



Belgium's leadership in Biopharma innovation

Time to act now

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Executive summary

Belgium stands as a well-known Biopharma powerhouse in Europe where R&D, manufacturing, and logistics converge.

With deep expertise in small molecules, vaccines, and antibodies, Belgium has long served as a logistical and biomanufacturing hub at the heart of the European life sciences engine.

Today, **the ecosystem is evolving beyond traditional therapeutic value chains toward more innovative, precise, and personalized modalities** such as next-generation biologics, cell and gene therapies, exosomes, radiopharmaceuticals, and microbiome-based treatments.

Belgium now faces a pivotal crossroads for the future of its Biopharma innovation model. The confluence of macroeconomic and geopolitical headwinds – from trade protectionism and U.S. policy combined with the erosion of Europe's competitiveness through fragmentation and an innovation gap – **calls for a strategic rethinking of how Belgium sustains and grows its leadership.**

We can either remain a valued contributor known for talent, scientific excellence, and manufacturing capacity – effectively acting as a subsidized “service lab” for foreign corporations – or evolve into a strategic headquarters where **intellectual property (IP), capital, and long-term value are anchored and retained domestically.**

More specifically, Belgium's long-term leadership position is today **jeopardized by multiple threats** of which three demonstrate to be existential:

- **The talent gap:** Although our scientific education is widely recognised for its quality and affordability, a deepening shortage of specialized professionals and a decline in STEM enrolment threatens the human capital vital for innovation across multiple scientific domains.

- **Capital and domestic IP drain:** Belgium has successfully deployed R&D incentives to nurture, anchor and valorize IP; nevertheless, the systemic market access and reimbursement barriers, coupled with a lack of domestic scale-up capital, diminish the commercial viability of homegrown IP, causing it and its associated capital to drain away.
- **Fragmented (health) data and patient access:** A fragmented data landscape puts Belgium at a disadvantage to competitors, hindering the advancement of data-driven and AI-enabled innovation, and significantly hindering timely and equitable patient access to innovative care treatments.

To anchor Belgium's leadership in the next generation of Biopharma innovation, a proactive, multi-layered strategy is required. This report proposes elements for the development of a future national roadmap focused on:

- **A unified talent strategy:** Implement a national, cross-sectoral agenda to cultivate and attract specialized Biopharma professionals and entrepreneurial scientists, including international talent, through stronger industry-academia collaboration and faster work and residence permit approvals.
- **An innovative investment climate as foundation:** Deploy aggressive public and private capital to anchor domestic scale-ups, attract international smart money, update R&D incentives to also support innovation in manufacturing capability for the next generation therapies.
- **Data-driven market access:** Leverage health data as a sovereign asset through initiatives like the Health Data Agency, enabling more efficient reimbursement processes through high-quality secondary health data.

By addressing these challenges **with a cohesive, forward-looking strategy**, Belgium can reinforce its competitive edge and redefine its position, not only as Europe's biomanufacturing hub, but as a **global model for sustainable, patient-centric Biopharma innovation.**



Innovation in Biopharma

Innovation in the biopharmaceutical sector is the process of translating scientific discovery into **tangible value** for patients, healthcare systems, and society. It extends beyond the development of novel molecules to **encompass new therapeutic modalities** (e.g., cell and gene therapies, radioligand therapies, antibody drug conjugates), **platform technologies**, **advanced biomanufacturing processes**, **diagnostic tools**, **medical devices** and **digital health solutions**.

The purpose of Innovation

The fundamental purpose of this innovation is to address **significant unmet medical needs**. This is achieved by delivering therapies that offer superior efficacy, improved safety and tolerability profiles, or enhanced convenience over existing standards of care. **For patients**, the goal is an enhanced quality of life and improved health outcomes, particularly for diseases with limited or no treatment options. **For the healthcare system**, innovation can provide greater efficiency and long-term value, for instance, by shifting treatment from chronic management to a one-time curative therapy. **From a corporate perspective**, sustained innovation is the primary driver of growth, competitive advantage, and long-term shareholder value, enabling companies to replenish pipelines and navigate patent expirations.

The burning platform in Biopharma R&D

While the purpose of innovation is clear, the path to achieving it is a rollercoaster. **After more than a decade of declining returns on R&D, the tide is turning**. Deloitte's 15th annual analysis of the projected average internal rate of return (IRR) for the leading 20 Biopharma companies reveals a **second year of growth**, with the rate rising to 5.9 per cent in 2024. This positive trend is driven by a **surge in high-value products entering the late-stage pipeline**, particularly in areas of high unmet need like obesity and diabetes. However, this progress is fragile. R&D costs remain high, driven by factors such as increasing research complexity and high competition in research areas, and continue to pose a threat to sustainable R&D and a productive Biopharma industry.

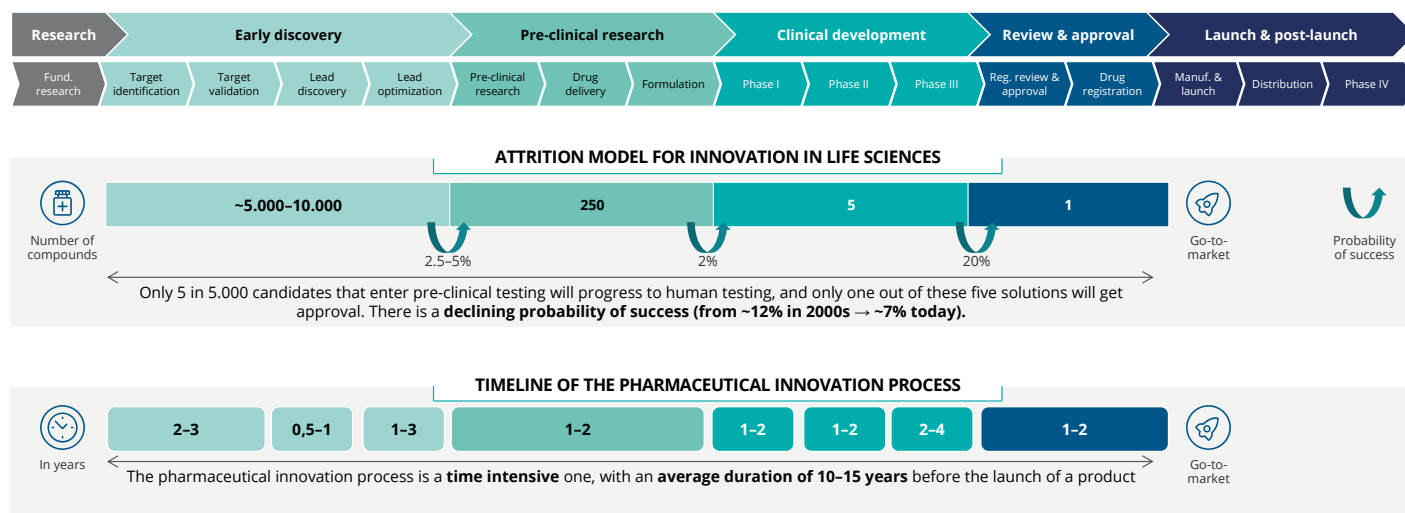
Although our knowledge of biology and pathology is rapidly advancing (thanks to multi-omics), interpreting the data becomes increasingly complex, with subpopulations and sub-diseases emerging as the norm, demanding more comprehensive clinical studies. **Furthermore, the financial burden of bringing**



a new drug to market remains exceedingly high, driving R&D organizations to identify synergies and innovative approaches to manage their cash flow effectively. A recent analysis of 63 novel therapeutic products approved by the FDA between 2009 and 2018 estimated the median capitalized R&D cost per product at \$1.3 billion (i.e., range of \$[1-3] billion depending on products, indications, and research methodologies). This trend, often termed "Eroom's Law," highlights that despite technological advancements, **drug development is becoming more expensive and time-consuming, driven partially by increasing regulatory demands for more complex clinical trial data.**

This **substantial cost is further amplified by the profound risk of failure**. A comprehensive 10-year retrospective analysis by the Biotechnology Innovation Organization (BIO) revealed that the overall likelihood of approval (LOA) for a drug entering Phase 1 trials between 2011 and 2020 was just 7.9%. The probability of success varies significantly by therapeutic area, with oncology programs showing an even lower LOA from Phase 1 at 5.3%. These statistics underscore the capital-intensive and unpredictable nature of (pre)clinical development (figure 1).

Figure 1. In life sciences, the innovation process is characterized by its lengthy, risky and complex character



Looking beyond R&D, the (capital) market is changing

These intrinsic scientific and developmental hurdles are further intensified by external headwinds stemming from a **challenging global macroeconomic environment, creating a dual-pressure scenario across the Biopharma sector.**

First, the global landscape is shifting toward protectionism, exemplified by the re-emergence of Tariff regulations and specific US legislative threats aimed at lowering drug prices. This pressure encourages large corporations to prioritize domestic US production and potentially localize supply chains, diminishing the attractiveness of non-headquarters locations like Belgium for high-value manufacturing and R&D.

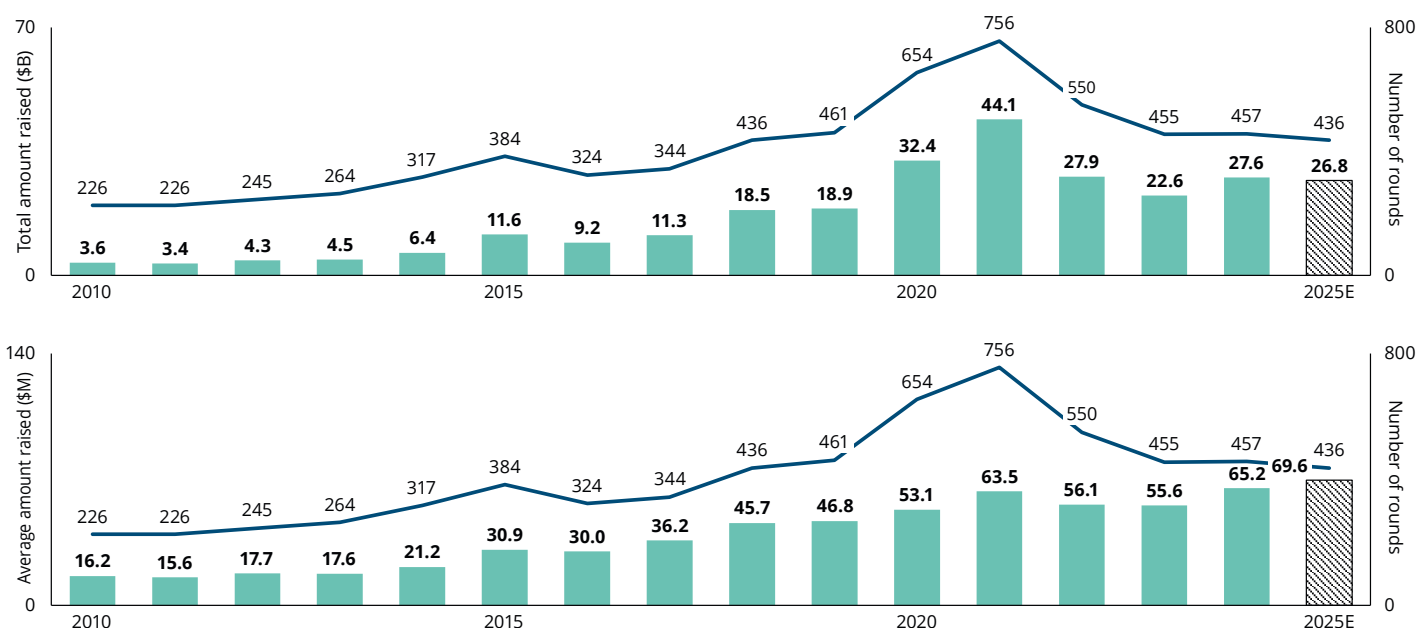
Second, Europe as a whole is grappling with a well-documented loss of economic dynamism. Draghi warns that Europe faces an existential challenge: **without a radical transformation in productivity and growth, it risks losing its global leadership, social model, and fundamental values.** Biopharma stands out as one of the priority sectors deserving dedicated focus. Today, Europe lags significantly behind the US and China in terms of R&D investments in the sector, particularly in frontier technologies like AI-driven drug discovery and Advanced Therapy Medicinal Products (ATMPs). To remain competitive, leading biopharmaceutical companies must sustain and grow their R&D capabilities within the EU and priorities innovation activities locally.

Following the peak of 2021, the biotechnology sector has entered a significant downturn, as reflected in the performance of key indices like the NASDAQ Biotechnology Index (NBI). Persistently high interest rates and market uncertainty have fostered a **climate of profound risk aversion among investors**. This has **led to critical shifts in venture capital (VC) strategy**, including constrained capital deployment and a sharp pivot towards late-stage assets (Phase IIb and later) with clear clinical data and de-risked regulatory pathways. There is a growing trend, even for early-stage VCs that are more risk-taker, to ask more data from animal models and additional pre-clinical validation studies. Overall, investors are prioritizing programs with shorter development timelines and a more predictable, near-term path to an exit, making it substantially more difficult for early-stage science to secure funding.

Concurrently, **large pharmaceutical companies are executing aggressive cost-cutting and portfolio prioritization programs**. These initiatives are driven by impending patent expiries on blockbuster products, downward pricing trends, and the need to reallocate capital towards the most promising R&D and strategic acquisitions.

This convergence of investor caution and large pharma austerity places the traditional biotech financing and exit model at significant risk in a complex, volatile and uncertain macroeconomic context. The IPO window remains largely closed, and while M&A continues, acquirers are more selective, favoring de-risked assets over early-stage platforms. This creates a critical funding gap, the “valley of death”, for early- and mid-stage biotech (figure 2).

Figure 2. The trend of fewer, larger venture capital firms investing predominantly in late-stage Biopharma therapeutic and platform assets raises concerns about funding scarcity for early-stage companies and the potential collapse of the biotech sector

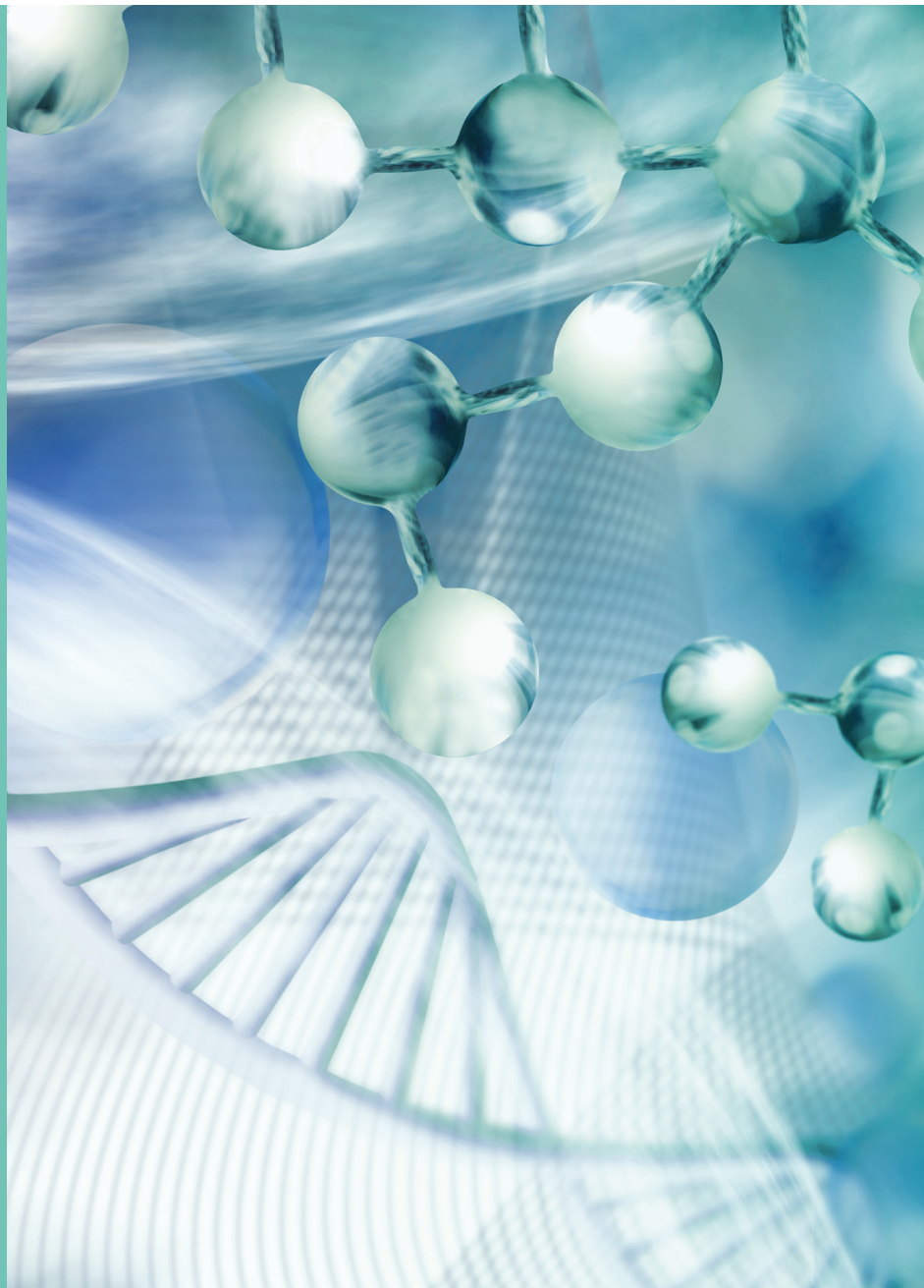


In conclusion, the biopharmaceutical industry stands at a pivotal moment. The scientific promise, particularly in next-generation therapies, has never been more promising; however, the operational and financial challenges are intensifying. Navigating this evolving landscape demands more than groundbreaking science alone. **Future success will belong to companies that demonstrate exceptional capital discipline, strategic focus on truly differentiating assets, and an integrated approach that embeds manufacturing, regulatory, and market access considerations early on within the R&D process.** Ultimately, the ability to close the growing gap between discovery and commercial viability will determine the next generation of leading innovators.

A bold perspective on the Biopharma ecosystem

A bolder perspective suggests that the current market instability reflects not just a cyclical downturn but a fundamental breakdown in the traditional VC-to-Pharma innovation model. This model, which has dominated for decades, relies on a symbiotic relationship where VCs fund high-risk early science with the expectation of a profitable exit via M&A or IPO within a 7-10-year fund lifecycle. However, the long timelines, binary risks, and complex commercial realities of next-generation therapies are fundamentally misaligned with this model's demand for rapid, predictable returns. We may be witnessing the emergence of a new paradigm shaped by non-traditional investors with long-term capital horizons. For instance, the "venture philanthropy" model, exemplified by the Cystic Fibrosis Foundation's ~\$150 million investment in Vertex Pharmaceuticals which led to transformative medicines and a multi-billion-dollar return, provides a proven alternative. In addition, sovereign wealth funds and large pension plans, which possess vast capital reserves and investment horizons measured in decades, not years, are increasingly participating in later-stage private investment rounds.

This transition implies that the future of genuinely disruptive innovation may depend less on revitalising the old model and more on creating a new ecosystem centred around patient, mission-driven capital, fundamentally transforming the journey from discovery to cure.



Belgium matters globally

The prominence of the Belgian Biopharma industry transcends its geographical size. Rooted in its structural importance across the entire biopharmaceutical value chain, from discovery and development to manufacturing and global trade, the quantitative evidence establishes **Belgium not merely as a participant, but as a critical, high-value node in the global ecosystem.**

A macroeconomic footprint signifying trade dominance

Belgium occupies a prominent position in the global pharmaceutical trade. Moreover, the nation is recognized as the fourth-largest exporter of pharmaceutical goods globally, ranking only behind Germany, Switzerland, and the United States. Within the European Union, Belgium's exports of medicinal and pharmaceutical products ranked second by dollar amount in 2022, trailing only Germany. The economic significance of the sector to Belgium's national balance is profound. In 2023, the biopharmaceutical sector generated a trade surplus of **€9.2 billion**. This contribution represented an overwhelming **56% of Belgium's overall national trade surplus** of €16.6 billion, confirming the sector's role as the single largest contributor to the country's positive trade balance. This overwhelming dependence of the national trade surplus on Biopharma means that sustained investments within the sector functions as an essential national economic security measure.

Belgium's role as a major exporter is underpinned by strategic trading relationships. The United States is the primary destination for these products, accounting for **over 50% of Belgium's**

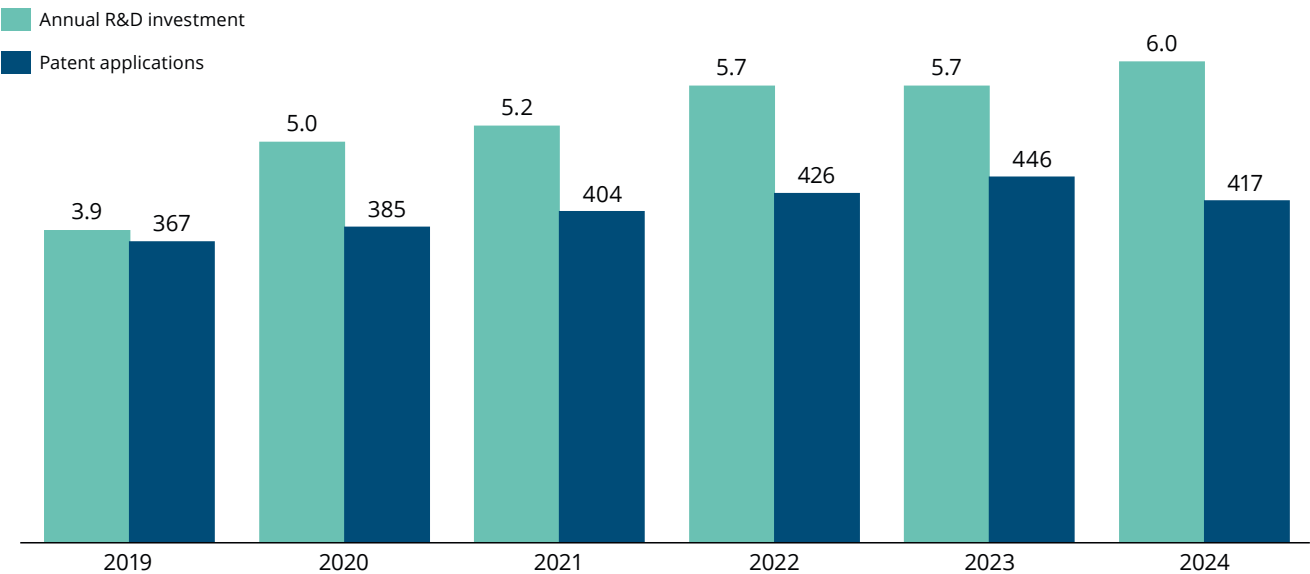
extra-EU medicinal and pharmaceutical product exports in 2024. The threat of introducing significant US tariffs on imported pharmaceuticals, at times proposed as high as 100% on branded products, puts pressure on non-US manufacturers. This is impacting the attractiveness of non-HQ locations such as Belgium. Other significant export destinations include Japan (22.8%) and the United Kingdom (16.1%).

An unparalleled R&D Investment intensity and commitment

The **foundation of Belgium's competitive success lies in its radical commitment to R&D investment**. In 2024, the biopharmaceutical sector invested a total of €6 billion in R&D. This immense spending is disproportionate to the country's size, representing the equivalent of 40% of all private investment made in Belgium and 32% of total national R&D investment. This confirms the sector's singular importance to the national innovation ecosystem.

Furthermore, the **growth trajectory of this investment is accelerating**. Between 2019 and 2024, R&D expenditure in the sector increased by over 53%. Over the same period, the **per-capita Belgian R&D expenditure grew by more than 56%**, a rate nearly two and a half times higher than the overall EU growth percentage for R&D expenditure per capita. Regardless of the significant investment growth, 2024 marked a critical inflection point as well, as the number of **patent applications dropped for a first time**, to 417 applications in 2024 (figure 3).

Figure 3. Evolution of R&D investments (€ billion) and patent applications in Belgium



An end-to-end ecosystem with high density of innovation and specialized talent

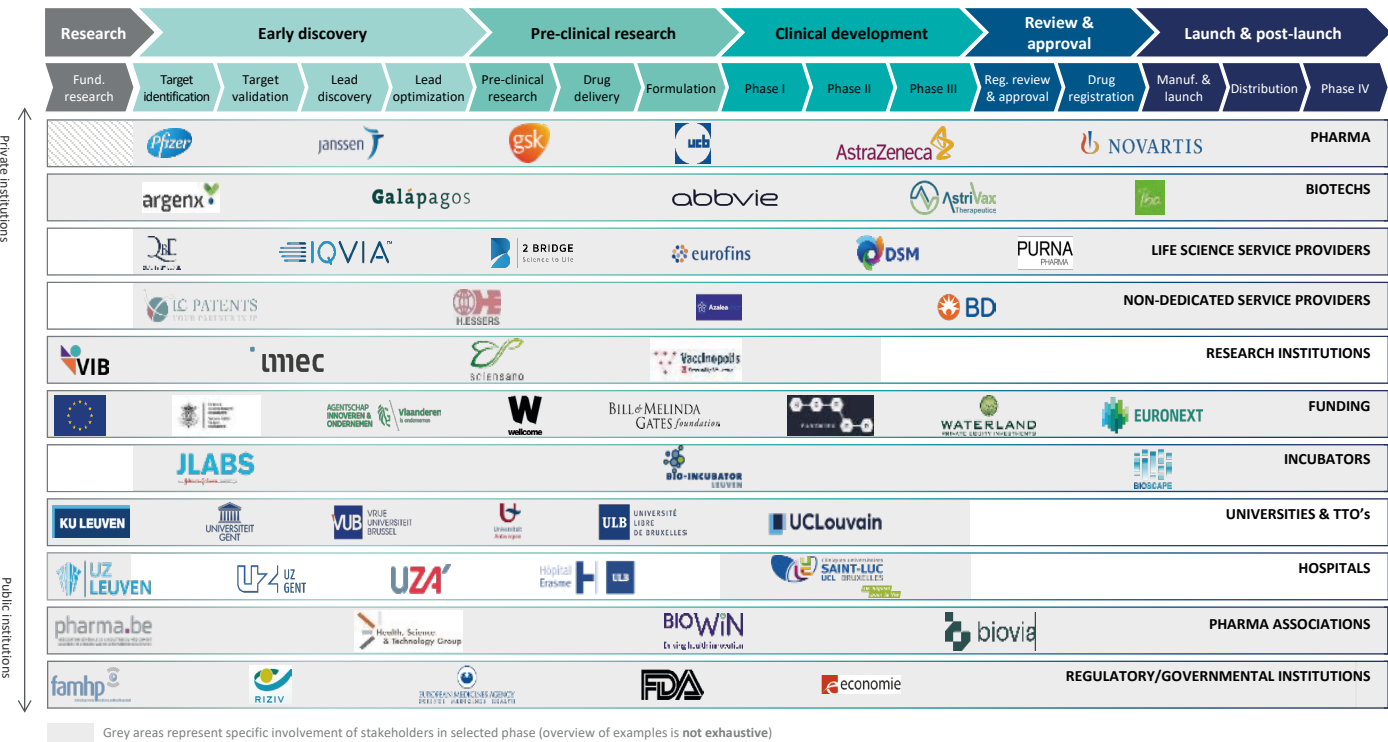
The strategic deployment of capital has attracted an extraordinary concentration of global Biopharma expertise. Belgium hosts subsidiaries of **29 of the world's top 30 biopharmaceutical companies**, 22 headquarters, and 52 R&D facilities. This corporate presence is deeply integrated with a vibrant public and academic network, including **12 universities** and **7 academic hospitals** with internationally recognized life science departments. Additionally, the commercial R&D is powerfully complemented by local biotech firms (and successful unicorns) and international service providers, offering traditional (e.g., synthetics) but also more niche capabilities (e.g., exosome, microbiome, viral vector). The launch of a first clinical trial for exosome in Europe by a Belgian biotech is a clear illustration of the strong innovation fostered by this rich ecosystem. This integrated model ensures that **specialized expertise** and capacity are present **across the entire product lifecycle**. It's even more relevant for ATMPs where co-location with late-stage research,

high-qualified staff and interconnected innovation ecosystem are critical decision factors to attract foreign investments.

Furthermore, this dense biopharmaceutical landscape sustains a significant workforce. In 2024, the biopharmaceutical industry employed over **50,000 people**, representing a notable **16.2% increase** over the preceding five years. However, after a decade of continuous growth, employment declined for the first time by half a percent. Given the broad ecosystem in which Biopharma operates, this decline is adversely impacting multiple sectors, leading to a reduction in **indirect employment as well**.

The result is a myriad of both international as well as local stakeholders operating in this broad ecosystem within a remarkably small geographical area (figure 4). **Capitalizing on this expertise (i.e., our strongholds) and presenting it with a unified voice will be essential to future-proof the ecosystem and to translate R&D investments into economic value.**

Figure 4. Non-exhaustive overview of the different types of private and public institutions presents in the (bio) pharmaceutical sector, and example organizations, active across the product value chain



Anchoring the value chain with innovation as the guarantee for future growth

The structural investments detailed above **translate directly into measurable innovation outputs**, defining Belgium's strategic role. The country is not merely a place with a strong science foundation in Biotechnology (e.g., VIB) and in next-generation biologics (e.g., Argenx), but is a **critical translational and manufacturing anchor for Europe**.

Belgium is firmly positioned as a Top 3 European leader in clinical trials when measured per capita, holding the second position in Europe for both approved clinical studies per capita and for actively enrolling First-in-Human (FIH) studies.

This concentration in early-phase and FIH trials, which grew by 12.5% over the last five years, indicates that global sponsors specifically seek out Belgium's reliable, high-quality environment for managing the most critical initial stages of drug development.

However, this position is under pressure due to the new European Clinical Trials Regulation, exemplified by the declining trends we are observing lately.

This leading position in clinical trials serves a **dual purpose**: it grants Belgian patients rapid, early access to innovative therapies, often years before market launch, and it institutionally anchors the highly complex supply chains and specialized operational expertise required for next-generation medicine development.

Belgium's specialization is particularly critical in the domain of **ATMPs**, including Cell and Gene Therapies (CGT). ATMP trials involve highly complex, often personalized supply chains that link clinical delivery directly to manufacturing and quality control expertise. By coordinating a significant proportion of cutting-edge trial activity, specifically managing 5.1% to 7.2% of all applications for ATMP-related clinical trials in the EU (2022), Belgium leverages clinical success to guarantee the associated manufacturing, and operational expertise remains within the country, reinforcing its position as a translational and manufacturing hotspot.

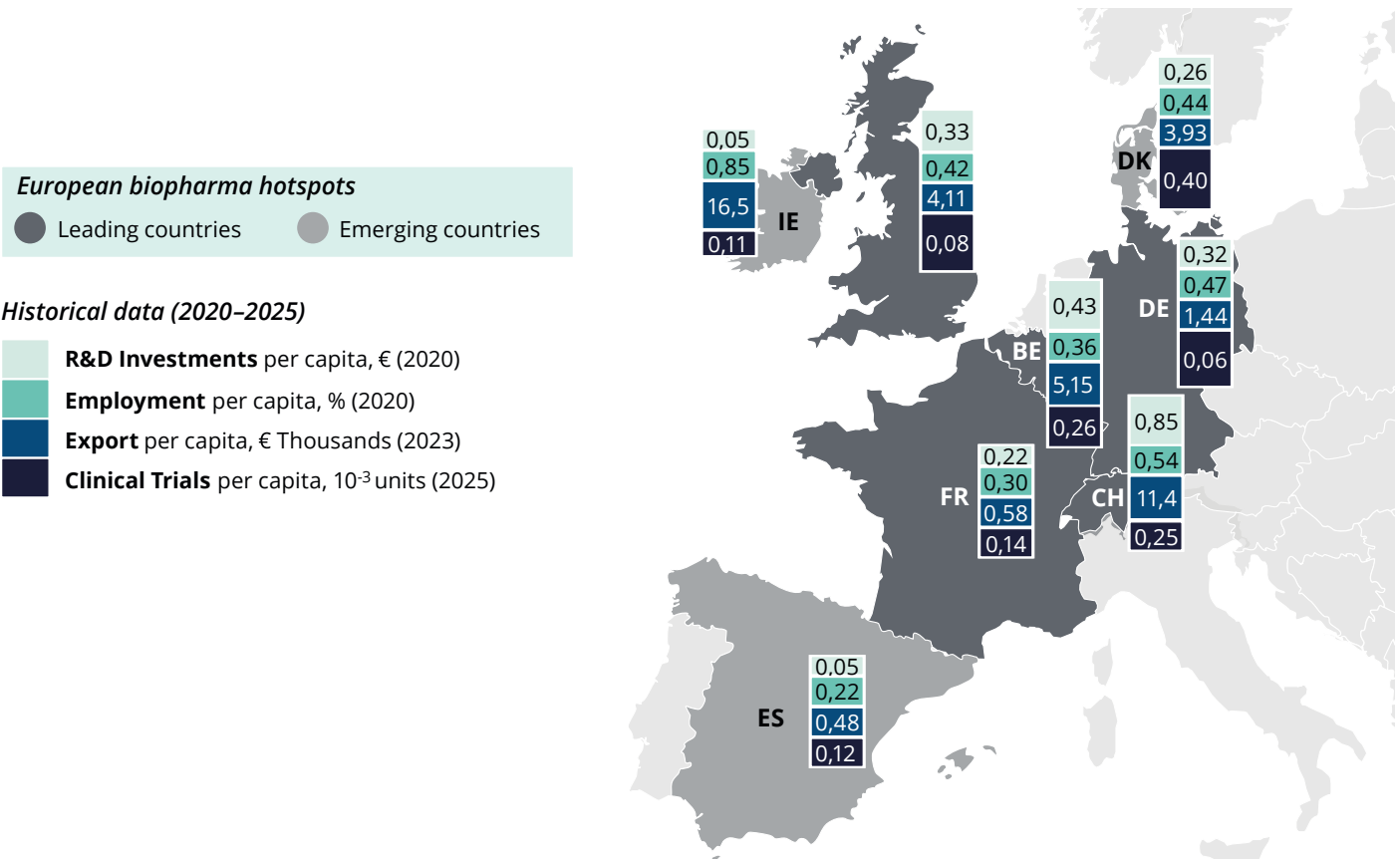
However, this leading position within the international Biopharma landscape cannot be taken for granted. In 2025, **Belgium falls from second to third place in the ranking in terms of**

investment in R&D, patent applications and exports. For the first time, the country is no longer in the top 3 in terms of employment and productivity. This highlights Belgium's position is at risk, and reinforced strategic federal commitment and regional alignments will be required to secure future growth.

Conclusion on Belgium's global positioning

When benchmarking Belgium with some of its peers inside Europe, it can be concluded (figure 5) that **Belgium takes a top three position in terms of clinical trials per capita** and tops the EU list in terms of export per capita, positioning it as a specialized powerhouse and one of the continent's most intensive Biopharma investment hubs. While Denmark leads in total trials per capita Belgium leverages its operational efficiency by pioneering early-phase clinical trials with strong center of excellences, and achieving regulatory approval in significantly faster timelines, far outpacing the standard European pace (see new accelerated timelines effective as of January 2026). **Belgium holds a strong position at the vital crossroads of foundational research, translational sciences, biomanufacturing capabilities, and early-stage trials** (from concept to initial clinical evidence). **However, this position is vulnerable.** We must avoid complacency, as other countries, such as Spain with its focus on clinical trials, are actively deploying aggressive strategies to attract innovation.

Figure 5. Non-exhaustive overview of European Biopharma regions



Understanding Belgium's recipe

Belgium's position as a global biopharmaceutical leader is rooted in a deep history of pioneering science. This legacy was forged in the 20th century through breakthroughs in small molecule drug discovery by Dr. Paul Janssen, whose work laid the foundation for Janssen Pharmaceutica, and in vaccinology by GSK, which operates one of the world's largest vaccine manufacturing facilities in the country. This foundation has effectively nurtured the emergence of novel therapeutic modalities.

A nation of innovators across multiple scientific domains

Today, Belgium is at the forefront of innovation, demonstrated by its first-mover status in cell and gene therapies with some of the earliest approved therapies originating from its ecosystem. This is complemented by world-class excellence in antibody engineering, led by companies like UCB, and the rapid emergence of a radiopharmaceutical hub, leveraging the unique nuclear medicine expertise of the SCK CEN research center. This innovative capacity is further amplified by its role as a global hub for Contract Development and Manufacturing Organizations (CDMOs), making Belgium as a strong biomanufacturing partner in the global supply chain landscape.

The ingredients of success

This **legacy of innovation is actively nurtured by one of the most supportive and advantageous ecosystems** in the world and through the deployment of policy measures incentivizing innovation.

The Belgian government has implemented **a suite of complementary fiscal and financial incentives designed to attract and retain R&D investments**. Key among these is the Innovation Income Deduction (IID), which allows companies to exempt up to 85% of their net IP revenues from corporate taxation, resulting in a highly competitive effective tax rate for companies who invest in the valorization of R&D within our ecosystem. This attractive regime is further complemented with an **R&D tax credit/investment deduction for capital investments, and payroll incentives for researchers** reducing the overall employment cost of innovation talent. The complementarity of these tax incentives are perceived as a unique differentiator of our ecosystem and demonstrated to be an effective tool to attract R&D investments. Additionally, **non-dilutive funding is offered for R&D projects** with preferential support rates for early research projects and small and medium-sized enterprises. However, despite their effectiveness, the support measures today are insufficiently supporting strategic flagship investments in R&D and manufacturing assets needed to secure the future-proofness of our Biopharma industry (OFI, 2024).

Beyond financial incentives, the Belgian healthcare system itself is a strategic asset. The ecosystem described features a high density of world-class hospitals and academic centers, with centers of excellence on specific disease (e.g., oncology) and



modality (e.g., vaccine), making the country a **premium location for clinical trials**. The country is recognized by strong clinical centers with Principal Investigators willing to innovate and adopt new technologies during trials. The **recent decision** by the Belgian Federal Agency for Medicines and Health Products to **fast-track clinical trial reviews as of January 2026** highlights the ambition to preserve this leading position.

These advantages are built upon a comprehensive, end-to-end biopharmaceutical backbone that covers the entire value chain from initial discovery to final delivery. The process begins with a **dense network of internationally acclaimed research institutes**, such as VIB, the de Duve Institute, Plotkin Institute and many others, which **generate a constant stream of high-potential assets and foundational scientific discoveries**. This scientific excellence feeds into a mature ecosystem of incubators, university spin-offs, and established companies. Critically, Belgium possesses a **formidable biomanufacturing capability**, hosting major production sites for numerous global pharmaceutical companies and specialized CDMOs. The final link in the chain is a world-leading logistics infrastructure, led by Brussels Airport. As the first airport in the world to receive the IATA CEIV Pharma certification, its specialized, temperature-controlled supply chain ensures the integrity of sensitive pharmaceutical products for global distribution.

This national backbone is powered by distinct, geographically concentrated hubs of specialization within the axes of the main three regions, Flanders, Brussels and Wallonia, creating a powerful network effect ("spider").

Ghent serves as the heart of the “Flanders biotech valley”, driven by the VIB life sciences research institute and a particular strength in plant biotechnology, agritech, and next-generation biologics. Antwerp, with its vast port and historic chemical industry, is a major cluster for chemical and pharmaceutical production and integrated supply chain hub. The cluster is focusing on vaccine research, mRNA and exploring new modalities such as microbiome. Brussels leverages its position as the capital of Europe to excel as a hub for clinical research organizations (CROs), regulatory affairs, and digital health technology, and specialized in Immunology. The axes around Louvain-La-Neuve, Charleroi and Liège with its CEIV-certified pharma airport, have cultivated

an international renowned specialization in cell and gene therapy, radiopharmaceuticals (diagnostics and therapeutics) and biomanufacturing capabilities (with shared infrastructures).

These interconnected clusters ensure that expertise, talent, and capital are concentrated, fostering rapid innovation and collaboration across the entire country. This complementary of knowledge and local specificities (i.e., cultural) is our famous Belgian recipe. **The strengths and weaknesses can complement each other, and the successes can be learned, shared, and reproduced when the ingredients work.**



Belgium as the global “innovation foundry”

A critical analysis reveals a recurring pattern: Belgian biotech achieve world-class scientific validation **but are frequently acquired by foreign multinationals before reaching full commercial scale.** Conventional wisdom views this as a failure to build standalone, global champions. A bolder perspective reframes this not as a weakness, but as the ecosystem’s ultimate, highly specialized function whereby the ecosystem is further strengthened through the anchoring of foreign capital, knowhow and talent. **Instead of attempting to replicate the US model of creating fully integrated “Big Pharma” companies, Belgium has unconsciously perfected the role of the world’s premier “Innovation Foundry.”** A foundry takes raw scientific ore (discovery) and forges it into high-value, de-risked clinical assets (Phase I/II data). Its entire infrastructure, from R&D incentives to its dense network of translational scientists, is optimized for this precise, capital-efficient de-risking process. By embracing this identity, **Belgium should strategically continue to double down on what it does best:** perfecting the science, validating the technology, and serving as the indispensable, high-value starting block for the entire global biopharmaceutical industry, systematically generating returns through strategic exits.

Headwinds threatening the Belgian advantages

Belgium has built a dense, high-performing Biopharma ecosystem. That position is now exposed to bottlenecks that, if left unaddressed, will/could erode the country's ability to translate science into patient value and domestic economic returns. These are not abstract risks; they are day-to-day frictions that slow hiring, delay access for patients, and weaken the evidence base that payers and investors need. The **pressure** does not come from a single weak spot; it comes **from three places that interact with each other every day: people, access, and data**. When hiring is slow, access decisions are unpredictable, and evidence is hard to assemble, projects hesitate, launches drift, and investors look elsewhere. This chapter explains the **bottlenecks** in plain terms **and why, collectively, they put Belgium's leading position at risk**.

Recent headlines underline this statement. Across parts of the ecosystem, many companies (small, medium, biotech or service providers) have navigated tougher funding cycles, pipeline reprioritizations, partner realignments, and execution resets. The stories differ, but the signal is consistent as previously explained and seen globally (see 2025 MassBio Industry Snapshot): **capital is more selective, evidence thresholds are higher, manufacturing and market-access readiness matter earlier and talent mobility cuts both ways**. None of this negates Belgium's strengths, but it clarifies what must improve to keep value creation here, in our country.

The lessons are practical: (1) Blend financing earlier (public-private co-investment, strategic partnerships) to reduce single-point risk, (2) Build hybrid skills in-house, bench plus GMP/clinical/data, so programs can pivot without losing speed, (3) Nail evidence plans upfront with HTA/payers, including real-world data pathways, to shorten the loop from trial to uptake, (4) Use shared manufacturing and data infrastructure to avoid duplicating fixed costs, and (5) set transparent governance and milestones so boards, payers, and partners can see progress and decide fast.



Without a tighter grip on talent, access predictability and an evidence backbone, Belgium's natural advantages can stall just when programs need to scale. With them, recent challenges become a forcing function – pushing the ecosystem toward stronger, more investable, and more launch-ready growth.

Talent imperative: Binding constraint

The first constraint is people. This involves two key challenges. First, it's about **establishing and maintaining a critical mass of talent across all necessary Biopharma roles, and continually growing that volume to keep pace with sector expansion**. This critical mass is essential, as it will be a key investment factor to attract international companies. Belgium has a **Biopharma talent gap of ~30%, mainly in R&D, biomanufacturing and supply chain** (OFI, 2023). The inflow of new relevant graduates is insufficient to close this gap for all high knowledge industries, including that of the Biopharma, who recruits ca. 4% out of the entire talent pool.

Second, it requires **upskilling the existing workforce to possess multimodal talents**, preparing them for future innovation, and attracting international expertise with deep technical and scientific know-how. Public-private collaboration, regulatory simplification and dedicated programs can make a huge difference in developing, attracting and keeping the right talent (OFI, 2023). Many initiatives are ongoing across the regions (e.g., ViTalent, aptaskill, CESPE, EU Biotech Campus and others) and going in the right directions to prepare our existing talent pool to existing and future innovations. Stronger coordination is needed to amplify existing initiatives and maximize their return for the ecosystem.

Companies, hospitals, and research centers all describe the same pattern: **specialist roles stay unfilled for too long, and the profiles that are hardest to find combine laboratory skills with data, GMP, clinical operations, or regulatory know-how**. These “hybrid” roles are now the norm in cell and gene therapy, radioligand therapy, and advanced biologics. We also see “sciborg” emerging globally, or the urgent needs to have scientific profiles understanding and mastering data and IT to be at the front end of digital transformation programs, ultimately accelerating drug discovery and trials execution. When mid-career staff cannot see clear, credible routes to reskill into these roles, they leave for places that offer them – or they leave the sector altogether. On top of that, **high labour cost and the uncertainty around the stability of payroll-tax incentives complicate workforce planning**. Employers hesitate to expand teams and that hesitation shows up as slower hiring and higher churn. The pinch is sharpest in hospitals, where advanced therapy pathways require tightly staffed, certified teams; gaps there ripple back into trial timelines and launch readiness.



Without predictable access to these skills, investors discount Belgian assets, timelines slip, and scale-up decisions are made up elsewhere.

Market access and reimbursement: Slow, variable and hard to plan against

The second constraint is the **path from assessment to real-world use**. Sponsors and hospitals cannot reliably forecast when decisions will land or what evidence will be considered sufficient. Time-to-reimbursement varies, steps are not always time-bound, and requirements can differ across levels of governance. For rare diseases and next-generation modalities, the combination of small populations, high upfront costs, and uncertainty around long-term outcomes makes decision-making even slower. Meanwhile, **digital health tools and diagnostics that should support therapy value**, by identifying the right patient or tracking outcomes, **face slow procurement and uneven adoption**. All of this blunts Belgium's traditional strength in early-phase trials: if sponsors cannot see a predictable track from trial to uptake, they will validate here and launch elsewhere.



Unpredictable access pathways push evidence generation and launch platforms toward markets with clearer clocks and more mature outcomes frameworks.

Health data fragmentation: The missing evidence backbone

The third constraint is evidence. **Belgium holds rich clinical data across hospitals, payers, and disease registries, but these assets are not consistently linkable, and approvals for secondary use can be slow and variable**. We however see good progress going into that direction, with recent partnership being made between patient center organizations and data-platform companies to better connect individuals with trials and ultimately increase early access innovations. Without secure linkage across care settings (including hospitals), it is hard to follow patient journeys over time (a true end-to-end, from the GP to trial and home monitoring), compare outcomes across centers, or build the real-world evidence that payers now expect to update prices and refine

coverage. Other European systems with more unified registries have moved faster in using real-world data to support decisions. **Belgium risks falling behind not because its data are weaker, but because they are harder to connect and analyze under clear, predictable rules. The result is a slower learning loop after launch and fewer opportunities to prove value in practice.**



Without a high-trust, privacy-preserving data fabric, Belgium cannot compete on RWE speed or quality – now a core driver of HTA decisions and price sustainability.

These three bottlenecks are existential

These constraints reinforce one another. If hiring is slow and skills do not match the work, programs slip. If access is unpredictable, sponsors design launches and evidence plan around other markets. If data cannot flow through a trusted, privacy-preserving pipeline, it takes longer to confirm value and negotiate sustainable prices. **The net effect is leakage: intellectual property is created and de-risked in Belgium, but revenue, scale jobs, and reinvestment occur elsewhere. Investors see the pattern and mark Belgium down on speed and reliability, which tightens late-stage funding and nudges scale-up choices away from the country.** Over time, that erodes clinical gravity: fewer pivotal studies, fewer first-in-human programs that stay through to adoption, and fewer reasons for the next generation of talent to build their careers here. This is why these headwinds are not just operational hassles; they strike at the heart of Belgium's competitive position.

Future Biopharma innovation platforms

The biopharmaceutical industry is undergoing a **structural transformation, evidenced by the dominance of new therapeutic modalities in the late-stage pipeline valuation.**

Small molecules are and will remain important in the development pipeline of Biopharma companies. In research stage, it represents roughly 40% of programs. As of 2025, new modalities capture **60% of the total pharmaceutical pipeline share.** This strategic shift confirms that platforms utilizing enhanced precision and novel delivery mechanisms are commanding a significant market premium. Looking forward, important breakthrough innovation will come from the development of **next generation biologics** (e.g., multi-specific nano-antibodies) and **cell and gene therapies** (e.g., in-vivo CAR-Ts), if the latter is delivering on their promise and proof to be scalable and affordable.

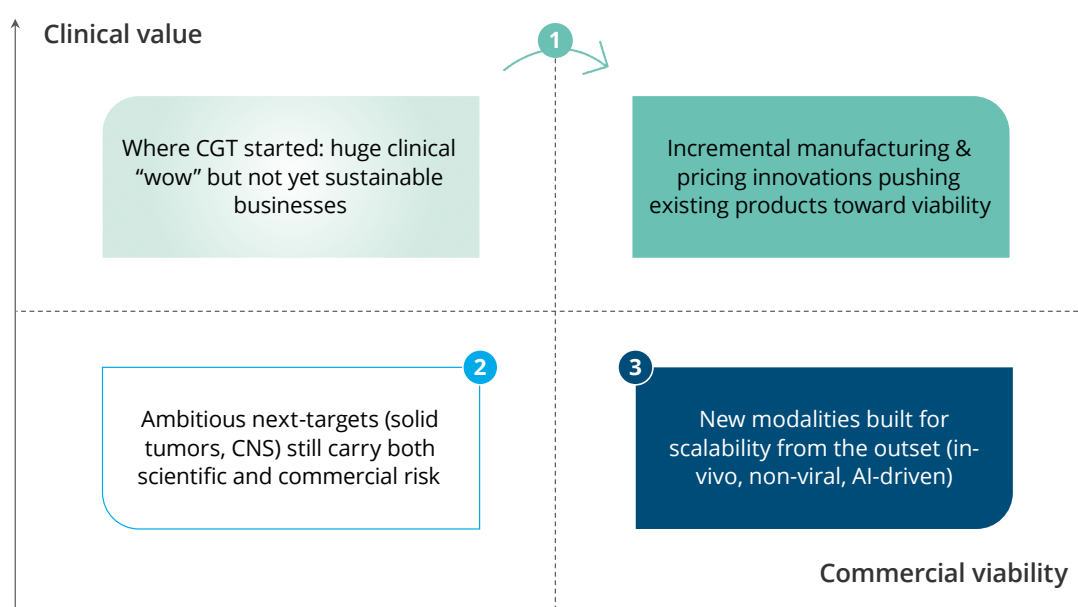
The learnings from the first generation of cell and gene therapies

When we look at innovation and new technologies to save patient's life and cure diseases, we cannot write without mentioning cell

and gene therapies. The **first wave of approved cell and gene therapies has provided critical, and often difficult, lessons.**

The potential is huge because they are addressing fundamentally the disease instead of the pathways. While demonstrating transformative clinical potential (i.e., patient being genetically cured or disease-free survival), products like Zynteglo and Luxturna have exposed **significant commercial, manufacturing and logistical hurdles.** Challenges with complex manufacturing, ultra-high upfront costs challenging reimbursement models, and the logistical burden on qualified treatment centers have limited patient uptake. The primary lesson is that **scientific and clinical success does not guarantee commercial viability** (figure 6). Innovation will come from (1) new technologies to reduce costs of existing products, (2) new assets to target complex tissues (e.g., brain), and (3) new delivery modalities built for scalability at the root. On top of that, innovation must be embedded across processes of our healthcare system to make these therapies a potential standard of care for many disease indications (e.g., innovative reimbursement models).

Figure 6. The cell and gene therapy sector is entering a maturing era, characterized by (1) scaling proven successes, (2) targeting more complex tissue, and (3) developing new delivery methods to address the commercial challenges



The five (+) modalities to watch

Beyond the established market of next-generation biologics that hold a lot of potential (focus of 76% of Biopharma leaders today, up from 50% last year) the selection of the top five pure-play and early-growth therapeutic modalities is **based on a convergence of quantitative clinical validation, technological scalability, and the strategic positioning** to disrupt some high-prevalence chronic diseases (figure 7):

01. In-vivo genomic editing platforms and CRISPR system

expansion (base and prime editing): These represent the highest therapeutic potential by offering single-dose, potentially curative treatments. The successful clinical deployment of LNP technology to achieve deep protein knockdown (e.g., ~90% reduction in transthyretin) establishes a technical standard that allows these platforms to pivot rapidly from rare genetic disorders to massive markets like cardiovascular disease, where the potential for disruption is maximal.

02. Allogeneic, multi-specific and multi-engineered CAR

therapies: This category is selected because it simultaneously solves the commercial and logistical constraints of first-generation cell therapies while maintaining exceptional efficacy. The move to allogeneic, off-the-shelf products lowers the cost of goods sold and expands patient accessibility, while the quantitative clinical superiority of multi-specific designs (e.g., CR rates of 0.77) ensures the highest chance of achieving deep, durable patient responses.

03. Circular RNA (circRNA) and optimized oligonucleotides:

This choice centers on delivery innovation and structural superiority. The technological focus on C16 conjugation and specialized LNPs provides the necessary pathway for oligonucleotides to enter the lucrative and high-need central nervous system market. Concurrently, circRNA's superior stability, evidenced by the exponential growth of its preclinical pipeline (over 40 assets in 2024), positions it as the successor to linear mRNA for long-acting therapeutics.

04. Engineered Live Biotherapeutic Products (LBPs):

The selection of LBPs reflects the maturation of microbiome science from empirical treatments to rational, engineered products. The market growth forecasts (up to 30% CAGR) reflect confidence in this shift. Crucially, the successful advancement of defined LBPs into Phase 2 for complex, systemic immune diseases like graft-versus host disease validates the ability to modulate host pathways effectively, ensuring their relevance far beyond infectious applications.

05. AI-Accelerated Multi-Target Directed Ligands (MTDLs):

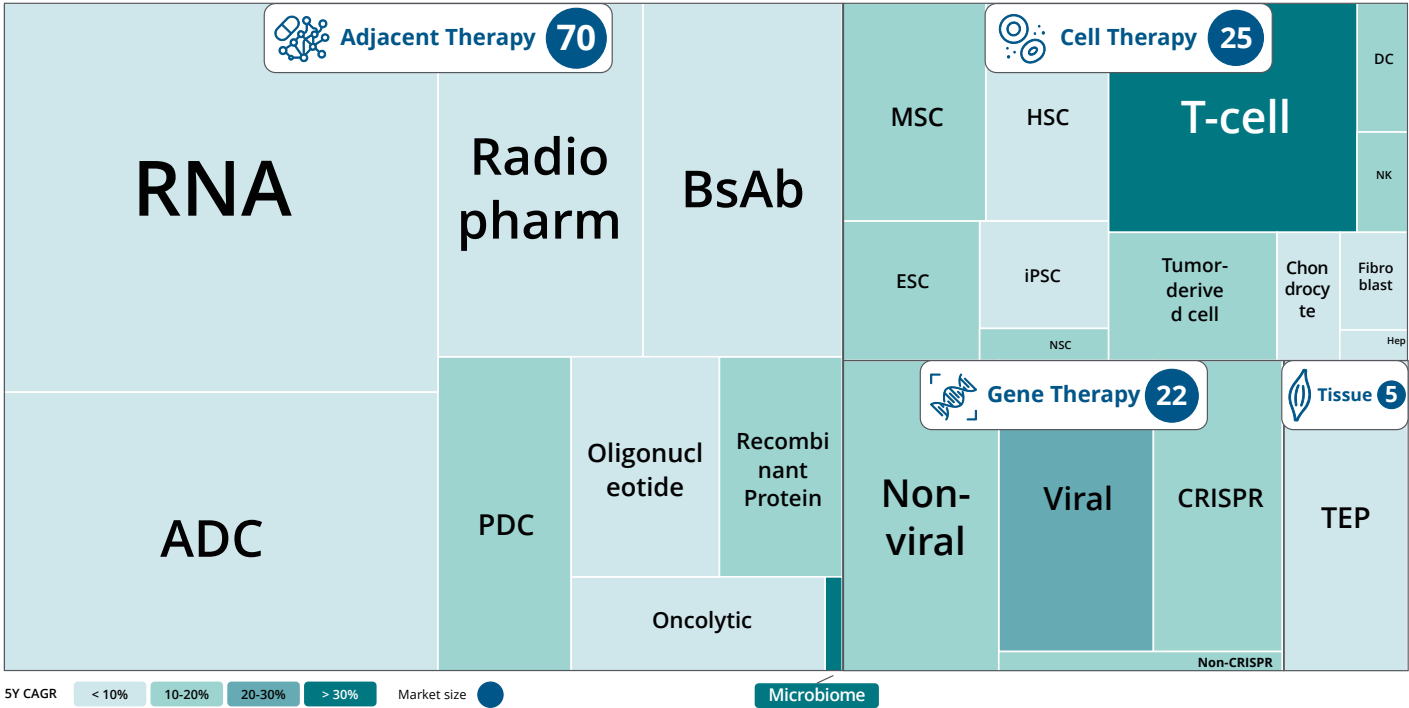
MTDLs are chosen not only because they constitute a significant portion of recent drug approvals (25%) but because their design principles are necessary to treat the most challenging multifactorial diseases. AI is the indispensable cofounder for this complexity, guaranteeing R&D acceleration and higher success rates for the novel therapeutics that enter the clinical pipeline.

New therapeutic concepts are emerging, most notably those that leverage the targeting precision of biologics (i.e., antibody) to deliver highly potent advanced therapies, such as oligonucleotides (RNA-based drugs) or radioisotopes (for radioligand therapies). Recent mega deal (\$10+ billion) confirms that highly sophisticated, targeted delivery methods are seen as the next frontier with multi-billion-dollar potential, particularly for diseases that were previously hard to treat. This **validates the strategic importance of developing technologies at the intersection of these two fields**, as they can drive significant premiums in the market.

Last, but not least, the **combination of physical technology** (e.g., devices) **and biology** (i.e., sciences) is **revolutionizing therapeutic delivery**, creating a robust, high-growth sector centered on Drug-Device Combinations (DDCs) designed for novel localized delivery modalities. These systems, such as advanced intravesical drug-releasing systems (e.g., for non-muscle invasive bladder cancer) and image-guided injections (e.g., endoscopic ultrasound-guided fine needle injection for targeted oncology), strategically aim to overcome systemic pharmacological limitations by achieving high local therapeutic concentrations while minimizing adverse events and tissue exposure time. The **global DDC market demonstrates impressive scale and stable growth**, projected to reach approximately \$200 billion by 2029 (CAGR of 9%), driven largely by improved patient adherence and the demand for home-based care. The strategic future of DDCs lies not in direct competition with CGT, LBP or other high-potential innovation, but in their critical role as enabling platforms: DDCs provide the necessary engineering solutions to unlock the therapeutic potential of new, high-science biological payloads, including localized delivery of biologics, radio enhancers, and potentially viral and non-viral vectors, thereby acting as an essential, lower-risk mechanism to monetize both established and cutting-edge therapeutic assets.

The optimal investment area is convergence, where DDC technology is applied to complex biological or more advanced modalities (e.g., delivering medicine directly to the brain) to mitigate the physiological delivery barrier or tissue complexities, which remains a key cause of failure for high-science biologics or ATMP drugs (e.g., off-targets and side-effects on healthy organs).

Figure 7. Global market size (\$B) and projected 5 years growth (%) of next generation therapies



Strategic elements of a future roadmap

Belgium requires more than ambition to retain innovation domestically and to be ready for the transformative and promising healthcare interventions currently in development. As a nation rich in talent and diverse institutions, it needs a comprehensive toolkit and multiple levers, all aligned towards keeping discovery, development, and patient access within its borders. To this end, four key levers – skills, predictable access, a functional data infrastructure, and patient, long-term capital – have been identified and mapped out in an initial proposed timeline (figure 8).

Unified talent strategy

Belgium's competitive edge is rooted in its people. The aim is to **build a steady flow of skills that match what R&D centers, biomanufacturing plants and hospitals need**, and to keep those people here as projects move from early research to real-world use. In practice, that means a **common view of priority roles**, simple routes for experienced staff to reskill, and predictable rules that make Belgium an easy place to hire and stay. Universities and training providers align curricula with industry demand; hospitals develop advanced-therapy capabilities as a core function, not an exception; employers can plan around stable and competitive incentives rather than one-off fixes. The near-term result is shorter time to fill key roles and less churn at scale-up; the longer-term result is a workforce that grows with new modalities instead of lagging behind.

Policy acceleration for market access

The second element is predictability from assessment to adoption. **Companies and hospitals should be able to forecast when decisions will be made, what evidence matters, and how real-world use feeds back into pricing and coverage.** The direction here is straightforward: time-bound pathways, early and joined-up dialogue between regulators, payers, and sponsors, and routine use of real-world evidence to refine decisions after launch. Patients benefit from earlier, safer access; payers gain confidence that funding follows value; sponsors can plan studies and launches without guessing. **The guiding principle: access should move at the speed of credible evidence, with transparent milestones and no hidden steps.**

Health data and evidence backbone

Belgium also needs a **data layer that makes everyday care usable as evidence**. The goal is simple: when a therapy is tested or used in Belgium, the country can show what happens to patients and budgets – quickly, while respecting data security. That requires a common way of structuring data across hospitals, payers, and registries, clear approval for responsible secondary use, and analysis environments where insights can be generated without shipping data around. Over time, diagnostics, digital measures, and patient-reported outcomes should flow into the same fabric so that access decisions can be made fast and be refined after launch. This would not be an IT project; it would be the mechanism that turns practice into proof and anchors high-value innovation in Belgium.

Ecosystem fortification and governance

Finally, Belgium requires a strong backbone that anchors scale decisions within its borders. That means **consistent, long-horizon capital for translation and growth, coordinated priorities across federal and regional levels, and a simple public narrative about what Belgium offers to innovators and investors**. It also requires innovation in manufacturing. Governance should be light but firm: a single table that sets direction, tracks a few meaningful indicators, and resolves bottlenecks before they become headlines. Regions play to their strengths; national coordination prevents duplication and mixed signals. Branding is not window dressing here – it tells a coherent story about Belgium as the best place in Europe to validate, manufacture, and launch next-generation therapies.

If Belgium means to tackle these four roadblocks – talent, market access, ecosystem strength, and the health-data backbone – it **needs a plan for change**. A plan that is structured, but also adaptable. The Implementation Playbook provides that plan: a practical, 36-month sequence that begins with quick wins, builds shared capacity, and then scales what works so it endures. However, it is a proposed guide and is meant to be modular and region aware. Actions can be phased, tailored to local capabilities, and refined through expert reviews, stakeholder input and public scorecards, so progress keeps happening, even as actions adapt to new insights and local realities.

Figure 8. Suggested elements and timeline to anchor innovation in the Belgian Biopharma sector

Pillar	Quick wins 0-12 months	Build 12-24 months	Scale & institutionalize 24-36 months
Unified talent strategy	Publish National Biopharma Skills Agenda.	Establish Inter-Regional Training Hubs with simulators, pilot lines, cleanrooms.	Link hospital reimbursement to certified advanced-therapy teams.
	Release role/competency maps for key biopharma roles.		
	Launch 6-12 week bootcamps for GMP/GCLP/QA/data roles.	Embed industry co-teaching and capstones in master's; link funding to placements.	Publish KPIs and public dashboards on vacancies, CoEs, trained staff, placement rates.
	Fast-track visas and clarify tax rules for hard-to-fill roles.		
Policy acceleration for market access	Start clinical fellowships for CoE staffing.	Pilot rapid access with conditional funding linked to registry participation.	Institutionalise annual access reviews to adjust prices by outcomes.
	Set decision clocks for advice, HTA, pricing, RWD approval; publish dashboard.		
	Run early parallel advice for ATMP/RLT/rare diseases; agree endpoints and RWE plans.		
Health data & evidence backbone	Issue risk-sharing templates; remove hospital exposure for unused products.	Pool regional procurement for complex therapies to concentrate volume and track outcomes.	Shift high-value launches to pre-agreed RWE pathways.
	Agree common data model and governance for EHRs, claims, registries, PROMs.		
	Create single approval channel for secondary use with timelines.		
Ecosystem fortification & long-horizon capital	Launch therapy-agnostic registries with minimal datasets and automation.	Integrate companion diagnostics and digital endpoints for value and post-launch support.	Publish RWE reports to guide label and price updates.
	Agree common data model and governance for EHRs, claims, registries, PROMs.		
	Create single approval channel for secondary use with timelines.		
Ecosystem fortification & long-horizon capital	Launch co-investment platform blending public, venture-philanthropy, pension/sovereign funds.	Create mid-scale manufacturing hubs with shared QA/QP, analytics, tech-transfer.	Establish national brand: "Belgium—Europe's Gateway for Next-Gen Therapies."
	Offer match-funding for shared GMP/radiopharm upgrades with open SME access.		
	Set up national launch-readiness office to coordinate trials, access, and RWE.		
Ecosystem fortification & long-horizon capital	Set up national launch-readiness office to coordinate trials, access, and RWE.	Renew co-investment mandates based on performance.	



Our three recommendations to anchor Biopharma innovation in Belgium

Belgium's pharmaceutical sector is a European R&D powerhouse that is **failing to capture its own value**. We excel at incubating innovation with public money, only to see our companies flee to the US for scale-up capital and our patients wait endlessly for therapies we invented. Our ecosystem is **currently optimized for discovery** (and we are good at it), **not for ultimate success and domestic benefit**. This potential competitive strategic asset is too often perceived as a cost driver or a niche sector, rather than a crucial investment with significant economic return.

To shift this paradigm and ensure the Biopharma sector is strategically managed rather than subject to political volatility,

Belgium could establish a dedicated Life Sciences Council. This body would consistently benchmark our performance as a pulse check against global competitors and ensure our national strategy is a competitive force.

Complacency is no longer an option. **To solidify our existing position as Innovation Foundry** and capitalize on core strengths – talent, science, biomanufacturing – Belgium has an opportunity to **take full ownership of R&D outcomes** through deployment of three bold, strategic actions:



Enhance R&D incentives.

Belgium has put in place robust R&D tax incentives and cash grants which have proven to be effective in attracting R&D investments. However, today, these support measures are no longer distinctive, as they fall short in adequately backing strategic flagship investments essential to ensure long-term resilience of our (bio)pharma industry. To secure the competitiveness of our innovation ecosystem, there is a need to **enhance the effectiveness and ticket sizes of the available R&D incentives** through an increased focus on de-risking and accelerating the valorisation of breakthrough innovation.



Building a patient-centric data backbone.

Our current approach to fragmented health data is hindering the full potential of our innovation. There is a need for a **single, state-supported "Health Data Utility" designed to establish the trustworthy rails for patient data usage**. This entity's core mission would be to legally and technically enable FAIR data usage. This utility would create the secure and ethical infrastructure that allows patients, who are the rightful owners of their data, to authorize the controlled sharing and pooling of their anonymized health information. The aggregated, high-quality data would then be securely licensed to researchers. This shift fundamentally addresses the "data-poverty crisis" for innovators by creating a superior national research dataset, ensuring that data serves science and innovation in a safe, transparent, and patient-approved way.



Launch a sovereign fund.

We need to move beyond applauding early-stage achievements and address the ongoing loss of our most promising scale-ups. Belgium should **launch a substantial (€10 billion, for example) sovereign wealth fund dedicated exclusively to late-stage (Series C+) financing and domestic manufacturing expansion**. It's also reflected by the need for more sizeable government support for accelerating and de-risking capital investments in R&D and (bio) manufacturing (OFI, 2024). While we may not rival the scientific depth of centers like Boston or the UK's Golden Triangle for "pure science origination", we can become the unrivalled European center for translational development and manufacturing. We should strategically focus on leveraging our existing strengths and promote them internationally to attract "Smart Money" investors.

To make these ambitious goals a reality, the final key to unlock the full potential of Belgian Biopharma innovation is **ensuring that administration acts as a platform to support innovation**, not a bottleneck. Regional political and administrative challenges must be simplified, as innovation does not stop at borders. The perspective needs to change from seeing strategic investment as a risk to recognising its benefits as vital for national competitiveness. Biopharma remains a cornerstone of the Belgian economy (OFI, 2024).

Thank you!

We would like to thank everyone who contributed to development of this whitepaper especially our partners Biovia and BioWin for their guidance, trust and support. In addition, we also thank all our Deloitte experts who provided valuable insights on innovations within Biopharma across the value chain, and on the future of next generation therapies including members of our Global and European community of practice.

BIOWin

biovia

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Deloitte's multidisciplinary team focuses on helping biopharma companies and their partners (hospitals, research institutions and service providers) to innovate and transform their R&D and manufacturing practices to ultimately accelerate the development of these novel therapies.



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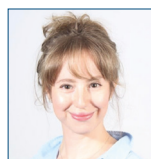
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Glossary

ATMP	Advanced Therapy Medicinal Product
CAGR	Compound Annual Growth Rate
CAR	Chimeric Antigen Receptor
CDMO	Contract Development Manufacturing Organization
CGT	Cell and Gene Therapy
circRNA	Circular RNA
CoE / CoEs	Centre(s) of Excellence
CR	Complete Response
CRO	Contract Research Organization
DDC	Drug-Device Combinations
EHR / EHRs	Electronic Health Record(s)
EU	European Union
FIH	First-In-Human
GCLP	Good Clinical Laboratory Practice
GMP	Good Manufacturing Practice
GP	General Practitioner
HQ	Headquarter
HTA	Health Technology Assessment
IP	Intellectual Property
IPO	Initial Public Offering
IRR	Internal Return Rate
KPI / KPIs	Key Performance Indicator(s)
LBP	Live Biotherapeutic Products
LNP	Lipid Nanoparticle
LOA	Likelihood Of Approval
M&A	Merger and Acquisition
MTDL	Multi-Target Directed Ligands
NLSC	National Life Sciences Council
PROMs	Patient-Reported Outcome Measures
QA	Quality Assurance
QP	Qualified Person (EU GMP-designated responsible person)
R&D	Research & development
RLT	Radioligand Therapy (targeted radiopharmaceutical therapy)
RWD	Real-World Data
RWE	Real-World Evidence
SME / SMEs	Small and Medium-sized Enterprise(s)
TRE	Trusted Research Environment
US	United States
VC	Venture Capital

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