UNIVERSITY OF LJUBLJANA
SCHOOL OF ECONOMICS AND BUSINESS

MASTER THESIS

BUILDING A BIOTECH HUB: THE STRATEGIC POSITIONING OF SLOVENIA IN THE GLOBAL PHARMACEUTICAL ENVIRONMENT

Ljubljana, January 2026 NIKA BOH, ZOJA CIGLENEČKI

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The undersigned Zoja Ciglenečki, a student at the University of Ljubljana, School of Economics and Business, (hereafter: UL SEB), author of this written final work of studies with the title Building a biotech hub: the strategic positioning of Slovenia in the global pharmaceutical environment, prepared in collaboration with mentor Andreja Cirman and co-mentor Denis Marinšek.

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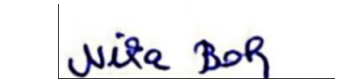
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ABSTRACT

This master's thesis examines Slovenia's strategic position within the global biopharmaceutical ecosystem and evaluates its potential to develop into a competitive European biotech hub. Combining a comprehensive literature review, ecosystem mapping and qualitative empirical analysis based on interviews with key industry, research and policy stakeholders, the study identifies Slovenia's core strengths, structural bottlenecks and developmental pathways.

Findings reveal that Slovenia holds a strong position in biomanufacturing, quality systems and specialised engineering capabilities, reinforced by substantial multinational investment and a highly reliable industrial workforce. However, the ecosystem remains constrained by limited translational infrastructure, no domestic venture capital, talent shortages and fragmented coordination across institutions. These conditions create a dual system: robust industrial performance but underdeveloped innovation capacity. The analysis shows that Slovenia's future competitiveness will depend on its ability to strengthen translational environments, improve governance and administrative efficiency, expand talent pipelines, and develop a more balanced funding landscape.

Overall, the thesis concludes that Slovenia has the structural foundations to become a specialised biopharmaceutical hub, but realising this potential requires ecosystem-wide alignment and targeted strategic interventions.

KEYWORDS: biopharmaceutical industry, innovation ecosystems, Slovenia, biotechnology, translational infrastructure, venture capital, talent, governance

SUSTAINABLE DEVELOPMENT GOALS



POVZETEK

Magistrsko delo preučuje strateški položaj Slovenije v globalnem biotehnološkem in biofarmacevtskem ekosistemu ter ocenjuje njen potencial za razvoj v konkurenčno evropsko biotehnološko vozlišče. Na podlagi celovitega pregleda literature, kartiranja ekosistema in kvalitativne empirične analize z intervjuji s ključnimi deležniki iz industrije, raziskovalnega okolja in javnih institucij, raziskava opredeli glavne prednosti, strukturne ovire in razvojne poti slovenskega ekosistema.

Ugotovitve kažejo, da Slovenija izkazuje močno vlogo na področju bioprodukcije, sistemov kakovosti in specializiranega inženiringa, kar dodatno podpirajo pomembne naložbe multinacionalk ter zelo zanesljiva industrijska delovna sila. Kljub temu, pa ekosistem omejuje nezadostna translacijska infrastruktura, šibek domači tvegan kapital, pomanjkanje kadrov ter razdrobljeno sodelovanje med institucijami. Nastaja dvojna struktura: visoka industrijska uspešnost, a hkrati premalo razvita inovacijska sposobnost. Analiza pokaže, da bo prihodnja konkurenčnost Slovenije odvisna od krepitve translacijskih zmogljivosti, izboljšanja upravljanja in administrativne učinkovitosti, širjenja kadrovskih baz ter razvoja bolj uravnoteženega finančnega okolja.

Sklepno lahko povzamemo, da ima Slovenija trdne temelje za razvoj v specializirano biofarmacevtsko vozlišče, vendar bo za uresničitev tega potenciala potrebna usklajena strateška podpora celotnega ekosistema.

KLJUČNE BESEDE: Biofarmacevtska industrija, inovacijski ekosistemi, Slovenija, biotehnologija, translacijska infrastruktura, tvegan kapital, kadri, upravljanje.

CILJI TRAJNOSTNEGA RAZVOJA



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LIST OF ABBREVIATIONS

AI – Artificial Intelligence
API – Active Pharmaceutical Ingredient
ARRS / ARIS – Javna agencija za raziskovalno dejavnost Republike Slovenije / Slovenian Research Agency
CDMO – Contract Development and Manufacturing Organization
CRO – Contract Research Organization
CAGR – Compound Annual Growth Rate
CAR-T – Chimeric Antigen Receptor T-cell therapy
CGT / CGTs – Cell and Gene Therapy / Cell and Gene Therapies
C21 / NACE C21 – Statistical classification: Manufacture of basic pharmaceutical products and pharmaceutical preparations
CTNNB1 – Catenin Beta 1 (rare disease; name of the foundation/project)
dPCR – Digital Polymerase Chain Reaction
DNA – Deoxyribonucleic acid
EMA – European Medicines Agency
EU – European Union
EFPIA – European Federation of Pharmaceutical Industries and Associations
EIS – European Innovation Scoreboard
FDA – United States Food and Drug Administration
GDP – Gross Domestic Product
GMP – Good Manufacturing Practice
GVA – Gross Value Added
GEM – Global Entrepreneurship Monitor
IP – Intellectual Property
JSI – Jožef Stefan Institute
JAZMP – Javna agencija za zdravila in medicinske pripomočke (Agency for Medicinal Products and Medical Devices of Slovenia)
MES – Manufacturing Execution System
mRNA – Messenger RNA
NIJZ – Nacionalni inštitut za javno zdravje (National Institute of Public Health)
NIB – National Institute of Biology
NACE – Statistical Classification of Economic Activities in the EU
OECD – Organisation for Economic Co-operation and Development

R&D – Research and Development
RNA – Ribonucleic Acid
SME / SMEs – Small and Medium-Sized Enterprise(s)
SEF – Slovenski podjetniški sklad (Slovenian Enterprise Fund)
SRIP – Strategic Research and Innovation Partnership
U.S. – United States
VC – Venture Capital

1 INTRODUCTION

The concept of ecosystems in management studies has undergone substantial refinement over the past three decades. Early contributions used the ecosystem analogy to describe interdependence among firms but lacked formal mechanisms explaining how coordination occurs. Moore (1999) first introduced the idea of business ecosystems as dynamic communities of organizations that co-evolve capabilities around shared innovations. This approach reframed competition from firm versus firm to ecosystem versus ecosystem, highlighting co-creation and collaborative advantage rather than isolated firm performance. Iansiti and Levien (2004) extended this view by identifying the role of keystone firms that stabilize ecosystems. They argued that central actors maintain coherence by providing standards, reducing uncertainty, and sustaining network health. Although influential, this work remained primarily descriptive and did not fully explain how interdependence is governed. Teece (2007) then linked ecosystems to the dynamic capability's framework, emphasizing firms' abilities to sense, seize, and reconfigure opportunities within interdependent environments. In this formulation, ecosystems became contextual arenas in which firms orchestrate complementary assets. Yet ecosystems still lacked a precise structural definition. The limitation of these early approaches was their metaphorical nature. They explained why collaboration matters but not how interdependent actors coordinate without hierarchy or full integration. This gap motivated the shift toward more formal and operational conceptualizations of ecosystems (Adner, 2017; Jacobides et al., 2018).

Ecosystem dynamics have become the dominant paradigm for organizing innovation in biopharma. Value creation increasingly depends on interdependent networks of firms, research institutions, regulators, investors, and patient organizations that collaborate across organizational boundaries. In contrast to the vertically integrated models of traditional pharmaceuticals, contemporary biopharma relies on alignment structures, configurations of actors and activities coordinated through shared standards, trust, and incentives (Adner, 2017; Jacobides et al., 2018). These ecosystems are not merely industrial clusters but dynamic governance systems where competitive advantage derives as much from the quality of coordination as from firm-level capabilities (Bettanti et al., 2021; Herzog et al., 2024).

The biopharmaceutical industry has become one of the defining technological and economic domains of the twenty-first century, bridging advances in biotechnology with the transformation of global healthcare systems. Over the past three decades, biopharma has evolved from a niche scientific pursuit into a central driver of biomedical innovation, fundamentally reshaping how medicines are discovered, developed, and delivered worldwide. Biopharma represents the intersection between biotechnology and pharmaceutical science, encompassing organizations engaged in the discovery, development, and production of biologically derived medicines. Within the European industrial classification (NACE C21: Manufacture of basic pharmaceutical products and pharmaceutical preparations), this sector includes firms producing complex biological molecules, such as proteins, monoclonal

antibodies, and nucleic acids, through advanced biotechnological processes (Eurostat, 2023; Szkodny et al., 2022).

Since the approval of the first recombinant human insulin in 1982, the global biopharmaceutical industry has experienced exponential growth, transforming both the technological base and the organizational logic of modern healthcare (Szkodny et al., 2022). This transformation has been fueled by breakthroughs in molecular biology, genomics, and bioengineering, as well as by increasing demand for targeted and personalized therapies (IQVIA, 2024). As a result, biopharma is now among the world's most innovation-intensive and capital-demanding sectors, characterized by extended R&D timelines, high regulatory complexity, and escalating development costs (CAS, 2023; Deloitte, 2025; Ging, 2024).

The thesis aims to examine how Slovenia's biopharmaceutical sector is developing as an ecosystem and to evaluate its potential to position itself as a competitive and sustainable biopharmaceutical hub within the European environment. The thesis focuses on the structural and institutional factors that shape the performance of such an ecosystem and looks at the conditions that support or limit biotechnology-based innovation in a small and science-driven country. To guide the purpose of the thesis we set the main research question: How do the structural and institutional characteristics of Slovenia's biopharmaceutical ecosystem influence its capacity to evolve into a competitive regional hub within the global biopharma landscape? The main research question will be divided into sub-questions which guide the structure of the thesis and are addressed throughout its chapters. It examines which structures and interdependencies are present in ecosystems. It explores how mature ecosystems are through evaluation actors, infrastructures, funding, demand, human capital and culture on the case of Lombardy. Additionally, it analyzes what role do corporations play in shaping ecosystem alignment, resource flows and institutional conditions. Finally, it assesses the current global biopharmaceutical trends, that are shaping the industry.

To answer this question, the thesis explores several related topics. First, it discusses which structures, interdependencies, and coordination mechanisms exist in biopharmaceutical ecosystems. Second, it examines how ecosystem maturity can be evaluated by analyzing actors, infrastructure, funding, demand, human capital, and culture, using the Lombardy region as a model. The thesis also considers the role of corporations and how they influence cooperation, resource flows, and institutional conditions. Finally, it looks at global biopharmaceutical trends and explains how these trends shape ecosystem development and affect smaller countries such as Slovenia. Together, these themes form the analytical basis for the later evaluation of Slovenia's ecosystem.

The primary methodological approach we applied is qualitative research design that combines a structured theoretical analysis with empirical evidence derived from semi-structured interviews. The approach is aligned with the thesis objective, which is to understand how

Slovenia's biopharmaceutical ecosystem is structured, how mature it is, and how different actors contribute to or constrain its development.

The theoretical part builds an analytical framework based on four key strands of literature. Adner (2017) work helps explain how alignment, roles, and interdependencies allow actors to cooperate. Jacobides et al. (2018) focus on complementarities and modularity and help clarify when and why ecosystems emerge. Bettanti et al. (2021) develop a model designed specifically for biopharmaceutical ecosystems, identifying important dimensions such as actors, infrastructure, funding, demand, human capital, and culture. Herzog at al. (2024) work adds a deeper understanding of the role that large corporations play in shaping innovation and entrepreneurship. These four perspectives together create a structured way to study an ecosystem. In addition, we also assess the current state of the biopharmaceutical industry globally and its current trends.

The analytical framework is then applied to Slovenia. The thesis examines the main actors, the relationships between them, and the level of interdependence in the Slovenian biopharmaceutical sector. It evaluates the maturity of the ecosystem through the key dimensions defined in the theoretical part and analyses how corporations shape knowledge flows, cooperation, and institutional practices. The study also looks at how global biopharma trends appear in the Slovenian context and what they mean for its future development.

To strengthen and validate the theoretical findings, semi-structured interviews were conducted with representatives from Slovenian start-ups, SMEs, and large corporations. These interviews offer practical insights into how the ecosystem functions and help confirm or challenge the theoretical assessment. During the writing process, the artificial intelligence tool ChatGPT was used to improve grammar and writing clarity and help analyze interconnected topics. All interpretation remains the responsibility of the authors.

The thesis is organized into six chapters. After the introduction, the second chapter presents the main ecosystem theories and explains the structures and mechanisms needed for an ecosystem to operate. The third chapter applies these theories to the biopharmaceutical sector and discusses how corporations influence innovation. The fourth chapter outlines global biopharmaceutical trends and their importance for smaller economies. The fifth chapter analyses the current state of Slovenia's biopharmaceutical ecosystem using the defined framework. The final chapter presents the interview results and combines both theoretical and empirical findings into a final evaluation of Slovenia's ecosystem.

By bringing together theory and empirical evidence, the thesis offers a clear and integrated assessment of Slovenia's biopharmaceutical ecosystem. It also identifies important structural gaps and opportunities and suggests directions for strengthening Slovenia's position in the global biopharmaceutical environment.

2 LITERATURE REVIEW

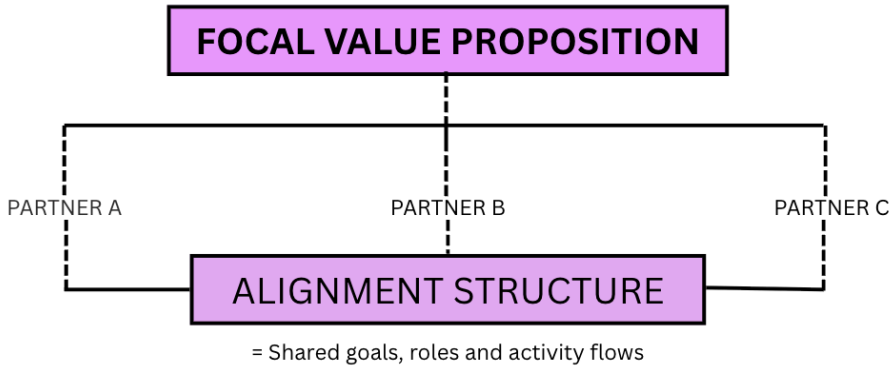
2.1 Ecosystem as structure

Understanding the development of Slovenia's biopharmaceutical sector requires more than observing firm-level dynamics or innovation policies. Classic cluster theories and linear models of innovation can no longer explain how complex, science-based industries coordinate interconnected activities across multiple partners. It requires an ecosystem perspective, a view that recognizes interdependence between four core structural elements

Adner (2017) marks a turning point by proposing the concept of ecosystem-as-structure, the first analytically precise definition of an ecosystem. Instead of viewing ecosystems as broad networks of firms, Adner defines an ecosystem as: *"the alignment structure of the multilateral set of partners that need to interact in order for a focal value proposition to materialize"* (Adner, 2017). He introduces the before mentioned four core structural elements:

a) Activities: the tasks required for the value proposition.
b) Actors: the organizations performing these tasks.
c) Positions: how actors are situated within the activity flow.
d) Links: the transfers, handoffs, and coordination mechanisms connecting positions.

Figure 1: Adner's ecosystem framework



Source: Own work based on Adner (2017).

As seen in Figure 1 the center of the framework is alignment: the degree to which interdependent actors share expectations, roles, sequencing, and incentives. Achieving alignment is essential because ecosystems involve multilateral rather than bilateral (two-party) interdependencies. The performance of one actor depends on coordinated actions by several others. Ecosystems differ from markets and hierarchies which coordinate through prices and authority, whereas they coordinate through mutual alignment without ownership. This requires

deliberate orchestration of tasks, shared design rules, or governance mechanisms that support collaboration among autonomous actors (Adner, 2017).

Adner (2017) emphasizes that ecosystems are relevant when value realization depends on complementary innovation or coordinated adoption. He identifies two systemic risks: co-innovation which occurs when one actor's progress depends on timely innovation by others and adoption chain risk which is present when intermediaries must adopt or adapt before end-users can access the innovation. Failure in any part of the ecosystem can undermine the entire value proposition. In this view, innovation is collective, and managerial attention must extend beyond internal research and development (R&D) to alignment management, sequencing, and partner coordination. The model transforms ecosystems into a strategic construct explaining how interdependent actors jointly create value and why ecosystem orchestration becomes a source of competitive advantage.

Apart from providing a definition and a structural analysis to ecosystems in general, it does as well provide a clear method for examining complex environments, because it allows researchers to map interdependencies, identify bottlenecks and understand why some innovations fail despite a technical success. It as well highlights that ecosystems cannot be managed through hierarchy or simple market transactions (Adner, 2017).

Another group of researchers has set out to further define ecosystem structures. While Adner clarifies the structure and coordination logic of ecosystems, Jacobides et al. (2018) explain when and why ecosystems emerge. Their theory integrates modularity and complementarity economics to define ecosystems as: sets of actors linked by multilateral, non-generic complementarities that are not fully coordinated by hierarchies; modularity enables separable contributions, but residual interdependence requires ongoing governance (Jacobides et al., 2018). At the heart of their theory lies a structural paradox of modern capitalism: firms are increasingly autonomous in ownership, yet interdependent in value creation (Jacobides et al., 2018).

Jacobides et al. (2018) first distinguish between three different ecosystem types, described in Table 1: business ecosystems, which are broad networks shaping firms' dynamic capabilities, innovation ecosystems, where actors coordinate around focal innovation and lastly platform ecosystems which are hub and spoke ecosystems, governed by platform interfaces.

Table 1: Three uses of ecosystems in literature

Ecosystem type	Unit of analysis	Core emphasis	Explanation
BUSINESS ECOSYSTEM	Focal firm and its broader network of organizations, institutions, and individuals beyond industry boundaries.	Firm's environment shaping dynamic capabilities; role of keystone/hub firms in ensuring stability and knowledge mobility.	How firms position within interdependent communities and how hubs orchestrate stability. Broad scope; limited on micro-level adaptation mechanisms.
INNOVATION ECOSYSTEM	Focal innovation or value proposition and its upstream components and downstream complements.	Coordination of interdependent actors in developing and commercializing innovations; importance of alignment and sequencing.	Why innovations succeed or fail based on coordination and complement alignment. Sharp focus on value realization; less on external institutional context.
PLATFORM ECOSYSTEM	Platform core (technology/product/service) and its complementors in a hub-and-spoke structure.	Interface governance, network effects, and balancing openness vs. control in multi-sided markets.	How governance, openness, and network effects drive complementor participation and platform performance. Rich governance insights; risk of overgeneralizing as platform-mediated.

Source: Own work based on Jacobides et al. (2018).

As grounds for emergence of the ecosystem types in Table 1 they present three mechanisms that underpin it:

a) Modularity: Ecosystems emerge in environments where activities can be divided into separate modules linked by standardized interfaces. Modularity enables distributed innovation while maintaining overall system coherence.
b) Non-generic complementarities: These are complementarities that are specific and not easily substitutable. Two types matter, first are unique complementarities (co-specialization), where actors invest specifically for each other. Second are super-modular complementarities where more investment by one actor increases the value of investment by another (network effects). These complementarities create interdependence that neither markets nor hierarchies can efficiently coordinate. Ecosystems often combine both forms,

unique complementarities ensure coordination between specific partners, while super modular complementarities generate reinforcing feedback loops that attract broader participation. Within modular architectures, these complementarities create an economic engine of joint value creation without requiring ownership integration.

c) Governance without hierarchy: because actors remain autonomous, coordination depends on participation rules, interface standards, non-fungible investments and distribute decision rights.

Ecosystems occupy space between markets and hierarchies. They are more structured than networks but do not have centralized authority. Together Adner (2017) and Jacobides et al. (2018) offer a coherent structural explanation of ecosystems. Adner (2017) provides the structural logic, which includes activities, positions, links and alignment around a focal value proposition. Jacobides et al. (2018) on the other hand provide the model to evaluate why ecosystems occur in the first place. Their work demonstrates that ecosystems arise when innovation requires multiple specialized contributions, rely on non-hierarchical coordination and demand alignment rather than ownership. With these come systemic risks of co-innovation and adoption chains. They generate competitive advantage through architectural leadership.

2.2 Biopharmaceutical innovation system

The following chapter translates general ecosystem theory into the specific context of the biopharmaceutical industry. It explains why biopharma is structurally dependent on ecosystem dynamics and presents the Bettanti et al. (2021) model as a comprehensive analytical framework. We also explain how ecosystem networks reshape business models in biopharmaceuticals. The chapter concludes by outlining how these insights will guide the Slovenian analysis in chapter 4.

The biopharmaceutical industry has transformed into one of the most science-intensive and interdependent technological fields. Unlike traditional small-molecule pharmaceuticals, modern biopharma relies on complex biological processes, advanced molecular engineering, and highly specialized knowledge distributed across research institutions, start-ups, clinical infrastructures, and regulatory bodies. This builds upon Jacobides et al. (2018), who define coordination of interdependent actors in developing and commercializing innovations as their importance of alignment and sequencing as innovation ecosystems. As Bettanti et al. (2021) explain, biotechnology has created a new technological regime where innovation depends on the coordinated contributions of numerous actors rather than on linear internal R&D pipelines. Three structural features make ecosystems essential in this sector (Bettanti et al., 2021):

a) Scientific and technological complexity: Biopharmaceutical innovation is built on recombinant DNA technologies, monoclonal antibodies, cell and gene therapies, and advanced biologics. These require tacit knowledge, interdisciplinary expertise, and laboratory capabilities that no single organization can fully internalize. The need to

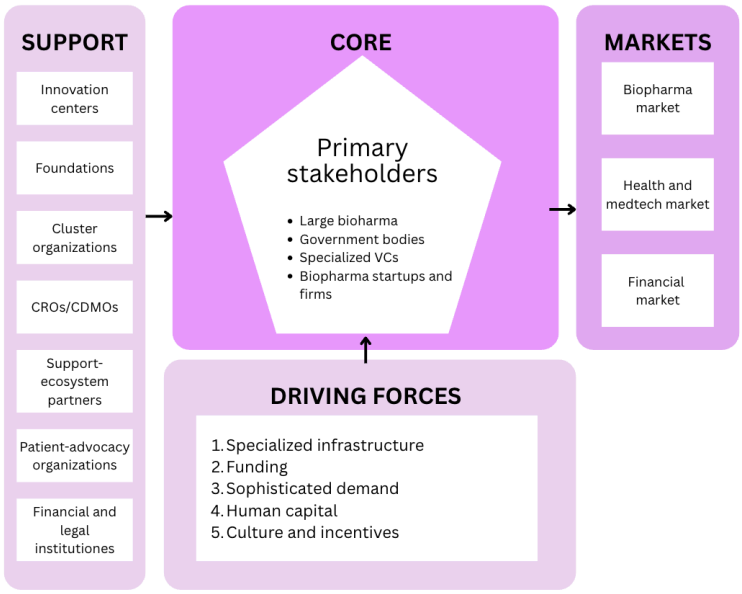
integrate genomics, molecular biology, clinical research, and regulatory compliance creates natural interdependencies across actors.

b) Co-innovation and adoption-chain risks: Following Adner's (2017) framework, biopharma innovation faces both co-innovation risk (several scientific components must be developed jointly) and adoption-chain risk (intermediaries such as hospitals, regulators, and payers must adapt before a therapy reaches patients). A therapeutic breakthrough is not sufficient; complementary technologies, manufacturing capacities, and clinical infrastructures must mature simultaneously. This multi-actor dependency reinforces the need for ecosystem-level alignment.

c) Long development cycles and high uncertainty: Drug development requires more than a decade, substantial capital investment, and numerous translational steps between basic research and market authorization. Feedback loops between science and commercialization are continuous, not linear. This demands network coordination, shared missions, and mechanisms to reduce uncertainty across actors.

These characteristics show why biopharmaceutical innovation increasingly depends on ecosystem dynamics: interdependent networks, distributed contributions, and alignment structures that enable scientific and commercial progress. In sum, biopharma requires ecosystems because innovation is systemic rather than linear, relying on collaborative networks that enable both scientific exploration and commercial scale-up.

Figure 2: Stakeholder-based model



Source: Own work based on Bettanti et al. (2021).

Bettanti et al. (2021) develop a comprehensive stakeholder-based model, visualized in Figure 2, which they test on the case of Lombardy, Italy. They explain how biopharma innovation

emerges and scales. The model identifies twelve actor groups, organized into five primary and seven supporting stakeholders, each contributing non-generic comparative advantages.

The primary stakeholders include large biopharma companies who provide financial resources and infrastructure and usually orchestrate partnerships and enable market access. Next to large companies are also government bodies who supply public funding and regulate and shape the industrial policy. One of the primary stakeholders are also specialized venture capital firms, who supply risk capital and entrepreneurial expertise. Finally, there are two other groups, first are the biopharma start-ups and small to medium companies (SMEs) who drive scientific innovation and niche specialization and second are universities, hospitals and research organizations who generate fundamental science and facilitate translational research. Together they form the scientific and economic ecosystem (Bettanti et al., 2021).

Next to the primary stakeholders Bettanti et al. (2021) also identified crucial supporting stakeholders such as: innovation centers, foundations, cluster organizations, contract research organizations/contract development and manufacturing organizations (CROs/CDMOs), patient access organizations, support-services providers, and financial/legal institutions. They enable and stabilize the ecosystem by providing infrastructure, legitimacy, patient access, modular capabilities, and service-based resources. Their presence ensures that scientific discoveries can move efficiently toward commercialization.

Bettanti et al. (2021) argue that biopharmaceutical ecosystems operate through two interdependent economies. First is research economy, driven by long-term scientific inquiry, public research organizations, and exploratory knowledge creation. The second is commercial economy, driven by firms, entrepreneurship, capital markets, and industrial scaling. Value arises when these two economies interact effectively, reflecting a balance between exploration and exploitation, consistent with broader innovation theory.

They identify five driving forces that shape ecosystem maturity: specialized infrastructure, funding availability and diversity, sophisticated demand, human capital and culture and incentives. Rather than analyzing actors separately, the five driving forces evaluate whether scientific, institutional, financial, and cultural elements are sufficiently aligned to support innovation. Specialized infrastructure covers advanced laboratories, hospitals and CDMOs, who provide the physical and institutional backbone for biopharma development. The availability, diversity and allocation of capital across stages from basic research to scale-ups determine innovation velocity. Presence of sophisticated demand stimulates quality, specialization and targeted innovation. Human capital plays an important role as ecosystem depends on deep scientific expertise as well as translational, managerial and regulatory skills. Finally, the culture and norms regarding risk-taking, collaboration and entrepreneurship significantly influence innovation behavior. These driving forces are used directly on the Lombardy assessment and can be used to understand its strengths and limitations and how an

ecosystem with strong scientific foundations can underperform when alignment is weak. (Bettanti et al., 2021).

The Lombardy case, analyzed by Bettanti et al. (2021), offers a valuable reference model for understanding how a European biopharma ecosystem evolves and where alignment gaps can limit performance. It is relevant for Slovenia because it is a small-to-medium European region with strong scientific institutions. It has a historic pharmaceutical base, similar to Slovenia's long-standing pharmaceutical industrial tradition and both regions combine public research strength with emerging biotechnology ventures and large corporations. The Bettanti et al. (2021) model and the Lombardy findings provide the analytical backbone for evaluating Slovenia's ecosystem maturity. This chapter therefore establishes the conceptual tools for diagnosing Slovenia's ecosystem maturity: stakeholder mapping, interdependencies, systemic drivers, and the translation between research and commercialization.

These models reflect Jacobides et al. (2018) logic of modularity and complementarity: innovation can be decomposed into interoperable components, enabling specialized actors to contribute where they have unique advantages. As biologics, biosimilars, and advanced therapies dominate pipelines, firms increasingly rely on ecosystems to access cell lines, analytical expertise, regulatory know-how, and specialized manufacturing. The rise of CROs/CDMOs is a direct response to this scientific complexity (Shimasaki, 2024).

2.3 The role of corporations in ecosystems

Although innovation ecosystems rely on collaboration between diverse actors, their overall shape, direction and performance are often influenced by the behavior of large established firms. In the previous sections, Adner et al. (2017) and Jacobides et al. (2018) explained how ecosystems operate through structural alignment, complementarities and distributed governance. Bettanti et al. (2021) then showed how these principles translate into the specific context of biopharmaceutical innovation, where scientific, industrial and regulatory actors must work together to deliver complex therapeutic solutions.

However, none of these frameworks fully address the question of how incumbents, large companies with extensive resources, established reputations and strong bargaining power, affect the evolution and functioning of ecosystems. This is particularly important in biopharma, where large corporations control advanced manufacturing, regulatory expertise and global distribution channels, and therefore play central roles in enabling or constraining innovation.

This chapter examines how large corporations influence entrepreneurial and biopharmaceutical ecosystems. Drawing on Herzog et al. (2024), it highlights how corporations act simultaneously as resource engines and institutional actors, shaping both the material and cultural foundations of their surrounding ecosystems. This dual role is especially relevant for Slovenia, where large

firms such as Lek, a Sandoz company and Novartis dominate the biopharmaceutical industrial landscape.

Herzog et al. (2024) demonstrate that corporations enrich ecosystems by supplying resources that smaller actors cannot easily generate, particularly in capital-intensive and knowledge-intensive sectors such as biopharma. Their contribution operates across four main domains: infrastructure, finance, talent, and knowledge. They empirically show evidence of these contributions on the Munich ecosystem case:

a) Finance: Corporations operate venture funds, participate in strategic partnerships, and act as stable co-investors. Their involvement reduces risk and expands the availability of capital for early-stage ventures.
b) Knowledge and infrastructure: Advanced laboratories, regulatory expertise, and IP portfolios provide start-ups with access to high-quality technical and scientific capabilities.
c) Talent: Corporations train specialized workers and contribute to the development of local human capital through mobility, internships, and skills transfer.
d) Market access: As early adopters, large firms validate emerging technologies and integrate smaller actors into global value chains.
e) Intermediation: Corporate accelerators and incubators add to the ecosystem's support infrastructure, although motives may blend genuine development with branding or recruitment.

Through these mechanisms, corporations function as resource engines, raising the overall capacity of the ecosystem. Beyond material resources, corporations influence the institutional conditions that structure entrepreneurial behavior. They shape regulations, incentives and funding mechanisms through lobbying and regular engagement with government bodies. Their typically hierarchical organizational cultures spill into the boarder ecosystem, affecting attitudes toward experimentation and failure. Corporations coordinate collaborative projects, set technical standards, and define interfaces that guide how actors interact. Their participation in events, mentorships, and partnerships influences informal norms and trust networks. Through these channels, corporations become institutional architects, shaping how the ecosystem functions and evolves (Herzog et al., 2024).

Herzog et al. (2024) emphasize that corporate influence is inherently dual. While they enrich ecosystems, they may also restrict entrepreneurial development. They contribute to entrepreneurial development by expanding access to finance and knowledge, professionalizing governance and operational practices, enhancing the ecosystem's visibility and offering validation and early market access. On the other hand, they can generate structural limitations with talent absorption, by attracting most skilled workers. Their preferences also influence public policy, and they may hesitate to acquire start-ups, weakening exist markets. Risk aversion and internal bureaucracy can permeate the ecosystem and suppress experimentation. This duality means that the presence of large corporations is not automatically beneficial and

it depends on how their power is balanced within the ecosystem. They conclude that ecosystems perform best when corporations balance their stabilizing role with openness to external collaboration and willingness to support novel technologies.

3 BIOPHARMACEUTICAL INDUSTRY AND GLOBAL TRENDS

The previous chapters established the theoretical foundations of ecosystems, translated these foundations into the biopharmaceutical context through the Bettanti et al. (2021) model, and examined the role of large corporations in shaping ecosystem structure and behavior.

Building on these theories, the present chapter moves to the biopharmaceuticals at a global level, outlining the scientific, technological, competitive, and organizational trends currently reshaping the industry. The trends such as modality shifts, compressed lifecycles, investment cycles, globalization frictions, and operating-model rewiring, form the external environment against which Slovenia's biopharmaceutical ecosystem must position itself.

These global patterns serve as a benchmark to assess Slovenia's alignment with international developments and to evaluate its readiness to compete within an increasingly dynamic and interconnected biopharmaceutical landscape.

3.1 Evolution of biopharmaceuticals

Innovative biologic medicine and their biosimilar equivalents are a part of healthcare products that fall under the category of biopharmaceuticals, a separate sector of the pharmaceutical industry. Innovative medicines, often referred to as originator biologics, are novel medicines developed through extensive research and development. It usually takes a longer time to bring such medicines to market, and the average cost of developing one originator biologic can reach approximately EUR 2 billion, making it by far the most time- and capital-intensive category of drug development (Deloitte, 2025). Originator biologics are also protected by patents and cannot be replicated during the exclusivity period. On the other hand, biosimilars can be developed only after those patents expire and are highly like the originator biologics. They are produced using living-organism cells and must comply with a streamlined regulatory pathway that demonstrates similarity in structure, immunogenicity, safety, and efficacy compared to the reference product (EMA, 2023).

The biopharmaceutical sector has advanced through several scientific and technological milestones that transformed drug discovery and development. Early progress was driven by recombinant DNA technologies, enabling the transition from extraction-based methods to engineered production of therapeutic proteins. The US Food and Drug association (FDA) approval of recombinant human insulin in 1982 demonstrated the scalability and reliability of rDNA-based medicines, marking the beginning of modern biopharmaceuticals. Subsequent

breakthroughs, such as recombinant human growth hormone and interferons, expanded the therapeutic potential of engineered proteins (Kesik-Brodacka, 2017; EMA, 2023).

The rise of biotechnology firms such as Amgen, Genentech and Biogen further accelerated innovation, hitting the peak in monoclonal antibodies (mAbs), first approved in 1986. Their ability to target disease-specific antigens revolutionized treatment of cancer, autoimmune disorders and transplant rejection (Shepard et al., 2017). Subsequent breakthroughs in gene and cell therapies marked another inflection point. Luxturna became the first gene therapy for an inherited disease, while Chimeric Antigen Receptor T-cell (CAR-T) therapies introduced the concept of engineered immune cells as personalized cancer treatments (FDA, 2018; Morrison, 2018). Most recently, advances in RNA stabilization and delivery enabled the rapid deployment of mRNA vaccines during the COVID-19 pandemic, opening new therapeutic avenues in infectious diseases, oncology and rare disorders (Pharmaphorum, 2020).

Overall, the industry's historical trajectory reflects a structural shift toward biologics, biosimilars and advanced modalities, requiring new manufacturing capabilities, more complex regulatory pathways and stronger ecosystem coordination but has as well greatly widened the range of treatment alternatives available to treat diseases, reshaping modern healthcare and human well-being (EFPIA, 2023; IQVIA, 2024; Pharmaphorum, 2020).

3.2 Current global trends in biopharmaceuticals

Several trends are reshaping the biopharmaceutical industry. These trends reflect both accelerating scientific progress and macroeconomic pressures.

a) Scientific and Technological Transformations

The global biopharmaceutical industry is defined by a rapid modality shift. According to the CAS (2023), the fastest-growing therapeutic classes globally include antibody–drug conjugates (ADCs), bispecific antibodies, RNA modalities, and cell and gene therapies (CGTs). These modalities require sophisticated bioprocessing, advanced analytical methods and highly coordinated R&D systems. Unlike traditional small molecules, modern biologics and genetic medicines rely on complex upstream and downstream processes that often require cross-institutional coordination and collaboration. According to Bleys et al. (2025), novel modalities are expected to expand from around 5 percent of the market in 2020 to approximately 15 percent by 2030, while first-in-class therapies have grown from about 20 percent of global sales in 2000 to nearly 50 percent today, underscoring the industry's structural transition.

Scientific progress is further accelerated by digitalization. Artificial intelligence and machine learning increasingly support molecular design, lead optimization, predictive toxicology, and translational modelling, enabling faster and more resource-efficient development. CAS (2023) highlights digital twins and AI-assisted bioprocess optimization as emerging technologies that enhance precision and scalability. Bleys et al. (2025) estimate that such AI-enabled approaches

can reduce preclinical timelines by 30–50 percent and cut associated costs by 25–50 percent, although adoption remains uneven across companies. McKinsey (2025) similarly identifies a shift toward model-first R&D, where in silico experimentation decreases reliance on traditional laboratory cycles.

b) Shorter product lifecycles and growing pricing pressures

Competitive intensity in biopharma has accelerated sharply. Bleys et al. (2025) show that the time for three or more competitors to enter a therapeutic area has collapsed from roughly fifteen years to about two, significantly shrinking the window in which companies can capture value. As a result, firms now secure 50 percent of lifetime revenues at least eighteen months faster than in previous cycles. Pricing pressures reinforce this trend. In the United States, the Inflation Reduction Act introduces mandatory price negotiations after seven years for small-molecule medicines and after eleven years for biologics (Cubanski, 2025), reducing post-launch price flexibility and shortening effective value windows. In Europe, increasingly strict health-technology assessments, external-reference pricing, and shorter renegotiation cycles continue to try to decrease the pressure on margins and accelerate the shift toward faster execution and next-generation therapies (EFPIA, 2023).

Shorter lifecycles are also shaped by clinical-development dynamics. According to IQVIA (2024), clinical programs spend on average 43 percent of development time in "white space," the inactive periods between trial phases. Large pharmaceutical companies and emerging biopharma show similar active-trial durations, but emerging biopharma's experience around 30 percent longer white space, reflecting operational constraints that slow phase transitions.

c) Patent Expiries and Financial Dynamics

The global biopharmaceutical industry is entering a period of substantial financial and market pressures, shaped by an upcoming patent cliff and biosimilar expansion. Deloitte (2025) estimates approximately EUR 230 billion in patent-based annual revenue will lose exclusivity by 2030 in the USA only. IQVIA (2024) and GlobalData (2025), confirm this transformation - as patents expire, the number of biosimilars and generics entering the market will increase, and subsequently originator pharma companies are going to be faced with aggressive pricing competition. Apart from the intensified competition, margins will as well start getting compressed (which are essential to funding such complex and costly R&D), accelerate consolidation among major pharmaceutical companies, but also put the shareholder returns at risk (Moeller et al., 2025). The rise of biosimilars further amplifies cost pressure, as more than 70 biologic products are expected to face biosimilar competition by the end of the decade (EFPIA, 2024). As a result, companies must diversify their pipelines, improve development efficiency and seek new sources of differentiation.

The biopharma industry faces a major drop in patented drug revenues, where Moeller et al. (2025) highlighted that patent cliffs have not been so common beforehand, however the current patent cliff is expected to be like the last major cliff, in the early 2000s. They have analyzed

that in the current cliff, the revenues from drugs still under the patent by 2031 will provide the equivalent to only 23 percent of 2021 revenues. They have estimated that approximately EUR 150 billion of revenue will be affected in 2027 alone (using 20 leading biopharma companies as a base for analysis).

Consequently, these market pressures are reshaping corporate strategies. M&A activity is rising significantly, with large pharmaceutical firms acquiring early-stage biotech firms to rebuild pipelines and access cutting-edge modalities. In 2023–2024 alone, acquisitions of SMEs increased sharply as public markets tightened, and early-stage financing became more volatile (McKinsey, 2025). At the same time, SME-led innovation continues to dominate early-stage innovation globally, IQVIA (2024) reports that most early-stage pipeline assets now originate from SME biotech companies, rather than major pharmaceutical firms.

This combination of patent expiries, financing constraints and innovation decentralization shows the significant structural shift concerns that generates innovation (IQVIA, 2024) and reinforces the need for strong collaborative networks and ecosystem-based operating models. (Deloitte, 2025; EFPIA, 2024; IQVIA, 2024; McKinsey, 2025).

d) Regulatory Evolution

Regulatory frameworks are evolving rapidly as agencies adapt to the scientific complexity of advanced modalities. Both the FDA and EMA are expanding the use of adaptive trial designs, accelerated approval pathways, and real-world evidence frameworks to accommodate cell and gene therapies, RNA platforms, and other novel technologies (EMA, 2023; FDA, 2024). In parallel, IQVIA (2024) highlights a global rise in decentralized and hybrid clinical-trial models, which enable greater patient access, reduce operational burdens, and shorten development timelines—particularly important for rare diseases and personalized therapies.

While these regulatory innovations facilitate faster development, the overall environment is becoming more uncertain due to parallel reforms in pricing, reimbursement, and market-access policies. EFPIA (2024) notes that Europe faces intensifying cost-containment measures, evolving Health Technology Assessment requirements, which include evaluation of clinical benefits, economic value, comparative effectiveness and societal value. Additionally, EFPIA (2024) points out increasingly frequent price renegotiations, all of which add unpredictability to launch planning. In the United States, the Inflation Reduction Act introduces long-term pricing uncertainty for novel therapies by linking reimbursement negotiations to post-approval timelines, altering incentives for investment in certain modalities (Deloitte, 2025).

For global companies, this combination of accelerated scientific pathways and frequent pricing examination increases operational risk and strategic complexity. Firms are responding by diversifying across regulatory jurisdictions, adopting more flexible development and submission models, and forming cross-border partnerships that spread regulatory and financial risk. As with geopolitical shifts, regulatory evolution reinforces the need for globally

coordinated yet locally adaptive ecosystem strategies These pressures push companies to diversify geographically, adopt flexible development models and engage in partnerships that spread risk (Deloitte, 2025; EFPIA, 2024; EMA, 2023; FDA, 2023).

e) Business-model transformation and strategic therapeutic focus: Ecosystem-based innovation The combined pressures of scientific complexity, market volatility and regulatory tightening are pushing biopharmaceutical companies to redesign their operating models around ecosystem-based innovation. Vertically integrated structures are giving way to distributed models built on deep outsourcing and collaboration. Contract research organizations (CROs) and Contract development and manufacturing organizations (CDMOs) now constitute critical extensions of internal capabilities, supporting discovery, analytics, clinical development and biologics manufacturing. McKinsey (2025) notes that CDMO capacity for advanced biologics continues to expand as companies pursue more flexible and capital-efficient operating structures. At the same time, platform-based R&D, built on reusable technologies such as mRNA, advanced antibody engineering or gene-editing systems, has become central to pipeline strategy, enabling multiple assets to emerge from shared technological foundations.

This structural shift is closely linked to how companies position themselves strategically across therapeutic areas. Global benchmarking shows that firms generating most revenues from one or two core therapeutic area consistently outperform diversified peers in growth and shareholder return, reflecting the advantage of deep scientific expertise, focused investment, and strong stakeholder networks (Bleys et al., 2025; McKinsey, 2023).

The rise of networked innovation models, such as Fully Integrated Pharmaceutical Network and Research-Integrated Pharmaceutical Company, further embeds this logic. The traditional fully integrated pharmaceutical company model, where firms internalized discovery, development, and manufacturing, is increasingly replaced by fully integrated pharmaceutical network, where firms retain control of core science but rely on contract research organizations and contract development and manufacturing development organizations (CROs/CDMOs) and licensing and by research-intensive pharmaceutical company where firms specialize in early-stage research and monetize intellectual property (IP) through out-licensing, milestones, and royalties (Shimasaki, 2024).

This is reflected in pipeline composition: IQVIA (2024) reports that emerging biopharma now accounts for approximately 60 percent of global clinical trial activity and nearly two-thirds of the R&D pipeline, confirming that innovation has become distributed across highly specialized actors.

4 BIOPHARMACEUTICAL ECOSYSTEM IN SLOVENIA

The following applies the theoretical foundations developed in the previous chapters to a detailed analysis of Slovenia's biopharmaceutical ecosystem. The objective is to translate the analytical frameworks into a systematic evaluation of Slovenia's current ecosystem configuration, its degree of maturity, and its strategic position within the global biopharmaceutical landscape.

4.1 Emergence and development of biopharma in Slovenia

The emergence of Slovenia's biopharmaceutical sector has been shaped by a long industrial tradition, strong scientific institutions, and the early presence of multinational pharmaceutical corporations. Historically, the sector developed around Lek (now part of Sandoz) and Krka, which became the foundational actors of the national pharmaceutical industry. Their success was enabled by high scientific capacity, a technically skilled workforce, and effective collaboration with research institutes, forming an industrial base that has remained one of the country's most productive sectors (Cirman et al., 2024).

Cirman et al. (2024) have done a research on Slovenian pharmaceutical industry, the evaluation of generics and the value chain of the industry (where does the industry get the most added value from), which will be further used as a foundation to stating facts about the Slovenian pharmaceutical sector in this chapter and in the following chapter of empirical analysis. As the publicly available data for the industry in is not disclosed frequently and remains quite unevenly stated, we decided to show the numbers regarding the pharmaceutical industry, using NACE C21 classification.

In Slovenia, the overall pharmaceutical industry is one of the main parts of the national economy, providing relatively high percentages of value added to the national gross domestic product (GDP) - reflecting the country's commitment to both innovation and healthcare industry. Slovenia's pharmaceutical sector is well known for its industry giants, Lek, a Sandoz company, and Krka, which became the cornerstones of the industry. The predisposition for their success was long heritage, high level of innovativeness and expertise and a good collaboration between the academia and research institutes. Lek and Krka are generic pharmaceutical companies, with Lek now shifting its focus towards biosimilars. However, through the years, the companies have accelerated the growth of other supporting SMEs in the ecosystem, who also cater to the needs of biopharmaceuticals (Cirman et al., 2024).

Table 2: Pharmaceutical industry in Slovenia

Indicator	**Value**
GDP contribution (in terms of value added, in 2023, in percent)	2.5
Pharmaceutical Gross Value Added (in EUR, in billion, in 2022)	2.857
GVA contribution per employee (in 2022, in EUR)	200,500
Number of employees (in 2022)	25,556
CAGR 2024-2029 (in percent)	3.75
Sales in 2023 (in EUR, billion)	3.4
R&D Expenditures in 2022 (in million EUR)	679.5

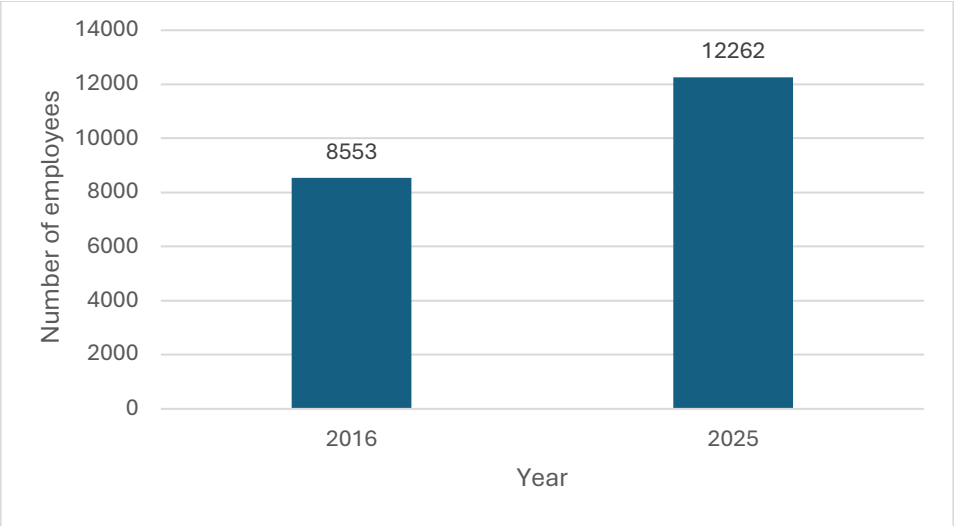
Source: EFPIA (2023), EFPIA (2024), SiStat (2024), Statista (2024), UMAR (2024), U.S. International Trade Administration (2024a).

Pharmaceutical industry has been one of the fastest growing industries in Slovenia, since its independence. As seen in Table 2, in 2023, it generated approximately EUR 3.4 billion in sales, accounting for approximately 2.5 percent of the country's GDP, and it is projected to grow at the CAGR (compound annual growth rate) of four percent between 2024 and 2029. Unlike historical growth indicators, the CAGR is delimited to the forward-looking period 2024 to 2029 and reflects projected rather than realized growth.(SiStat, 2024; Statista, 2024; UMAR, 2024).

EFPIA (2024) report has presented analysis regarding the GVA contributions for each EU-27 country. The pharmaceutical sector has contributed EUR 311 billion in Gross Value Added (GVA) and 2.3 million jobs to the EU economy, in 2022-highlighting that the average GVA per worker in the pharmaceutical industry in the EU is three times higher than in the EU economy. Slovenia contributed roughly EUR 2.857 million in GVA and had employed 25,556 people. Each EUR invested directly to the Slovenian pharmaceutical sector, EUR 1.22 is created across the national economy.

EFPIA (2024) created a comparison analysis of direct GVA per employee of the pharmaceutical industry to the national average GVA per employee in Slovenia. They have identified that the average GVA per employee, in 2022, amounts to EUR 200.500, and that productivity of the pharmaceutical industry in Slovenia is on average 335.9 percent higher than the average productivity of all industries, between 2016 and 2022. To further confirm this, according to EFPIA (2023), Slovenia is ranked among the top European countries in drug production per capita, which shows industry's high productivity and strong global positioning.

Figure 3: Number of employees in pharmaceutical industry



Source: Gole (2025).

According to Gole (2025), Figure 3 shows that employment in the Slovenian pharmaceutical industry has increased by approximately 40 percent from the year 2016 to 2025. This sustained growth in the workforce is a strong indicator of sectoral stability and long-term competitiveness. It demonstrates not only the industry's capacity to expand its production and innovation activities, but also its ability to support the rising GVA contribution of the pharmaceutical sector to the national economy.

The sector has as well undergone a strategic transition from traditional generics toward biosimilars and biologics, mirroring global shifts in scientific and technological paradigms. Slovenia's industrial capabilities have expanded accordingly. Sandoz's EUR 500 million investment in a new biologics and API facility in Lendava (Lek, 2023), along with the development of new biosimilar and aseptic facilities in Mengeš and Ljubljana, underscores the country's accelerated entry into research-intensive biologics manufacturing (Bizovičar, 2025). This expansion is expected to significantly enhance Slovenia's manufacturing capabilities in biosimilars, strengthening its position in the European pharmaceutical market (Sandoz Group, 2023).

Parallel to industrial expansion, Slovenia has also built a solid scientific and research foundation that supports biopharmaceutical development. Key institutions such as the Jožef Stefan Institute, the National Institute of Chemistry, and the National Institute of Biology play integral roles in synthetic biology, drug development, molecular engineering, and precision medicine. Their partnerships with industry actors, ranging from early-stage collaborations to advanced contract research projects, have accelerated knowledge transfer and strengthened Slovenia's innovation potential (Biotech Swiss, 2024; European Commission, 2021; SPIRIT, 2023).

Slovenia has recently launched deliberate efforts to orchestrate a national biopharmaceutical ecosystem. The Biotech Hills initiative, supported by government and leading corporations, aims to integrate R&D, industrial scale-up, education, and international partnerships within a unified cluster platform. The initiative positions biotechnology as a strategic national priority and sets ambitious goals: increasing the sector's GDP contribution from 6 percent to 9 percent by 2030, generating 1000 additional high-skilled jobs, and enhancing the overall innovation and investment climate (Biotech Hills, n.d.)

4.2 Actor roles and interdependencies in Slovenia

This chapter applies the theoretical concepts from Adner (2017) and Jacobides et al. (2018) to the Slovenian biopharmaceutical sector. The chapter examines how Slovenian actors in biopharmaceuticals depend on each other for knowledge, technology, manufacturing, and regulation. This means looking at how companies such as Novartis and Lek, a Sandoz company, rely on specialized SMEs (for example, in biotechnology, analytics, or engineering), and how smaller firms depend on these large companies for market access, good manufacturing practice (GMP) integration, and long-term projects. In Slovenia, this can be seen in situations where firms cannot innovate alone and therefore build partnerships with universities, public institutes, or engineering companies.

We identified the main actors, what they can do, what kind of interdependencies they create, and how they coordinate their work. The mapping also reveals gaps and weaknesses, such as limited translational capacity, fragmented early-stage financing, or the fact that strong orchestrators are mostly subsidiaries of multinational companies instead of domestic firms.

Table 3: Actor roles of selected actors in biopharmaceuticals

Actor	**Role in Ecosystem**	**Key Capabilities**	**Interdependencies (Adner, 2017)**	**Complementarities (Jacobides et al., 2018)**	**Governance / Coordination Mode**
Novartis	Downstream anchor (biologics)	Biologics & biosimilars, API, aseptic ops	Depends on SMEs (AciesBio, Niba), Brinox, Metronik; SMEs depend on Novartis for integration	Industrial-scale GMP & global distribution	Hierarchical + ecosystem orchestration
Lek / Sandoz	Downstream anchor (biosimilars)	Chemical synthesis, formulations, global exports	Depends on engineering, analytics, research; SMEs depend on Sandoz for market access	Deep process IP	Hierarchical + networked procurement
AciesBio	Upstream/midstream SME	Synthetic biology, strain engineering, bioprocesses	Corporates rely on AciesBio for innovation; AciesBio relies on contracts & VC	Non-generic strain engineering	Network partnerships
Niba Labs	Upstream specialist SME	dPCR, viral-vector analytics, AAV testing	CGT developers rely on Niba; Niba relies on upstream research	Highly specialised analytics	Project-based network governance
Labena Group (CRO)	Midstream support	GMP analytics, regulatory support	SMEs rely on Labena; Labena depends on industry demand	High-end analytical services	Contractual governance
Labena Ventures	Ecosystem intermediary	Deep-tech acceleration, investor access	Startups depend on Ventures; Ventures depend on deal flow	Regulatory + business-model complementarity	Network orchestration
Metronik	Automation support	MES, automation, digitalisation	Pharma firms rely on automation; Metronik depends on pharma growth	Domain-specific automation	Project-based coordination

To be continued

Table 4: Actor roles of selected actors in biopharmaceuticals (continues)

Actor	**Role in Ecosystem**	**Key Capabilities**	**Interdependencies (Adner, 2017)**	**Complementarities (Jacobides et al., 2018)**	**Governance / Coordination Mode**
Brinox	Engineering support	Bioprocess equipment (CIP/SIP, fermenters)	Corporates need Brinox systems; Brinox depends on investment cycles	Custom GMP equipment	Co-design governance
BIA Separations (Sartorius)	Upstream technology Provider	Monolithic chromatography	CGT/biologics rely on BIA columns	Unique chromatography tech	Networked + global hierarchy
CleanGrad	GMP cleanroom engineering & infrastructure support	Design, construction, and qualification of GMP cleanrooms	Corporates and SMEs depend on CleanGrad for compliant production spaces; CleanGrad depends on pharma investment cycles	Specialized cleanroom expertise enabling aseptic and biologics production (non-generic)	Project-based coordination; regulatory-driven integration
NIB	Upstream research	Molecular biology, virology	SMEs and corporates depend on research; NIB depends on collaborations	Scientific knowledge module	Public research governance
KI	Upstream research	Structural biology, analytics	Downstream firms rely on KI	Advanced analytical capabilities	Institutional governance
JSI	Upstream research & innovation	Bioinformatics, AI, systems biology	Industry relies on JSI; JSI depends on applied projects	Unique scientific infrastructure	Cross-institutional governance
ELIXIR-SI	Digital infrastructure	HPC, multi-omics pipelines	Entire ecosystem depends on ELIXIR	Non-generic digital complementarity	EU–national network governance
University of Ljubljana (spin-outs)	Academic entrepreneurship	Talent, research, IP	Spin-outs depend on UL; UL depends on industry for translation	Academic–industry linkage	Institutional + network ties

To be continued

Table 5: Actor roles of selected actors in biopharmaceuticals (continues)

Actor	**Role in Ecosystem**	**Key Capabilities**	**Interdependencies (Adner, 2017)**	**Complementarities (Jacobides et al., 2018)**	**Governance / Coordination Mode**
SEF	Public financing	Grants, loans, training	SMEs rely on SEF; SEF depends on absorptive capacity	Capability-building complementarity	Public network governance
VESNA VC	Private venture capital	Capital, mentoring	Startups depend on VC; VC depends on pipeline	Financial complementarity	Network-based governance
SRIP Health–Medicine	Policy coordination	Cluster support, strategic projects	Coordinates research & industry	Institutional complementarity	Networked governance
Biotech Hills	Emerging orchestrator	Cluster building, talent, strategy	Coordinates multi-actor ecosystem	Ecosystem-level complementarity	Early-stage orchestration
SPIRIT Slovenia	Export & investment promotion	FDI attraction	Corporates rely on SPIRIT; SPIRIT depends on industry	Policy complementarity	State coordination
Ministries (Economy/Health/ Science)	Policy & regulation	Regulation, incentives, frameworks	All actors rely on policy; ministries depend on industrial input	Regulatory complementarity	Hierarchical + network governance

Source: Own work.

Table 3 summarizes how Slovenia's biopharmaceutical landscape reflects the core ideas of Adner (2017) ecosystem-as-structure and Jacobides et al. (2018) theory of ecosystem emergence. According to Adner (2017), an ecosystem can be understood through its alignment structure, meaning how actors' roles, sequences of activities, and mutual dependencies come together to deliver a final value proposition. Table 3 shows that in Slovenia this alignment is anchored by downstream industrial leaders such as Novartis and Lek, whose large-scale GMP manufacturing, regulatory capabilities, and global market access position them at the center of most interdependencies. Companies such as AciesBio, Niba Labs, Brinox, Labena, and Metronik depend on these corporations for integration into supply chains and access to commercialization channels. At the same time, the large companies also rely heavily on these SMEs for innovation, specialized analytics, and engineering expertise, demonstrating what Adner describes as reciprocal interdependencies that require coordination across organizational boundaries (Adner, 2017; Bettanti et al., 2021).

Jacobides et al. (2018) add that ecosystems emerge when industries develop non-generic complementarities, which are highly specialized capabilities that cannot be easily substituted or internalized. The Slovenian biopharmaceutical ecosystem fits this pattern well. Niba Labs' viral-vector analytics, AciesBio's synthetic biology and strain engineering, Brinox's custom GMP bioprocess equipment, and ELIXIR-SI's high-performance digital infrastructure all represent unique competencies that are non-generic and essential for advanced biopharma development (AciesBio, n.d.; Brinox, n.d., ELIXIR Slovenia, n.d.; Niba Labs, n.d.). Research institutes such as NIB, KI, and JSI contribute scientific modules, such as structural biology, medicinal chemistry, systems biology, that complement industrial activities but remain outside the scope of private firms (National Institue of Biology, n.d.). These complementarities explain why Slovenia's ecosystem is composed of many specialized actors rather than vertically integrated companies.

Finally, the table reflects Jacobides et al. (2018) emphasis on governance without hierarchy. Slovenia uses hybrid coordination modes: hierarchical structures exist within Novartis and Lek, but most cooperation across the ecosystem takes place through network-based arrangements, public–private interfaces, and institutional governance. Actors like SEF, SRIP Health–Medicine, Labena Ventures, and the emerging Biotech Hills initiative help orchestrate interactions by providing financing, cluster coordination, regulatory readiness, or strategic alignment (Labena Ventures, n.d.; Slovenski podjetniški sklad, n.d.; SRIP Zdravje–medicina, n.d.; VESNA VC, n.d.).

4.3 Slovenia's biopharmaceutical ecosystem maturity

In this chapter Bettanti et al. (2021) five driving forces of ecosystem performance: specialized infrastructure, funding, sophisticated demand, human capital, and culture and incentives, are

applied to Slovenia. The goal is to assess ecosystem maturity and to identify value-creation pathways.

4.3.1 Specialized infrastructure

Bettanti et al. (2021) define specialized infrastructure as all tech equipment and facilities that are available within the innovation ecosystem (IE) and enable discovery, development, testing and production in a biopharmaceutical innovation ecosystem. It covers hospitals and clinical centers, public research institutes, industrial plants, CDMOs and engineering suppliers, as well as data and digital infrastructures.

Slovenia's biopharmaceutical industrial infrastructure is dominated by two large corporations. First is Lek, a Sandoz company, which is being transformed into a major European hub for biosimilars. Sandoz has committed approximately EUR 1 billion of investment in Slovenia by 2029, including a large new biologics production plant and expansion of biosimilar development and production capacities in Lendava and Ljubljana (Sandoz, 2025). The European Commission also approved a EUR 52 million state-aid measure to support Lek's production of biological drug substances, which confirms that this infrastructure is not only large in scale but also strategically important at EU level (European Commission, 2024). The second is Novartis, which specializes in the production of biologics and has as well a very strong CDMO department. The company's EUR 500 million investment in the Mengeš Biocampus aims to integrate Slovenia into Novartis' global network of research excellence (Novartis, 2024). More than half of Novartis' most strategically valuable medicines are developed or produced in Slovenia, underscoring the country's importance within the company's supply chain (Kristan Fazarinc, 2024). They are as well constructing a new aseptic production facility in Ljubljana (Bizovičar, 2025).

Around these leading corporations, Slovenia has built a supporting layer of specialized industrial and bioprocess infrastructure. Brinox designs and supplies custom upstream and downstream process systems, bioreactors and equipment for active pharmaceutical ingredients for leading global pharma companies, positioning itself as a key provider of engineered process equipment for the biopharmaceutical industry (Brinox, n.d.). Metronik develops manufacturing execution system (MES) and automation solutions which provides traceability, electronic batch records, and integration with other IT systems, and it is recognized as a leading regional provider of digitalization and automation in pharmaceutical production (Metronik, n.d.). Labena Group offers integrated laboratory and process-analytics solutions and operates a good manufacturing process compliant CRO laboratory for analytical services to the pharmaceutical industry, including work aligned with FDA guidelines (Labena, n.d.). In addition, Sartorius BIA Separations maintains a multi-use research, production and training facility in Ajdovščina, developing monolithic chromatography columns and bioprocessing solutions for biomolecule purification and offering specialized services for pDNA, mRNA, viral vectors and other

advanced modalities (BIA Separations., n.d.). CleanGrad adds a further layer of specialised industrial infrastructure to the Slovenian biopharmaceutical ecosystem by providing GMP-compliant cleanroom design, construction and validation. Its expertise represents a non-generic complementarity, as both large corporations and SMEs depend on CleanGrad to establish the controlled environments required for biologics, aseptic processing and advanced analytics (CleanGrad, n.d.). This combination of industrial anchors and specialized suppliers gives Slovenia a complete process infrastructure from upstream to downstream, which is relatively advanced compared with the country's size.

The science and clinical-research infrastructure form a second important layer. The Jožef Stefan Institute (JSI) is Slovenia's leading public research organization, employing over 900 researchers in natural sciences, life sciences and engineering and playing a central role in advanced technologies, including biotechnologies, materials and information science (Jožef Stefan Institute, n.d.). The National Institute of Chemistry (KI) is the second largest natural-science institute, with around 460 employees and strong equipment for structural analysis and conducts cutting-edge research in chemistry, life sciences and materials science (National Institute of Chemistry, n.d.). The National Institute of Biology (NIB) complements this with expertise in molecular biology, virology and biotechnology and participates in advanced research on biologics and cell and gene therapy analytics, often together with spinoffs such as Niba Labs (National Institute of Biology, n.d.; Niba Labs n.d.).

Universities also play an important R&D role beyond education. At the University of Ljubljana, the Faculty of Pharmacy, the Biotechnical Faculty, and the Faculty of Chemistry and Chemical Technology host specialized research groups active in medicinal chemistry, biotechnology, bioprocessing, pharmacology, structural biology, synthetic biology and bioinformatics (Univerza v Ljubljani, 2024a; Univerza v Ljubljani, 2024b). These faculties coordinate and participate in Horizon Europe, ERC and industry-driven R&D projects, operate shared core facilities, and collaborate with hospitals and national institutes on translational research. These institutes provide the high-end laboratory infrastructure and research platforms needed for a biopharmaceutical ecosystem, like the university- and hospital-based centers in Lombardy (Bettanti et al., 2021).

It is important to maintain a high level of expertise and strong collaboration with Slovenian educational and research institutions. Slovenia has a high-quality pharmaceutical-chemical and technical study programs, which consistently produce well-qualified professionals. In discussions with academia, the corporate companies provide input on the types of profiles most needed in the industry and suggest areas where student enrolment should be increased. They also contribute to the development of new academic programs, including a recent initiative in biotechnology. Furthermore, the companies support international recruitment, recognizing the value of diverse expertise in strengthening its workforce (Kristan Fazarinc, 2024). Representatives of the University of Ljubljana, the University of Maribor, and the University of Primorska have signed a strategic cooperation agreement with Lek, a member of the Sandoz

group, aimed at strengthening collaboration in education, research, development, and strategic activities (Univerza v Ljubljani, 2024a), and Novartis in Slovenia has as well signed a strategic cooperation agreement with University of Ljubljana to strengthen and expand their long-standing partnership in areas such as talent development, lifelong learning, scientific research, and innovation (Univerza v Ljubljani, 2024b). The primary goals of these partnerships are to accelerate innovation, scientific research and support the development of young talent. Key areas of collaboration include the establishment of practical training opportunities for students, support for their final thesis projects, and the integration of experts into the academic curriculum through guest lectures. The agreement also envisions joint applications for national and international funding, the development of research and innovation projects, and the enhancement of existing and new academic programs. Additional cooperation will focus on lifelong learning and the organization of joint events such as summer schools, hackathons, and informational days. The agreement is planned to create a robust ecosystem for knowledge and experience exchange, strengthening innovation capacity and enabling breakthrough scientific achievements (Univerza v Ljubljani, 2024a).

Clinical and hospital infrastructure also contributes to research capacity. The NIJZ (2021) overview of achievements in public health highlights a dense network of hospitals and specialized health institutions and emphasizes public-health laboratories, registries and surveillance systems as core elements of the national infrastructure. The Ministry of Health (2023) review of the health system shows that Slovenia has a developed hospital network but suffers from fragmented data structures and unstandardized information systems, which complicates planning and management. Klemenc (2019) study of research work in general hospitals adds important detail: all general hospitals have the status of teaching hospitals and most of them have a dedicated research department, which coordinates projects, bibliographies and participation in national and EU research programs. However, the share of physicians with MSc/PhD degrees and academic titles is much lower in general hospitals than in university medical centers, and research capacity is constrained by staffing shortages and lack of time for scientific work. Slovenia's clinical-research infrastructure is well distributed physically, but the more advanced research work remains concentrated in the two university centers and national institutes. The more advanced medical procedures and research work is mostly being conducted at the terciar level (Ministry of Health, 2023).

A distinctive strength of the Slovenian ecosystem is its specialized biotech SME and platform infrastructure. AciesBio operates as a microbial biotechnology company with an integrated platform for synthetic biology, strain engineering, high-throughput screening and bioprocess development, and has expanded its pilot facilities to support end-to-end development from lab to industrial scale in collaboration with global partners such as ADM and BASF (AciesBio, n.d.). Niba Labs, a spin-out linked to NIB, provides highly specialized analytics for cell and gene therapy, a multiplex digital PCR platform for viral vector genome integrity, which is emerging as a new standard in viral-vector characterization and is recognized in international scientific and industry publications (Niba Labs, n.d.). These firms represent non-generic

(Jacobides et al., 2018), globally competitive technology niches and function as critical infrastructure for advanced therapies, comparable to specialized technology providers in Lombardy (Bettanti et al., 2021).

Finally, Slovenia has invested in digital and data infrastructure for life sciences and health. NIJZ (2021) report on public-health achievements describes the development of a national health-information system, including digital registries, surveillance platforms and tools such as "Zdravje v občini", which provide health indicators for all municipalities and underpin data-driven decision-making. The Ministry of Health (2023) system review confirms that eHealth platforms and registries exist but also notes that data across the system remain poorly centralized and standardized, which limits their full potential. On the research side, ELIXIR Slovenia (n.d.) serves as the national node of the European ELIXIR infrastructure and is upgrading state-of-the-art life-science infrastructure through three pillars: high-throughput genomic technologies, a central national life-science data node, and a training center for bioinformatics and data analysis. This gives Slovenian researchers and companies access to advanced data-generation and data-management capabilities, which are increasingly central to biopharmaceutical R&D.

4.3.2 Funding

Funding represents one of the central driving forces in Bettanti et al. (2021) framework, since it determines whether scientific ideas can be transformed into technologies, products and companies.

Slovenia's strongest element is the corporate funding base, mentioned already under specialized infrastructure. Both global corporations Sandoz and Novartis are actively investing in expansion of Slovenian biologics and biosimilars. Together their investments stand at more than EUR 1 billion (Sandoz, 2025). As mentioned as well additional support comes from the European Commission's approval of a EUR 52 million state-aid measure (European Commission, 2024; Novartis, 2024; Sandoz, 2025). The result is a stable corporate funding engine that supports long-term R&D, process innovation and incremental upgrading of capabilities, like the pattern identified for Lombardy's industrial base (Betantti et al., 2021).

On the public side, Slovenia has increased government R&D funding considerably over the last decade. Eurostat (2024) data show that Slovenia has increased its public spending on research quite strongly over the last decade. Government budget allocations for R&D rose from 0.43 percent of GDP in 2014 to 0.59 percent in 2024. This means that Slovenia expanded its public research budget by about one third, which is a faster growth rate than in many countries of Central and Eastern Europe. Although Slovenia still invests less than the EU average of 0.71 percent of GDP, the steady upward trend suggests that the country is slowly moving closer to European leaders. This growth is important because public R&D funding creates the basic

scientific and institutional conditions that support innovation. Complementing this, Statistical Office of the Republic of Slovenia (2025) reports that Slovenia's total gross domestic expenditure on R&D (GERD) reached EUR 1.364 billion in 2023, equivalent to 2.1 percent of GDP, with business enterprises accounting for 69 percent of that spending and contributing nearly 47 percent of funds. Klemenc (2019) study on general hospitals demonstrates that even regional hospitals participate in ARRS-funded research and EU projects such as United4Health, which shows that public funding stimulates research beyond university centers.

However, Cirman et al. (2025) research shows that Slovenia shows weaknesses in patient capital necessary to support biotechnology ventures especially in early-stage and growth financing. The European Innovation Scoreboard for 2025 confirms that Slovenia's venture capital investment is only 27.3 percent of the EU average, placing it among the lowest-performing countries in the innovation-driven segment (European Commission, 2025). The OECD (2025b) review of industrial policy similarly identifies venture capital (VC) supply as structurally limited, with government VC accounting for only about 5 percent of all VC deals and application procedures for public instruments described as slow and administratively demanding. Although private investors such as VESNA VC and Labena Ventures are emerging as early-stage actors, the domestic venture capital pool remains too small to fund advanced biologics or platform biotechnologies start-ups at scale (Labena Ventures, n.d.; VESNA VC, n.d.). Mission-driven funds from foundations and patient groups exist in Slovenia, for example in CTNNB1 syndrome and spinal muscular atrophy gene therapy initiatives, but they remain modest in financial volume (CTNNB1 Foundation, 2025).

The Slovenian Enterprise Fund (SEF) plays an important role in early-stage financing, offering grants, microloans and training programs to SMEs and start-ups (Slovenski podjetniški sklad. (n.d.). The Ministry of Health (2023) report adds an important macro-financial perspective: Slovenia faces high growth in ageing-related expenditure, which may limit future fiscal space for major investments in health and research. This means that public support for biopharma innovation must navigate long-term sustainability pressures. NIJZ (2021) public-health report further shows that digitalization and health-data infrastructure require continuous funding to achieve integration and modernization goals.

When compared to Lombardy, Slovenia shares a similar pattern: robust industrial and project-based funding but a limited risk-capital market, which restricts the ecosystem's ability to generate fast-growing, innovation-driven biopharma firms (Bettanti et al., 2021).

4.3.3 Sophisticated demand

Sophisticated demand refers to demand that pushes the ecosystem towards the technological frontier. It arises when health-care organizations, firms and public bodies request solutions that are scientifically advanced, clinically complex or strongly data-driven, thereby stimulating innovation and entrepreneurship (Bettanti et al., 2021). In Slovenia, sophisticated demand

comes from four main sources: the structure of the health-care system and its disease burden, export-oriented pharmaceutical production, emerging demand for advanced therapies and rare-disease solutions, and the growing digital-health and data-analytics agenda.

First, Slovenia's health-care system and population structure create a stable but increasingly complex demand for pharmaceutical and biopharmaceutical products. The OECD (2023), reports health expenditure grew to 9.5 percent of GDP in 2021, which is below EU average of 11 percent. Per capita expenditure has as well increased to EUR 2,665, roughly two-thirds of the EU average, with public spending accounting for 73.7 percent of total health expenditure. It is noted that 21.3 percent of the population was aged 65 or older in 2021, above the EU average, and that demographic ageing will significantly increase spending pressures. According to the U.S. International Trade Administration (2024b), pharmaceutical expenditure in 2022 amounted to EUR 679.5 million, with each inhabitant spending on average EUR 322 and consuming around nine prescription medicines per year. Out-of-pocket patient spending presents 13 percent of overall health spending in Slovenia. Pharmaceuticals present 31 percent of out-of-pocket spending, which is above EU average of 24 percent (The OECD, 2023).

Second, sophisticated demand is amplified by export-oriented industrial structures and international customers. Pharmaceuticals in general, including generics and biopharmaceuticals, have become one of the pillars of Slovenia's export economy. Recent export rankings place Krka and Lek as the two largest Slovenian exporters, with export values of approximately EUR 1.69 billion and EUR 1.38 billion respectively in 2024 (SPIRIT, 2025). Earlier data showed both firms among the top three exporters already in 2022 (SPIRIT, 2022). A Swiss analysis of the sector notes that pharmaceutical exports increased from about EUR 1.7 billion in 2010 to EUR 13 billion in 2022, and that the industry now accounts for around 5 percent of Slovenia's GDP and directly employs roughly 12,000 workers (Pluss & Stegmuller, 2024).

A third, increasingly important source of sophisticated demand arises from advanced therapies and rare-disease treatment, where Slovenia has moved beyond being a passive adopter of imported technologies. In oncology, the first gene therapy trial for cancer patients in Slovenia was approved in 2021 at the Institute of Oncology Ljubljana. The entire development and production of the therapeutic were the result of domestic collaboration between research institutions and industry (KMŽ, 2021).

Slovenia has emerged as an early adopter of advanced gene therapies in the field of rare diseases, particularly in spinal muscular atrophy and several ultra-rare metabolic and neurodevelopmental disorders. Grošelj et al. (2025) document the country's first applications of gene therapy not only for spinal muscular atrophy but also for inborn errors of metabolism, CTNNB1 syndrome, and for interleukin-12–based cancer immunotherapy. Among these, the CTNNB1 case is especially illustrative of how highly specialized demand can stimulate the development of an innovation ecosystem. The Slovenian government approved a EUR 1

million grant to support URBAGEN, a gene-therapy program for CTNNB1 syndrome led by the CTNNB1 Foundation, which represents one of the first examples in Europe where a government publicly financed a non-profit organization at such an early stage of gene-therapy development (CTNNB1 Foundation, 2025). The project's selection by the European Medicines Agency's Innovation Task Force as one of the most promising gene-therapy initiatives in Europe further demonstrates its scientific and regulatory significance.

These developments have created sophisticated downstream demand for viral-vector analytics, bioinformatics, regulatory expertise and clinical-trial capabilities. They also show how ecosystem coordination emerges in practice: according to the CTNNB1 Foundation (n.d.), the actors from Table 3 are included in the process. Preclinical studies were conducted at the National Institute of Chemistry (KI), biodistribution studies were carried out at Labena, and Sartorius provided part of the project's financial support. Together, these activities highlight how rare-disease initiatives can mobilize research institutes, analytical companies, funders and regulators, thereby operationalizing the principles of innovation-ecosystem functioning in Slovenia.

Fourth, Slovenia is experiencing growing sophisticated demand in digital health, data analytics and med-tech, which further expands the innovation space. The NIJZ (2021) report on public-health achievements emphasizes the development of national health-information systems, disease registries and tools such as "Zdravje v občini", which provide indicator dashboards for all municipalities and require robust data-management and analytical capabilities. The Ministry of Health (2023) describes the national eHealth architecture (ePrescription, eReferral, patient registers) and notes both its potential and the challenges linked to fragmentation and incomplete integration. On the innovation side, HealthDay (n.d.) has emerged as a key community platform and digital-innovation hub, bringing together start-ups, SMEs, hospitals, research institutes and corporate actors to stimulate digital transformation in healthcare. Its conferences and initiatives explicitly focus on the intersection of biotechnology and data analytics, including diagnostics and advanced cell and gene therapies.

Finally, sophisticated demand is also expressed through the internal research needs of hospitals and clinical centers. Klemenc (2019) study shows that all general hospitals have teaching status and most have research departments, and that many participate in ARRS and EU-funded projects. However, the same study reveals that the proportion of physicians with MSc/PhD degrees and academic titles is much lower in general hospitals than in university centers, and that limited staffing and weak incentives constrain their research intensity.

4.3.4 Human capital

In Bettanti et al. (2021) model, human capital refers to the availability, quality and configuration of skills needed along the whole innovation chain: from basic science and clinical

practice to regulatory expertise, entrepreneurship and scale-up management. In Slovenia, the human-capital base for biopharma is relatively strong in scientific and technical terms, and reasonably solid in clinical medicine, but thinner in translational, entrepreneurial and managerial capacities.

At the macro level, international indices consistently rank Slovenia well in education and research-related human capital. The WIPO (2025) places Slovenia 35th overall and highlights human capital and research as one of the country's strongest dimensions, where Slovenia ranks 24th in the world, above both the European and high-income-country averages. The Ministry of the Economy, Tourism and Sport similarly notes that Slovenia ranks 14th on the World Bank's Human Capital Index and that in the OECD PISA assessment Slovenian fifteen-year-olds achieved the sixth best combined score in mathematics, science and reading, indicating a strong pipeline of scientifically literate youth (SPIRIT, n.d.). European Commission (2025) in the country innovation scoreboard for 2025 classify Slovenia as a Moderate Innovator (close to the "Strong Innovator" threshold), with particularly high scores for international scientific co-publications, public–private co-publications and lifelong learning participation, which all point to a comparatively well-developed research workforce and collaborative culture.

These aggregate assessments are consistent with national statistics on R&D personnel. According to the Statistical Office of Slovenia (2025), 25,863 people were involved in research and development activities in 2023, their workload was equivalent to 17,879 full-time equivalents, and 17,587 of them were classified as researchers. The business enterprise sector employs most of these R&D workers: in 2023 around 69 percent of gross domestic expenditure on R&D and a corresponding share of research personnel were in firms, with 16 percent of expenditure in the government sector, 14 percent in higher education and 1 percent in the private non-profit sector. For biopharma, this distribution could potentially mean that a large part of the advanced technical human capital is embedded in companies such as Novarts, Lek, Brinox, Labena, AciesBio and Niba Labs, rather than exclusively in universities and public institutes.

At the science and research-institute level, according to Ministry of Higher Education, Science and Innovation (2025) Slovenia possesses several centers of excellence that concentrate high-level human capital. The Jožef Stefan Institute (JSI) employs around 1,000 researchers and staff and covers physics, chemistry, biochemistry, information and environmental sciences, with growing activity in life sciences and biotechnology. The National Institute of Chemistry (KI) has about 460 employees, including over 300 researchers and doctoral candidates, and hosts advanced research groups in structural biology, analytics, chemical biology and materials. The National Institute of Biology (NIB) employs over 200 staff members with expertise in molecular and systems biology, virology and biotechnology, and explicitly describes itself as a project-oriented institution financed through the Slovenian Research Agency (ARIS/ARRS) and a broad spectrum of EU programs. These institutes not only train PhD students and

postdocs but also act as hubs of specialized knowledge for industry, particularly in areas such as bioprocess development, analytics, bioinformatics and genomics.

On the clinical side, the Klemenc (2019) study provides a detailed view of research-related human capital in Slovenian general hospitals. The article shows that all general hospitals have the status of teaching hospital and most have a dedicated research department, but the share of physicians with MSc/PhD degrees and academic titles is very uneven. While the University Medical Centre Ljubljana reports that around 35.6 percent of its physicians have an MSc or PhD and 15.5 percent hold a university teaching title, and University Medical Centre Maribor shows similar figures (29.2 percent and 11.8 percent, respectively), the average across general hospitals is only 8.6 percent for MSc/PhD and 1.1 percent for teaching titles. The study further notes that general hospitals struggle with staff shortages, lack of junior researchers and limited time for research, which restricts their ability to engage in systematic clinical studies and technology evaluation. This indicates that high-end clinical research capacity, and sophisticated clinical human capital, is concentrated primarily in the two university medical centers and a few specialized institutes, while most hospitals mainly provide service delivery with relatively limited research engagement.

In the industrial segment, large pharmaceutical firms and specialized SMEs represent important domain-specific human capital. Lek for example employs thousands of skilled workers, including pharmacists, chemists, biotechnologists, engineers and regulatory specialists, and maintain in-house training and development programs to support GMP compliance and continuous improvement (Lek, 2025). Process and analytics companies such as Brinox, Metronik and Labena rely on multidisciplinary teams that combine engineering, automation, software, analytical chemistry and regulatory knowledge to design and operate complex bioprocess systems and CRO services (Brinox, n.d.; Labena, n.d.; Metronik, n.d.). SMEs including AciesBio and Niba Labs employ highly specialized scientists with expertise in synthetic biology, strain engineering, digital PCR, viral-vector analytics and bioprocess development, often with PhD or postdoctoral backgrounds (AciesBio, n.d.; NibaLabs, n.d.). From an ecosystem perspective, this indicates that Slovenia has a dense core of highly skilled biopharma professionals, concentrated in a relatively small number of organizations that operate at or near the international frontier in their segments (Statistical Office of Slovenia, 2025).

By contrast, there are clear gaps in entrepreneurial, managerial and translational skills, particularly outside the largest organizations. Data from the Global Entrepreneurship Monitor (GEM) show that Slovenians perceived entrepreneurial capabilities are moderate, but fear of failure remains a barrier to business creation and scaling (Bradač Hojnik et al., 2025). The Bradač Hojnik et al. (2025) GEM country profile for Slovenia highlights that many adults see good business opportunities, but a significant share would refrain from starting a business because of fear of failure. An OECD (2025a) Inclusive Entrepreneurship Policy Assessment for Slovenia confirms this finding, stating that about 47 percent of Slovenians who see good

opportunities report fear of failure as a barrier, with particularly higher rates among women and youth.

Policy documents also acknowledge brain-drain and researcher-mobility issues. Ministry of Higher Education, Science and Innovation (2025) describes efforts to attract back Slovenian researchers working abroad and to make the country a more attractive destination for international research and innovation talent. The Amanatidou et al. (2025) ERA-LEARN country report on Slovenia highlights strong international collaboration and participation in European research programs but also underlines the need for better framework conditions to retain talent and improve career prospects, especially for younger researchers.

4.3.5 Culture and incentives

In Bettanti et al. (2021) framework, culture and incentives capture the informal norms, attitudes and formal reward systems that shape how actors behave in an innovation ecosystem. It explains whether they take risks, collaborate, invest in translation, and engage in long-term projects.

Human capital at the level of societal attitudes to entrepreneurship fears risk. Slovenian Bradač Hojnik et al. (2022) GEM executive summary on entrepreneurship in 2021 notes that although perceptions of opportunities improved, fear of failure remains comparable to European averages and continues to limit entrepreneurial engagement. For a biopharma ecosystem, which depends on high-risk, long-cycle ventures, such attitudinal and skill-related barriers might be especially problematic. Analyses for Slovenia note that, although around 56 percent of adults perceive good business opportunities, approximately 46 percent of the population report that fear of failure would prevent them from starting a business which is among the highest in Europe.

From a regulatory and administrative perspective, the formal business environment in Slovenia is ranked 37th of 190 economies in overall ease of doing business, indicating generally solid conditions but not top-tier performance (World Bank, 2019). In health, the Ministry of Health (2023) review explicitly states that the Slovenian health system suffers from fragmented and non-standardized data, which makes planning, needs assessment and system management difficult or impossible. The national anti-corruption commission’s analysis the public health sector quotes the same ministry report and emphasizes that large volumes of unverified, unconnected data create administrative burdens for health staff without adding value, reinforcing a culture where compliance paperwork can crowd out innovation-oriented work (Komisija za preprečevanje korupcije, 2023).

For biopharma actors, this context means that regulatory systems are stable but often slow and administratively heavy. Regulation of biopharmaceuticals in Slovenia is anchored within the

European Union framework but significantly shaped by domestic implementation and institutional configuration under the Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (JAZMP). JAZMP operates under the national Medicinal Products Act (ZZdr 2), which transposes key EU directives, including Directive 2001/83/EC on human medicinal products and Regulation 726/2004/EC, into Slovenian legislation, incorporating EMA's centralized approvals and domestic policy for national, decentralized, and mutual recognition procedures. Despite robust legislative alignment, notable weaknesses have been identified in JAZMP's practical implementation, including constrained human resources, longer administrative cycles, and limited digital infrastructure. While Slovenia has embraced GMP certification efficiency, issuing certificates within 15 days of inspection, the duration for complete marketing authorization and wholesale licensing can extend up to 90 days. These delays are exacerbated by multi-layered reviews involving reimbursement bodies such as the Health Insurance Institute, which inflates time-to-market beyond EMA benchmarks. Due to these delays approval timelines often exceed 500 days cycle, particularly for national or mutual recognition procedures (Jadek & Pensa, 2023).

Within hospitals and clinical institutions, incentive structures are another key bottleneck. Klemenc (2019) analysis of research in general hospitals shows that research-active doctors often face weak institutional recognition: promotions and career advancement are largely disconnected from research output, and hospital management is primarily focused on meeting contractual service obligations rather than fostering research. The study notes that physicians in general hospitals have limited time for research because of staffing shortages and heavy clinical workloads, and that research activities can be perceived as a disturbing element in day-to-day operations. This configuration mirrors the cultural and incentive problems Bettanti et al. (2021) identify in Lombardy: high scientific potential but low translational throughput because institutional reward systems do not prioritize innovation.

At the ecosystem-governance level, new initiatives seek to reshape incentives towards coordination and long-term strategic positioning. The SRIP Zdravje–medicina (n.d.) strategic research and innovation partnership explicitly aims to connect stakeholders from the five-helix model, including industry, research, government, healthcare providers and civil society into a national program aligned with the Mission: Beat Cancer and healthy ageing. Its SRIP Zdravje – medicina (2018) action plan includes the establishment of a center for translational and pharmaceutical research and a platform for shared research infrastructure, which, if implemented, would strengthen incentives for collaboration and reduce duplication.

The Biotech Hills (n.d.) initiative goes even further by framing biotechnology as a strategic development opportunity for Slovenia and calling for professional cluster management. It explicitly argues that without a professional management structure, clusters remain a declaration without effect and positions the Biotech Hills institute as a potential orchestrator, lobbyist and connector with a clear mandate, stable financing and European partnerships.

Public support institutions also influence entrepreneurial incentives. The Slovenian Enterprise Fund (SEF) acts as a promoter of entrepreneurship and innovativeness, providing vouchers, mentoring programs with over 150 experienced mentors, and specialized training and networking programs for start-up and scale-up firms (Slovenski podjetniški sklad. (n.d.). Together with the before mentioned private actors such as Labena Ventures and VESNA VC, which provide acceleration and early-stage funding for deep-tech ventures, these institutions contribute to a slowly improving incentive environment for technology-based entrepreneurship, including in biopharma (Labena Ventures, n.d.; VESNA VC, n.d.).

Finally, broader quality-of-life and institutional context shape cultural incentives indirectly. Slovenia's Institute of Macroeconomic Analysis and Development (2025) notes that the country ranks in the top half of EU Member States on most composite quality-of-life indicators and that perceived life satisfaction is relatively high. While this creates a stable and attractive environment for residents and foreign experts, it can also reduce perceived urgency to undertake high-risk entrepreneurial projects. The ERA-LEARN country report observes that Slovenia's Research and Innovation Strategy 2030 explicitly aim to position the country among leading innovators on the European Innovation Scoreboard and stresses the importance of European partnerships and digital and green transitions, signalling a strong strategic commitment at policy level (Amanatidou & Cox, 2025).

5 EMPIRICAL ANALYSIS

This chapter examines how Slovenia's biopharmaceutical ecosystem operates in practice and how its key actors perceive the country's capabilities, constraints, and future trajectory.

5.1 Methodology

The empirical analysis investigates the following research questions:

RQ1: Which ecosystem structures and interdependencies are present in Slovenia's biopharmaceutical sector?
RQ2: How mature is Slovenia's biopharma ecosystem when evaluated through actors, infrastructures, funding, demand, human capital and culture?
RQ3: What role do corporations play in shaping ecosystem alignment, resource flows, and institutional conditions in Slovenia?
RQ4: To what extent are global biopharmaceutical trends, such as modality shifts, compressed product life cycles, capital cycles, and organizational rewiring, reflected in Slovenia's industry?

The empirical analysis presented in this chapter is based on three semi-structured interviews conducted between 29th of August 2024 and 4th of July 2025 with four senior experts from organizations operating within or closely connected to Slovenia's biopharmaceutical sector. The goal of the empirical analysis is to validate, refine, or challenge the theoretical assumptions derived in chapters two to four and to identify additional dynamics that theory alone cannot

capture. The purpose of this methodological design is to generate in-depth, practice-based insights that complement and critically assess the theoretical ecosystem diagnosis developed in chapter 4. Some of the best-performing companies under the C21 classification were selected (NACE Rev. 2), as well as those working closely with the companies in C21 (European Union, 2023). The analysis uses three semi-structured interviews with senior experts from key organizations in the Slovenian pharmaceutical and biotechnology sector.

In-depth interviews are a widely used qualitative research method that enables researchers to obtain a detailed understanding of the experiences, behaviours, and perspectives of individuals within specific contexts. Through one-on-one conversations, this method allows researchers to explore the underlying processes and to identify potential solutions to complex problems. Semi-structured interview formats ensure both comparability across respondents and the flexibility to probe emerging topics (Xu et al., 2025).

Table 4 provides an overview of these companies and the interviewees. While the core questions remained consistent across all companies, some were customized to address specific aspects of each company's operations.

Table 6: Sample characteristics[1]

Company	**Type of Company**	**Interviewees**	**Code**	**NACE Classification**
Company A	Startup	Operational unit head	Biopharma1-1	C72
Company B	Innovative SME	General Manager	Biopharma2-1	C72
Company C	Multinational subsidiary	Operational unit head	Biopharma3-1	C21
		Operational unit head	Biopharma3-2	C21

Source: Own work.

Each interview lasted between 45 and 90 minutes and followed a semi-structured protocol. Core questions were consistent across all organizations to ensure comparability, while additional prompts were adapted to reflect the specific technological, organizational, or strategic context of each actor. The interviews explored themes such as ecosystem strengths and weaknesses, collaboration patterns, human-capital dynamics, regulatory and institutional conditions, and the influence of global biopharma trends. The interviewees give different but complementary views: from innovative small and medium-sized companies, from service providers that support the industry, and from multinational corporations that are part of global networks. This composition enables a balanced view of how small, medium, and large actors experience interdependencies, constraints, and opportunities in Slovenia's biopharma landscape.

[1] The full transcripts of all conducted interviews are available from the authors upon request.

The findings are presented in chapters 5.2 to 5.6, following the same ecosystem-theory structure established in chapter 4. This ensures a direct comparison between theoretical expectations and empirical realities and provides a coherent analytical basis for the final integrated discussion in chapter 5.7.

5.2 Evidence on ecosystem development and structural evolution

This section examines how interviewees describe the historical development and current trajectory of Slovenia's biopharmaceutical ecosystem. Their reflections reveal how decades of scientific investment, industrial growth, and evolving collaboration patterns have shaped the ecosystem's present configuration. Taken together, the interviews confirm that Slovenia's biopharma sector is the result of path-dependent capability building, reinforced by large industrial anchors, specialized SMEs, and a growing innovation-support infrastructure. At the same time, interviewees emphasize that the ecosystem has entered a transformational period marked by foreign investment, increasing complexity, and rising strategic stakes.

For the multinational subsidiary, Slovenia's scientific background is central to its reliability and attractiveness: *"Going back to the Yugoslav times, there was significant investment in natural sciences, pharmacy, and technological disciplines. That legacy continues"* (Biopharma 3-1). The interviewee adds that this tradition is still visible in the quality of graduates: *"Although we're small, we still produce strong early-career professionals" (*Biopharma3-1). This long history results in culturally embedded norms of precision and discipline: *"Slovenians are very disciplined, we want to do the job right and we do it"* (Biopharma3-2).

Another representative similarly emphasizes the depth of local scientific knowledge as a key competitive resource: *"There is a 50-year tradition in natural sciences, chemistry, pharmacy, and biotechnology, and this is the base that makes Slovenia strong"* (Biopharma1-1). This aligns with Cirman et al. (2024), which highlight Slovenia's persistent strategic orientation toward high-technology pharmaceutical manufacturing in the last three decades.

They also underscore the decisive influence of multinational corporations in upgrading national capabilities and enabling the development of an integrated biopharmaceutical ecosystem. Their presence provided Slovenia with access to global regulatory standards, advanced production technologies, and professionalized operational processes. *"Since 1995 we've been FDA certified and that track record matters"* (Biopharma 3-2).

This international credibility did not remain confined within corporate boundaries. It diffused into Slovenia's broader ecosystem through long-term supplier relationships and workforce mobility. The interviewees describe how local engineering and automation firms built their competencies through repeated collaboration with multinational sites: *"Many external partners*

grew with us and now operate internationally". Everyone here, even in global roles, has grown from production." (Biopharma3-2). *"And from development, from lab work too"* (Biopharma3-1).

Interviewees identify the rise of specialized small and medium-sized enterprises as a transformative phase in the ecosystem's evolution. These firms occupy niches that multinationals either do not prioritize or cannot maintain internally, such as advanced strain engineering, complex analytics, and rapid-response engineering solutions.

One interviewee explains that their company became indispensable precisely because it operates in domains where internal corporate capacity has declined: *"They come to us when something is not in focus internally or when they downsized those departments"* (Biopharma1-1). He further emphasizes the trust-based interdependence underpinning these relationships: *"The essential thing is that they can trust you. When you solve it once, they trust you next time"* (Biopharma1-1).

This dynamic confirms Jacobides et al. (2018) argument about non-generic complementarities, where certain capabilities develop only in specialized firms and become essential components of the broader value creation system. Innovation intermediaries also represent a newer layer of ecosystem infrastructure. *"We started to focus on true innovation, helping ideas reach commercialization"* (Biopharma 2-1).

Perhaps the most striking empirical insight is that all interviewees perceive Slovenia to be at a historical turning point due to the unprecedented scale of recent investments: *"This is a historic opportunity, 1 billion came within a year. Before, Novartis invested around 10 to 100 million over 20 years, now we received 1 billion in one year"* (Biopharma 2-1). Yet the interviewees also warn that this opportunity is fragile. *"Right now, Slovenia is in a sweet spot, but in two years investments might drop 50 to 60 percent"* (Biopharma 3-2).

As investment volume and technological complexity increase, interviewees describe growing interdependencies across the ecosystem. SMEs support multinational project timelines by solving highly specialized scientific and technical problems, while multinationals generate demand that sustains SME growth and supplier development: *"At the end of the day, we solve the problem, they have huge teams, but in the end, we are the ones who solve it"* (Biopharma1-1).
Similarly, another interviewee highlights that large firms cannot function without a strong ecosystem around them: *"The big corporations will need an ecosystem, and a critical mass will be needed to build and service these companies"* (Biopharma 2-1).

All interviewees identify fragmentation as a critical misalignment that prevents the Slovenian ecosystem from functioning optimally. They point out that innovation often fails to progress because actors are not connecting or collaborating: *"Everyone works on their own and*

technologies stay in drawers, we lose potential patents. We should be winning together, but everyone works in their own bubble and that is Slovenia's biggest problem." (Biopharma 2-1). This misalignment disrupts commercialization pathways, weakens knowledge transfer, and reduces innovation density. The SME interviewee frames it more directly:

This lack of coordination affects not only start-ups but also academia, SMEs, and even parts of the corporate environment. Interviewees suggest that fragmentation reduces the country's ability to commercialize research, attract foreign start-ups, and build large-scale innovation pipelines. Another interviewee similarly emphasizes that Slovenia's strengths are undermined by organizational disconnection: *"If we got together, it would be crazy, networking is the key"* (Biopharma1-1).

As a response to fragmentation and rising coordination needs, interviewees highlight the creation of Biotech Hills as an important structuring development. The initiative aims to align actors across industry, academia, government, and investment. *"Biotech Hills brings together large and small industry, academia, institutes, government and startups, they are aligning everyone's interests*. (Biopharma 2-1). The initiative also introduces quantifiable ecosystem-level goals: *"By 2035 they want to raise value added to more than 100,000 euros per employee increase employment to 70,000 and raise GDP contribution to 8 to 10 percent"* (Biopharma 2-1).

5.3 Actor roles, interdependencies and complementarities

The interviews emphasize that multinational corporations perform central anchoring roles in Slovenia's ecosystem, shaping quality norms, workforce skills, and supplier development. Their influence does not only come from scale but also from organizational integration and long-term presence. As one representative explains: *"We have had tasks and responsibilities transferred here because we deliver and we have the people who understand how development and production fit together"* (Biopharma 3-1).

This illustrates the internal logic behind corporate commitments to Slovenia: demonstrated capability enables the transfer of more complex value-chain segments. Another interviewee describes ecosystem-wide learning effects generated by multinational investment: *"When we introduce new technologies, the whole supply chain learns with us. The engineering companies learn, the automation groups learn…"* (Biopharma 3-2).

Slovenian SMEs play a vital role as non-generic complementors, providing highly specialized scientific and technological functions that multinational companies no longer maintain internally. These firms operate in advanced biotechnology, analytics, and engineering niches. As one SME founder notes: *"What we do is extremely specific and our people spend years learning just one platform or one organism"* (Biopharma 1-1).

This confirms that SME capabilities are difficult to substitute, an essential condition for the formation of complementarity-based ecosystems described by Jacobides et al. (2018). The same interviewee highlights how deeply intertwined SME contributions have become with multinational development processes: *"When they bring us a problem, it is usually something where they hit a wall internally and we take it further, step by step, until it works"* (Biopharma 1-1).

Interviewees consistently stress that Slovenia's ecosystem has lacked an actor capable of aligning diverse interests across government, academia, corporates, and SMEs. Innovation intermediaries are now emerging to fill that gap. *"They (Biotech hills) realized no one was connecting the dots. Industry talks to government, academia talks to itself, startups talk to no one. So, they want built a structure that forces these conversations to happen. They don't want to replace anyone; they want to be the place where agreements are made because otherwise each group optimizes only for itself"* (Biopharma 2-1).

The interviews illustrate numerous forms of interdependence that structure the Slovenian ecosystem. These range from technological dependencies to shared workforce pools and collaborative development processes. For example, SMEs depend on corporates for project continuity, while corporates depend on SMEs for specialized knowledge: *"If they stop coming to us with their difficult projects, half of our strategic pipeline disappears and if we stop solving these problems, their timelines fall apart too"* (Biopharma 1-1).

Multinationals similarly recognize reciprocal dependence on local suppliers: *"When we scale up manufacturing, we rely on local partners to build, automate and validate the systems. Without them, nothing moves"* (Biopharma 3-2).

Innovation intermediaries also describe ecosystem-wide labour interdependencies*: "The same 200 people are being chased by ten companies, if one organization grows quickly, the others feel it immediately"* (Biopharma 2-1).

The interviews confirm that Slovenia's biopharma competitiveness relies on non-generic complementarities and capabilities that are unique, hard to imitate, and embedded in local knowledge networks. SMEs articulate this clearly: *"You cannot copy what we do with a manual, it's the sum of tiny insights built over decades"* (Biopharma 1-1).

Multinationals echo this logic, highlighting complementarities in engineering and automation: *"Our Slovenian engineering partners understand biopharma better than many global firms, they know what regulators expect, they know how we work"* (Biopharma 3-1).

However, as noted, complementarities also create vulnerabilities: *"If we lose these capabilities because companies cannot hire or keep people, then the whole chain weakens"* (Biopharma 2-1).

Across interviews, trust emerges as a central coordination mechanism in the absence of formal governance structures. Firms depend on long-term relationships to manage interdependencies: *"The whole system works because we know each other, you can pick up the phone and things happen*" (Biopharma 2-1).

SMEs also describe trust as essential to securing complex development projects: *"Once we prove ourselves, they don't shop around, trust is the governance model"* (Biopharma 1-1). However, trust-based governance becomes less effective as the ecosystem grows more complex. The multinational interviewees note: *"When we deal with institutions or bigger systems, trust is not enough, processes slow everything down"* (Biopharma 3-2).

5.4 Ecosystem maturity in practice

Across the interviews, Slovenia's specialized infrastructure, industrial, scientific, and technological, is consistently portrayed as a major strength of the ecosystem. The multinational subsidiary highlights Slovenia's ability to host sophisticated development and production processes on the same site, a capability rarely found in comparable countries: *"We can do early development, pilot work, and full production within one integrated space, this is not common in Europe"* (Biopharma 3-1).

Interviewees consistently highlight that Slovenian firms operate in technically demanding global value chains. They noted: *"We strive to keep the customers satisfied. The first thing that separates us from the competition is that we are very flexible in adapting to their expectations about ways of collaborating with them and the expected outcomes of services rendered; the second would be that we are very flexible in meeting their needs or addressing urgencies, for example if a client wants us to increase capacity we can do it quite quickly"* (Biopharma2-1). This flexibility helps local firms compete with much larger international players, especially in specialized niches.

This integration creates a structure, enabling smoother transitions between development stages. The presence of high-quality local suppliers also enhances infrastructural maturity. As one interviewee notes: "*When we go into a new project, our engineering partners know exactly what is needed. They've built these systems with us for years"* (Biopharma 3-2).

SMEs likewise emphasize the scientific infrastructure available to them. They highlight their advanced fermentation and analytics facilities: *"We have built capabilities here that many Western European labs don't have, especially in strain optimization and analytics"* (Biopharma1-1).
However, the interviews also reveal key gaps, particularly in the upstream research infrastructure. The SME interviewee comments: *"For many advanced biology projects, we still lack the scale or equipment universities abroad have. There is no early-stage biotech infrastructure. We rely on foreign providers for almost everything"* (Biopharma 1-1). Another

interviewee states: *"We will not have enough capacity for everything, perhaps for 90 percent, but certainly not for all services needed"* (Biopharma 2-1).

The interviews paint a contrast between strong corporate investment and weak domestic financing mechanisms, particularly for start-ups and advanced biotechnology ventures. *"We simply don't have enough risk capital. Even good ideas die not because they're bad, but because no one funds the first critical steps"* (Biopharma 2-1).

They further explain that Slovenia's financial environment limits early-stage development: *"Startups struggle here not because of science, but because of capital. Investors tell us that the deal flow is too small and the barriers too high"* (Biopharma 2-1).

Meanwhile, corporate investment is described as unprecedented in scale but dependent on global strategic cycles rather than domestic policy incentives. The multinational subsidiary remarks: *"The big investments now are part of a global cycle. They are fantastic for Slovenia, but they are not guaranteed to be repeated"* (Biopharma 3-2).

This means Slovenia cannot rely on corporate investment alone to sustain ecosystem growth. The SME perspective reinforces this vulnerability: *"If you want to build something new here, it's almost impossible without foreign partners. Local money is very limited"* (Biopharma 1-1).

The interview evidence points to a persistent funding gap for smaller, innovation-driven actors. SMEs repeatedly noted the absence of tax or liquidity instruments comparable to neighboring ecosystems. As one interviewee explained, *"in Austria for every euro invested, you get 14 euro cents from contributed directly by the state: not just tax incentive, but cash, money that is. This is hugely important liquidity-wise, especially for small companies and makes Austria hugely competitive as a destination for companies investing in R&D… in Slovenia we don't have this"* (Biopharma2-1). Another highlighted the structural weakness of the domestic VC environment: *"There is effectively no venture capital here and grants are slow"* (Biopharma 1-1).

Bettanti et al. (2021) emphasize the importance of sophisticated demand to stimulate innovation. Interviewees confirm that Slovenia indeed has such demand, but it is concentrated primarily within a small number of large firms and niche technology users. The multinational subsidiary provides the clearest example of internal demand sophistication*: "Our development teams constantly need advanced analytics, novel assays, fast turnaround. Without that, our timelines collapse"* (Biopharma 3-1).

This drives continuous innovation among SMEs, who adapt to evolving requirements. *"Our clients push us technically. They come with problems no one else has solved, and that's why we innovate"* (Biopharma 1-1).

Innovation intermediaries further note that sophisticated demand also emerges from the regional start-up pipeline: *"We see brilliant founders with very deep-tech problems: omics, cancer gene therapy analytics, process intensification. They create demand for tools that barely exist"* (Biopharma 2-1).

However, this demand is uneven. Slovenia lacks broad domestic clinical or translational demand, and many innovations still require foreign markets for validation: *"If you want an innovative biotech to thrive, you still need foreign customers, Slovenia alone cannot support it"* (Biopharma 2-1).

Slovenia's small size is frequently cited as an advantage for ecosystem building: "*The geostrategic location is excellent… small but just the right size to build an ecosystem, because you are everywhere in an hour, it can be one hub, not just 'Hub Ljubljana*" (Biopharma 2-1). This compactness facilitates national-level support and coordination.

All interviewees identify human capital as the ecosystem's most serious constraint. Slovenia produces strong graduates but cannot meet growing labour-market needs, particularly as investments expand. *"In a single year we will need more skilled people than universities can produce in five. The math simply doesn't work. Although things are moving in the right direction, it's great that there is now a lot of university-industry talks and adjustments to programs. Strategic partnerships are being forged between key public universities and the industry in response to increased demand for skilled and trained professionals in the sector, these actions will produce results in 3-4 years, whereas demand for highly skilled professionals is immediate"* (Biopharma 2-1).

The multinational interviewees reinforce this concern: *"We have the knowledge here, but not the numbers. Every new investment increases the pressure"* (Biopharma 3-2). At the same time, Slovenia's training environment is described as a strength. The multinational representatives observe: *"People here learn quickly because they start hands-on. They see the whole process, not just a slice of it"* (Biopharma 3-1).

SMEs also emphasize the high scientific quality of Slovenian employees: *"Our staff is extremely strong scientifically. The problem is finding them, not training them"* (Biopharma 1-1).

Interviewees highlight several cultural and institutional factors that hinder ecosystem maturation. A recurring theme is risk aversion, which limits entrepreneurial activity and slows commercialization. *"People here stay in their comfort zone. They don't share ideas because they worry someone will take them and then nothing happens"* (Biopharma 2-1).

This hesitation is compounded by institutional and administrative challenges. The multinational subsidiary explains: *"Processes outside the company move slowly, permits, decisions, anything involving public systems. It drags us down"* (Biopharma 3-2).

SMEs likewise express frustration with administrative barriers: *"If you want to scale something quickly, the system gets in the way, not the science, not the market, but the procedures"* (Biopharma 1-1). Another respondent proposes the idea of predefined "biotech zones" with predictable timelines: "*You could have, for example, some sectors where you know you are building… for example, you can sort everything out in 6 months. Outside of that area it can take 5 years*." (Biopharma 2-1).

Finally, some interviewees stress that Slovenia cannot change core pharmaceutical regulation, which is determined at EU or global level. *"There is no big impact here, positive or negative, from Slovenia. If anybody wants to do anything for the pharmaceutical industry…everything flows into global standards"* (Biopharma1-1).

5.5 Corporate influence in practice

Interviewees across organizational types emphasize the profound contribution of multinational corporations to Slovenia's scientific and industrial capabilities. The subsidiaries serve as long-term anchors that elevate standards, build expertise, and generate opportunities for complementary firms. One multinational representative describes how their operations have gradually expanded into higher-value functions based on demonstrated capability: *"We earned our way into more complex work, the global organization saw that we could handle development, not just production"* (Biopharma 3-1).

This suggests that multinational corporations do not merely transplant activities into Slovenia; they develop local capabilities through performance-based trust. This, in turn, enriches the ecosystem by increasing its functional diversity and technological depth. Corporations also play a critical role in shaping the supplier and SME landscape. As another multinational interviewee explains: *"Our projects force local suppliers to upgrade, automation, quality systems, validation. They grow because we push them to the next level"* (Biopharma 3-2).

Such spillover effects illustrate the resource-engine function Herzog et al. (2024) describe: corporate anchors diffuse knowledge, build competencies, and elevate ecosystem readiness. SMEs confirm these dynamics from their perspective. They explain that multinational demand has driven their scientific and technological advancement*: "They bring us problems that are right at the edge of what is possible and we grow because we must solve them."* (Biopharma 1-1).
This demonstrates the catalytic role of multinational actors in stimulating innovation among complementors. Even ecosystem intermediaries recognize the structuring influence of

corporations. *"Without the big companies, none of this would be happening. They set the rhythm for the entire ecosystem"* (Biopharma 2-1).

Beyond their economic weight, multinationals play a significant institutional role in Slovenia's ecosystem. They introduce regulatory discipline, compliance norms, and organizational practices that diffuse outward. *"When you work with us, you work at a global standard and that standard then becomes the expectation for everyone else"* (Biopharma 3-1).

While corporations enrich the ecosystem, the interviews also reveal significant constraints emerging from their scale, talent needs, and strategic priorities.

Large corporations absorb a substantial share of Slovenia's limited talent pool, intensifying competition and limiting labour availability for SMEs and start-ups. *"We see the pressure already, new investments come, salaries rise, and suddenly everyone struggles to hire. It's not sustainable"* (Biopharma 3-2).

SMEs mirror this concern. *"When a big investment wave comes, we feel it immediately, people are drawn to the corporates and we cannot match that"* (Biopharma 1-1).

Corporations also create structural dependence, where ecosystem actors rely heavily on a few dominant players. "*If the big companies slow down, the whole system slows down. A lot depends on their plans, their cycles, their priorities"* (Biopharma 2-1).

This exposes the ecosystem to global strategic decisions beyond Slovenia's control. Interviewees suggest that corporations shape not only resources but also the discourse around innovation: *"In Slovenia, innovation often means whatever the big companies are doing. Everything else is secondary"* (Biopharma 2-1).

This dominance can overshadow alternative innovation pathways, limiting the perceived value of startups, academic spinouts, or unconventional biotechnology ventures. Corporations impose global quality norms that, while beneficial for ecosystem maturity, can act as barriers for smaller actors: *"The level of documentation and validation we need is extreme, smaller companies struggle to keep up unless they specialize very deeply"* (Biopharma 3-1).

In contrast, multinationals do not perceive capital as a binding constraint. Their investment cycles are determined by global corporate priorities, not local financing conditions. As one interviewee noted, the main risks relate to talent and regulation, not to investment availability. *"Capital is not our issue; regulatory and talent constraints matter more"* (Biopharma3-1).

5.6 Presence of global biopharma trends in Slovenia

Interviewees confirm that Slovenia is fully aligned with global shifts from small molecules to biologics. The multinational subsidiary emphasizes that biologics now dominate the development and manufacturing landscape: *"Most of the growth and future work is in biologics. Our entire site is shifting more in that direction because that is where global demand is going"* (Biopharma 3-1).

This shift influences infrastructure investment, workforce needs, and supplier capabilities. Slovenia's SMEs also experience rising demand for biologics-related technologies. The SME interviewee notes: *"Biologics projects are becoming a larger part of what we do, companies need strain optimization, analytics, faster development cycles"* (Biopharma 1-1).

However, when it comes to advanced modalities such as cell and gene therapies alignment is more nuanced. The multinational interviewee acknowledges that cell and gene therapy capability building is underway but still limited: *"We are developing capabilities in gene and cell technologies, but these things take time and the ecosystem is not yet fully prepared"* (Biopharma 3-2).

Interviewees generally view digitalization and AI as supportive tools rather than disruptive forces. Slovenia's biopharma actors are adopting digital systems, automation, and data-driven processes, but they do not see these technologies replacing experimental biology or core scientific workflows in the foreseeable future.

The SME interviewee is particularly explicit: *"AI helps, but it doesn't solve the biology, you still have to do the experiments, the modelling, the iterations"* (Biopharma 1-1).

This suggests that Slovenia follows global industry sentiment in which digitalization is valuable but not yet transformative. The multinational subsidiary reinforces this incremental view: *"Digital is becoming more important each year, but it is integrated step by step as these are not overnight changes"* (Biopharma 3-1).

Ecosystems have grown through the expansion of CDMOs and CROs, and Slovenia mirrors this trend. For example, some companies had transitioned from a laboratory-equipment provider into a regionally recognized CRO with deep-tech competencies. "*We're no longer just a service lab, companies come to us with extremely complex biological questions because they know we can solve them"* (Biopharma 2-1).

Similarly, some SMEs operate as innovation service providers, offering early development, process optimization, and feasibility studies: *"A lot of what we do is development for other companies where we take their concepts and make them industrial"* (Biopharma 1-1).

The interviews reveal that Slovenia is deeply aligned with global environmental, social, governance and Net Zero trends, largely because multinational corporations must meet stringent European and internal corporate obligations. *"We are going fully off gas, and everything will be electricity and clean steam. This is part of our Net Zero 2030 plan"* (Biopharma 3-2).

These transitions require new infrastructure and operational redesign, all of which have ecosystem-wide implications. *"Companies come to us because they know biological production is the future of sustainable materials"* (Biopharma 1-1).

However, SMEs emphasize that sustainability-driven adoption is constrained by market incentives: *"Industry won't pay a green premium unless regulators force it and the technology is ready, but the economics are not"* (Biopharma 1-1).

Global biopharma faces fluctuating investment cycles, and Slovenia is highly exposed due to its dependence on multinational investment rather than diversified funding. Interviewees describe a significant boom in capital inflows but warn that this may not be sustained: *"This investment cycle is huge, but cycles don't last forever, it will slow down again"* (Biopharma 3-1). They also express concern that Slovenia's institutional environment is not ready to absorb long-term volatility: *"If the big companies reduce investment, we have nothing to cushion the fall because domestic capital is almost non-existent"* (Biopharma 2-1).

Interviewees highlight significant organizational adaptation in response to global trends. For example, the multinational subsidiary emphasizes the value of end-to-end integration combined with flexible structures: *"We are reorganizing the site to be more agile - development, pilot, and production must be tightly connected"* (Biopharma 3-1).

However, they also point out that institutional systems outside companies are not adapting at the same pace: *"The companies are rewiring but the country's processes are not. We move fast; the environment does not"* (Biopharma 3-2).

SMEs similarly observe that organizational agility is a competitive advantage: *"We can pivot or scale quickly, but big companies cannot, which is why they come to us"* (Biopharma 1-1).

5.7 Discussion

The empirical findings largely confirm the theoretical expectations established in chapter 4, yet they also reveal important complexities and that extend beyond the theoretical frameworks. The main empirical findings of the thesis are presented in Table 5.

Table 7: Key empirical findings

Topic	**Key empirical findings**	**Relevant research question(s)**
Ecosystem development	Strong scientific and industrial base. Ecosystem growth is driven by multinational anchors. Fragmentation and administrative delays limit progress. Large investment cycles create windows of opportunity but also systemic vulnerability when cycles slow.	RQ1, RQ2
Actor roles & interdependencies	Multinational firms act as ecosystem anchors, shaping standards, labour markets, and supplier capabilities. SMEs serve as specialised problem-solvers and complementors, essential for resolving bottlenecks that corporates cannot solve internally. Interdependencies are strong at the bilateral level but weak at the ecosystem level due to insufficient coordination structures.	RQ1
Complementarities (Jacobides et al., 2018)	SMEs hold unique, hard-to-replace expertise: complementarities strengthen competitiveness but increase fragility due to talent shortages.	RQ1
Ecosystem maturity (Bettanti et al., 2021)	High-quality infrastructure but limited translational capacity. Funding gaps are severe: domestic venture capital is too shallow to support biotech growth. Talent quality is high, but talent quantity is critically low. Cultural risk aversion and procedural delays hinder commercialisation and start-up formation.	RQ2, RQ3
Corporate influence (Herzog et al., 2024)	Corporations upgrade supplier capabilities and raise standards but also absorb talent and dominate strategic direction, creating dependency risks.	RQ1, RQ3
Global trends	Slovenia is fully aligned with the global shift toward biologics and biosimilars, supported by EUR 1 billion recent investments. Early capabilities emerging in CGT analytics, but the ecosystem lacks infrastructure to lead in advanced modalities. Digitalisation is progressing incrementally, viewed as supportive rather than transformative. Slovenia is exposed to global trends but not yet structurally equipped to drive them.	RQ1, RQ4
Demand and innovation	Sophisticated corporate demand drives SME innovation. Domestic clinical and translational demand remains weak.	RQ2
Talent conditions	High competence but insufficient supply; labour shortages affect SMEs and corporations; workforce pressure increasing with new investments.	RQ2, RQ3
Institutional environment	Slow procedures and regulatory rigidity hinder scaling and project execution; limited agility reduces competitiveness.	RQ3
Ecosystem coordination	Collaboration remains fragmented: lack of orchestrator, however Biotech Hills is emerging but is still early-stage.	RQ1, RQ4
System vulnerabilities	High sensitivity to investment cycles and labour-market shifts. Small-country dynamics amplify risks.	RQ3, RQ4

Source: Own work.

Across the interviews, actors describe an ecosystem built on dense interdependencies, specialized complementarities, and strong industrial anchors. At the same time, they highlight persistent misalignments, institutional frictions, and demographic constraints that complicate the ecosystem's ability to realize its full potential.

Interviewees consistently affirm the core premise of Adner et al. (2017) ecosystem-as-structure: that biopharmaceutical activity in Slovenia depends on coordinated roles and tightly linked interdependencies. The multinational subsidiary emphasizes this mutual dependence when explaining project execution: *"When we transfer a project from development to production, there are many steps in between, and every actor must understand their role or timelines slip"* (Biopharma 3-1). SMEs similarly describe their work as embedded within value chains that require strong upstream and downstream performance: *"The projects we take on are usually in the middle of the value chain and we depend on good upstream work from them, and they depend on our downstream expertise"* (Biopharma 1-1). These observations reinforce the theoretical expectation that ecosystems function effectively only when actors are aligned across sequential and reciprocal interdependencies.

The interview material also strongly supports Jacobides et al. (2018) theory of non-generic complementarities. The SMEs interviewed highlight how their specialized expertise defines their role in the ecosystem. One respondent notes, *"What we do is extremely specific, our people spend years learning just one platform or one organism"* (Biopharma 1-1), emphasizing the cumulative nature of these capabilities. Such expertise cannot simply be substituted or replicated inside multinational firms, making SMEs indispensable complementors in the ecosystem. This is further illustrated by their contribution to problem-solving and innovation: The empirical findings therefore validate the theoretical emphasis on complementarities as key structural drivers of ecosystem emergence.

However, Slovenia diverges from theoretical expectations around governance. While theory acknowledges that emerging ecosystems often rely on informal coordination, the interviews reveal a system that depends almost entirely on relational governance, with limited institutional support for ecosystem-wide alignment. As one interviewee explains, *"We have great pieces, but they don't talk to each other unless someone forces the conversation"* (Biopharma 2-1). This confirms the presence of informal governance but highlights a significant gap in systemic coordination. Although initiatives such as Biotech Hills are emerging to fulfil an orchestrating function, stakeholders perceive these efforts as nascent*: "It's a beginning, not a full solution, but at least it puts everyone in the same room"* (Biopharma 2-1). This suggests partial alignment with theory - ecosystem coordination exists, but not at the maturity level required for strategic coherence.

Bettanti et al. (2021) five forces framework is strongly reflected in interview data, especially in the contrast between Slovenia's sophisticated infrastructure and its underdeveloped capital and talent systems. Interviewees regard Slovenia's industrial and scientific assets as highly

advanced. As one multinational representative notes, *"We can run some very advanced operations here that even larger countries struggle to do end-to-end"* (Biopharma 3-1). Yet this strength is counterbalanced by chronic limitations in domestic funding: *"If we look only at Slovenia, there is not enough capital to take even a handful of promising ideas to scale"* (Biopharma 2-1). Talent shortages further constrain ecosystem maturity. Demand for highly educated workers greatly exceeds supply, as interviewees point out: *"There is just not enough talent for the growth happening now, everyone feels the shortage at the same time"* (Biopharma 3-2). Cultural hesitation around risk-taking and collaboration compounds these structural challenges. These findings confirm that ecosystems may possess strong infrastructure and technological capability yet remain stalled by weak talent pipelines, limited financial mechanisms, and risk-averse cultural norms.

A synthesis across Bettanti et al. (2021) stakeholder groups reveal several recurrent patterns. Multinational corporations function as ecosystem anchors, providing stability, advanced infrastructure, regulatory capability and global integration, while absorbing a disproportionate share of specialized talent. SMEs supply high-value specialized services in analytics, engineering, automation and bioprocessing, but remain structurally dependent on multinational demand and lack independent pathways to scale. Research institutes such as JSI, KI and NIB demonstrate strong scientific output but lack intermediary translational capacities needed to convert research into industrial or entrepreneurial activity (Amanatidou & Cox, 2025; Ministry of Health, 2023; OECD, 2025b). Clinical institutions are fragmented and under-resourced, with limited early-phase clinical research capacity, constraining clinical pull and slowing translational development (Klemenc, 2019; Ministry of Health, 2023). Start-ups face severe early-stage funding constraints, restrictive taxation and insufficient access to translational infrastructure, inhibiting venture formation and growth (European Commission, 2025; OECD, 2025b). Government bodies show alignment at the strategic level, especially in attracting large investments, but their effectiveness is limited by slow administrative execution, inconsistent procedures and permitting delays (OECD, 2025b; Ministry of Health, 2023). Investors remain few and narrow in sectoral expertise, resulting in shallow venture capital depth relative to EU benchmarks and increasing dependence on EU programs (European Commission, 2025). Lastly, support organizations, including SRIP Zdravje–Medicina, technology parks and emerging initiatives such as Biotech Hills, contribute to coordination and ecosystem visibility but currently lack the authority, mandate or resources to overcome structural bottlenecks (SRIP Zdravje–Medicina, n.d.).

The interviews also validate Herzog et al. (2024) dual perspective on corporate influence. Corporations enrich the ecosystem by bringing resources, expertise, and legitimacy. As one multinational representative explains, *"Every major project brings new competencies into the country… suppliers grow, our people grow, the whole chain grows*" (Biopharma 3-1). Yet their influence also produces systemic constraints, especially in talent markets. This confirms the theoretical expectation that corporations simultaneously drive ecosystem development and inadvertently inhibit diversification or entrepreneurial emergence.

Finally, interviewees highlight Slovenia's exposure to global biopharmaceutical trends, though often without full ecosystem readiness. The shift to biologics, digitalization, and ESG mandates is clearly visible. As one corporate respondent notes, "*We feel global priorities immediately, whether it's sustainability, biologics, or digital requirements"* (Biopharma 3-2). Yet readiness for more advanced trends, such as cell and gene therapy or AI-driven discovery, remains partial: *"Slovenia will feel these trends, but we do not yet have the structures to lead them"* (Biopharma 2-1).

Beyond theoretical confirmation or contradiction, the interviews reveal additional ecosystem dynamics not fully captured in the literature. Stakeholders emphasize the volatility of investment cycles, noting that Slovenia's current boom may not be sustainable: *"This cycle is exceptional, but cycles end. What happens after?"* (Biopharma 3-2). They also note the disproportionate impact of corporate decisions in a small country: *"One decision by a big company can shift the entire labor market in a week"* (Biopharma 2-1). Administrative and bureaucratic friction emerges as another decisive factor limiting innovation: *"We can innovate faster than the environment can support and procedures slow everything down"* (Biopharma 1-1).

Taken together, the interviews show that Slovenia's biopharmaceutical ecosystem is both strong and fragile at the same time. On the one hand, the country has very good scientific knowledge, advanced industrial facilities, and companies that work well together through specialized roles and complementarities. Large multinational firms also act as important anchors that bring stability and set high standards. On the other hand, the ecosystem faces several important weaknesses. There are gaps in coordination between key actors, not enough skilled workers to support rapid growth, and slow institutional processes that make it difficult to act quickly. In addition, Slovenia depends heavily on investment decisions made abroad, which makes the system sensitive to global changes.

The theories discussed in chapter 4 help explain many of these patterns, but the empirical findings give a clearer picture: Slovenia's ecosystem is standing "on the threshold". This means it has many opportunities to grow into a strong biotechnology hub, but these opportunities cannot be fully realized unless the country addresses its structural challenges, especially talent shortages, weak coordination, and limited long-term support structures. Without tackling these issues, the ecosystem may struggle to maintain momentum and achieve sustainable development.

This research is subject to several limitations that should be considered when interpreting the findings. First, the study is based on a qualitative research design relying on semi-structured interviews with a limited number of key ecosystem actors. While this approach is appropriate for analysing ecosystem structure, interdependencies, and governance, it does not aim for statistical representativeness. The findings therefore support analytical rather than empirical

generalisation. In addition, the interview sample is weighted toward multinational subsidiaries, advanced SMEs, and ecosystem intermediaries, while perspectives of early-stage start-ups, venture capital investors, regulators, and purely academic actors are less represented.

Second, the analysis captures the Slovenian biopharmaceutical ecosystem at a specific point in time, during a period of strong multinational investment activity. As such, some findings, particularly those related to infrastructure expansion, talent pressure, and ecosystem optimism, may be influenced by cyclical investment dynamics. Furthermore, the study focuses on structural and institutional characteristics rather than quantitative performance indicators, such as patent activity or R&D productivity, which limits direct measurement of economic outcomes. Finally, the findings are context-specific to Slovenia as a small, open economy and may not be directly transferable to larger or structurally different ecosystems.

6 CONCLUSION

The analysis shows that Slovenia possesses a set of strong foundational capabilities. Its biopharmaceutical sector has developed through decades of investment in natural sciences, industrial upgrading, and sustained collaboration between multinational corporations, specialized SMEs, and public research institutions. As a result, Slovenia now hosts advanced biologics and biosimilar manufacturing sites, a technically skilled workforce, and globally competitive niche companies in fields such as synthetic biology, viral-vector analytics, and bioprocess engineering. These capabilities reflect what Jacobides et al. (2018) describe as non-generic complementarities, unique, difficult-to-replicate competencies that position Slovenia advantageously within specialized segments of the global value chain.

At the same time, the study confirms the relevance of Adner's (2017) concept of alignment structure. Slovenia's ecosystem exhibits strong bilateral interdependencies, particularly between multinational anchors and specialized SMEs, but weaker system-level coordination mechanisms. Interviews consistently highlight fragmentation between research organizations, industry, government bodies, and potential investors, as well as limited translational capacity and slow administrative processes. These weaknesses create misalignments that prevent the ecosystem from fully leveraging its scientific and industrial strengths. According to Adner (2017) framework, such misalignments increase the risk of co-innovation failures and adoption-chain breakdowns, especially in a domain as interdependent as biopharmaceutical development.

Applying Bettanti et al. (2021) five driving forces further highlights Slovenia's uneven ecosystem maturity. Specialized infrastructure emerges as Slovenia's strongest dimension, with advanced production facilities, national research institutes, CDMOs/CROs, and digital platforms forming a coherent physical and scientific base. Demand is sophisticated in pockets, particularly within multinational development pipelines and rare disease initiatives, but remains limited in scope at the national level. Human capital constitutes a critical bottleneck,

as talent quality is high, but talent quantity is insufficient to meet rapid industrial expansion. Funding represents the most significant structural gap: Slovenia lacks a deep venture-capital market for biotechnology, and early-stage financing remains fragmented and risk-averse. Cultural and institutional conditions further constrain entrepreneurial activity, with interviewees highlighting risk aversion, slow procedures, and limited incentives for translational research. Altogether, these findings suggest that Slovenia's ecosystem is strong in its technological core but weaker in the systemic conditions needed to generate continuous, innovation-driven growth.

Herzog et al. (2024) framework helps explain the dual role of multinational corporations in this context. Corporations such as Novartis and Sandoz act as resource engines, driving supplier upgrading, skill development, and diffusion of global regulatory and operational standards. Their presence significantly enriches the ecosystem and enhances Slovenia's international credibility. However, the empirical analysis also demonstrates that these corporations unintentionally impose constraints: they absorb a disproportionate share of limited talent, shape ecosystem priorities according to global rather than national needs and create structural dependencies that amplify vulnerability to external investment cycles. While multinational anchors remain indispensable, the Slovenian ecosystem cannot rely solely on them as long-term orchestrators of national innovation.

Across all findings, a central theme emerges: Slovenia stands at an inflection point. The country has acquired scientific depth, industrial capability, and specialized expertise that are rare for a small state. Yet these advantages have not yet translated into a fully coherent, strategically aligned biopharmaceutical ecosystem. The empirical evidence suggests that Slovenia's primary constraints are fragmented coordination, insufficient talent supply, limited venture financing, and administrative inertia. They are systemic rather than technological and without addressing these issues, Slovenia risks underutilizing its existing strengths. With that it might miss the opportunity created by the current wave of investment and global interest in biologics and advanced therapies.

The establishment of the Biotech Hills initiative, together with SRIP Health–Medicine, appears to represent an emerging response to these systemic coordination gaps. Both initiatives aim to strengthen ecosystem governance by linking industry, academia, government, and capital providers into a coherent strategic platform. Whether these initiatives can evolve into effective orchestrators, in the sense suggested by ecosystem literature, will depend on their ability to secure stable governance mandates, institutional legitimacy, and long-term funding.

The research question, how do the structural and institutional characteristics of Slovenia's biopharmaceutical ecosystem influence its capacity to evolve into a competitive regional hub, can now be answered directly. Slovenia possesses many of the technological and scientific prerequisites of a regional biopharma hub, including advanced production facilities, strong public research institutes, globally competitive SMEs, and demonstrated capabilities in

biologics, analytics, and bioprocess engineering. These strengths give Slovenia a distinctive competitive profile grounded in non-generic complementarities. However, the country's capacity to develop into a sustainable and competitive hub is constrained by systemic weaknesses in coordination, financing, talent availability, and institutional responsiveness. These characteristics do not preclude hub formation but require deliberate policy design and ecosystem governance to overcome.

The empirical and theoretical analysis converges on a clear conclusion: Slovenia is a capable but incomplete biopharmaceutical ecosystem. Its growth potential is significant, particularly if the country succeeds in mobilizing its scientific assets, strengthening translational infrastructures, expanding talent pipelines, and institutionalizing an orchestrator capable of building long-term alignment. Failure to address these structural gaps may lead to dependency on multinational investment cycles and limit Slovenia's ability to generate homegrown biotechnological innovation.

In simple terms, Slovenia is a capable but incomplete ecosystem. It has the potential to grow into a recognized European biopharma hub, but this will happen only if it strengthens the connections between its actors, invests in people and infrastructure, encourages risk-taking, and builds clear governance structures for long-term ecosystem management. If these improvements are made, Slovenia can transform its existing strengths into a competitive advantage and take an active role in the future of European biopharmaceutical innovation.

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