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Scaling Health Innovation: Academic Origins and Global Growth in the Oculis Journey

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ABSTRACT

This paper explores the transformation of Oculis, an Icelandic biotech company, from an academic research initiative into a publicly listed pharmaceutical firm on NASDAQ. Drawing on four in-depth interviews with the company's scientific founders, an early-stage investor, and a senior executive, the study examines how health innovations are scaled through a deliberate interplay of identity transformation, strategic financing, regulatory engagement, and global team building. Using a qualitative case study approach, the paper identifies four central themes: [1] the shift from academic to entrepreneurial identities; [2] the use of phased investment and strategic partnerships to support growth; [3] regulatory navigation, especially engagement with the U.S. FDA, as a tool for institutional legitimacy; and [4] the development of a decentralized, cross-cultural leadership team. Situated within the literature on health care entrepreneurship, academic spin-offs, and institutional theory, this case contributes new insights into how science-based ventures can achieve credibility and scale in highly regulated, global markets. The findings underscore the importance of hybrid leadership, legitimacy-building narratives, and cross-sector collaboration in successfully commercializing scientific research.

Keywords: Health care entrepreneurship, academic spin-offs, institutional legitimacy, biotech scaling, hybrid identities

Introduction

This paper examines Oculis's entrepreneurial evolution as a case study in science-based venture scaling [5], providing insights into how hybrid identities, strategic financing, regulatory legitimacy, and global leadership interact in the journey from laboratory discovery to commercial product [6]. It explores how entrepreneurial leadership and institutional navigation can transform a university-based scientific project into a globally operating biotech firm. Focusing on Oculis as a representative case, the paper presents organizational, financial, and regulatory strategies for scaling health innovations. The scope includes identity transformation, venture financing, regulatory engagement, and international team development, drawing on qualitative insights from key decision-makers in the company's growth.

Founded in 2000 by ophthalmologist Einar Stefánsson and pharmacist Thorsteinn Loftsson. Oculis began as a purely scientific endeavor to solve a specific ophthalmological problem through novel drug delivery mechanisms [7]. With over a dozen PhD students and hundreds of academic publications, the project's early years exemplified the deep scientific roots of many academic spin-offs. However, turning this robust research base into a viable business required an entirely different set of capabilities, an entrepreneurial leap that the founders, over time, came to embrace. Their journey encapsulates a critical tension at the heart of many university-born ventures: the shift from knowledge generation to value creation, from the ethos of science to business exigencies [7].

The research explores how the founders and leadership team of Oculis navigated the multifaceted challenges of scaling a health science innovation. It aims to uncover the strategies used to build credibility with investors, engage regulatory bodies, structure a globally distributed leadership team, and transition from a university project to a public company. To achieve this, we conducted four in-depth interviews with key actors in the Oculis story: its scientific founders, the CFO-turned-CEO, and an early-stage venture investor. Their collective narratives offer a rare window into the lived experiences behind a successful health science scale-up.

This research is situated within several intersecting bodies of literature. The entrepreneurship literature has long emphasized the role of academic spin-offs in commercializing scientific research [8,9], particularly in biotechnology, where regulatory, financial, and organizational complexities abound [10,11]. Scholars have noted that such ventures often require founders to develop hybrid identities, those capable of bridging the cultural and operational divides between academia and industry [12,13]. Legitimacy theory also provides a crucial lens: ventures must continually construct and communicate narratives of competence, credibility, and conformity to institutional norms to secure resources and stakeholder trust [1415]. Moreover, the case of Oculis contributes to emerging discussions about organizational culture and leadership in global biotech firms, including the strategic value of diverse, distributed teams [16,17].

The study contributes to the literature through four interlinked themes. First, identity transformation proved crucial: the founders had to evolve from academic researchers into mission-driven entrepreneurs [18] without compromising scientific integrity. Second, investment strategy played a decisive role. Oculis's ability to raise successive funding rounds, from Icelandic seed funds to global health-tech investors, hinged on meeting strategic milestones and aligning with experienced intermediaries such as the Novartis Venture Fund [19]. Third, regulatory navigation, particularly with the U.S. Food and Drug Administration [20], was not merely a compliance task but a strategic lever that conferred institutional legitimacy [21]. The company's structured, transparent engagement with the FDA helped attract investment and guided clinical strategy. Finally, corporate governance, its composition, and culture of the team emerged as a foundational element in Oculis's global growth [22]. The company deliberately recruited specialized talent from Iceland to Boston to Switzerland and embedded a collaborative, cross-cultural ethos to support decentralized leadership.

Beyond confirming existing theoretical frameworks, the Oculis case offers three important contributions. First, it highlights how academic ventures can evolve successfully without abandoning their scientific ethos, provided they strategically adopt business-oriented leadership and governance structures [23]. Second, it demonstrates how, through anticipatory governance culture [24], engaging regulatory agencies early and proactively, rather than treating them as post hoc hurdles, can serve as a powerful instrument of legitimation. Third, it illustrates the critical importance of human capital: technical expertise, interpersonal synergy, global cultural fluency, and advisory network building. As a venture capital investor [19], a high-ranked manager emphasized that success depends less on ideas than on people, especially those who can adapt and persist through uncertainty.

The paper is structured as follows. The next section reviews relevant literature on health care entrepreneurship, academic spin-offs, and institutional legitimacy. The methodology section outlines the qualitative case study approach and details the interview design and analysis strategy. The findings section presents the four central themes that emerged from the interviews: identity transformation, investment and scaling, regulatory navigation, and global team evolution. The discussion section situates these findings within existing theory and draws broader implications for

practice and policy. Finally, the conclusion reflects on the study's contributions and limitations, and suggests directions for future research on scaling science-based ventures.

By examining the Oculis story in depth [25], this paper offers a nuanced understanding of how innovation in health care can move from idea to impact, not by chance, but through a deliberate choreography of science, entrepreneurship, and institution-building.

Literature review

Entrepreneurship in health care [26,27] has emerged as a vital domain for scholarly inquiry and public policy, driven by increased medical innovation, digital health solutions, and biotechnology startups. Unlike entrepreneurship in many other sectors, health care ventures must operate within a framework of intense regulation, high capital requirements, and long development timelines. Scholars such as Herzlinger [28] and Shane and Venkataraman [29] argue that transforming scientific knowledge into viable commercial products involves innovation and technology and a deep engagement with institutional, regulatory, and financial systems. Translating academic research into market-ready health care solutions is particularly complex [30].

Academic spin-offs, defined as companies emerging from university research to commercialize new knowledge, play a critical role in this ecosystem [3,18]. These ventures are often founded by scientists who may lack entrepreneurial training, making transitioning from academic to business environments a significant challenge [9,32]. Central to this transition is the development of hybrid identities, individuals capable of embodying both the scientist and the entrepreneur [33,13,12]. These hybrid actors serve as crucial mediators between the institutional norms of academia and those of industry, enabling the startup to gain credibility in both domains. The case of Oculis, where its founders made this transition over a multi-decade period, offers empirical support for these theoretical constructs.

Scaling ventures in highly regulated sectors such as health care is about more than expanding operations; it entails building legitimacy across several domains. Scholars, including Zimmerman and Zeitz [34] and Suchman [35], emphasize that legitimacy is foundational for attracting resources, navigating institutions, and entering markets. In biotech, legitimacy is not simply reputational but often hinges on demonstrating regulatory readiness, scientific credibility, and alignment with market expectations. Regulatory approval, mainly from institutions like the U.S. Food and Drug Administration [20], acts as a gateway and a signal of quality to investors and stakeholders. Kaplan et al. [36] highlight the strategic value of forming alliances with regulatory experts and intermediaries. In the Oculis case, active collaboration with FDA consultants and a clear regulatory roadmap were instrumental in moving the venture from a research-focused entity to an investable biotech company. These actions served operational needs and functioned as powerful tools of institutional legitimation.

Financing health science ventures is another area marked by complexity and risk. Hall and Lerner [37] and Gompers and Lerner [38] note that biotech financing typically unfolds in stages, Series A, B, and C, aligned with scientific and regulatory milestones. This staged approach allows investors to manage risk while enabling firms to build capabilities gradually. However, this model places a premium on the venture's ability to demonstrate progress at each stage, justifying subsequent funding. Research by Hellmann and Puri [34] emphasizes the importance of early alignment between founders and investors on timelines, expectations, and governance. The evolution of Oculis from initial funding by Icelandic seed investors to participation by global health-tech funds like the Novartis Venture Fund illustrates how investor trust is often contingent upon demonstrable scientific advancement and sound strategic planning. Murray [36] further argues that the quality of early-stage scientific leadership can significantly influence the startup's credibility, especially in life sciences, where domain expertise is non-negotiable.

Team dynamics and leadership transitions play a pivotal role in the evolution of health care ventures. As startups grow, they often outgrow the founder-led model and require new leadership structures to manage complexity. Beckman et al. [39] and Ensley et al. [28] demonstrate that team composition, diversity of skills, and the ability to recruit experienced professionals are critical for long-term success. Oculis's expansion into a multinational firm with decentralized leadership in Switzerland, the U.S., and Iceland highlights this shift. Boeker [40] notes that introducing experienced executives can catalyze professionalization and improve decision-making. The case also reflects a growing body of literature emphasizing the value of advisory boards in providing strategic guidance and symbolic capital.

Organizational culture is another underexplored but essential aspect of scaling global ventures. According to Schein [37], an organization's culture reflects its internal dynamics and influences its adaptability to external environments. Startups across multiple geographies must navigate cultural heterogeneity in norms, communication styles, and work practices. Hofstede [38] and Edmondson [41] highlight the importance of psychological safety and cultural competence in enabling high-performing teams. In Oculis's case, leadership's awareness of cross-cultural communication helped foster inclusivity and alignment. Implementing equity incentives and internal

communication protocols served to maintain cohesion across time zones and national borders.

Institutional theory provides a meta-level framework for understanding how ventures like Oculis secure their place in established fields. According to Suchman [35], legitimacy is a function of performance and conformity to institutional expectations. New ventures must therefore engage in what Navis and Glynn [42] describe as legitimacy narratives, crafting stories that make their novel pursuits appear both credible and necessary. The journey of Oculis from academic project to NASDAQ-listed company involved constructing a narrative that integrated scientific excellence, regulatory prudence, and global business strategy. Each phase of the company's evolution from patent development and academic publication to FDA planning and investor engagement can be seen as a chapter in this broader narrative of legitimation.

In conclusion, the literature on health care entrepreneurship [26,27] underscores the necessity of managing complexity across multiple institutional, scientific, financial, regulatory, and organizational dimensions.

Research methods

This study adopts a qualitative case study approach [43] to explore the entrepreneurial journey and scaling trajectory of Oculis. This biotechnology company transitioned from an academic research initiative to a publicly listed firm on the NASDAQ [7]. The case study design is well-suited for examining complex phenomena within their real-life context [44], such as the interplay between science, entrepreneurship, and institutional structures in the highly regulated health care sector. The primary data for this study consists of four in-depth, semi-structured interviews conducted between February and April 2025. Each interviewee played a key role in the development of Oculis, either as a founder, executive, or early investor. All four interviewees were male. The interviews ranged in length from 70 to 95 minutes. They were conducted in a conversational, open-ended format [45] that allowed for exploration of both factual and experiential aspects of the Oculis journey. Interviewees were selected using purposive sampling to ensure that the data would capture diverse perspectives across scientific, managerial, and financial domains. The interview guide included themes such as the origin and development of the business idea, challenges in clinical development and regulation, interactions with investors, and organizational evolution [45].

All interviews were transcribed verbatim and subjected to thematic analysis. Thematic coding was done iteratively to identify patterns across the narratives. Initial open coding was followed by axial coding to group emergent codes into broader categories and themes. NVivo software was used to assist in the organization and visualization of themes. Themes were developed inductively from the raw data and deductively, drawing on established concepts in the literature on health care entrepreneurship, institutional theory, and scaling science-based ventures. Attention was paid to the alignment and divergence between the literature and the lived experiences of the interviewees. All interviewees provided informed consent and were assured of confidentiality. Interviewees were a high-ranked manager at Oculis, the two founders, and a high-ranked manager of the venture capital firm that brought the first outside investment to Oculis. Interview data were anonymized during transcription, and any identifying details were modified or omitted to protect privacy.

While the case study offers deep insight into the Oculis journey, it is based on a small number of interviews. It reflects the perspectives of a specific set of male interviewees in senior roles. As such, the findings are not generalizable but aim to provide a rich, contextual understanding that can inform theory and practice in similar settings.

Results

This section presents the condensed thematic findings from four in-depth interviews with key figures involved in the creation and growth of Oculis, which successfully transitioned from a university research project to a publicly listed company on the NASDAQ. Using the lens of entrepreneurship in health care and scaling up, four core themes emerged that encapsulate the startup's unique journey.

FROM ACADEMIA TO ENTREPRENEURSHIP: IDENTITY TRANSFORMATION AND FOUNDATIONAL SYNERGY

Oculis was born from a long-standing academic partnership between Einar, an ophthalmologist, and Thorsteinn, a pharmacist. Their complementary expertise was instrumental in addressing a specific clinical problem through novel drug delivery technology. Initially, the project had no commercial aims and was grounded entirely in academic research.

> The collaboration began as a scientific project. It was not an idea aimed at commercial success or making money. (A founder).

The transformation began when they recognized that scaling the solution would require substantial funding, business leadership, and investor engagement. This shift catalyzed a profound identity transformation for both founders. Einar, in particular, spoke about the urgency and reward of stepping out of the academic mindset and adopting entrepreneurial responsibility.

> In business, the money runs out in 18 months.

> Either you secure more funding, or you cease to exist. (A founder).

The entry of the high-ranked manager at Oculis, with a background in finance, marked a crucial inflection point. He brought the necessary investor relations skills and financial discipline to turn the project into a viable business. The team's ability to evolve identities and adapt to market realities was foundational to Oculis's eventual success. This theme also reflects the evolution of values: from scientific inquiry for knowledge's sake to a mission-driven enterprise focused on therapeutic outcomes and public value. Both founders embraced this evolution while staying rooted in academic integrity. Their ability to straddle both worlds contributed to sustained credibility and long-term vision. Furthermore, this identity shift underscores the increasing need for translational leadership in healthcare entrepreneurship, leaders who can move fluidly between the lab bench and the boardroom. Oculis exemplifies how such hybrid identities are possible and necessary for meaningful innovation.

STRATEGIC PARTNERSHIPS, INVESTMENT, AND SCALING TRAJECTORY

Securing early-stage funding proved difficult due to initial overvaluation and the venture's academic framing. Eventually, one venture capital firm and shortly after another one, provided critical seed capital, contingent on strategic realignment. A high-ranked manager from the first one emphasized that the investment decision was based on the team's strength and willingness to adjust expectations.

> We look for outstanding talent... The founders wanted to seek more capital quickly, but we wanted to stick to the plan. (A high-ranked manager of a venture capital firm).

The company evolved through three major funding rounds, culminating in a Series C backed by health-tech growth funds. Each round brought strategic shifts, board realignments, and increased global presence. The investment journey involved capital and discipline, prioritizing milestones and valuation growth over fast fundraising.

> Going public wasn't the end goal; it was simply the next step in the venture capital funding process. (A high-ranked manager at Oculis).

Oculis's IPO on NASDAQ in 2023 represented both a financial milestone and a validation of the model. However, a new phase involving regulatory compliance, stakeholder management, and global visibility also began.

What stands out is the calculated use of each funding round to raise capital and attract knowledge, experience, and legitimacy through board composition and investor partnerships. The decision to align with the Novartis Venture Fund brought money and validation from one of the most credible pharmaceutical brands globally. Another strategic aspect was the geographic relocation to Switzerland, which was seen as a move to align structurally and reputationally with global investor expectations. This demonstrates how startups in healthcare must often align their operations not just scientifically or commercially but institutionally with the centers of credibility in their industry.

REGULATORY NAVIGATION AND INSTITUTIONAL LEGITIMACY

The interviews consistently highlighted the role of regulatory engagement, particularly with the U.S. Food and Drug Administration [20], in building legitimacy. The founders spoke of a striking contrast between their experiences with European and American regulatory bodies. The FDA was described as thorough but highly collaborative, which helped Oculis refine its trial protocols and appeal to investors.

> We walked into the meeting in the morning, four of us on one side, and 20–30 FDA specialists... The FDA's support was fantastic. (A founder).

Working with FDA-approved facilities and U.S.-based consultants signaled to global investors that Oculis was serious about reaching the market. Regulatory preparedness thus served both scientific and strategic functions. It demonstrated that the company could operate at the highest international standards, an essential factor in attracting venture and institutional investment. This theme also reveals the double role of regulatory navigation in healthcare startups: it serves as a safeguard for patient welfare and a signal of readiness to scale. Meeting FDA standards was not simply a barrier to overcome; it was a form of certification that legitimized Oculis in the eyes of stakeholders. In this way, regulatory engagement enables entrepreneurial legitimacy, allowing companies to move from promise to proof, from the lab to the clinic. Oculis's ability to meet this threshold accelerated its entry into international markets and de-risked the opportunity for later-stage investors.

TEAM COMPOSITION, CULTURE, AND GLOBAL GROWTH

Oculis's success was deeply tied to the composition and evolution of its team. Strategic human capital was central from the early synergy between Einar and Thorsteinn to recruiting experienced executives and advisors. A high-ranked manager of the venture capital firm noted the value of the founders' complementary personalities, while Páll emphasized the company's deliberate recruitment of global experts.

> We have leadership distributed across several countries... We've had to be conscious of communication. (A high-ranked manager at Oculis).

Cultural diversity, distributed teams, and high-level expertise contributed to Oculis's adaptability and resilience. Retaining and expanding the right talent became a top priority as the company transitioned from academia to scale-up. The use of stock options for key employees and the reliance on a global advisory board exemplify this strategic focus.

> Key employees need to own a significant stake in the company's shares. This worked well and generated strong momentum within the company. (A high-ranked manager at a venture capital firm).

This theme reflects a mature understanding of team building in global biotech ventures. The decision to decentralize operations and locate talent in the U.S., Switzerland, and Iceland was not accidental; it was aligned with the need for local regulatory knowledge, access to markets, and proximity to talent hubs. Additionally, the emphasis on cultural literacy, understanding how different communication styles impact team functioning, demonstrates an awareness that human capital is not only about credentials but about cohesion. Maintaining trust, transparency, and shared vision across time zones and cultures is a critical asset. Moreover, Oculis's approach to human capital is notable for its recognition of legacy and continuity. Several interviewees mentioned how earlier PhD students and junior researchers involved in the academic phase are now leaders in the field, creating a reinforcing loop of reputation, network, and talent attraction.

The case of Oculis illustrates how health care startups can navigate the complex journey from research to public markets. Four central themes emerged: transforming academic identities into entrepreneurial leadership, the strategic navigation of investment and scaling, regulatory engagement as a trust-building mechanism, and the evolution of a globally distributed, high-performance team. Together, these themes reflect the broader demands of entrepreneurship in health care, where success depends not only on innovation but also on institutional agility, cross-sector collaboration, and resilient leadership. Oculis's experience is a model for future ventures operating at the intersection of academia and industry. It reveals that success in this space requires more than a breakthrough technology; it demands a sustained commitment to legitimacy, learning, and long-term value creation. From the lab bench to the stock exchange, Oculis's journey encapsulates the intricate choreography required to scale innovation in one of the world's most regulated and impactful sectors.

Discussion

The findings from the Oculis case offer rich insights into the dynamic interplay between scientific discovery, entrepreneurial identity transformation, strategic governance, and institutional legitimacy within the complex and highly regulated field of health care innovation. This discussion connects the empirical themes that emerged from the case with broader theoretical frameworks in entrepreneurship, institutional theory, and innovation studies, shedding light on how science-based ventures can successfully evolve from academic projects into globally recognized enterprises.

One of the most salient contributions of the Oculis case is its illustration of identity transformation in academic entrepreneurship. The founders' transition from established researchers to business leaders underscores the personal and professional evolution required to drive scientific innovation toward commercialization. This transformation required adopting new logics, moving from the values of open inquiry and academic rigor to those of strategic vision, investor communication, and resource acquisition. This aligns with the literature on hybrid identities [12,13,33], which suggests that academic entrepreneurs must learn to straddle and reconcile the conflicting demands of academia and industry. Oculis provides an empirical example of how such hybridity is not merely a transitional phase but a sustained, strategic posture that supports long-term venture development.

The case also highlights the importance of staged financing strategies and credible investor alignment in the biotech sector. Oculis's experience reinforces previous findings that biotech ventures must manage capital in phases, using each funding round to extend runway and strengthen legitimacy through milestone achievements [11]. In the Oculis case, credibility was reinforced by disciplined investor relations, alignment with global funds like the Novartis Venture Fund, and adherence to regulatory milestones. The cautious but committed approach of early investors, who demanded realistic valuations and disciplined progress, enabled Oculis to build a reputation for reliability in a space where investor trust is often fragile. This offers a practical lesson for founders and funders: alignment on expectations and governance is as critical as capital.

A key finding concerns regulatory engagement as a strategic asset. In contrast to the often adversarial or compliance-focused perception of regulatory bodies, Oculis treated its relationship with the U.S. Food and Drug Administration [20] as a collaborative partnership and a source of institutional legitimacy. This approach aligns with emerging research on anticipatory governance [24], which advocates early and proactive engagement with regulators to preempt misalignment and signal readiness.

Oculis's deliberate interactions with the FDA served technical and symbolic functions; they clarified clinical pathways while simultaneously signaling maturity and professionalism to external stakeholders. Notably, the case underscores differences between regulatory regimes, with the U.S. system offering a more transparent and navigable path than some European contexts. This suggests a need for policymakers, particularly in smaller or less harmonized markets, to improve their regulatory systems' clarity, predictability, and responsiveness if they wish to foster innovation-driven entrepreneurship.

The evolution of Oculis's organizational structure and leadership model provides insight into how globally oriented biotech firms scale. Rather than relying solely on the founding team, Oculis deliberately recruited executives and advisors with diverse functional and geographic expertise. With hubs in Iceland, Switzerland, and the U.S., the distributed leadership model reflects an intentional design for cross-border coordination, knowledge transfer, and institutional legitimacy in key markets. This organizational agility is consistent with research on high-growth firms [16], emphasizing the value of professionalization and strategic hiring during phases of rapid scaling. Moreover, the cultural competence demonstrated by Oculis's leadership team, manifest in communication norms, team integration, and employee incentives, shows how organizational culture, when cultivated consciously, becomes a strategic resource. For instance, Oculis's emphasis on stock ownership reflects a long-term commitment to alignment and retention, especially in knowledge-intensive sectors where human capital is paramount.

Theoretically, the Oculis case advances institutional theory by demonstrating how new ventures craft legitimacy narratives to bridge disparate institutional logics [14]. These narratives, rooted in scientific excellence, global partnerships, and regulatory success, helped Oculis align with the expectations of different audiences: academic peers, investors, regulators, and global collaborators. The company's evolution was not merely structural but also discursive: each funding round, regulatory engagement, and leadership transition was framed within a broader story of credibility, capability, and mission. This confirms that storytelling in entrepreneurship is not an afterthought but central to how ventures mobilize resources and sustain momentum in environments marked by high uncertainty.

The Oculis case also speaks to the often-underestimated role of time in science-based entrepreneurship. The venture unfolded over two decades, requiring long-term vision, patience, and adaptive learning. This extended time horizon challenges familiar narratives of rapid scale and unicorn valuation and instead suggests that deep science innovations often follow a slower, more deliberate path to market. This raises important questions about how funding mechanisms, university support systems, and national innovation policies are structured, especially in small economies like Iceland's. Supporting ventures like Oculis may require capital, temporal flexibility, regulatory foresight, and global integration pathways.

Finally, the case has important implications for practice. For academic entrepreneurs, it illustrates the necessity of embracing business acumen, regulatory literacy, and team-building skills without abandoning scientific integrity. For investors, it reinforces the value of aligning early with capable founders who can grow into global leaders. Furthermore, for regulators and policymakers, it highlights the importance of creating environments that are not only rigorous but also navigable and internationally credible. In sum, Oculis's journey illustrates a broader blueprint for health innovation: one that combines translational science, hybrid leadership, phased investment, and strategic legitimacy-building in pursuit of public and commercial impact.

Conclusion

This study of Oculis's journey from an academic research project to a NASDAQ-listed biotechnology firm offers a multifaceted contribution to scholarship and practice in health-care entrepreneurship. First, it demonstrates that the successful scaling of science-based ventures hinges on cultivating hybrid entrepreneurial identities. The founders' ability to navigate fluidly between academic norms and commercial imperatives provided the emotional resilience and intellectual agility necessary for long-term venture development. Their experience confirms that identity transformation is neither a one-time event nor a purely individual process, but an ongoing negotiation between institutional logics.

Second, our findings reinforce the centrality of legitimacy-building strategies in highly regulated sectors. By treating regulatory bodies, particularly the U.S. FDA, as proactive partners rather than adversaries, Oculis leveraged compliance activities as strategic levers for credibility with investors, clinical collaborators, and global markets. This approach to anticipatory governance illustrates how early, transparent, and structured engagement with regulators can accelerate clinical development and capital-raising efforts.

Third, the case underscores the importance of phased, milestone-driven financing. Oculis's capital strategy, sequenced from local seed funding to global health-tech investors, enabled the venture to de-risk scientific development, align expectations with financiers, and maintain governance discipline. This staged approach offers a replicable model for academic spin-offs seeking

to build momentum without overextending their resources or diluting their scientific vision.

Our analysis highlights how organizational culture and human capital decisions shape global growth trajectories. The deliberate recruitment of cross-border leadership, equity incentives, and the cultivation of cultural competence across time zones created a resilient structure capable of adapting to new regulatory, market, and scientific challenges. This underscores that scaling health innovation is as much about people and culture as technology.

Finally, by tracing Oculis's two-decade evolution, this study calls attention to the temporal dimension of translating science to impact. In contrast to narratives of rapid unicorn growth, deep-science ventures often require extended time horizons, patient capital, and adaptive learning. Consequently, universities, investors, and policymakers must design support systems that recognize and accommodate the long-term nature of life-science innovation.

The Oculis case offers a comprehensive blueprint for translating academic discoveries into commercial health solutions: one built on hybrid leadership, strategic legitimacy work, phased financing, and a people-centered culture. It provides actionable lessons for entrepreneurs, funders, and regulators aiming to foster sustainable, impactful biotech ventures in an era of increasing regulatory scrutiny and global competition.

One key limitation of this study is its reliance on a small, homogeneous sample of four male interviewees in senior leadership or investor roles, which may narrow the scope of perspectives captured. The focus on these actors means that potentially valuable insights from other stakeholders, such as junior scientists, regulatory advisors, or clinical partners, are absent. Moreover, while rich in contextual detail, the case study approach limits generalizability. The findings are embedded in the specific institutional, cultural, and temporal context of Oculis and Iceland and may not directly translate to ventures operating in different regulatory or entrepreneurial ecosystems.

Future studies could expand on this work by incorporating comparative case analyses of other academic spin-offs across different countries and regulatory regimes to identify patterns and divergences in scaling strategies. A broader and more diverse set of interviewees, including middle management, regulatory officials, and patient advocacy groups, would enrich the understanding of leadership dynamics, organizational culture, and stakeholder engagement. Finally, more attention could be given to the role of digital platforms, data analytics, and AI in scaling biotech ventures, which remains an underexplored area in the current case.

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