

## New clinically-proven device for chronic pain (Co-investment)

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<b>Type Klant</b>	B2B
<b>Gewenst Type Investeerder</b>	Angel Investor, Incubator-Accelerator, Strategische-Investeerder
<b>Benodigd Kapitaal</b>	€ 700.000,-
<b>Reeds toegezegde financiering</b>	€ 350.000,-
<b>Minimale Ticketsize</b>	€350.000,-

<b>Sector</b>	Health
<b>Bedrijfsfase</b>	Seed
<b>Aantal Founders</b>	4
<b>Aantal Huidige Werknemers</b>	2
<b>Maandelijkse Omzet</b>	€ 0,-
<b>Omzet (prognose) komende 12 maanden</b>	€ 40.000,-
<b>Omzet (prognose) maand 13 - 24</b>	€ 360.000,-
<b>Huidige Kosten (maandelijks)</b>	€ 17.000,-

## Bedrijfsbeschrijving

### **A Non-Invasive, Drug-Free treatment for Chronic Back Pain Relief and Recovery**

Established in 2022, this medical device innovator is at the forefront of the medical device sector, focusing on the innovative treatment of chronic lower back pain (cLBP) with cutting-edge technology.

Its product line includes a clinically validated (700+ patients) phototherapy device using blue light, ready for market, and a pioneering version that merges blue and infrared light, awaiting further clinical trials to prove its added benefits.

With the cLBP market projected at €8.73 billion globally, the company is strategically positioned to capture a significant share by delivering solutions that are drug-free and non-invasive. This approach marks a departure from traditional cLBP treatments that typically depend on opioids and addictive medications, invasive surgeries, or inconsistently effective alternative therapies.

The medical community's response has been enthusiastic, evidenced by substantial clinical endorsements and commitments from professionals ready to adopt this technology. The company's core values—drug-free, non-invasive, and clinically effective treatments—resonate deeply with healthcare providers, distinguishing the company in a competitive landscape.

The venture operates with a patient-first, provider-focused mindset. The B2B model reinforces its commitment to healthcare professionals by offering the clinically validated blue light device as an effective pain relief alternative. Simultaneously, the company is gearing up for the anticipated release of the blue and infrared light device, poised to elevate the standard of care. The venture's dedication to innovation, reflected in its in-house development and high-quality partnerships with medical device manufacturers, is preparing it for rapid scaling to meet growing demand.

As it proceeds with its clinical trials for the new combo device, the company is prepared not just to enter the market but to redefine it, championing a vision of personalized pain management that's both effective and respectful of patient well-being.

## Business Model

The company foresees a total addressable market (TAM) of €8.73 billion globally for cLBP, with a serviceable available market (SAM) of €4.21 billion in Western countries, and a serviceable obtainable market (SOM) goal of €421 million, targeting a 10% market share by year five. The cLBP treatment market value is expected to increase from \$9.7 billion in 2023 to \$15.4 billion by 2028, showcasing a substantial growth opportunity. The market potential is sizable, as the demand for non-pharmacological pain management solutions is growing, and reliance on opioids is a critical concern in healthcare.

This enterprise adopts a direct sales strategy, focusing on healthcare professionals and institutions. It offers its clinically validated phototherapy devices directly to clinicians for patient treatment. An advanced product, merging blue and infrared light technologies, is ready to adopt the same sales framework post-clinical validation.

The pricing model is crafted to balance affordability for healthcare providers with sustainable profit margins, underpinning continuous research and scalability. This competitive pricing reflects the innovation and quality intrinsic to their offerings.

Exploratory steps are being taken towards forming strategic partnerships and collaborations with health institutions and insurance entities. Such alliances may introduce volume-based pricing, facilitating broader adoption and offering cost advantages to larger organizations.

Dedicated to product line growth and enhancement, the company emphasizes cost-effectiveness, leveraging manufacturing partnerships to reduce production expenses. This strategy ensures that their technologies remain financially accessible to healthcare entities, promoting the company's sustainability and expansion.

The business model is strategically designed to leverage the ready-for-market phototherapy device to penetrate the market effectively, laying the foundation for the future launch of their dual-technology device. Through an evidence-based and value-centric approach, the company aspires to establish itself as a leader in drug-free pain management solutions.

## USP's

- **Clinically Validated Solutions** : This company stands out with a phototherapy device that has undergone clinical validation, offering healthcare providers a proven, evidence-based option for treating chronic lower back pain. This ready-to-use solution sets it apart in a market where many alternatives lack such validation.
- **Innovative Dual-Light Technology** : A cutting-edge approach is taken towards pain management, integrating both blue and infrared light therapies. This advanced technology, aimed at simultaneously facilitating pain relief and tissue repair, is a distinctive feature not widely available in existing market options.
- **Non-Invasive, Drug-Free Approach** : Amidst increasing concerns about the opioid crisis, this company's non-invasive, drug-free solution resonates with the growing demand among patients and healthcare professionals for safer, more effective pain management alternatives.
- **Personalized Treatment through Supportive App** : Unlike generic solutions, this enterprise leverages a user-friendly app to tailor treatment plans to individual patient needs, enhancing outcomes and differentiating its offerings.
- **Dedication to In-House R&D** : The firm's commitment to internal research and development ensures that its products remain on the forefront of medical device technology, allowing for swift adaptations to the healthcare industry's changing needs.
- **Strategic Partnerships with Healthcare Providers** : By strictly collaboration with healthcare practitioners, the company ensures its products are continuously refined based on direct feedback and real-world application, maintaining relevance and effectiveness.
- **Proactive Market Entry Strategy** : With one device already clinically validated and another innovative solution in development, the company's phased market entry strategy builds a strong brand presence from the outset, signaling ongoing commitment to innovation.
- **Scalable Operations Model** : Through strategic manufacturing partnerships, the company is geared for scalability, ready to meet growing demand efficiently without sacrificing product quality, maintaining a competitive edge as it expands its market share.
- **Commitment to Education and Provider Support** : More than just supplying medical devices, this organization is devoted to educating healthcare providers on the optimal use and benefits of its products, boosting adoption rates and enhancing the effectiveness of treatments.

## Investeringsbehoefte

- **R&D Costs (€400,000 - 57%)** : Allocation for clinical trials of the version 2 device to evaluate efficacy and compliance with regulatory standards, crucial for market differentiation and establishing technological advancements.
- **Personnel Costs (€192,300 - 27%)** : Investment in essential team members to drive the launch and development of both the existing and new device, supporting key operations and enabling market penetration.
- **Regulatory Costs (€48,000 - 7%)** : Essential for ensuring compliance, documentation, product registration, CE Mark, and MDR approval, foundational for market access and credibility.
- **General & Administrative Costs (€59,700 - 9%)** : Overhead costs covering operational expenses, office space, travel, and contingencies, essential for the smooth operation of the company.

These financial allocations are meticulously planned to ensure that each aspect of the company's operations is well-funded, from the ground up, reinforcing the company's trajectory towards successful market entry and growth.

+/- 50% of the required funding is already secured via founders, Rabobank and a venture capital firm.

## Gewenste competenties investeerder

The desired competencies might include:

- **Healthcare Industry Expertise:** An investor with a strong background in the healthcare industry can provide invaluable insights into market trends, regulatory pathways, and patient care standards.
- **Medical Device Commercialization:** Experience in launching medical devices, navigating FDA/CE approval processes, and understanding the challenges of bringing medical technology from concept to market.
- **Strategic Partnerships and Networking:** Connections within the healthcare and medical technology sectors that can be leveraged for partnerships, collaborations, and growth opportunities.
- **Financial Acumen:** Strong financial expertise to assist with capital management, pricing strategies, and scaling operations in a cost-effective manner.
- **Marketing and Sales Strategy:** Knowledge in building and executing effective marketing campaigns, especially within the medical and healthcare fields, to drive product adoption and brand awareness.
- **International Business Development:** Experience in global market entry and expansion, particularly in regions that are key to the company's growth strategy.
- **Supply Chain and Operations:** Skills in optimizing supply chain management and scaling production to meet demand while maintaining quality standards.

An investor who brings “smart money” to the table, equipped with these competencies, can significantly enhance the company's ability to achieve its strategic goals and overcome any gaps in the current team's expertise.

## Ervaring Founder(s)

The founding team of this medical device company is comprised of industry veterans, collectively boasting over 50 years of experience across entrepreneurship, medical device innovation, and healthcare sectors. Their extensive knowledge and track record of success are pivotal to the company's prominence in non-invasive pain management technologies.

- **CEO** : With a dynamic entrepreneurial career, the Chief Executive Officer has led multiple organizations through varying phases of growth, showcasing a knack for steering companies towards success in competitive markets. His international leadership roles have honed a strategic mindset and a deep understanding of market dynamics, significantly contributing to the company's strategic direction.
- **CTO** : The Chief Technical Officer's background in medical device development, including direct involvement in project management and R&D at a renowned corporation, provides a solid foundation in innovation and intellectual property strategy. This experience, coupled with an intimate understanding of the medical device landscape, drives the company's technological advancements.
- **CMO** : Bringing a global perspective to R&D and medical affairs in both pharmaceuticals and medical devices, the Chief Medical Officer has a profound grasp of the pain management domain. Their experience in high-level leadership positions enriches the company's alignment with healthcare standards and patient needs, ensuring product relevance and efficacy.
- **CPO** : With a decade's worth of international experience in operations and supply chain management, the Chief Procurement Officer has a proven track record in launching medical and consumer products across different markets. Their expertise is critical in scaling the company's operations and ensuring efficient product delivery to the market.

This team's combined expertise in entrepreneurship, product development, market insight, and operational efficiency sets a solid foundation for the company's leadership in providing innovative solutions for pain management. Their proven abilities across diverse yet complementary healthcare sectors foster confidence in the company's trajectory towards growth and innovation.

## Overige Relevante Informatie

- **Total Capital Invested to Date:** €317,000
- **Investment Sources:**
  - Founding Team: €67,000
  - Health VC: €100,000
  - Rabo Innovation Loan: €150,000
- **Investment Rounds:** The investments mentioned have occurred in the pre-seed funding round.
- **Current Funding Objective:** Seeking to raise an additional €700,000 in the seed round, with a commitment from our Health VC partner to match any external investment of at least €350,000.

## Samenvatting

**Datum:** 18 April 2024

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