Important Components for an Efficient Business Plan in Biomed Applications

Investor perspective on building a spin-out from scientific infrastructure

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What This Talk Is

What This Is *Not*

- A business plan for IFIGENEIA
- A finance lecture

What This *Is*

A frank look at how investors interrogate a spin-out opportunity — the questions they ask, the gaps they find, and the arguments that hold up under scrutiny.

> *A business plan is not a document. It is a structured argument for why and how a company should exist.*

The Investor Lens

Biomed spin-outs are judged on **risk reduction**, not just scientific novelty.
Every investor enters the room with the same five questions.

1

Large Enough?

Is the opportunity large enough to justify venture-scale capital?

2

Right Timing?

Is the timing right — is the market ready, and is the science mature?

3

Unfair Advantage?

Does this team or technology hold a defensible, structural edge?

4

Can They Execute?

Does the team have the capability to navigate uncertainty and deliver?

5

Capital Efficiency?

Can capital turn today's science into future enterprise value?

The Four Pillars of any Spin-Out

Team

Can they execute under uncertainty? Do they have the right mix of scientific credibility and commercial acumen?

Product

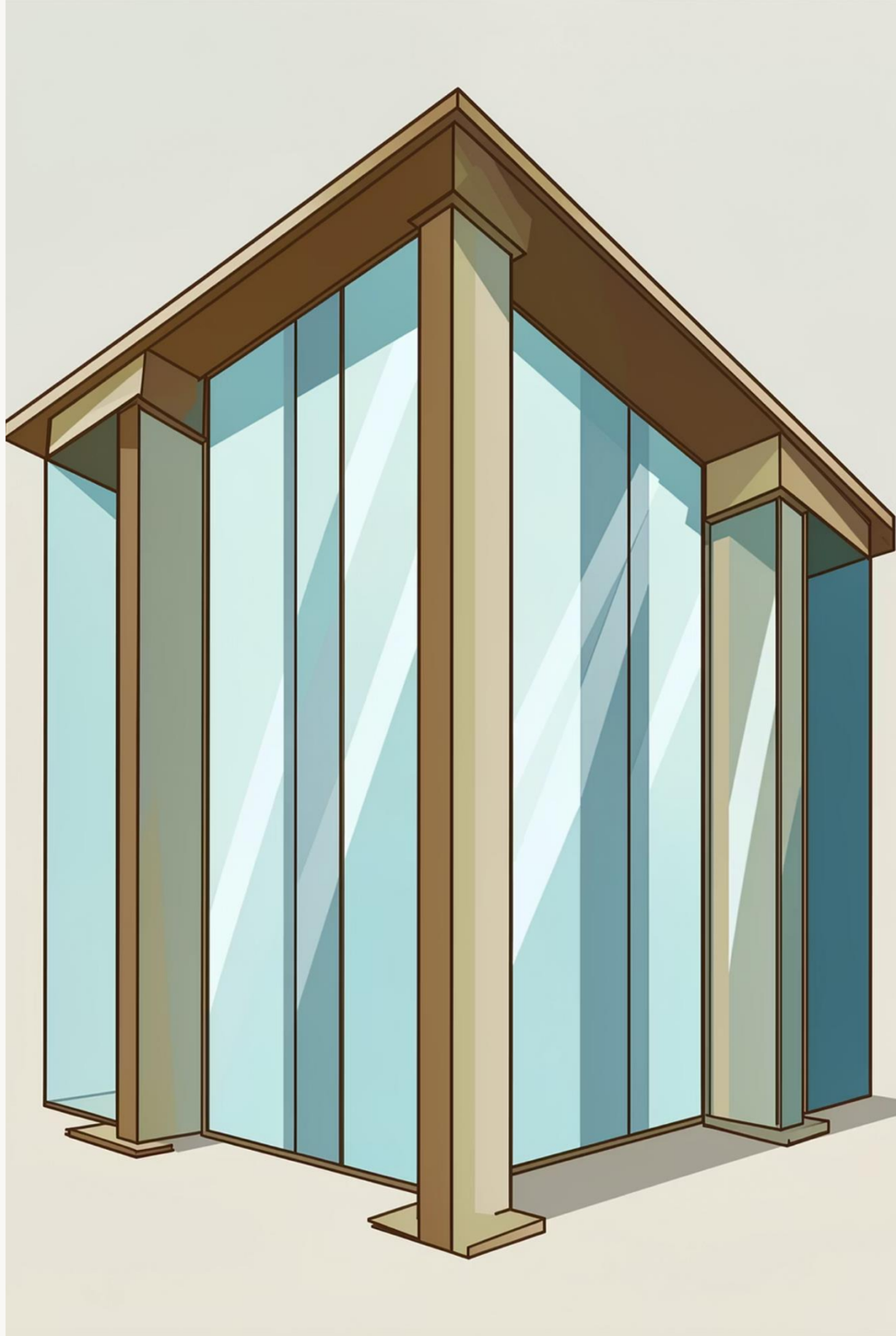
What exactly is being sold? Is it a device, a therapy, a diagnostic, a platform? Clarity here is non-negotiable.

Market

Who needs it, and why now? A compelling market narrative requires both size and urgency.

Route to Success

What does value creation look like? Milestones, exits, partnerships — the path must be credible and specific.



Team is the first filter

Investors expect gaps in early companies. They do not expect confusion about who owns which decision.

Scientific Authority

Company-Building Experience

Regulatory & Clinical Judgement

Capital Raising Experience

Ability to Recruit

⚠ **Investor red flag:** Brilliant science with no accountable company leadership.

What "Good" Team Looks Like

A strong spin-out team usually combines complementary roles that span science, execution, and governance.

Founder-Scientists

Credibility, insight, access to know-how

CEO / COO

Execution, fundraising, hiring

CMO / Regulatory Lead

Clinical translation

BD / Commercial

Partnerships, licensing, market access

Board / Advisors / Investors

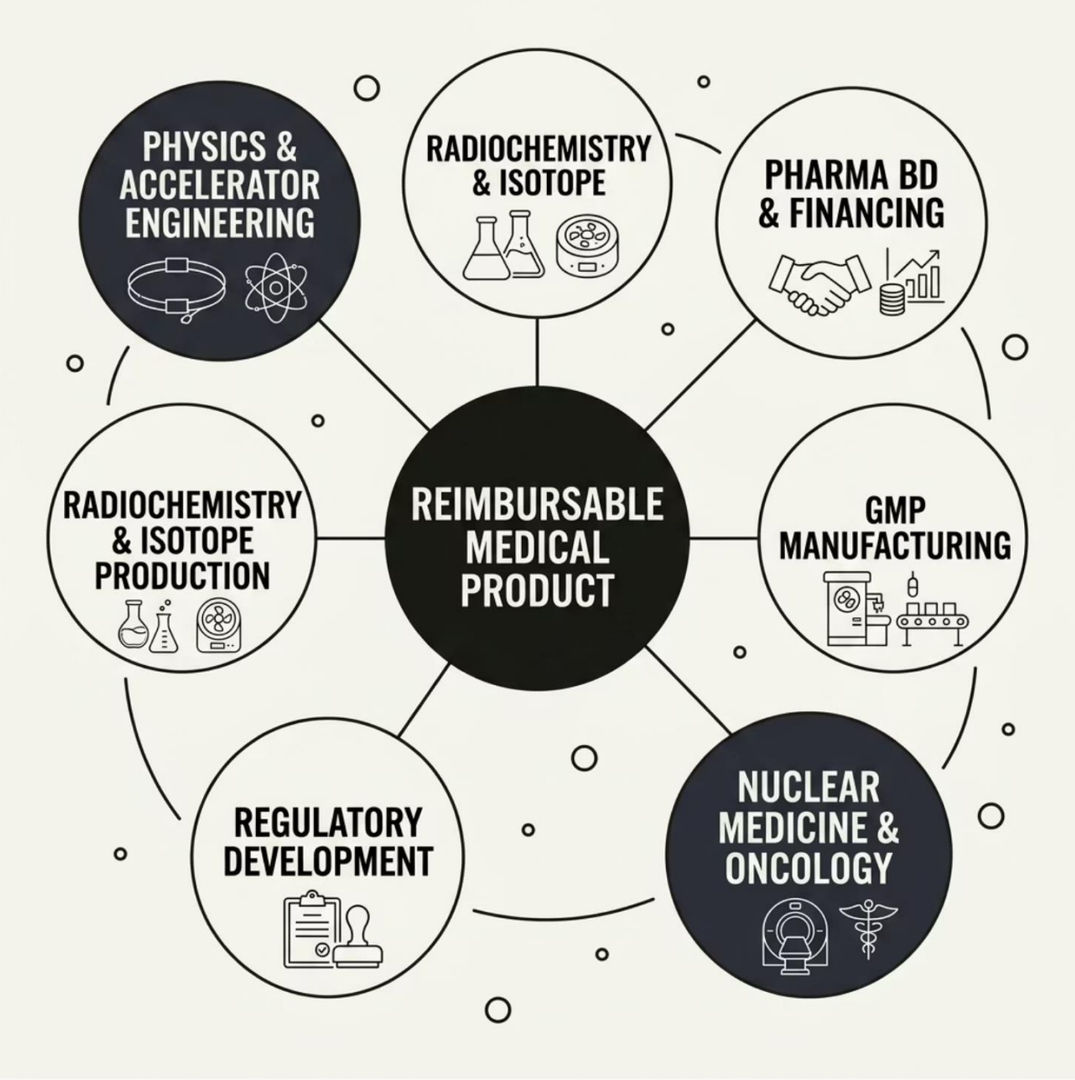
Governance and pattern recognition

> *In biotech, the first product of the company is often the team itself.*

Team Complementarity

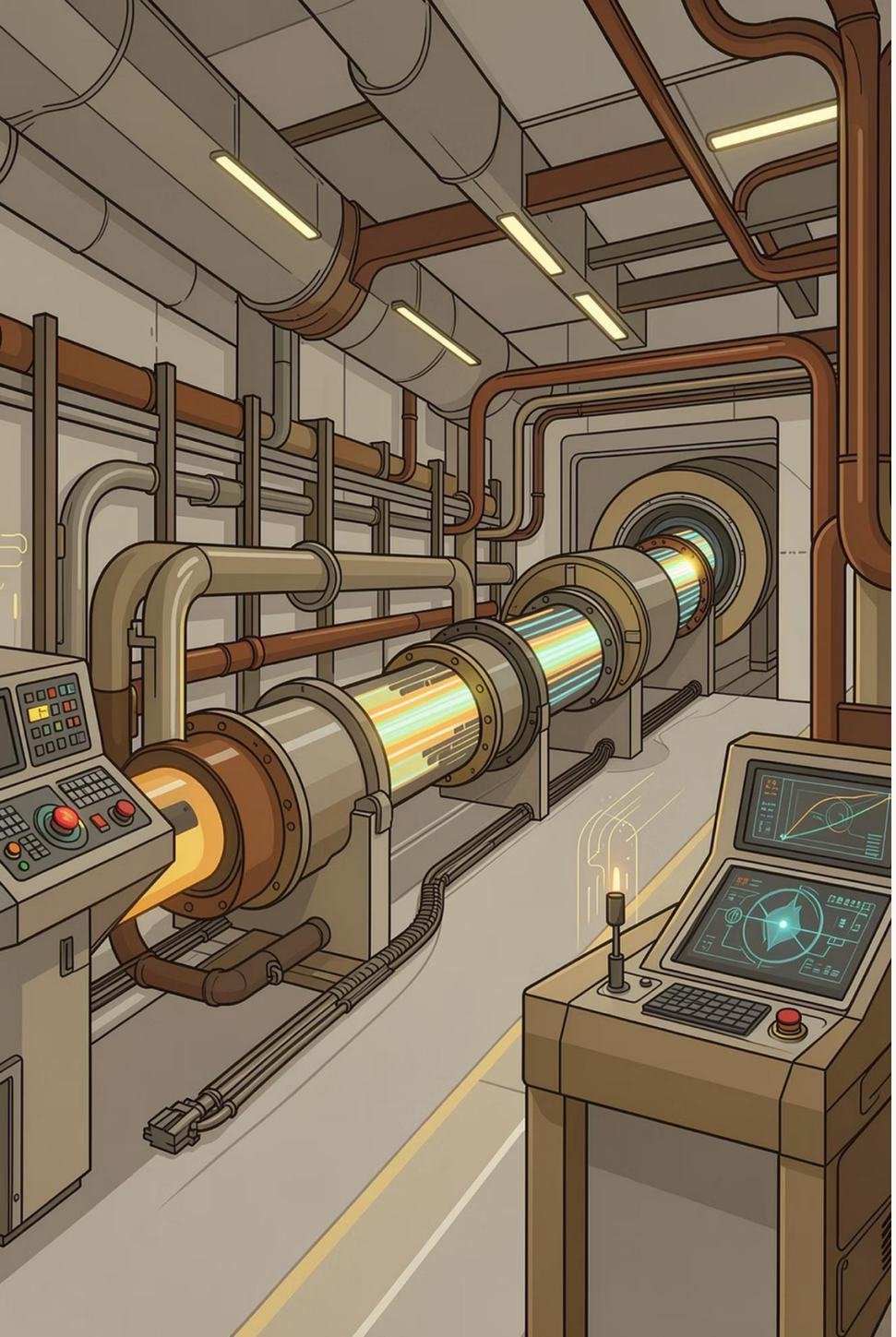
For a radiopharma/infrastructure spin-out, complementarity is unusually important.

The team must span a uniquely broad set of disciplines to connect physics excellence to a reimbursable medical product.



- Physics & Accelerator Engineering
- Radiochemistry & Isotope Production
- GMP Manufacturing
- Nuclear Medicine & Oncology
- Regulatory Development
- Pharma BD & Financing

Investor question: Can the team connect physics excellence to a reimbursable medical product?



Product

Duality as a strategic choice, that must be resolved for investors.

Platform

LINAC-enabled isotope production — the underlying infrastructure capability that makes everything else possible.

Drug / Product

A radioisotope linked to a targeting vector — such as a peptide, small molecule, mAb, or other ligand — delivered to the patient.

The project aims to deliver both a conceptual design study for a LINAC-based facility and a business/investment plan, with **Lu-177** as the initial focus whilst assessing other isotopes.

Where Is Value Created?

Infrastructure
LINAC facility & production capability

Isotope
Lu-177 and other radionuclides

Radiochemistry
Purification, conjugation, formulation

Drug Candidate
Targeted radiopharmaceutical

Clinical Data
Safety, efficacy, regulatory evidence

Approved Product
Maximum value realisation

Value usually increases as risk moves closer to the patient. In public markets and M&A, the highest value is typically attached to clinical-stage or approved products — not to production capability alone.

Investor question: Is the company an enabling infrastructure company, a supplier, or a therapeutic products company?

Academic Relationship

Academic infrastructure can be a powerful launchpad — but privileged access must become defensible access.

Advantages

- Lower initial capex
- Access to deep expertise
- Institutional credibility
- Early validation of technology

Risks

- Unclear IP ownership
- Slow contracting processes
- Dependency on institutional priorities
- Difficulty scaling beyond academic production

⚠ **Key point:** Privileged access must become defensible access.
The transition from academic partner to independent operator is a critical inflection point for investors.

Defensibility – barriers for competitors

IP Protection

Patents around production processes, targets, purification, conjugates, and formulations

Infrastructure Access

Exclusive or preferred access to LINAC and production infrastructure

Operational Know-How

Isotope know-how and operational recipes that are difficult to replicate

GMP Qualification

Validated, GMP-qualified processes that meet regulatory standards

Clinical Relationships

First-mover clinical data and established relationships with clinical sites

Supply Reliability

Demonstrated ability to deliver consistently at quality and at scale

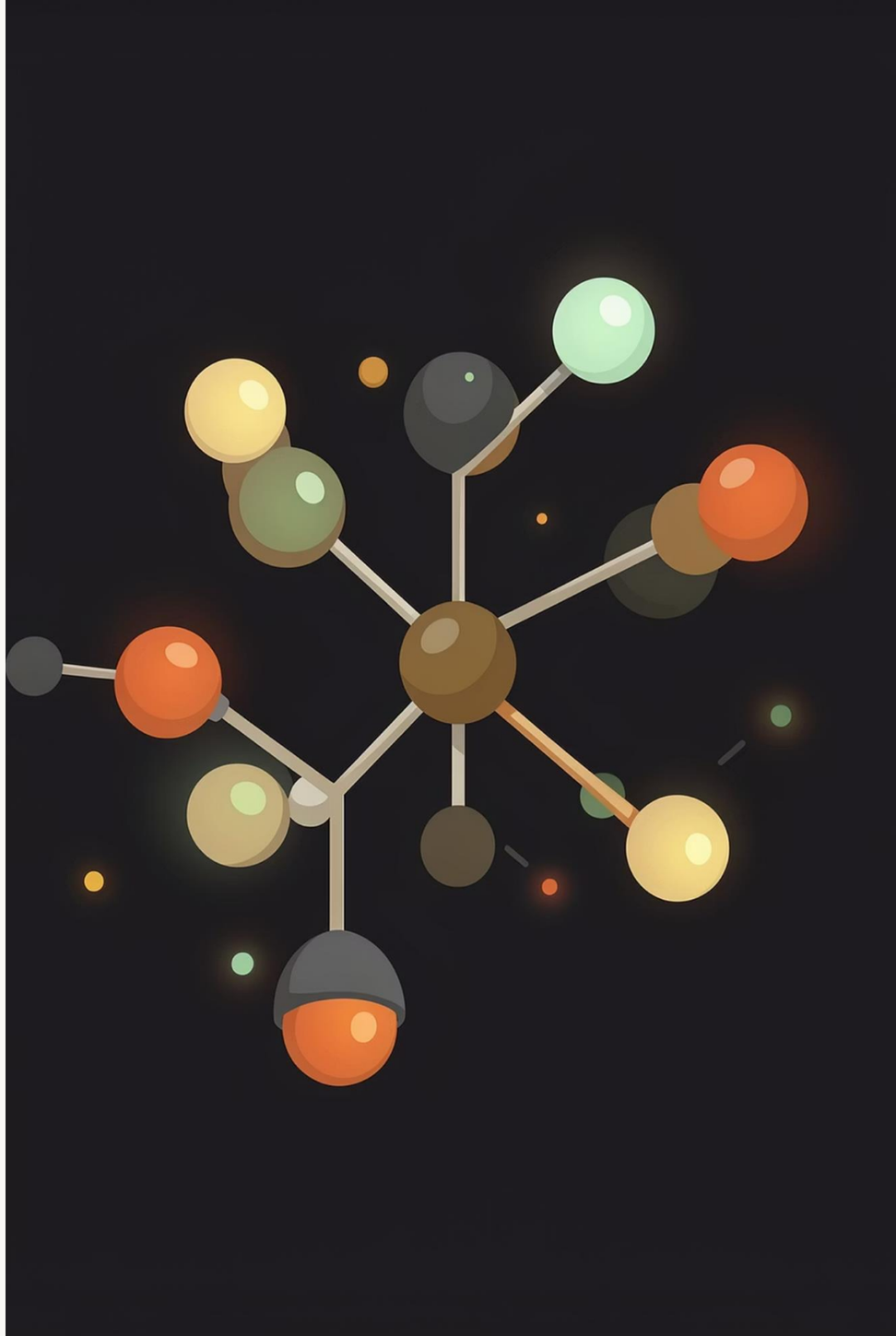
Weak barrier: "We know how to do it."

Stronger barrier: "We can do it reproducibly, at quality, at scale, with protected rights."

Market

Radioligand Therapy · Competitive Landscape

A strategic framework for understanding market positioning, competitive dynamics, and the path to commercial success in radioligand therapy and radiopharmaceutical manufacturing.



Market Attractiveness

MARKET SIZING

Radioligand Therapy: A Major Strategic Arena

Radioligand therapy is now a major strategic area, not a niche. Current published forecasts place the global radioligand therapy market at approximately **$9.2B in 2024**, growing toward **~$13.4–13.8B by 2030**.

> Investor takeaway: market timing is favourable, but competition is rising quickly.

Growth Drivers

- Precision oncology driving demand for targeted therapies
- Clinical success of Lu-177 products validating the modality
- Broader isotope innovation expanding the therapeutic toolkit
- Pharma interest in targeted radiation payloads
- Supply chain bottlenecks creating infrastructure opportunity

$9.2B

Global RLT Market 2024

$13.8B

Projected by 2030

Source: P&S Intelligence market analysis on radioligand therapy

Competitive Landscape

Layer 1: Isotope Production

- Nuclear reactors — established, high-volume
- Cyclotrons — flexible, regional
- Emerging accelerator / LINAC approaches

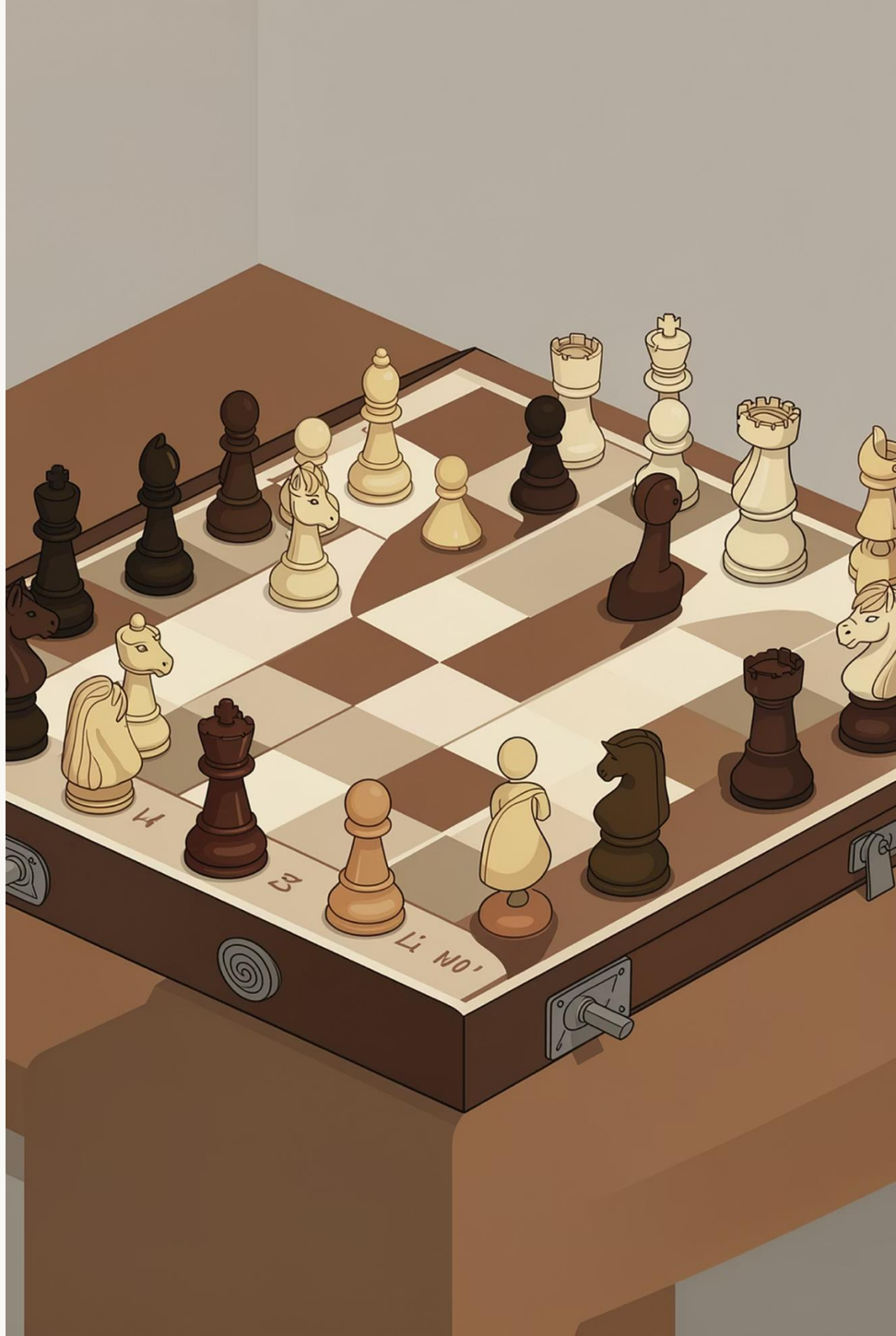
Layer 2: Radiopharma Biotech

- Asset-focused companies
- Ligand/isotope platforms
- Alpha and beta emitter specialists

Layer 3: Big Pharma

- Novartis, BMS, AstraZeneca and others
- Increasingly acquiring capabilities rather than building from zero
- Deep pockets, strategic urgency

Europe is explicitly focused on strengthening reliable medical radioisotope access. The **SAMIRA Action Plan** is positioned as the EU's first comprehensive plan for safe, high-quality and reliable radiological/nuclear technology in healthcare.



Positioning

The Five Strategic Questions

A good business plan must answer each of these clearly and credibly:

- → Is it better?
- → Is it faster?
- → Is it cheaper?
- → Is it uniquely available?
- → Is it difficult to be copied?

For a LINAC-Enabled Approach

Flexibility Over Unit Cost

Adaptability across isotope types may outweigh marginal cost advantages of established producers.

Non-Conventional Isotope Access

Access to isotopes unavailable via reactor or cyclotron may be more valuable than head-on competition.

Regional Resilience

Strategic value of sovereign, reliable supply may command premium positioning with public and institutional funders.

⚠ Key question: Who cares enough to pay, and what budget do they use?

Case Study: Novartis Builds Radioligand Capability

1

2017

Novartis acquires **Advanced Accelerator Applications** for **~$3.9B**, bringing Lutathera and a full radioligand therapy platform into the portfolio.

2

2018

Novartis acquires **Endocyte** for **~$2.1B**, adding 177Lu-PSMA-617 — later approved as Pluvicto — to its oncology pipeline.

3

Lesson

Novartis did not just buy "science." It bought clinical momentum, manufacturing know-how, supply chain capability, and strategic positioning in oncology.

Product Candidates	Clinical Momentum	Manufacturing Know-How
Late-stage assets with regulatory pathway	De-risked programmes with data packages	GMP-ready radiopharma production

Supply Chain	Strategic Position
Integrated isotope-to-patient capability	Oncology leadership in targeted radiation

Comparable Deals

Recent M&A Shows Strategic Demand

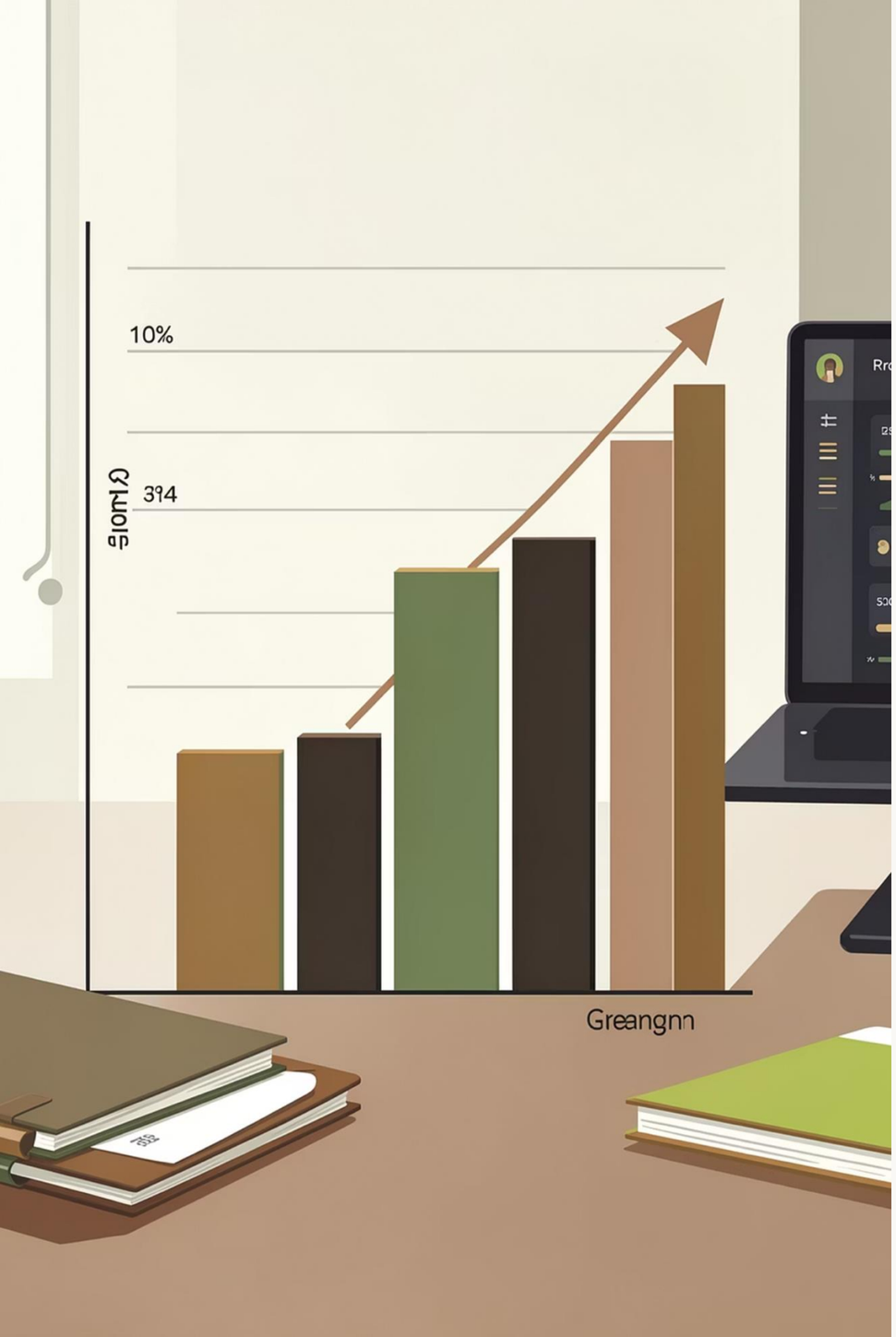
RayzeBio → Bristol Myers Squibb

~$4.1B equity value. Included actinium-based platform, clinical pipeline, and manufacturing capabilities. Signals BMS commitment to alpha-emitter leadership.

Fusion Pharmaceuticals → AstraZeneca

Up to **~$2.4B**, adding a clinical-stage radioconjugate pipeline. AstraZeneca accelerating its oncology radioligand strategy through acquisition.

Pattern: buyers pay for de-risked platforms with assets, not just technical optionality. The premium is on clinical proof, not scientific promise alone.



Commercial Proof Point

Radioligand therapy has moved decisively from concept to commercial reality. The question is no longer whether radiopharma can be commercial.

$1.994B

Pluvicto Net Sales 2025

Up **43%** year-on-year. Novartis's PSMA-targeted radioligand therapy for prostate cancer demonstrating blockbuster trajectory.

$816M

Lutathera Net Sales 2025

Up **13%** year-on-year. The first approved radioligand therapy continues to grow as a standard of care in neuroendocrine tumours.

Outstanding Sales Growth Rate

Exceptional commercial momentum validating the radioligand therapy modality at scale.

> The question is no longer whether radiopharma can be commercial. The question is **who controls the next differentiated products and supply chains.**

Route to Success – What Does Success Look Like?

Stakeholder Definitions of Success

Different stakeholders define success differently — and a credible business plan must make these definitions compatible.

Founders
Translation of science into impact, recognition, and lasting contribution to medicine.

Patients
Access to effective treatments and improved clinical outcomes.

Institutions
Ecosystem building, visibility, and return on IP investment.

Public Funders
Regional resilience and sovereign nuclear medicine capacity.

Investors
Value inflection events and a clear path to liquidity.

Three Credible End States

Early Strategic Acquisition
Sell technology or platform before major clinical spend. Lower capital requirement, lower upside ceiling. Attractive to risk-averse founders and early-stage investors.

Clinical-Stage Asset Company
Develop selected isotope-ligand products to IND, Phase I, or Phase II. Value inflection at key clinical milestones. More biotech-like capital and governance structure.

Integrated Radiopharma Company
Own production, development, and manufacturing end-to-end. Highest strategic ambition and highest capital intensity. Requires sustained institutional and investor commitment.

Building the Path

Milestones investors can underwrite — across technical, product, and business dimensions — define the credible roadmap for IFIGENEIA.

Technical Milestones

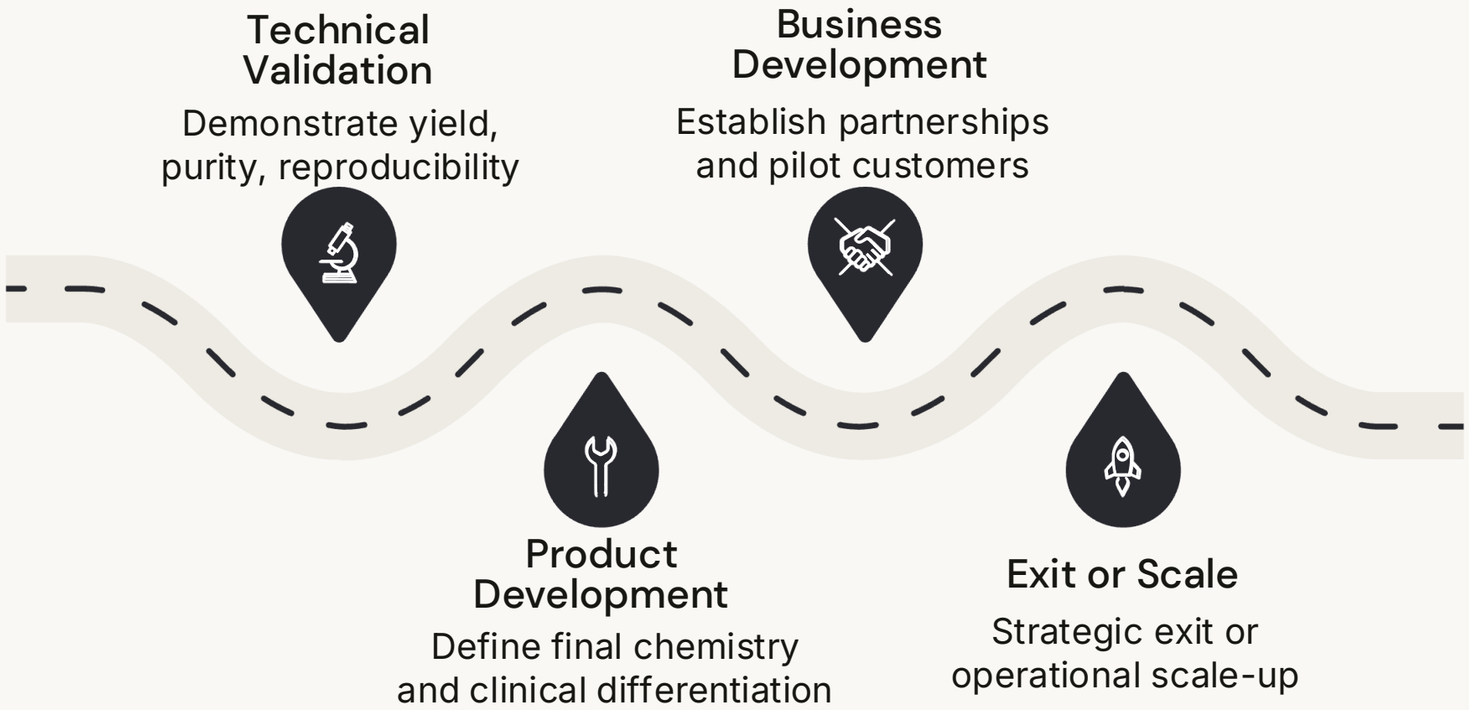
- Yield, purity, and reproducibility demonstrated
- Targetry and separation processes validated
- GMP-compatible process established
- Beam parameters optimised and documented
- WP3/WP4 alignment and subsystem integration confirmed

Product Milestones

- Isotope prioritisation completed
- Target and vector selection
- Binder and chelator chemistry defined
- Preclinical proof of concept achieved
- Clinical differentiation demonstrated

Business Milestones

- IP package secured and filed
- Access and licensing agreements in place
- First pharma or clinical partner signed
- Financing plan agreed and committed
- Focus maintained across broad project scope



Common Mistakes That Kill Investment Cases

→ Technology ≠ Product
Confusing a scientific breakthrough with a commercially defined product is the most common and most costly error.

→ No Clear First Indication
Without a defined beachhead indication, the regulatory and commercial path remains undefined.

→ No Freedom-to-Operate Analysis
Ignoring IP landscape risks invalidates the entire investment thesis before it begins.

→ Academic Access ≠ Commercial Scale
Assuming that laboratory access translates directly to manufacturing scalability is a fatal assumption.

→ Underestimating GMP, QA & Regulatory Burden
Regulatory compliance in biomed is not a checkbox — it is a multi-year, capital-intensive commitment.

→ Building the Team Too Late
Investors back people first. A team assembled after funding is sought signals poor commercial readiness.

→ Not Defining the Buyer
Who is the actual customer — a hospital, a pharma company, a payer? Without this, there is no business model.

Thanks for your attention.

> *Science creates possibility.*
> *Business planning defines the investable path.*