

THESES OF THE DOCTORAL (PhD) DISSERTATION

MARKET RISK MITIGATION IN RED BIOTECHNOLOGY THROUGH ORGANIZATIONAL RELATIONSHIPS AND NETWORK COLLABORATIONS

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1. RESEARCH BACKGROUND, OBJECTIVES, AND RESEARCH HYPOTHESES

Red biotechnology—biotechnological activity focused on healthcare, pharmaceutical, therapeutic, and diagnostic applications—is one of the most knowledge-intensive and, at the same time, one of the riskiest industrial domains of the twenty-first century. In 2022, its direct gross value added reached USD 755 billion, corresponding to approximately 0.7% of global GDP, while its total GDP contribution, including indirect and induced effects, amounted to USD 2.3 trillion. Between 2012 and 2022, the sector’s direct contribution to GDP increased by 20%, while its total impact expanded by 25%. Every USD 1 of direct pharmaceutical income generated an additional USD 2.04 elsewhere in the economy. In 2022, the sector directly sustained 7.8 million jobs and, together with supplier and consumption effects, supported the employment of nearly 74.9 million people (JUNEJA et al., 2024).

These figures clearly indicate that the evolution of business risks in red biotechnology directly affects not only the profitability of individual firms but also global employment and growth trajectories. The European pharmaceutical industry has become a pillar of the EU’s long-term competitiveness, generating EUR 163 billion in direct gross value added and EUR 311 billion in total GVA contribution to the EU-27 economy in 2022. Labor productivity in pharmaceutical manufacturing is outstanding: in the EU-27, a pharmaceutical employee generates an average of EUR 197 thousand in gross value added, approximately three times the average level of the overall European economy, and significantly more than employees in other knowledge-intensive sectors such as telecommunications or financial services. However, this high productivity is coupled with substantial capital requirements, a highly complex knowledge base, and a high probability of failure (JUNEJA et al., 2024).

The dynamics of biotechnology innovation and the volume of capital flowing into the sector are now comparable to the pace of development observed in the information technology industry. The pharmaceutical biotechnology value chain is an exceptionally complex, multi-stage process extending from gene sequencing to therapeutic application. This process may be divided into major stages: discovery and preclinical development (3–6 years), human clinical trials (6–7 years), manufacturing and quality assurance (from year 8 onward), and market authorization and monitoring (from year 10 onward). This long development cycle

and high probability of failure sharpen the business risk profile of red biotechnology, as the innovation portfolio is concentrated in a relatively small number of products, each of which is costly and highly uncertain to develop (ZHOU et al., 2019).

The industry's structure is inherently fragile and highly sensitive to technological, regulatory, and market changes, as well as to external shocks. Over the past two to three decades, the structure of the red biotechnology sector has undergone radical transformation. Whereas large, vertically integrated pharmaceutical corporations (Big Pharma) once dominated the entire value chain from research and development to commercialization, today a highly segmented and networked ecosystem has emerged. Within this ecosystem, small and innovative biotechnology firms, university research centers, and specialized research and development organizations play key roles. This transformation has not merely represented an organizational change, but a fundamental reconfiguration of business models and risk profiles (WILLIAMSON & SPICER, 2023).

The financial fragility of biotechnology SMEs is closely intertwined with the networked structure of innovation. Between 1982 and 2005, biotechnology firms operating since the 1980s exhibited an average R&D intensity (R&D expenditure as a share of total assets) of 38%, compared with 25% among traditional pharmaceutical firms (GOLEC & VERNON, 2009). This high R&D intensity is unsurprising in the context of the productivity crisis in innovation: whereas the clinical success rate of a new molecular entity was around 14% in the 1990s, it has now fallen below 10%, while the cost of bringing a new drug to market has risen from approximately USD 2.5 billion to well above USD 3 billion (EFPIA, 2022).

The vast majority of R&D projects—up to 90%—fail during the development process, and attrition is especially high during the clinical phases. Between Phase II and Phase III trials, 60–70% of new molecules are discontinued for reasons of inefficacy or toxicity (HAVENAAR & HISCOCKS, 2012). This level of failure means that successful products must generate exceptionally high market revenues in order to offset the multi-billion-dollar costs of unsuccessful projects. This, in turn, intensifies financing risks, which arise directly from the fact that biotechnology companies—unlike Big Pharma firms, which may finance their R&D from internal cash flow—are fully dependent on external capital raising, including venture capital, public support, and strategic partnerships.

Reducing business risks in red biotechnology is therefore not merely a firm-level strategic issue; it requires a complex, systemic solution integrated into the macroeconomic context, the specific structure of R&D, and the role of open innovation and strategic cooperation. The central premise of the present research is that network embeddedness, the centrality of network position, and the diversification of strategic partnerships provide mechanisms for reducing market and business risks in the highly uncertain and capital-intensive environment of red biotechnology.

Over the past two to three decades, the structure of the red biotechnology sector has changed radically. Whereas large, vertically integrated pharmaceutical firms once dominated the entire value chain from research and development to market entry, today a highly segmented and networked ecosystem has emerged. In this ecosystem, small, innovative biotechnology firms, university research centers, and specialized R&D organizations play key roles. This shift was not simply an organizational transformation, but a fundamental rearrangement of business models and risk profiles.

The financial fragility of biotechnology SMEs also reveals another critical dimension related to the contractual inflexibility of alliance agreements. The detailed analysis of biotech–pharma strategic alliances by HAVENAAR & HISCOCKS (2012) showed that the classical milestone-royalty contractual structure is not sufficiently flexible to adapt to changing market conditions. Based on data from 1977 to 2010, 71% of all product partnerships were terminated before the drug reached the market, and only 33% of these terminations could be explained by efficacy or safety concerns. This implies that most partnerships ended for economic or strategic reasons, meaning that their contractual frameworks were not sufficiently flexible to absorb market changes such as a sharp decline in projected peak sales or the emergence of competing products.

At the root of contractual inflexibility lies the problem of misaligned incentives. When a contract is concluded between a smaller biotechnology company and a Big Pharma partner, value sharing is typically structured around a “most likely scenario” (for example, peak sales of USD 800 million with a corresponding milestone-royalty scheme). However, when it becomes evident during development that the real market potential differs from projections—whether higher or lower—the dynamics of the original contract may become

distorted, because the parties' expectations diverge under the new circumstances. In a contract with fixed milestones and a constant royalty rate, the Big Pharma partner is likely to abandon the project once expected peak sales fall below a given threshold (for example, USD 173–228 million), because the development costs and milestone payments then appear too high relative to the remaining market potential (HAVENAAR & HISCOCKS, 2012). This situation may be tragic, because the abandoned drug candidate may in fact remain viable and capable of helping thousands of patients, yet is discarded simply because the original financial model did not account for the prevailing market reality.

The paradigm of open innovation (OI)—which, since CHESBROUGH (2003), has referred to the organized search for external sources of knowledge and the systematic external utilization of internal knowledge—has become increasingly prominent in red biotechnology as a possible response to these structural risks. Over the past two decades, OI has become one of the most influential innovation paradigms, especially in knowledge-intensive sectors such as pharmaceuticals and biotechnology. Traditional closed innovation models have gradually been replaced by hybrid, multi-actor structures based on regulated knowledge sharing. Even so, practical implementation is still far from widespread.

The web-based analysis of open innovation platforms among the top 100 pharmaceutical companies conducted by TORRES & POULSEN (2020) identified only seven platforms that genuinely engaged in compound-specific collaboration with biotechnology SMEs. Even among these, most functioned as biased, pre-selected forms of OI, in which the large pharmaceutical company predefined therapeutic areas, molecule types, and intellectual property terms. Biotechnology start-ups and small firms display a deep trust deficit toward OI platforms, as concerns over data ownership and intellectual property rights—that is, fear that a larger partner may improperly appropriate the smaller firm's intellectual assets—remain major barriers to close collaboration. This problem of appropriation is closely related to the fundamentally collective challenge of defining intellectual property. In open innovation, especially in coupled OI models involving bidirectional knowledge flows, it is exceptionally difficult to determine precisely which innovative result is attributable to which party's intellectual contribution. This inherent uncertainty makes open innovation attractive in theory but extremely difficult to implement in practice, often rendering genuine two-way

knowledge exchange nearly impossible because of IP-related fears on one side or the other (TORRES & POULSEN, 2020).

At the operational level of red biotechnology, further systemic risks arise from supply chain complexity and vulnerability. System dynamics modeling of supply chains in Iranian pharmaceutical manufacturing firms revealed that the accuracy and flexibility of pharmaceutical supply chains depend on several interdependent factors, any single weakness among which may cause severe consequences. Four critical challenges may be identified: forecasting inaccuracy, which leads either to stockouts or overstocking; long lead times, especially in the procurement of imported active pharmaceutical ingredients; the lack of an optimal target inventory, which paradoxically generates both shortages and high distribution costs; and elevated supply chain costs resulting from the foregoing problems. These issues are not linear, but are organized into dynamic feedback loops—for example, the bullwhip effect, through which a small change in demand at one end of the supply chain is amplified and transmitted to the other end (MOOSIVAND et al., 2019).

The success of biotechnology companies depends crucially on the formation of collaborative networks that enable access to complementary resources and expertise (LESSER & HEFNER, 2017). Empirical studies have also shown that the success of regional clusters depends heavily on the presence of so-called anchor tenants—organizations capable of catalyzing collaboration among diverse partners. In U.S. biotechnology superclusters such as Boston and the Bay Area, these key organizations were outstanding research institutes or sophisticated venture capital funds capable of connecting actors across the full value chain (GILDING et al., 2020; KISS et al., 2023).

The present research seeks to determine which solutions are currently required in innovation, social, scientific, financial, and economic environments in order for an organization to succeed in red biotechnology despite its high business risks. The focal point of the dissertation is the set of collaborative networks that emerge among biotechnology companies and that may potentially mitigate the multiple risks borne by actors in the sector. The dissertation rests on the fundamental assumption that network embeddedness, network centrality, and the diversification of strategic partnerships offer mechanisms for reducing

market and business risks in the highly uncertain and capital-intensive environment of red biotechnology.

The thematic framework of the analysis integrates network theory, financial risk management, portfolio theory, and the literature on open innovation. The analysis focuses particularly on the following questions:

- To what extent does network centrality affect the systematic financial risks of biotechnology firms?
- How does the diversification of the partnership portfolio influence the success of R&D projects and financial stability?
- Which structural network properties determine the collective innovation performance of biotechnology clusters?
- What mediating role does intellectual property (IP) management strategy play in the relationship between network openness and partnership success?
- How do macroeconomic factors—especially capital market cycles and technological and regulatory changes—moderate the risk-reducing effects of network collaborations?
- How does revenue influence the willingness to apply open innovation, and, once introduced, how does it affect firm performance indicators and profitability?

1.1. Objectives of the Secondary Research

The secondary research is aimed at the systematic processing, theoretical synthesis, and critical evaluation of the existing international literature. Its purpose is to develop an integrative theoretical framework connecting the relevant theoretical and empirical findings of network theory, financial economics, portfolio theory, and innovation management.

The first objective of the secondary research is the systematic review of the theoretical literature on the relationship between network centrality and financial risks. This includes critical analysis of literature ranging from the classical works of social network analysis to empirical studies applied to the biotechnology industry. The purpose is to clarify which mechanisms are described by the existing theories regarding the beneficial effects of

network position and which of these mechanisms are relevant to the reduction of financial risks.

The second objective of the secondary research is the integration of the literature on partnership diversification, portfolio theory, and innovation performance. This involves connecting Markowitz's modern portfolio theory (FABOZZI et al., 2008) with the context of biotechnology R&D portfolios, reviewing the real options approach in drug development, and examining empirical evidence on the trade-off between diversification and specialization. The objective is to identify which theoretical models and empirical studies suggest optimal levels of diversification for biotechnology firms.

The third objective of the secondary research is the processing of the literature on biotechnology clusters, network structure, and innovation performance. The review covers biotechnology applications of regional cluster literature as well as empirical research examining the relationship between network structure and innovation performance. The objective is to clarify which network structures are favorable from the perspective of innovation performance and collective risk management.

The fourth objective of the secondary research is the synthesis of literature on the relationship between the macroeconomic environment, regulatory policy, and biotechnology innovation. It reviews studies addressing the effects of capital market development, interest rates, market volatility, and regulatory shocks on the financing and innovation activities of biotechnology companies. The objective is to clarify which macroeconomic and institutional conditions support flourishing biotechnology innovation and how these conditions change over time.

The overarching objective of the secondary research is to establish a conceptual framework integrating the relevant theoretical building blocks of network theory, financial economics, innovation management, and strategic management, thereby providing a foundation for formulating and interpreting the hypotheses of the primary research.

1.2. Objectives of the Primary Research

The primary research focuses on the application of open innovation in red biotechnology. Its aim is to answer specific research questions capable of providing a tangible explanation

for actors in the red biotechnology industry as to the advantages and disadvantages associated with the introduction and use of open innovation in their operations. On this basis, the research hypotheses summarized in Table 1 were defined.

Regarding Hypotheses H1 and H2, it may be stated that, under the increasingly dynamic and complex boundary conditions of the global economy, maintaining organizational competitiveness requires new strategic approaches. The paradigm of open innovation—based on the organized, cross-boundary sharing of intellectual and material resources—has become a fundamental strategic framework over the past two decades, particularly in biotechnology, pharmaceuticals, and other high-value-added technological sectors. However, the timing, extent, and strategic orientation of open innovation adoption are not uniform across the corporate sphere, and significant differences can be observed depending on organizational size. The research question therefore aims to explore the relationship between the willingness to introduce open innovation and firm size. This investigation is built on a two-sided hypothesis system: on the one hand, it assumes that larger firms with higher revenues are more open to introducing open innovation, partly owing to their resource abundance, market position, and expansion capacity; on the other hand, it assumes that smaller organizations, although endowed with fewer resources, may nevertheless take greater risks in implementing open innovation strategies because, for them, radical innovation and ecosystem embeddedness often constitute the only viable source of competitive advantage.

Regarding Hypotheses H3 and H4, it may be stated that the open innovation approach has triggered a radical paradigm shift in the organization of corporate innovation over the past decade and a half, especially in the resource-intensive biotechnology and pharmaceutical sectors. Historically, during the 1980s and 1990s, closed innovation models predominated, with firms relying exclusively on internal R&D capacities. However, increasing complexity, the acceleration of scientific advances, and rising R&D costs made cross-boundary sharing of knowledge and resources necessary. Experience suggests that pharmaceutical and biotechnology firms perceive the industry effects of open innovation along multiple dimensions, including partnership relations, concerns over innovation and information control, classical market competition, costs and financial constraints, as well as opportunities for knowledge access and brand building. The present research question

therefore examines whether the deep implementation of open innovation has a measurable positive effect on firm performance indicators and whether the rejection or merely superficial application of open innovation results in a disadvantage in profitability. The empirical data suggest that open innovation is not merely an innovation strategy, but a fundamental mechanism for generating financial opportunity, directly influencing organizational economic performance and long-term sustainability.

Today, pharmaceutical and biotechnology firms find themselves in a paradoxical position. On the one hand, the strategy of open innovation is indispensable for participating in accelerated technological development and for making more efficient use of limited resources. On the other hand, uncontrolled openness may entail significant risks both for the protection of intellectual property and for operational stability.

Table 1. Research Questions and Hypotheses of the Doctoral Dissertation

Scientific problem	Research question	Hypothesis
Lack of clarity regarding the relationship between network position and financial risks	To what extent does network centrality affect the systematic financial risks of biotechnology firms?	H1: Larger firms with higher revenues are more open to the introduction of open innovation.
The causal mechanism linking partnership portfolio diversification to innovation and financial performance remains unclear	How does the diversification of the partnership portfolio influence the success of R&D projects and financial stability?	
The mechanisms linking network structure to collective innovation performance remain unclear	Which structural network properties determine the collective innovation performance of biotechnology clusters?	H2: Smaller organizations with lower revenues assume greater risk in introducing open innovation.
The mediating role of intellectual property management strategy in the relationship between network openness and partnership success remains unclear	What mediating role does intellectual property management strategy play in the relationship between network openness and partnership success?	H3: Deeply implemented open innovation has a positive effect on firm performance indicators.
The moderating effects of the macroeconomic and regulatory environment remain unclear	How do macroeconomic factors—especially capital market cycles and technological and regulatory changes—moderate the risk-reducing effects of network collaborations?	H4: The rejection of open innovation places firms at a disadvantage in terms of profitability.
The role and risk-mitigating capability of open innovation, integrating the full set of organizational relationships and network collaborations, remain unclear	How does revenue influence the willingness to apply open innovation, and, once introduced, what effect does it have on firm performance indicators and profitability?	H5: The introduction of open innovation reduces business risk in the pharma/biotech industry.

Source: author's own compilation

2. MATERIALS AND METHODS

The research is built on a dual methodological framework combining secondary and primary research, thereby enabling the empirical testing and extension of findings from the literature.

2.1. Methodological Background of the Secondary Research

The secondary research was aimed at the systematic processing, theoretical synthesis, and critical evaluation of the existing international literature. In particular, it reviewed publications presenting relevant theoretical and empirical findings in industrial network theory, financial economics, portfolio theory, and innovation management, seeking their relevance to the topics of the research questions.

The secondary research began with the identification of the existing literature in the field and the determination of its relevance. Drawing on more than twenty years of professional experience in red biotechnology, it was already clear which forums would be most suitable for examining the relevant topics and hypotheses. However, it also became apparent that, in the business world, although information may be credible, it is not primarily published within academic literature frameworks, but rather on various professional and business platforms. It was therefore judged that collecting information published on LinkedIn or business websites would not constitute an adequate scholarly basis for the research. Nevertheless, such sources provided valuable starting points for identifying the original sources or thematic areas of the published data, thereby enabling access to appropriate and reliable scholarly literature for the purposes of the secondary research.

The secondary research was based on systematic searches in the following literature databases: PubMed, Scopus, Web of Science, and Google Scholar. Keyword combinations included open innovation, biotechnology, pharmaceutical partnerships, R&D, network, risk management, and intellectual property. In total, more than 200 scientific publications, industry studies, and regulatory documents were analyzed. The processing methodology consisted of the following phases: intensive reading and critical evaluation of the literature, thematic classification, synthesis, and critical reflection. The result was a coherent, multi-

relational theoretical framework revealing the interconnected dimensions of the risk profile of red biotechnology.

2.2. Methodological Background of the Primary Research and Data Collection

The primary research consisted of an empirical study based on a comprehensive questionnaire survey conducted among selected actors in the biotechnology sector. The sample represented the biotechnology sector, including small and medium-sized enterprises, large multinational corporations, and university and research institute actors. A total of 61 biotechnology stakeholders responded to the questionnaire.

The questionnaire focused on the following main themes: the advantages, disadvantages, and barriers of open innovation; firms' financial and operational risks; the level and depth of open innovation implementation; the characteristics and number of alliances and partner relationships; strategies for intellectual property management; alliance success indicators; and organizational performance indicators. The questionnaire employed five-point Likert scales and ordinal categories, enabling multidimensional statistical analyses.

In processing the data, several statistical and multivariate analytical methods were applied. The calculation of the Open Innovation Index (OII) was based on the validation of a complex multidimensional scale capturing at least five to six relevant dimensions of organizational innovation openness. Principal component analysis (PCA) was used to identify the latent structural dimensions underlying the data, dimensions that were orthogonal (independent) of one another. To test the effects of corporate background variables such as size, revenue, number of alliances, and financial status, non-parametric methods (Kruskal–Wallis test and Dunn's test) were applied, given the use of ordinal scales and the relatively small sample sizes. Cronbach's alpha was used to examine the internal consistency of the scales. Spearman's rank correlation analysis was applied to explore relationships among ordinal variables.

The open innovation climate scale (OICM scale) used in the research measured the aspect of organizational culture that directly supports or hinders the willingness to adopt and implement open innovation. The scale captured the following dimensions: organizational

reflexivity, openness to external knowledge sources, the culture of alliance cooperation, and willingness to share intellectual property.

3. MAJOR FINDINGS AND NOVEL RESULTS OF THE DISSERTATION

The empirical investigation of the research led to several important findings that enrich the literature on open innovation and knowledge concerning the biotechnology sector. The scientific contribution of the dissertation may be interpreted on multiple levels and is significant, with numerous theoretical and practical implications for the fields of open innovation and biotechnology management.

3.1. Adaptation and Validation of the Open Innovation Index in the European Biotechnology Context

By validating the Open Innovation Index (OII) in the European context, the research demonstrates that a complex, multidimensional OII provides a more accurate picture of organizational innovation maturity than isolated indicators and is suitable as a diagnostic tool for identifying stages of innovation diffusion. Of particular importance is the study's novel finding of the phenomenon of OI pulsation: the biotech sector is related to open innovation not in a linear but in a U-shaped, cyclical manner, linked to financing and organizational phases. This empirically confirms that successful OI management cannot rely on a single linear approach; instead, strategies must be aligned with the firm's current phase of development.

3.2. Conceptualizing Depth of Integration: The Broad but Shallow Profile and Its Organizational Implications

The research identified a critical phenomenon characteristic of the biotechnology sector, which may be termed a broad but shallow profile, whereby biotechnology firms establish a large number of alliances, yet the depth of their integration remains limited. This phenomenon does not primarily reflect a deficiency in portfolio management, but rather the sector's low level of structural reflexivity—in other words, a fundamentally organizational-cultural problem. This empirical finding indicates that innovation performance depends not only on the number of alliances, but also on the depth of integration and reflexive management, thereby extending the theoretical framework from portfolio-level modeling to functional-level analysis.

The applied implications of this result are substantial. Organizations operating in the biotechnology sector should not focus primarily on seeking new alliance relationships, but rather on increasing the depth of existing collaborations, managing IP-related fears, and establishing joint R&D teams. In this way, the dissertation introduces a new interpretive framework that extends management theory from the alliance-portfolio level to the level of functionality.

3.3. A Five-Pillar Framework Based on Orthogonal Dimensions

The PCA identified a framework of orthogonal (independent) dimensions—Alliance Risk, External Constraints, Knowledge Management, Network Synergy, and Organizational Resistance—that provides a practice-oriented foundation for OI management. The novelty of the theory lies in the fact that these dimensions are not redundant, but independent from one another. Accordingly, an organization may be strong in one dimension and weak in another, demonstrating that OI is not a monolithic capability but a multidimensional system in which success depends on achieving the right balance across dimensions.

The dissertation therefore introduces a new evaluation framework capable of characterizing organizations through OI profiles. For example, an organization may display high network synergy but low alliance risk-management capability, directly indicating the areas in which development is needed.

3.4. Theoretical Foundation of the OI Pulsation Phenomenon

The theoretical foundation of the OI pulsation phenomenon lies in the interconnection between the financing cycle, the technological life cycle, and alliance strategy. Early-stage start-ups are open (high OII) out of necessity; around the IPO phase, in-house control becomes dominant (OII declines); while in the Big Pharma phase, the OII increases again, though at that stage it is driven by the value of real options rather than necessity. Connected to the Real Options framework, this perspective implies that biotechnology alliances should not be assessed solely on the basis of immediate knowledge transfer, but above all in terms of the value of embedded future options, such as acquisition or licensing opportunities. This represents a fundamentally new concept in the evaluation of OI strategy.

3.5. Innovation Vulnerability in the Intermediate Tra

The OII analysis by organizational size identified a critical and hitherto underexplored phenomenon: the innovation vulnerability of medium-sized biotechnology firms (251–1000 employees), which is associated with the lowest OII value (0.096) across all size categories. This theoretically important finding indicates that such firms become trapped in an intermediate position: they have already lost the informal network flexibility of start-ups, yet have not built the formalized partnership systems and absorptive capacity of large corporations. This constitutes a significant contribution to the literature on life-cycle theory and strategic management, as it identifies the specific OI challenges of a structurally underrepresented stage of corporate development. These new and novel findings are summarized in Table 2.

Table 2. Summary of the New and Novel Results of the Doctoral Dissertation

#	Brief formulation of the new or novel result
1	The European validation of the Open Innovation Index (OII) demonstrates that the complex, multidimensional OII provides a more accurate picture of innovation maturity and identifies stages of innovation diffusion, while also revealing the U-shaped, cyclical relationship of OI pulsation in the biotech sector.
2	The research identifies a broad but shallow OI profile in which the biotech sector forms numerous but weakly integrated alliances, showing that innovation performance depends on the depth of integration and structural reflexivity rather than merely on the number of alliances.
3	The PCA identifies a framework of orthogonal dimensions—Alliance Risk, External Constraints, Knowledge Management, Network Synergy, and Organizational Resistance—demonstrating that OI is not a uniform capability but a multidimensional system in which success depends on balance among dimensions.
4	The theoretical basis of OI pulsation lies in the linkage between the financing cycle, technological life cycle, and alliance strategy, where start-ups are open out of necessity, in-house control dominates during the IPO phase, and later the value of real options drives OII in the Big Pharma phase, thereby redefining the evaluation of OI strategy within a Real Options framework.
5	The OII analysis reveals that medium-sized biotech firms (251–1000 employees) are critically vulnerable in innovation terms because they exhibit the lowest OII value and become trapped between the informal network flexibility of start-ups and the formalized partnership systems and absorptive capacity of large corporations.

Source: author's own compilation

4. PRACTICAL APPLICABILITY OF THE RESULTS

The findings of the dissertation may be directly applied in the decision-making and strategic planning of actors in the biotechnology industry, and at several levels they provide concrete operational recommendations.

Based on the findings, the most important strategic message for small firms is as follows: the conscious exploitation of network synergies and an understanding of OI pulsation as a strategic planning tool are critical, because OI dependence is a temporary state. In the initial phase it should be maximized, whereas before an IPO firms must deliberately prepare for the preservation of control through in-house development, while IP protection (patents, contractual safeguards, trade secrets) must already be integrated into the business model during the early stages of partnership formation. For medium-sized firms with 250–1000 employees, the research issues a warning that the intermediate trap requires proactive transformation: internal incentive systems must be redesigned to reward external collaborations as well, with the aim of reaching a 40% open innovation ratio and deepening the broad but shallow profile by increasing OICM reflexivity. More concretely, the recommendation for early-stage biotechnology firms is to focus on OI strategy because their individual R&D resources are limited and innovation pressure is high. In such cases, OI is not a luxury but a necessity. At the same time, they are advised to manage IP-related fears consciously, establishing contractual frameworks that clearly regulate the allocation of IP arising from shared development. The recommendation for firms in the medium term differs: as resources grow, investment in internal R&D capacity becomes possible and natural. Even so, firms are advised not to abandon OI altogether, because it will once again become necessary as market competition intensifies. In the case of large corporations, in addition to strengthening alliance control and absorptive capacity, it is necessary to reinforce their platform role, evaluating OI alliances through a Real Options approach—as option values representing future acquisition or licensing opportunities—rather than merely as direct R&D outputs.

For financial investors, including venture capital and private equity, the dissertation suggests that firms pursuing open innovation strategies exhibit lower systematic risk because OI alliances enable the sharing of innovation risks. The data also suggest that firms whose OII

values are above the 75th percentile require significantly fewer financing rounds to reach Phase III clinical trials than firms with lower OII values. The dissertation proposes a new due diligence metric for venture capital investors: the application of the OII in start-up evaluation. Whereas traditional due diligence focuses on the management team, market opportunity, and technological attractiveness, the dissertation recommends including the assessment of OI capacity, encompassing the depth of the alliance portfolio, approaches to IP management, and alliance success rates in previous projects.

For policymakers and regulatory decision-makers, the dissertation's findings suggest that the development of the industry requires support not only for the existence of networks—which is the traditional approach of EU Horizon Europe funding—but also for integration depth and a culture of reflexive management. The dissertation recommends that EU innovation financing frameworks introduce new indicators and conditions measuring integration depth in the selection of fundable consortia. It further highlights that the sluggishness of regulatory frameworks (e.g., more flexible EMA/FDA GMP arrangements) does not necessarily arise from regulatory failure, but also from the fact that industry actors often do not prepare OI alliances adequately for adaptability. The recommendation is that EU regulatory authorities should more actively support industry actors in the design of adaptive alliance contracts capable of flexibly handling changing market conditions.

The ultimate conclusion of the dissertation is that, in the future of red biotechnology, not individual organizations but alliance ecosystems will compete with one another. Successful organizations must therefore treat not only individual competitiveness, but also ecosystem competitiveness, as a strategic priority. This means that an alliance ecosystem that is developed in a balanced manner across the dimensions outlined above, and that is directed toward deeper integration, will perform better in the long run than alliances that are merely broad but shallow.

The future of biotechnology innovation does not lie in making a final choice between closed and open innovation, but in adaptive organizational intelligence capable of determining when, how, and to what depth one strategy or the other should be applied. Organizations that possess such intelligence will not only be more successful in addressing their own innovation challenges, but will also contribute to the stability and resilience of the wider

ecosystem. In this sense, the dissertation is intended to serve as a guide for current and future biotechnology leaders in this turbulent yet extraordinarily value-creating ecosystem.

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Registry number: DEENK/147/2026.PL
Subject: PhD Publication List

Candidate: Balázs Kiss
Doctoral School: Doctoral School of Management and Business
MTMT ID: 10080825

List of publications related to the dissertation

Articles, studies (4)

1. Domonkos, D., Papp, L. A., Miklós, I., Ács-Szabó, L., Kádas, J., **Kiss, B.**: Economic Impact of Antibiotic-Resistant *Streptococcus pneumoniae*: Quantifying the Healthcare Burden Associated with High-Prevalence Drug-Resistant Isolates.
The European Journal of Health Economics. [megjelenés alatt], 1-33, 2026. ISSN: 1439-6637.
IF: 3 (2024)
2. **Kiss, B.**, Borbély, J.: Business Risk Mitigation in the Development Process of New Monoclonal Antibody Drug Conjugates for Cancer Treatment.
Pharmaceutics. 15 (6), 1-18, 2023. EISSN: 1999-4923.
DOI: <http://dx.doi.org/10.3390/pharmaceutics15061761>
IF: 4.9
3. **Kiss, B.**, Domonkos, D., Felföldi, J.: Együtműködések szükségessége a gyógyszeripari, biotechnológiai fejlesztési folyamatokban az Észak-alföldi régióban.
Régió kutatás szemle. 8 (1), 30-46, 2023. EISSN: 2559-9941.
DOI: <http://dx.doi.org/10.30716/RSZ/23/1/4>
4. **Kiss, B.**, Domonkos, D., Felföldi, J.: New methods for structural development caused by open innovation in red biotechnology.
Apstract. 17 (1), 1-15, 2023. ISSN: 1789-221X.
DOI: <http://dx.doi.org/10.19041/APSTRACT/2023/1/3>

Total IF of journals (all publications): 7,9

Total IF of journals (publications related to the dissertation): 7,9

The Candidate's publication data submitted to the Tudóstér have been validated by DEENK on the basis of the Journal Citation Report (Impact Factor) database.



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