Contents

ATMPs Matter, Now & Tomorrow

From promise to industrial reality

Advanced therapies — cell therapies, gene therapies, and tissue-engineered products — have crossed a critical threshold. What began as a scientific frontier is now reshaping how medicine is practiced, financed, and manufactured. The question is no longer whether ATMPs will matter on the long term. It is whether Belgium is positioned to capture the value they create, for the ecosystem and for the patients. This document is an introduction (i.e., teaser) to a larger analysis that will be published later this year, aiming to shape strategic recommendations for Belgium to stay competitive in that space.

The numbers confirm the shift

The Deloitte CGT Market Index doubled in value between 2023 and early 2026, from $77B to $144B. It outperformed the broader biotech index and tracked in line with the S&P 500 — a signal that mainstream capital markets have moved past scepticism. Thirteen of the fifteen largest biopharma companies by market cap now have active positions in advanced therapies. Across the top ten M&A transactions between 2019 and 2024, roughly $400 billion changed hands. Cell and gene therapy's share of total European biotech deal value grew from 1% in 2019 to 14% in 2024. Updated analysis will be provided later this year in our white paper.

First-generation products prove the model

Early doubts about commercial viability have been addressed. For example, Zolgensma, the gene therapy for spinal muscular atrophy, is approved in over 60 countries and has treated more than 5,000 children. It became a blockbuster in 2021 and is on track for $2 billion in annual sales by 2028. Yescarta, the CAR-T therapy for B-cell lymphoma, followed the same arc — 30 countries, 20,000 patients treated, blockbuster since 2023. Rare disease gene therapies are 2.5 times more likely than traditional therapies to progress from Phase I to approval. Hematologic CAR-T therapies are 40% more likely to receive FDA approval than other oncology drugs. By 2030, the field expects at least ten products of comparable scale. Looking ahead, the market signals from this year are confirming the shift towards the next generation of products. In-vivo modalities are clearly one of them, dominated by large deals with high-premium for companies with limited clinical evidence yet.

The rules have changed

The era of 'launch and learn' is over. Early movers were rewarded simply for novelty and first-mover status. That is no longer sufficient. Investors now demand clinical data that clearly surpasses the standard of care, commercial launches with tracked KPIs — patient starts, site activation rates, reimbursement access — and manufacturing strategies that are integrated into commercial planning from the outset. Companies that miss these expectations face market cap declines that are hard to reverse.

Three structural dynamics are driving the next phase of innovation: the shift from autologous to in-vivo cell therapies; the evolution from gene augmentation to gene editing; and the transition from contract manufacturing to integrated development and manufacturing models. These will determine which players — and which ecosystems — remain competitive in Europe, and beyond (i.e., China). Belgium has a stake in all three, but only if it makes deliberate choices about where to focus.

> *The strategic implication for Belgium is crystal clear: the window is open, but it will not stay open indefinitely. The ecosystems that capture position in the next two to three years will be the ones that shape who develops, manufactures, and launches the next generation of ATMPs in Europe.*

The Belgian ATMP Ecosystem

Many movements, many lessons — and resilience

Belgium has been in the ATMP space from the start. The journey has included genuine scientific breakthroughs, strategic pivots, company exits, and difficult funding decisions. Understanding this history clearly is the starting point for any credible strategy going forward — not to celebrate progress that has already been made, but to assess honestly what the ecosystem is capable of and where it needs to close gaps.

A tale of two halves

Belgium's advanced therapy landscape reflects a broader global pattern: significant scientific achievement on one side, commercial and industrial challenges on the other. Innovation is anchored — in academic labs, in hospital units, and in a small number of companies that have built real know-how. At the same time, several actors have faced R&D setbacks or strategic pivots that forced direction changes, scale-downs, or exits.

Belgium remains a critical node for ATMP manufacturing and logistics — a fact recognized both domestically and internationally. The country has built infrastructure, regulatory capabilities, and a CDMO ecosystem that is not easily replicated. Eighty-six percent of ecosystem respondents view Wallonia as competitive to very competitive on the global stage. The future of CDMOs and CROs, especially in the precision therapy space where many organizations recently decided to divest their business unit, will be further elaborated in our white paper.

Public investment has held the line

In the past few years, significant public investments were performed across Belgium in the field of ATMP, which have generated tangible outcomes for both the public and private sectors. For instance, in Wallonia, the ATMP-PIT program mobilized €81 million (public/private) over three years, bringing together 26 partners across the value chain. As of April 2026, this project had generated seven patents, thirty publications, and eleven industrial contracts. Beyond such measurable outputs, the expertise, infrastructure, collaborations, and economic benefits of large public initiatives have had a much wider impact, consolidating critical know-how across gene therapy, cell therapy and emerging modalities and increasing international visibility and attractiveness of the Belgian ecosystem. This provides a sustainable foundation for future innovation, industrial scale-up, talent development and the launch of new collaborative R&D initiatives.

In Flanders, the recently launched ATMP XB initiative provides another example of targeted public investment in ecosystem capacity. Co-funded through the Interreg Flanders–Netherlands programme, the approximately €3.5 million project brings together companies, hospitals, universities, training institutions and regional organisations from both sides of the border. Its activities focus on shared QA/QC capabilities, testing capacity, scalable GMP practices, specialised training and access to infrastructure. Although smaller in scale than ATMP-PIT, ATMP XB illustrates the value of investing in shared operational capabilities and strengthening collaboration between academic, clinical and industrial actors.

Other complementary initiatives have reinforced specific links in the value chain. The Precision Therapy Logistic Gateway project at Brussels Airport for example, brings together Brussels Airport, Pharma.Aero, Air Cargo Belgium and the Antwerp ATMP ecosystem at.las to develop and test logistics solutions for the safe, rapid and temperature-controlled transport of cell, gene and other precision therapies. Together, these initiatives strengthen Belgium’s capabilities across R&D, manufacturing, quality control, specialised training, supply-chain management and, ultimately, patient access.

However, fragmentation remains a challenge. Programs operate in parallel without sufficient coordination, and the ecosystem lacks a single-entry point for companies looking to develop or

expand in Belgium. So, it is clear the country needs a North Star and a strategy to achieve its ambitions as one of the best places for ATMP developers and manufacturers and increase access to patients.

External pressures are intensifying

Global capital dynamics are working against small ecosystems. Venture rounds are getting larger — averaging nearly $70 million in 2025 — but fewer in number and increasingly concentrated in late-stage assets. This creates a structural funding gap for early-stage companies. Addressing this gap will likely require new public-private risk-sharing mechanisms capable of supporting companies through the most capital-intensive stages of clinical development. At the same time, China has emerged as a major global source of biopharma innovation and investment, with its share of global biopharma deal value rising from 3% in 2020 to an estimated 38% by 2025.The EU pharmaceutical legislation reform adds further administrative complexity, with changes to data exclusivity periods, orphan designations, the use of hospital exemption for ATMPs, and the Bolar exemption all directly affecting how therapies are developed and commercialized in Europe.

> *ATMP development economics are structurally different from conventional drugs. Cost of goods ranges from 30% to 70% of revenue, compared to under 10% for small molecules. Without deliberate investment in process innovation and shared infrastructure, Belgian companies will find it difficult to make the commercial economics of an ATMP work — regardless of the quality of the science. The in-vivo thesis will probably unlock a new archetype where the financial and operating model can be more affordable for the system.*

Belgium's Starting Position

Genuine strengths — and structural constraints that must be named

An honest (and humble) assessment of Belgium's ATMP position is the precondition for a credible strategy. The country has real assets that differentiate it from other European ecosystems. It also has structural constraints that will limit its ability to compete if they are treated as background assumptions rather than active problems to solve. Both need to be stated plainly.

Genuine strengths

The first strength is clinical depth combined with dense geography. Belgium combines strong academic hospitals, dense clinical networks, extensive experience in early-phase trials, and a long-standing culture of clinical research. That matters disproportionately in ATMPs because patient pathways, investigator experience, and site capabilities are as important as abstract R&D capacity. Belgium's compact size can be turned into an operational asset — for therapies requiring coordinated referral, apheresis, manufacturing, release, and administration, distance and fragmentation matter, and Belgium minimizes both.

The second strength is regulatory know-how. FAMHP's National Innovation Office offers scientific, technical, and regulatory advice for medicines in development and specifically supports SMEs, spin-offs, academic hospitals, and research centres in the preparatory phase of advice requests (the ATMP spearhead). This creates a practical and differentiated entry point for early-stage innovators — provided it is packaged as part of a broader national offer rather than accessed case by case.

The third strength is manufacturing and quality heritage. The ATMP GMP environment is demanding. Belgium's experience in aseptic technology systems, release capabilities, and regulated biomanufacturing capacity is a genuine strategic asset — not just an industrial background fact. This heritage, combined with the country's logistics infrastructure and central European location, supports a credible and defensible manufacturing proposition.

The fourth strength is translational capacity. Belgium has invested heavily in linking academic excellence directly to clinical development. University-based GMP facilities are physically connected to academic hospitals, allowing research, manufacturing, and first-in-human studies to operate within a single translational environment. This reduces the distance between laboratory discoveries and clinical application and creates a practical ecosystem for early clinical proof of concept rather than a collection of isolated research centres.

The fifth strength is scientific and human capital excellence. Belgium combines internationally recognised academic expertise with a highly skilled workforce capable of operating in one of the world's most demanding manufacturing environments. This excellence is reinforced by dedicated ATMP and biomanufacturing training programmes, mock GMP facilities, and industry-developed curricula that continuously translate scientific expertise into manufacturing, quality and regulatory capabilities. In advanced therapies, where talent and execution are as critical as infrastructure, this creates a durable competitive advantage that extends well beyond academic research.

Structural constraints

Belgium is a relatively small market with limited patient volumes. That makes it unsuitable as a scale market for every ATMP business model and limits its ability to influence commercial outcomes through domestic demand alone. The country is also institutionally fragmented, with federal and regional responsibilities split across health, innovation, investment, and industrial policy. That fragmentation can slow decision-making precisely where ATMPs require cross-functional speed.

Belgium also does not have the scale to compete everywhere in manufacturing (i.e., large-scale production). ATMPs require specialised and often small-batch capabilities, but large industrial capacity plays are capital intensive and exposed to international competition (e.g., Netherlands, Ireland, Germany). A strategy that over-indexes on large undifferentiated capacity would risk creating underutilised assets. Hospital readiness and access pathways remain uneven as well — even when the science and regulation are favourable, real-world ATMP use depends on referral discipline, training, budget handling, and longitudinal follow-up.

The strategic implication: focus

Belgium's advantage lies in being coordinated, specialised, and fast — not comprehensive or massive. The country should lean into its density, proximity, and quality culture. It should avoid strategies that require very large domestic patient pools, broad reimbursement capacity across many products simultaneously, or generic manufacturing scale. This means the question is not 'how do we strengthen every part of the ecosystem?' It is 'where do we concentrate so that the whole chain can work?'

> *Belgium should not attempt to be a full-spectrum ATMP leader. It should become Europe's most execution-ready ATMP launchpad in a limited set of chosen arenas — combining translational strength, rapid clinical development, specialised manufacturing, treatment-centre readiness, and pragmatic access pathways.*

Wallonia’s contribution to the Belgian ambition:the ATMP innovators aim for a deeper, more structured, and more impactful collaboration

The Belgian's innovation ecosystem has all the key ingredients to establish itself as a globally recognized, highly connected, and competitive hub for advanced therapies. However, challenges remain across the country when it comes to attracting international talents, scaling up innovation efficiently and delivering accessible treatments to patients. For instance, in Wallonia, the ecosystem mostly depends on the capacity of the local talent pool to remain agile and responsive, and to train and upskill itself in line with the evolving industry needs. Transforming this will require a step change in international positioning and attractiveness. This implies not only increasing global visibility through communication and international events but also creating the conditions to attract and retain world-class talents, including through more competitive frameworks and a more integrated ecosystem.

The deployment of scalable and flexible infrastructure is proposed as an enabler of a more integrated ecosystem. To this end, the Wallon innovators envisaged a shift toward shared, service-based, and automated manufacturing platforms, capable of supporting companies at different stages of development. Better use of existing capacities, combined with new models such as shared facilities, incubators and accelerators, to enable more efficient scaling and reduce barriers to industrialization are also seen attractive, particularly for smaller players.

From a financial perspective, the members of the Walloon ecosystem are advocating for a more powerful and coordinated funding environment. The ambition is to move beyond fragmented national approaches toward larger, more harmonized funding mechanisms both at national and European level, enabling access to greater investment volumes and reducing structural disadvantages compared to global competitors. More flexible and performance-driven funding models would also be needed to support high-potential projects in their development.

Finally, the ambition of the ecosystem is anchored in the objective of delivering real and sustainable patient impact. This means ensuring that innovation is not only scientifically successful but also scalable, accessible, and economically viable. Improving access to clinical trials, simplifying regulatory pathways, and addressing cost challenges will be essential to bring advanced therapies to patients more efficiently.

Priority Arenas

Belgium's best where-to-play bets – a first attempt

Not every wave of ATMP innovation is equally relevant for Belgium. A disciplined selection framework must test each candidate arena against five criteria: scientific depth, concentration of patients and referral pathways, fit with Belgium's trial strengths, fit with specialised manufacturing and logistics capabilities, and feasibility of evidence and access implementation. This framework of arenas pushes Belgium toward positions where the whole chain can work, and away from areas where one link is structurally weak or missing. It also rules out several attractive-sounding but fragile positions: branding Belgium as the European leader for all ATMP modalities, maximising the number of announcements, or building broad commodity-like capacity without a differentiated demand case. The four arenas below are the priorities for near-term strategic concentration because they combine existing Belgian strengths with a credible ability to execute across the full value chain. Other emerging fields — including exosomes and tissue-engineered products — remain scientifically relevant and should continue to be monitored and supported through exploratory or enabling programmes, likely in mid-term horizon (3-5 years).

Arena 1 — Cell therapies in oncology and haematology

This is Belgium's primary arena. Oncology already accounts for the largest share of Belgian clinical trial applications, and the country has strong university hospitals, specialised clinical teams, and an established trial culture in haematology and oncology. These are precisely the settings where cell therapies require multidisciplinary coordination, sophisticated site capabilities, and rapid access to eligible patients.

Belgium's right to win here is not based on being the largest market. It is based on being a dense network where early development, treatment-centre readiness, and post-treatment follow-up can be organised with less friction than in more fragmented systems. The strategic ambition should be to make Belgium the preferred European launchpad for selected oncology and haematology cell therapies — from early clinical development through first commercial centres. Global deal flow confirms the direction: in-vivo CAR-T attracted over $7 billion in strategic transactions in 2025 alone.

Arena 2 — Gene therapies for rare diseases and advanced paediatrics

Belgium should also prioritise selected gene therapies in rare diseases and paediatric settings (promotion of the Belgian Plan for Rare disease). The rationale is not broad disease prevalence — it is the concentration of specialist expertise in university hospitals, referral pathways, and long-term patient management. Rare disease and paediatric ATMPs place a premium on accurate diagnosis (and widely used by hospitals), coordinated referral, registry-quality follow-up (central registry of rare diseases), and trusted relationships between centres and families. Small, well-networked countries can punch above their weight here.

Selectivity matters in this arena too. Belgium should not claim all rare-disease ATMPs. It should identify subdomains where specialist centres already have credibility (e.g., dedicated rare disease function), patient pathways are manageable, and the evidence-generation burden is feasible — including areas where Belgian centres already attract cross-border referrals or carry meaningful research profiles in the relevant disease.

Arena 3 — Specialised manufacturing, release, and logistics

Belgium should position itself in specialised manufacturing and logistics rather than in undifferentiated volume manufacturing. The country's opportunity is strongest where value lies in technical complexity and trust: process development, analytical characterisation, QC, qualified person release, cryogenic logistics, chain-of-identity management, and flexible small-batch operations.

This focus is more realistic than aspiring to become the default location for large-scale manufacturing across many ATMP classes. It aligns with Belgium's industrial heritage and geography, avoids the capital intensity and demand risk of commodity capacity plays, and complements the clinical and regulatory strengths in the first two arenas.

Arena 4 — Bridging academic innovation to scalable development

Belgium's hospital-exemption framework should be treated as a strategic translational bridge, not a parallel system. It allows academic centres and hospitals to generate clinically meaningful innovation before a full commercial pathway is established. The policy goal is to use it where appropriate for patient need and translational learning — while creating clear pathways toward broader development, stronger evidence packages, quality maturity, and commercial or multicentre expansion. Belgium can differentiate itself by becoming the country that helps academic ATMP innovation cross that bridge rather than stall on it. Translational sciences is a strength, many academic labs have seen their innovation reaching patient through unique pharma and biotech collaborations (e.g., identification of cancer antigens, antibody to activate regulatory cells, etc).

> *The four arenas are mutually reinforcing. Strong clinical trial capability in oncology attracts manufacturing partners. Specialised manufacturing credibility makes Belgium a more compelling development location for rare-disease gene therapies. A functioning hospital-exemption-to-development bridge keeps academic innovation inside the ecosystem rather than exporting it.*

Conclusions and Next Steps

From diagnosis to decision

The argument across these five pages is straightforward. ATMPs have moved from scientific promise to industrial reality, and the competitive dynamics of the field have fundamentally changed. Belgium enters this phase with genuine assets — clinical depth, regulatory know-how, manufacturing heritage, and a culture of collaboration — and with structural constraints that cannot be ignored. The strategic response is not to strengthen everything, but to concentrate where the complete chain can work and where Belgium's specific profile creates a defensible advantage. This is where the approach of a set of portfolio of projects supported by public investment, focus on specific arenas or technological innovations, is maximizing value and economic return for the system and the patients.

What the ecosystem has demonstrated

Recent Belgian initiatives have demonstrated that collaboration across academia, industry and hospitals can generate tangible scientific, industrial and economic value. ATMP-PIT is one illustration among several, alongside initiatives such as ATMP XB and the Precision Therapy Logistic Gateway. Together, these programmes have strengthened Belgium's overall ATMP ecosystem while also highlighting the structural challenges that remain.

The ecosystem has shown that collaboration across academia, industry, and hospitals is possible and productive. The program has generated patents, publications, and industrial contracts of genuine value. It has also surfaced the structural challenges that will limit progress if left unaddressed: thin early-stage capital, fragmented governance, manufacturing costs that make commercialization difficult, and an international positioning that has not been fully activated.

The global market is not waiting. Cell and gene therapies are attracting billions in annual investment. Companies choose where to develop, manufacture, and launch based on a clear-eyed assessment of where the ecosystem supports their success. Belgium needs to be able to answer that question with confidence — and with specificity. A general claim to ecosystem strength is no longer sufficient.

Three decisions that matter most

First, commit to the four priority arenas explicitly. Oncology and haematology cell therapy, gene therapy for rare diseases and paediatrics, specialised manufacturing and logistics, and the academic-to-development bridge are not aspirations — they are the fields where Belgium can create a defensible position because we are good at it. Stating them publicly and resourcing them accordingly is the act that turns a strategy into a plan. Additionally, more niche/emerging technologies (e.g., TEP, exosomes) should continue to be supported through exploratory research and capability-building initiatives without diluting the strategic concentration around the four priority arenas. Belgium has strong sciences, and we should continue feeding the tunnel.

Second, establish a co-financing mechanism in equal parts between public and private actors to support the clinical phases of biotech projects. This would reduce the risk for companies, stimulate private investment, and accelerate the time to market while consolidating Belgium's position as a European centre for clinical research.

Third, establish a coordinated Belgian ATMP one-stop shop as an operational interface.. A single point of entry that connects regulatory guidance, GMP access, clinical trial partnership, and reimbursement navigation would change the cost and speed of developing an ATMP in Belgium. A multi-modular place where cross-functions (Research, Translational, CMC) can work together, innovate, and adapt to future technological shifts.

> *The strategic choice is binary: Belgium either concentrates its effort and becomes the most execution-ready ATMP launchpad in Europe for a defined set of arenas, or it disperses its resources and remains a credible but undifferentiated player in a field where selectivity is what creates value. The foundations are in place. The priority now is to choose and actionize.*

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