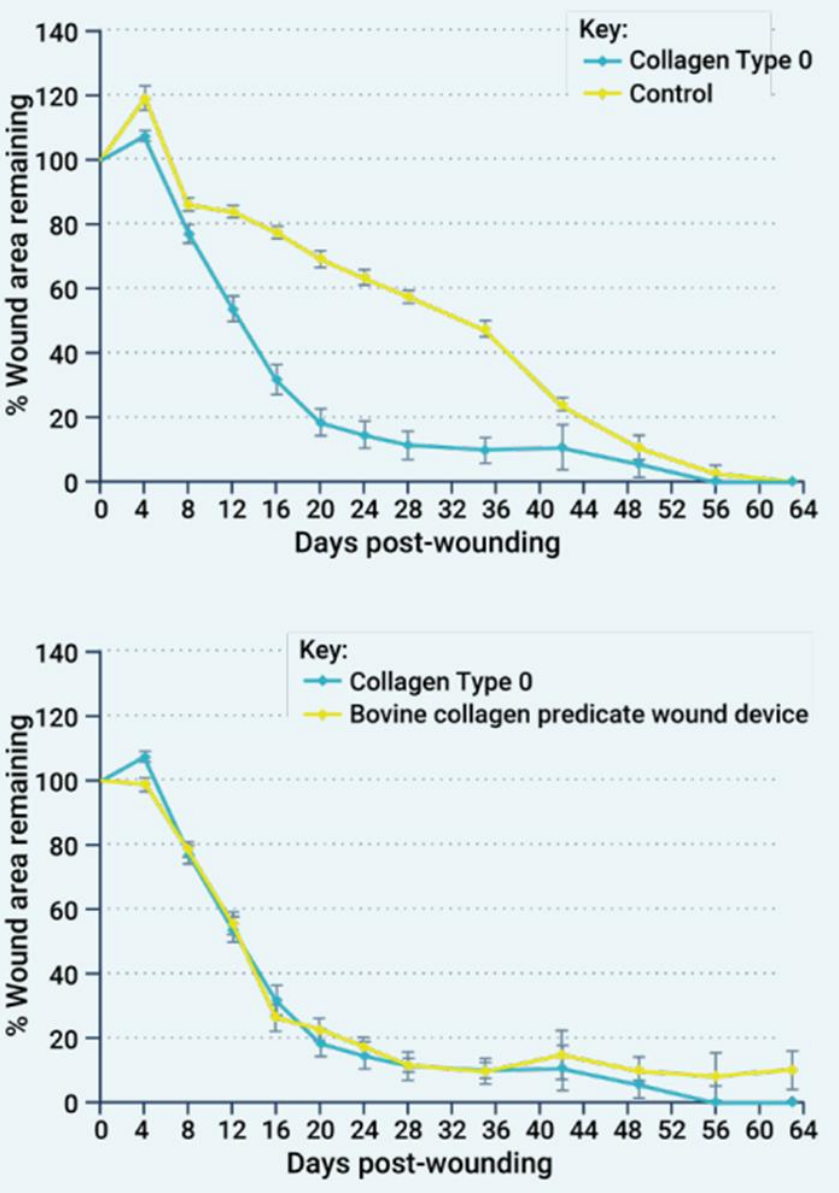
List of Abbreviations

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.

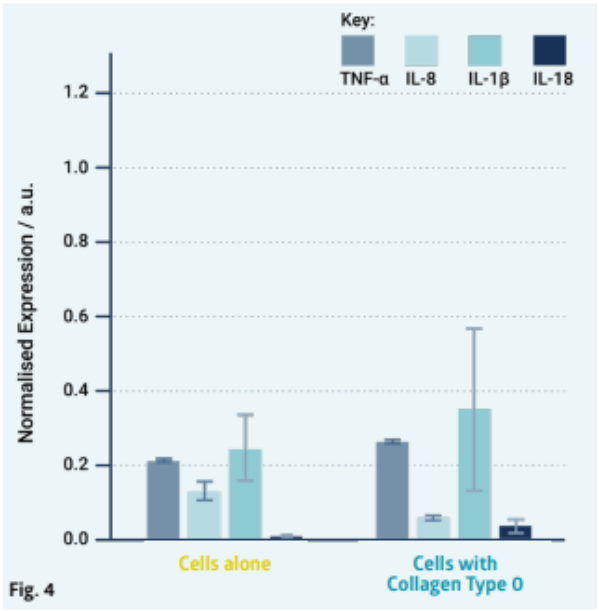


Fig. 4

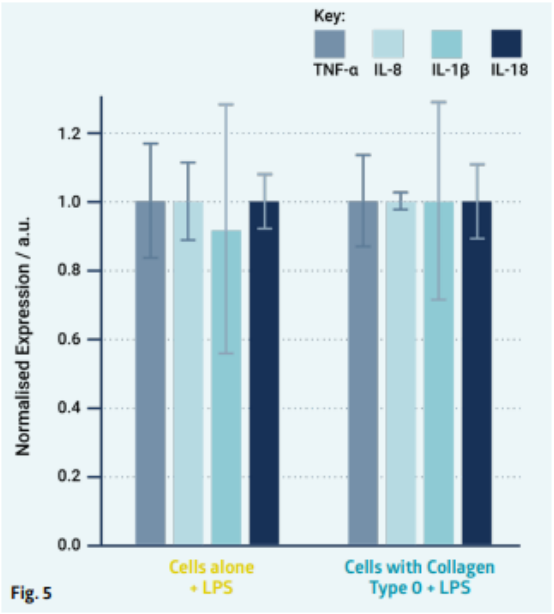


Fig. 5

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).

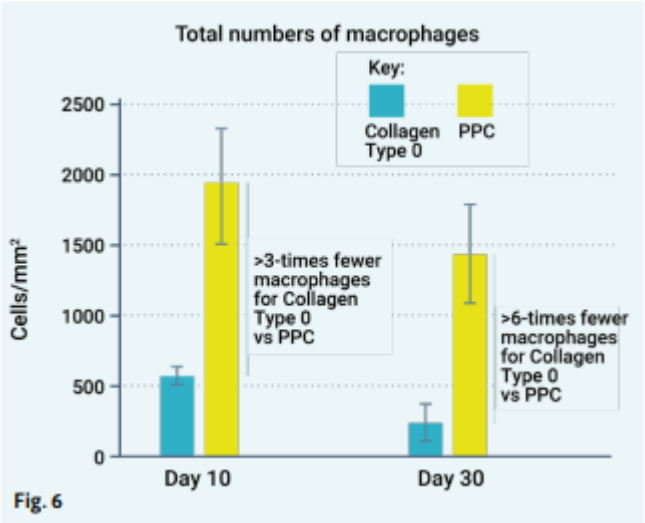


Fig. 6

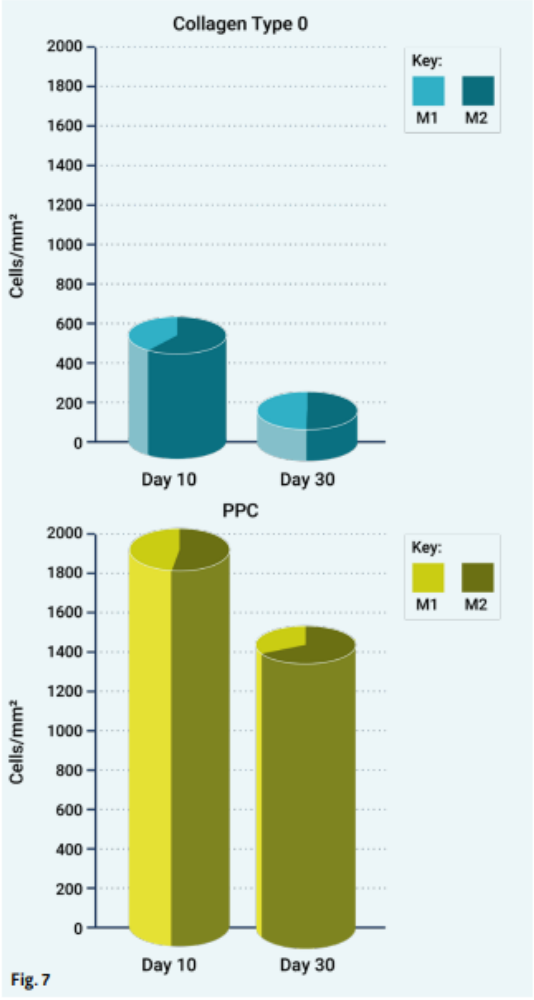


Fig. 7

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.

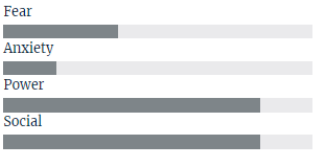
Challenges & Needs

- **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

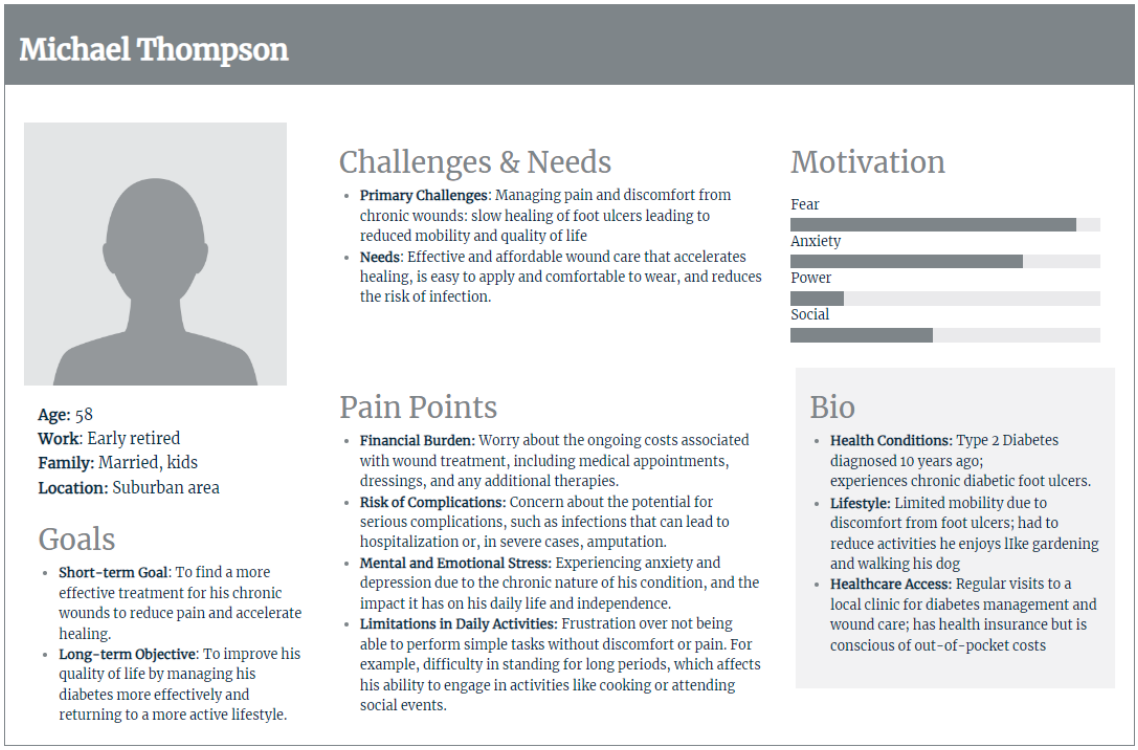
- **Limited Treatment Options:** Encountering a lack of effective treatment modalities for chronic wounds, which can lead to patient frustration and decreased trust in medical advice.
- **Time Constraints:** Facing time pressure in her practice, with the need to see a high volume of patients, which limits 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.



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

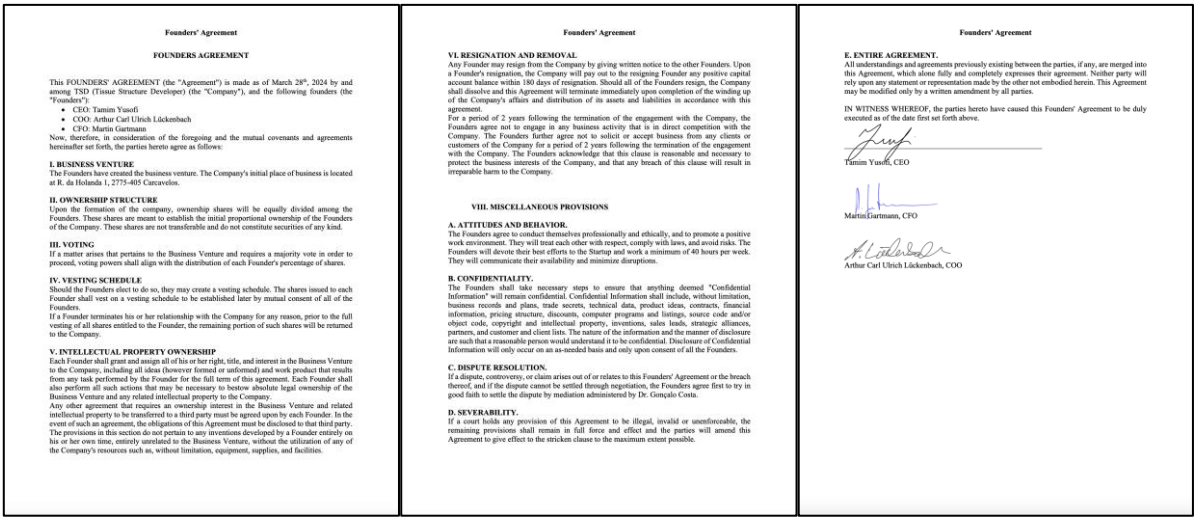
Likelihood of Approval	Phase I to Approval		Phase II to Approval		Phase III to Approval		NDA/BLA to Approval	
	LOA n	Phase LOA	LOA n	Phase LOA	LOA n	Phase LOA	LOA n	Phase LOA
Hematology	352	23.9%	260	34.4%	154	71.5%	72	93.1%
Metabolic	399	15.5%	263	25.0%	114	55.7%	48	87.5%
Infectious disease	1170	13.2%	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.

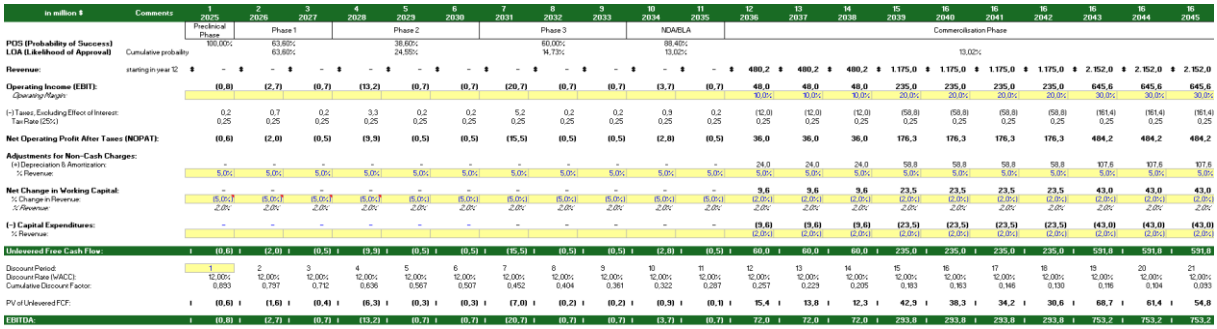
IN WITNESS WHEREOF, the parties hereto have caused this Founders' Agreement to be duly executed as of the date first set forth above.

Tamim Yusofi, CEO

Martin Gartmann, CFO

Arthur Carl Ulrich Lückenbach, COO

Appendix 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	16 2041	16 2042	16 2043	16 2044	16 2045
		Preclinical Phase	Phase 1			Phase 2			Phase 3		NDA/BLA		Commercialization Phaze									
POS (Probability of Success)		100,00%	63,60%			38,60%			60,00%		88,46%											
LOA (Likelihood of Approval)	Cumulative probality		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:		-	-	-	-	-	-	-	-	-	-	-	24,0	24,0	24,0	58,8	58,8	58,8	58,8	107,6	107,6	107,6
(+) Depreciation & Amortization:																						
% 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:		-	-	-	-	-	-	-	-	-	-	-	9,6	9,6	9,6	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 €