

A Work Project, presented as part of the requirements for the Award of a Master's degree in Impact Entrepreneurship and Innovation with a specialization in Health Care Innovation from the Nova School of Business and Economics and Nova Medical School in Portugal.

HOW CAN REZOLVE MEDICAL BEST POSITION ITSELF TO SECURE EUR 1–1.5  
MILLION IN GROWTH CAPITAL AT OPTIMAL TERMS?

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## **1 Abstract**

The aim of this study was to examine how Rezolve Medical can secure early-stage growth capital within the European MedTech investment landscape. To achieve this, the study combined a structured review of peer reviewed journal articles and grey literature with four semi structured interviews conducted with European healthcare investors. The findings show that investment decisions are driven by the reduction of regulatory, clinical, reimbursement, and operational uncertainty rather than by technical novelty alone. The study outlines how Rezolve can structure a 1-to-1.5-million-euro funding round by aligning evidence generation, milestone timing, and governance preparation with investor evaluation patterns in early stage MedTech.

**Keywords:** MedTech, fundraising, reimbursement, market entry, early-stage investment, commercialization, financing, orthotics, entrepreneurial finance, personalized medical devices, startup valuation

## 2 List of Abbreviations

<b>Abbreviation</b>	<b>Significance</b>
AFO	Ankle Foot Orthosis
CE	Conformité Européenne
EU	European Union
et al.	et alia (and others)
HTA	Health Technology Assessment
IP	Intellectual Property
ISO	International Organization for Standardization
KOL	Key Opinion Leader
LP	Limited Partner
MDR	Medical Device Regulation
NB	Notified Body
PCT	Patent Cooperation Treaty
PMCF	Post Market Clinical Follow-up
PMS	Post Market Surveillance
QMS	Quality Management System
R&D	Research and Development
TRL	Technology Readiness Level
US	United States
VC	Venture Capital

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### **3. Introduction**

Foot drop is a neurological or musculoskeletal condition in which the patient cannot achieve active ankle dorsiflexion during gait. It often follows stroke, peroneal nerve injury, or neuromuscular disease, that may be temporary or permanent. The resulting deficit leads to reduced toe clearance and altered gait patterns, which increase the risk of tripping and falling. These limitations can persist depending on the underlying cause and have measurable effects on functional mobility and patient-reported quality of life (Stewart 2008).

AFOs are commonly prescribed to support dorsiflexion and stabilize the ankle during walking. However, conventional rigid devices often restrict plantarflexion and interfere with natural gait patterns. Empirical clinical studies based on patient-reported outcomes and functional assessments report low long-term adherence as patients frequently experience discomfort, pressure points, and reduced mobility in daily tasks (Elisabeth Carolus et al. 2019). A lack of personalization is identified as a contributing factor.

Rezolve Medical develops the Rise AFO, a 3D-printed device customized using individual patient's leg scans. A proprietary algorithm adjusts device geometry and stiffness according to the patient-specific morphology and gait requirements. The device complies with the Medical Device Regulation (MDR) requirements for custom-made Class I medical devices, with full documentation finalized in September 2025.

Rezolve operates an asset-light business model. Orthopedic clinics perform patient scanning while certified partners manufacture the device using 3D-printing workflows across Europe. Rezolve focuses on design automation, software development, and scaling. This division of roles reduces capital intensity and supports expansion.

Development to date has been financed through a combination of non-dilutive grants, targeted innovation programs, and early angel investment.

Rezolve is now transitioning from early clinical validation to commercial deployment. To support this phase, the company plans to raise between €1–1.5 million in growth capital. The funding will be allocated to clinical studies, reimbursement evidence, further automation of design workflows, and expansion through orthopedic partners. Fundraising in medical technology relies on evidence generation rather than early revenue. Investors assess regulatory progress, clinical data, and reimbursement potential before allocating capital (Sardar et al. 2024).

While the academic literature provides important insights into venture capital decision making, milestone-based valuation, and risk management in high uncertainty environments, it remains fragmented when applied to early stage MedTech ventures in Europe. Research in entrepreneurial finance often abstracts from regulatory and reimbursement constraints, while MedTech specific studies typically address regulation, clinical validation, or health technology assessment in isolation. Few studies integrate these dimensions to explain how early stage MedTech companies position themselves for a first growth round.

This project addresses this gap by examining early stage MedTech fundraising through an applied case study combined with qualitative investor insights. It analyses the investment environment faced by European medical device companies operating the orthopedic field where regulatory compliance under the Medical Device Regulation, clinical validation requirements, and reimbursement pathways strongly shape capital allocation.

The study combines a structured literature review with qualitative insights from four semi-structured interviews with European MedTech investors.

Using Rezolve Medical as the focal case, the study examines how early-stage investors evaluate orthopedic medical device ventures with respect to clinical evidence, regulatory progress, reimbursement logic, operational scalability, and governance readiness. The central research question guiding this project is therefore:

**“How can Rezolve Medical best position itself to secure €1–1.5 million in early-stage growth capital under optimal terms within the European MedTech landscape?”**

#### **4. Objectives of the Internship**

This internship supports Rezolve Medical’s transition from early validation to growth. Its aim is to strengthen the company’s investor readiness and to develop a well-defined fundraising strategy informed by academic research, investor perspectives, and direct operational experience within the startup.

This includes assessing the role of non-dilutive funding in early-stage capital formation, identifying investor expectations through qualitative interviews, analyzing comparable MedTech fundraising cases, and synthesizing insights into a strategic roadmap.

##### **4.1 Strengthen Investor Readiness**

The work involved refining the pitch deck, improving the coherence of the investment narrative, and linking technical progress to well-defined milestones. These milestones include automation of design workflows, validation of clinical outcomes, and early steps toward building reimbursement evidence. Presenting these elements in a structured and measurable way strengthens Rezolve’s ability to demonstrate progress during due diligence and provides a clearer basis for investor assessment.

## **4.2 Support Non-Dilutive Funding Preparation**

I supported the team in preparing the Rabo Innovatielening application by reviewing eligibility criteria, defining technical and financial milestones, and aligning the proposal with Rezolve's capital plan. This work clarifies how non-dilutive funding extends the runway and reduces capital requirements during the equity round. It also illustrates how public financing can lower early-stage risk, which in turn affects the terms under which investors negotiate.

## **4.3 Analyze Investor Expectations and Comparable Cases**

Instead of assembling a formal database, the work focused on qualitative insights derived from interviews with European MedTech investors and the examination of startups that recently raised €1–2 million. The analysis identifies consistent patterns regarding team evaluation, regulatory readiness, evidence thresholds, and reimbursement visibility. These insights provide a benchmark for Rezolve's current stage and clarify which milestones are likely to influence investor decision-making.

## **4.4 Develop a Research-Based Fundraising Strategy**

The analysis examines how MedTech founders can design financing milestones, select investors, prepare governance structures, and negotiate terms. The resulting recommendations form a structured roadmap for Rezolve's upcoming €1–1.5 million raise and clarify how the company can position itself to attract capital under conditions consistent with sector practices.

Overall, the internship connects theory with implementation. It contributes to the academic understanding of early-stage MedTech financing and produces practical outputs Rezolve can use directly during its next investment phase. The chapter outlines how each component of the internship supports the two core aims and how the tasks conducted relate to both the dissertation and the operational needs of the company.

## **5 Literature Review**

This literature review examines the factors that shape early-stage fundraising for medical device ventures and links these mechanisms directly to the research question guiding this project. Evidence is drawn from peer-reviewed research in entrepreneurial finance, MedTech commercialization studies, industry valuation reports, regulatory publications, and health-economic analyses in orthotics and prosthetics. Three themes structure the review. The first concerns investor decision-making and the contracting mechanisms used to manage uncertainty. The second examines how risk, milestones, and non-dilutive funding influence valuation and deal structures. The third reviews the European regulatory and reimbursement environment, which significantly affects investor expectations and market-entry strategies.

### **5.1 Investor Decision**

#### *5.1.1 Team Quality*

Team quality consistently emerges as the most influential factor in early-stage investment decisions. In the largest available survey of venture capital decision-making, 95 percent of investors rated the founding team as important, and nearly half selected it as the single most decisive criterion (Gompers et al., 2020). This pattern is amplified in MedTech because execution depends on competencies in clinical study design, regulatory engagement, and reimbursement planning (Lehoux et al. 2016). Research shows that signals such as documented Notified Body interactions, commitments from clinical pilot sites, involvement of qualified advisors, and initial payer-relevant considerations reduce information asymmetry, which is central in investor evaluations at this stage (Lehoux et al. 2016).

### *5.1.2 Venture Contracting and Control Rights*

Venture finance research shows that governance terms reflect investors' exposure to uncertainty (Kaplan and Strömberg 2004). In MedTech, high regulatory and clinical risks lead to contract structures that include liquidation preferences, anti-dilution protections, board representation, and enhanced voting rights (Gompers et al., 2020). Staged financing is particularly important because it ties capital release to predefined milestones and enables active monitoring (Kaplan and Strömberg 2004). Founders influence contract balance primarily by reducing uncertainty before negotiation.

## **5.2 Value, Risk, and Milestones**

### *5.2.1 Milestone-Based Valuation and Deal Structuring*

According to the literature, early-stage MedTech ventures typically raise €1 to 2 million in their first institutional financing round, reflecting the capital required for regulatory preparation, early clinical data, and initial reimbursement groundwork (Kalinowska-Beszczyńska and Prędkiewicz 2024). Recent industry analyses show that investors fund fewer companies than in previous high-liquidity periods but deploy slightly larger checks to those demonstrating disciplined execution and regulatory or clinical de-risking (Sardar et al. 2024).

Valuation research shows that price increases follow step-wise milestone progression, defined as externally verifiable achievements that reduce specific risks ('Mercer-Capital-Value-Focus-MedTech-and-Device-Q2-2025.Pdf', 2025).

Pre-clinical milestones include a design freeze aligned with intended claims, verification testing, and Notified Body classification feedback (Ladd 2023).

Clinical milestones include ethics approval, first-in-human studies, and multi-site pilots demonstrating patient-relevant outcomes. Market access milestones include early payer signals, preliminary budget-impact analyses, and clarity on reimbursement pathways (Kannenbergh and Seidinger 2021).

### *5.2.2 Early-Stage Valuation Methodologies*

Early-stage MedTech valuation diverges from corporate finance methods because pre-commercial cash flows are too uncertain for discounted cash-flow modelling (Gompers et al., 2020). Venture investors instead rely on internal rate of return estimates, target ownership thresholds, and cash-on-cash multiples, defined as the ratio of exit proceeds to invested capital (Gompers et al., 2020). Value increases when key risks are removed with relatively limited capital. Literature shows that rounds structured around one well-defined milestone achievable within twelve to eighteen months have a higher probability of closing and yield more balanced negotiation conditions ('Mercer-Capital-Value-Focus-MedTech-and-Device-Q2-2025.Pdf', 2025).

### *5.2.3 Non-Dilutive Capital and External Validation*

Non-dilutive funding, grants, public innovation programs, and awards, plays a significant role in early-stage MedTech financing. Peer-reviewed grant programs reduce information asymmetry by validating feasibility and providing external scientific or clinical endorsement (Chaturvedi and Srinivas 2021). These programs also facilitate early access to clinical partners and key opinion leaders. Scoping reviews show that in markets with fewer active venture investors, public and philanthropic funding frequently supports the highest-risk phases of evidence generation (Kalinowska-Beszczyńska and Prędkiewicz 2024). Combining non-dilutive capital with equity increases runway, improves the probability of reaching milestones, and reduces early dilution.

## **5.3 European Market, Regulatory, and Reimbursement Dynamics**

### *5.3.1 Regulatory and Payer Environments*

The European regulatory environment shapes investor expectations through the Medical Device Regulation (MDR), which increases evidence requirements, stricter quality management obligations, and heightened dependence on limited Notified Body capacity (Ladd 2023). Although MDR transition extensions to 2027–2028 apply to legacy devices, they do not affect expectations for new devices. Investors gain confidence when early-stage companies document regulatory classification, engage with Notified Bodies, and implement a Quality Management System (QMS), defined as the regulated processes governing design, risk, manufacturing, and post-market surveillance (Ladd 2023).

Regulatory approval enables market entry, but reimbursement determines whether a device is adopted at scale. Payer adoption refers to the willingness of insurers or health systems to reimburse a device. Evidence from orthotics and prosthetics shows that diffusion, defined as broad and sustained across a health system, depends on alignment with patient-relevant outcomes, provider workflow considerations, and payer budget impact (Kannenberg and Seidinger 2021).

Research on MedTech startups shows that ventures engaging regulators, providers, and payers early gain strategic advantage (Kalinowska-Beszczynska and Prędkiewicz 2024).

### *5.3.2 Positioning Strategies*

Literature on MedTech commercialization suggests that effective positioning requires alignment between team capabilities, technical development, regulatory trajectory, clinical validation plans, and early reimbursement logic (Lehoux et al. 2016).

Successful ventures articulate clear milestones across pre-clinical, clinical, and market access domains, secure early clinical partnerships, and develop payer-relevant outcome frameworks. Studies emphasize the importance of selecting investors whose check sizes, sector expertise, and time horizons align with the company's development path (Gompers et al., 2020). These patterns appear consistently across MedTech venture cases and qualitative interviews with European healthcare investors.

### *5.3.3 Synthesis and Implications for a 1-1.5 million Raise*

Across the literature, four determinants consistently shape early stage MedTech fundraising outcomes: team quality, well defined milestones, contract structures aligned with risk, and integration of non-dilutive capital. Investors focus on the probability that the next value inflection, defined as a milestone that materially reduces regulatory, clinical, or market risk, will be reached within the planned horizon ('Mercer-Capital-Value-Focus-MedTech-and-Device-Q2-2025.Pdf', n.d.). For Rezolve Medical, this suggests that preparing a credible team, establishing one or two clear milestones within twelve to eighteen months, engaging stakeholders early, and combining equity with targeted non-dilutive funding increases the likelihood of securing a raise in the €1 to 1.5 million range under sector consistent terms.

## **6 Investor Perspectives on Early-Stage MedTech Fundraising: Insights from Expert Interviews**

To complement and validate the conclusions drawn from the literature review, four semi structured interviews were conducted with European investors active in medical technology and health innovation.

The sample includes: 1. Abigail Forson (Investment Analyst VC, Brightlands Venture Partners), 2. Paul van Ooik (Investment Associate, Nextgen Ventures and Noaber Ventures), 3. Sijm Romme (Director, IFOZ Health Innovation Fund), and 4. Teun van de Weijer (Investment Associate, Holland Capital).

This sample is appropriate for qualitative analysis because each participant represents a distinct investment model, allowing comparison across institutional venture capital, hybrid public private vehicles, and founder investor perspectives. Interviews followed the thematic domains defined in the literature review, including decision criteria, evidence expectations, reimbursement and economic logic, scalability, governance, and communication. All interviews were recorded, transcribed, and thematically coded.

## **6.1 Investment Decision Criteria**

Investors consistently emphasized that early validation is necessary for meaningful valuation. Paul van Ooik applies four connected filters when evaluating new opportunities: an urgent unmet medical need, differentiation relative to existing solutions, credible early evidence of efficacy, and a business model grounded in reimbursement and pricing logic.

Abigail Forson prioritizes verification of problem solution fit and intellectual property strength. She reviews freedom to operate and patent defensibility and benchmarks comparable transactions to assess whether an exit is feasible within an eight-to-ten-year fund cycle.

In contrast, Sijm Romme focuses primarily on founder discipline. He values clarity, responsiveness, and consistent execution, noting that observable reliability is more informative than ambitious projections. Teun van de Weijer approaches validation through commercial repeatability. He views consistent customer behavior and predictable sales cycles as the strongest indicators that demand is real.

These perspectives align with evidence that team quality, execution capacity, and milestone achievement drive early-stage investor decisions (Kaplan and Strömberg 2004; Gompers et al., 2020).

## **6.2 Reimbursement, Market Access, and Scalability**

Reimbursement was described as a determining factor in market viability. Sijm Romme's fund prioritizes technologies with measurable system level impact, such as improved labor productivity or reduced care demand. Devices that improve clinical quality without economic benefit fall outside its scope. Paul van Ooik summarized this position by stating that without reimbursement there is no business. He therefore examines whether payers reimburse at levels that protect margins.

Abigail Forson highlighted dual value creation for patients and clinicians. She noted that devices reducing clinician workload or treatment time offer stronger financial rationale. Teun van de Weijer reinforced the centrality of economic validation, focusing on improving unit economics, increased conversion ratios, and scalable revenue without erosion in margin.

Teun van de Weijer described operational scalability as decreasing unit cost with volume, distribution scalability as expansion through partner networks, and financial scalability as predictable conversion and shorter cash cycles. Paul van Ooik observed that direct business to business sales validate early traction but rarely scale without external distributors.

Abigail Forson and Sijm Romme stressed demonstrating repeatability in one geography before expanding. These perspectives reinforce findings that delivery and reimbursement scalability are common bottlenecks for early MedTech ventures (Lehoux et al. 2016). For Rezolve Medical, showing that multiple clinics can independently scan, order, and fit the Rise AFO would demonstrate a scalable operational and commercial model.

### **6.3 Governance, Communication, and Founder-Investor Fit**

Governance expectations were closely linked to fund incentives. Abigail Forson and Teun van de Weijer explained that venture capital participation brings structured oversight, including board involvement and formal milestone tracking.

Paul van Ooik reinforced this logic by noting that unclear exit timelines undermine fund credibility. In contrast, Sijm Romme favors momentum-based governance with fewer formalities and greater emphasis on consistent execution.

Communication was also considered central to investor engagement. All participants defined storytelling as the coherent framing of clinical evidence, market logic, and business feasibility. Abigail Forson emphasized concise materials that connect patient benefit, payer incentives, and realistic projections. Sijm Romme prefers straightforward communication based on transparency and logic. Paul van Ooik values explicit financial assumptions and scenario-based modelling.

Teun van de Weijer noted that consistency between the narrative and the financials is a strong signal of credibility. These observations align with research showing that clarity in founder communication builds investor trust (Gompers et al., 2020).

## 6.4 Cross Case Synthesis

Theme	Abigail Forson (Brightlands VP)	Paul van Ooik (Nextgen / Noaber)	Sijm Romme (IFOZ)	Teun van de Weijer (Holland Capital)	Supporting Literature
Participant nb	1	2	3	4	
<b>Investment Filters</b>	Problem–solution validation, IP strength, team cohesion	Unmet need, differentiation, reimbursement clarity	Team discipline, steady progress	Scalability, repeatable sales	Kaplan & Strömberg (2002); Kalinowska-Beszczynska (2024)
<b>Reimbursement / Economics</b>	Patient benefit, reduced clinician workload	Economic clarity, sustainable pricing	Productivity gains, reduced system demand	Unit-economics improvement	Kannenber & Seidinger (2021)
<b>Scalability</b>	Scalable execution aligned with team capacity	Partner-led channels	Low-dependency solutions	Operational + distribution leverage	Lehoux et al. (2016)
<b>Governance &amp; Exit</b>	Board accountability, milestone pressure	Exit ≤ 10 years, LP confidence	Keep building while raising	Staged fundraising, exit readiness	Mercer Capital (2025)
<b>Communication</b>	Story-driven narrative	Transparent economics	Clear, concise materials	Coherence between story and data	Gompers et al. (2016)

The interview findings show a high degree of convergence across investors and strong alignment with the academic evidence reviewed in Chapter 3. Participant 1, Participant 2, Participant 3, and Participant 4 converge on three core principles. First, disciplined teams that demonstrate consistent progress are preferred over founders who rely primarily on vision.

This reflects evidence that team quality is central in high uncertainty environments (Kaplan and Strömberg 2004). Second, reimbursement visibility and economic clarity are essential. This aligns with findings that payer decisions depend on both clinical and economic outcomes (Kannenberg and Seidinger 2021). Third, scalable execution and operational repeatability are necessary to justify early investment, reflecting limits identified in MedTech commercialization research (Lehoux et al. 2016). These elements reinforce the conclusion that validation, economic rationale, and reproducible execution drive investor confidence in early stage MedTech ventures.

## **6.5 Managerial Implications for Rezolve Medical**

These insights suggest several priorities for Rezolve Medical. Strengthening defensibility through documented intellectual property, algorithmic know how, and a confirmed freedom to operate assessment will support credibility with institutional investors. Converting the biomechanical benefits of the Rise AFO into payer relevant measures, such as reductions in orthotist time, fewer refits, or lower device failure rates, will strengthen the economic rationale. Demonstrating scalable operations by showing that clinics can independently scan, order, and fit the device will support claims of repeatable execution. Clarifying preferred governance structure will help identify suitable investor partners. Developing a coherent narrative that integrates clinical outcomes, reimbursement strategy, and commercial scalability will enhance communication effectiveness during the fundraising process.

## **7 Applying the Evidence to Rezolve: Valuation Logic, Investment Narrative, and Strategic Recommendations**

This chapter synthesizes the arguments developed across this thesis and applies them directly to Rezolve.

The goal is to demonstrate, in a structured and academically rigorous way, how the literature on early-stage medical device financing and the insights from the investor interviews can be used to construct a coherent investment narrative and a concrete strategic plan for the company's next phase of development. The chapter is organised into four parts. The first part examines commercial repeatability using only Rezolve's internal performance data. The second part applies valuation logic to Rezolve's actual progress and compares this position with the most relevant external reference point case, namely Manometric.

The third part clarifies the investment terms that Rezolve should be prepared to accept, illustrated through concrete examples. The final part integrates these insights into a single fundraising narrative that is aligned with investor expectations and grounded in Rezolve's real achievements.

## **7.1 Commercial Repeatability Based on Rezolve's Internal Data**

The academic literature on early stage MedTech financing emphasises that investors evaluate companies according to their ability to reduce uncertainty. Clinical repeatability is one of the strongest indicators of this reduction. In the context of orthopaedic medical devices, clinical repeatability refers to the ability of a device and its associated workflow to be adopted consistently across different orthopaedic care environments, such as independent orthopaedic clinics, hospital affiliated departments, and outpatient rehabilitation settings. Investors explained in the interviews that they look for evidence that clinicians can apply the same scanning, ordering, and fitting process across sites with varying resources and operational constraints. The key question is therefore not how much revenue the company has generated, but whether the workflow is stable, predictable, and compatible with routine clinical practice across multiple care settings.

Rezolve's internal data provide an initial indication of clinical repeatability. Since commercialisation began in September, Rezolve has onboarded three orthopaedic clinics. Across these three clinics combined, the company has delivered approximately ten fittings per month that were prescribed by physicians and reimbursed by insurers under the Dutch Bismarck-type reimbursement system. This corresponds to an average of approximately three point three reimbursed fittings per clinic per month.

While this figure reflects early-stage activity within a limited sample, it indicates that clinicians are able to integrate the scanning, ordering, and reimbursement process into their routine workflow, resulting in recurrent prescriptions rather than isolated trial use.

However, these figures must be interpreted with caution. The current clinical network consists of only three clinics, and the observation period covers only the first months following commercialisation, which began in September 2025. Such a short time horizon does not allow the calculation of a stable long-term average, and month-to-month variation is expected in early adoption phases. For this reason, this thesis adopts a conservative working assumption that a clinic may eventually stabilise between two and three reimbursed fittings per month once it has been fully onboarded and has gained experience with the workflow. This assumption is grounded in Rezolve's initial internal data while explicitly acknowledging the statistical limitations associated with a small sample size and a short observation period.

The implication for Rezolve is clear. As the clinic network expands, the company should systematically collect data, such as throughput, refits, scan to delivery time and reimbursement approval durations. A broader dataset will allow Rezolve to replace provisional assumptions with actual volume numbers and will provide robust evidence to investors and payers that the adoption mechanism is consistent, scalable and reproducible.

## **7.2 Valuation Logic Applied to Rezolve's Real Progress**

The academic literature describes early-stage valuation in MedTech as a function of risk reduction rather than cash flow or short-term revenue. Investors focus on whether the most important uncertainties have been sufficiently reduced. These uncertainties typically include regulatory acceptance, reimbursement approval, clinical adoption and operational scalability. Interviews conducted for this thesis confirmed this perspective. Investors across the interview sample independently emphasised that early-stage companies are not evaluated according to the size of their revenue but according to the clarity of their pathway toward predictable growth. Rezolve has already achieved several milestones that reduce these uncertainties. The Rise AFO is CE compliant under the custom-made medical device pathway. The company has obtained reimbursement approval in the Netherlands. Clinicians prescribe the device regularly and are able to incorporate it into their workflow. The unit economics are also attractive. Each device generates approximately six hundred euros of gross profit. As an illustrative case, Rezolve's early clinical activity suggests that prescriptions occur on a recurrent basis once clinics are onboarded and familiar with the workflow. From an investor perspective, these observations do not serve to demonstrate near-term profitability but to indicate whether the operating model can support a meaningful increase in clinical volume. At this stage, scalability cannot be inferred from simple extrapolations of unit economics, as expansion would involve both potential economies of scale, such as increased automation, and additional operational complexity, including broader geographic coverage and higher support requirements. For this reason, investors focus less on projected margins and more on whether prescription behavior and workflow stability provide a credible foundation for scaling the organisation beyond its initial clinical footprint. To contextualise this position, insights from the interview with Paul van Ooik at Nextgen Ventures are particularly relevant.

He explained that Nextgen participated in the seed investment round of Manometric in early two thousand twenty-one. According to his account, the decision to invest was based on clear evidence that the company had reached a point where regulatory acceptance, workflow integration, and early clinical adoption were sufficiently demonstrated. In this context, reproducible clinical behaviour refers to consistent prescribing and usage patterns by clinicians across different orthopaedic practices, indicating that the device could be integrated into routine care rather than relying on isolated or experimental use. Although he did not disclose a valuation, he emphasised that the investment decision relied on these repeatable prescribing patterns, early signs of operational scalability, and a credible plan for automation.

This reasoning aligns closely with Rezolve's current position. Both the literature and the interviews suggest that investors interpret companies at this stage through their demonstrated ability to reduce uncertainty, generate evidence and scale the operating model. Rezolve can therefore frame its valuation expectations not by asserting a specific numerical target, but by demonstrating that its current stage corresponds to the milestones that experienced MedTech investors consider sufficient to justify early growth capital.

### **7.3 Investment Terms That Support Alignment and Enable Future Funding**

The investor interviews revealed that early stage MedTech investors expect certain protective terms when committing capital. At the same time, investors emphasised that these protections should support long term alignment rather than create future obstacles.

The first term concerns protection when the company is sold. Investors expect to recover the amount invested before proceeds are distributed among all shareholders. This is achieved through a one times non participating liquidation preference.

A simple example clarifies the logic. If an investor provides one million euros and the company is later acquired, the investor receives one million euros before the remainder is divided among all shareholders. This structure does not grant any additional share of the upside and is considered balanced and adequate at this stage.

The second protective term relates to how ownership adjusts in the event of future financing rounds at a lower valuation. The broad-based weighted average anti-dilution mechanism makes a modest correction and is widely regarded as the most aligned option. It ensures that investors are protected without placing excessive burden on founders or discouraging future investors. In contrast, the full ratchet mechanism would reset the investor's share price entirely to the lower valuation, which could significantly reduce founder ownership and create difficulties in future financing. Interviews emphasised that this structure is rarely appropriate for scientific or regulatory ventures, because the normal variability of development cycles would expose founders to excessive dilution.

By expressing willingness to accept balanced protections and by declining structures that distort long term incentives, Rezolve can present itself as a professional and reliable partner. This reinforces the narrative that the company understands how early stage MedTech financing works and is committed to building long term alignment.

#### **7.4 Constructing Rezolve's Fundraising Narrative**

The findings from the literature, the investor interviews and Rezolve's internal data converge into a coherent fundraising narrative. The narrative is built around the principle that investors reward companies that reduce uncertainty in a structured and transparent way.

The first element of the narrative is regulatory readiness. Rezolve has achieved CE compliance under the custom-made framework, which removes an early source of uncertainty.

The second element is reimbursement validation. Approval in the Netherlands demonstrates that payers recognise the clinical benefit of the device. The third element is clinical adoption. The internal average of three point three reimbursed fittings per clinic per month shows that clinicians can incorporate the workflow into routine practice.

Two additional elements strengthen the narrative and signal progressing toward long-term defensibility. First, the company is preparing an international patent application under the PCT framework. This strategy allows Rezolve to protect its core technology in future markets and reduces competitive uncertainty. Second, Rezolve is progressing toward increased automation of the design and production process. Automation reduces dependence on manual steps, improves consistency and enhances scalability. Investors described this type of operational improvement as one of the clearest indicators that a MedTech company is moving from early experimentation to structured growth.

The narrative concludes by explaining how the capital raised will reduce the next layer of unresolved uncertainty. Rezolve intends to expand its clinic network, deepen its evidence base for patient outcomes, strengthen its reimbursement strategy and advance its automation and intellectual property work. Presenting the fundraising in this way aligns the company with the decision-making logic described in the literature and in the interviews. It frames the round not as a request for capital but as an organised plan to reduce the specific uncertainties that still remain.

## **8 Conclusion**

This work examined how Rezolve Medical can secure early-stage growth capital under conditions consistent with European MedTech investment practice. The analysis combined academic evidence, industry data, and investor interviews to clarify the factors that drive funding decisions in health technology.

The findings show that MedTech fundraising outcomes depend on disciplined execution rather than technical novelty alone. Investors evaluate companies based on regulatory progress, defined in this work as documented classification, early interaction with a Notified Body, and the implementation of a quality management system. They assess clinical validation through patient relevant outcomes and early pilot data, and they evaluate reimbursement potential through evidence that the technology aligns with payer requirements. These dimensions were emphasised both by the investors interviewed and in the academic literature. In particular, Sardar et al. (2024) conceptualise regulatory progress as the progressive reduction of uncertainty related to safety, performance, and regulatory pathway. The interpretation expressed by the interview participants was consistent with this analytical framing. Across both sources, evidence of execution was shown to carry more weight than projections, with progress assessed through verifiable milestones rather than aspirational forecasts.

Across the literature and the investor interviews, a consistent pattern emerged regarding what constitutes a positive economic rationale in early stage MedTech ventures. One central factor is the ability to link patient benefit to measurable efficiency gains within the healthcare delivery system. Investors emphasised that clinical improvement alone is insufficient if it does not translate into economic value for providers or payers.

A positive economic rationale therefore arises when a medical device demonstrably reduces resource consumption, such as clinician time, follow up visits, or workflow complexity, while maintaining or improving patient outcomes. This linkage between patient benefit and system level efficiency was highlighted by multiple interview participants and is supported by the literature on MedTech commercialisation and health technology assessment, which emphasises that technologies are more likely to be adopted and reimbursed when clinical value is accompanied by observable economic impact.

For Rezolve Medical, four elements stand out from the analysis. Strengthening intellectual property and demonstrating defensibility enhances credibility with institutional investors. Quantifying economic outcomes for payers, such as reduced clinician time or fewer refits, aligns the Rise AFO with reimbursement logic. Demonstrating repeatability across clinical partners shows that the model can scale operationally. Clarifying preferred governance structures supports alignment with compatible investors.

In addition to these points, two further observations emerge from the interviews and align closely with Rezolve's current trajectory. First, investors place significant weight on whether a company has a clear roadmap for the reduction of future uncertainty. Rezolve's ongoing work toward an international patent filing under the PCT framework responds directly to this expectation. A well-structured patent strategy strengthens defensibility before entering larger and more competitive markets and signals long term strategic planning. Second, investors repeatedly highlighted the importance of operational scalability. Rezolve's efforts to automate key stages of the design and production workflow reduce dependence on manual processes and increase consistency. This work directly addresses investor concerns about scalability and operational risk.

More broadly, the study contributes to understanding how early stage MedTech ventures navigate Europe's current investment environment. The evidence suggests that the most investable companies are those that link technology to system level efficiency, align evidence generation with regulatory and payer expectations, and maintain financial discipline while expanding. The case of Rezolve Medical illustrates how the combination of regulatory clarity, measurable outcomes, and operational readiness, patent strategy and process automation can shape investor confidence and influence the terms under which capital is raised. Rezolve's trajectory shows that the ability to demonstrate progress across these interconnected dimensions is a central component of building a credible and attractive investment proposition.

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## **10 Appendix**

### **Appendix 1 : Script for Investors Interviews**

#### **Script for Fundraising Interviews**

##### **Please introduce yourself**

- Could you briefly describe your background and current role?
- What is your investment focus at [fund name], and how does MedTech fit into it?

##### **1. Metrics & Milestones**

- What are the most relevant metrics a MedTech company at Rezolve's stage should communicate to investors?
  - Clinical: CE mark, pilot studies, reimbursement progress.
  - Financial: early revenues, gross margins, unit economics.
- What key milestones must a MedTech like Rezolve deliver before raising €1–1.5M?
  - Regulatory / clinical evidence.
  - Partnerships / adoption.
- How do you typically assess the potential of a MedTech solution when considering funding?
- What deal metrics are common at this stage (pre-money valuation, equity percentage, instrument preference)?

## **2. Communicating the Business Model**

- How would you recommend Rezolve position its business model to investors (capital-light, outsourced manufacturing, B2B via orthotists)?
- What are the pros and cons of focusing on early revenues vs. prioritizing technology validation?
- In your experience, how do communication styles differ between EU and US investors, and what should Rezolve be mindful of?
- How important is demonstrating scalability early on in MedTech pitches?

## **3. Exit Potential & Market Trends**

- From your perspective, what does a successful exit look like for an early-stage MedTech device company?
- What are the most common exit paths you have seen (acquisition, IPO, secondary VC rounds)?
- What are the main difficulties MedTech startups face compared to digital health or pharma when reaching exits?
- How do you currently view the MedTech investment climate in Europe (post-Covid, reimbursement environment, VC appetite)?

## **4. Financing Strategy**

- What financing options do you think are best suited for MedTech startups raising €1–2M?
  - Equity round vs. convertible note vs. SAFE.

- How do you see the role of non-dilutive funding (grants, subsidies) alongside private capital?
- At this stage, what ownership percentage or terms would investors typically target?

### **5. Resolve-Specific Insights**

- Based on what you know about Resolve (CE mark, clinical pilots, personalized orthotic technology), what do you see as its main strengths and weaknesses from an investor perspective?
- What would make Resolve most attractive to a fund like yours in the near term?
- If you were advising Resolve, what would you emphasize in the fundraising narrative?

### **6. Final Advice**

- What advice would you give to an early-stage MedTech founder preparing for their first growth round?
- Are there common mistakes you see MedTech companies make when approaching investors?

## **Statement of GenAI use**

The authors hereby certify that the authors adhered to the Nova SBE guidelines on the use of GenAI tools such as ChatGPT in the master thesis. Below, the authors document how and for what purposes they used GenAI:

During the preparation of this work, the authors used GenAI for the following purposes:

- Search engine:

- o Consensus: Used to find relevant scientific papers and extract insights on research questions, ensuring academic rigor.

- o Google Scholar: Utilized to identify and source peer-reviewed articles.

- Ideation helper:

- o ChatGPT: Used to brainstorm ideas for thesis topics, structure outlines, and refine research questions during the early stages of the thesis

- Text summarizer:

- o ChatGPT: Employed to summarize long articles and papers for a concise understanding of relevant findings.

- o Consensus: Leveraged to extract core findings and conclusions from academic papers.

- Explanation provider:

- o ChatGPT: Used to clarify complex concepts, theories, and statistical methods

in simplified language for better comprehension.

- Language assistant & Translator:

- o Grammarly: Applied to improve grammar, punctuation, and overall language quality to ensure a polished final document.

- o ChatGPT: Used for paraphrasing and refining sentences to enhance clarity and readability.

- o DeepL: Utilized for translating non-English academic sources into English and ensuring accuracy in multilingual references.

After using these tools, the authors reviewed, quality-checked, and edited the content as needed and took full responsibility for the final text and arguments presented in this work.

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