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Leveraging Opportunities in Radiopharmaceuticals

Summary

In the evolving landscape of innovative therapeutics, Radiopharmaceuticals stand out as a powerful modality to diagnose, target and treat disease at the molecular level. This excitement is being reflected by clinical data and deployment of investment capital alike. The launches of PLUVICTO and LUTATHERA by Novartis have shown improved outcomes over traditional standards of care, with the former approaching blockbuster status in 2023 as it gains traction in oncology markets.

The global Radiopharmaceuticals market is set to reach nearly

$14bn **by 2033, growing 8-10% year-on-year.**

Given their utility in precision oncology, and potentially other therapeutic areas, we believe that Radiopharmaceuticals and their surrounding tools and services afford credible investment opportunities to both Pharma and financial investors. However, as with all classes of innovative therapeutics, the widespread adoption of Radiopharmaceuticals will only be made possible with accompanied progress in their manufacturing, distribution and storage and incorporation into clinical care pathways. Therefore, actionable areas in this space include clinical-stage Radiopharmaceutical companies, specialised CDMOs and logistics solutions providers.

In our view, Radiopharmaceuticals are a potentially attractive investment area owing to their status as a protected channel with a high barrier to entry and a clear market need for scaled tools and services to serve growing demand. However, to fully realise the value of this modality, regulatory (both from a medical and nuclear standpoint), safety and logistical challenges must be anticipated and mitigated.

1. Novartis Pluvicto™ approved by FDA as first targeted radioligand therapy for treatment of progressive, PSMA positive metastatic castration-resistant prostate cancer, Novartis (2022)
2. Advanced Accelerator Applications Receives FDA Approval for Lutathera® for Treatment of Gastroenteropancreatic Neuroendocrine Tumors, Novartis (2018)
3. Novartis 2023 Financial Results, Novartis (2023)
4. Radiopharmaceuticals Market Size, Share and Trends 2024 to 2033, Precedence Research (2023)
5. Radiopharmaceuticals Market Size, Share, Competitive Landscape and Trend Analysis Report, by End User, by Radioisotope, by Application, by Type: Global Opportunity Analysis and Industry Forecast, 2024-2033, Applied Market Research (2023)

Introduction

Whilst the use of radiation for medical purposes dates back decades, more recent advances in tissue targeting, imaging and the wider availability of radioactive isotopes have allowed developers to target disease-affected tissues with deeper precision, improving efficacy and reducing the side effects associated with high-dose radiation. From a diagnostic perspective, improvements in imaging technologies such as SPECT-CT, PET-CT, and PET-MRI have vastly improved the specificity and sensitivity of imaging agents. These innovations have paved the way for theragnostics, allowing clinicians to not only visualise disease with greater accuracy but also treat it in a more targeted manner (Figure 1).

Figure 1:
Radiopharmaceuticals use cases

Diagnostics	Therapeutics	Theragnostics
Isotopes emitting gamma radiation which can be monitored by external imaging techniques including PET, SPECT MRI and gamma cameras	Contain isotopes emitting high energy radiation in a short range in tissues through the use of alpha or beta particles or auger electrons	Combination of diagnostic and therapeutic technologies in a single compound, offering a more personalised treatment approach
Enables imaging of different organs such as brain, heart, kidney, and bone	Can be combined with targeting molecules to more precisely targeted disease areas, to minimize radiation exposure to healthy cells and tissues	Leverages specific biomarkers to facilitate the direct visualisation and eradication of tumors
Used for diagnosis of oncology (e.g., prostate cancer, breast cancer, neuroendocrine tumours) and non oncology conditions (e.g., cardiovascular disease, thyroid disorders, neurodegenerative disease)	Enable targeted radionuclide therapy which can improve patient outcomes by limiting radiation exposure to affected tissues	Enables real time monitoring of treatment efficacy, enabling personalised adjustments based on individual response
These techniques can be used for early disease detection, enabling more timely therapeutic intervention	Applications both in and outside of oncology	Non invasive alternative to traditional biopsy methods, providing an alternative to invasive surgical intervention

1. Jalilian, A., Decristoforo, C., Denecke, M. et al. Proceedings of international symposium of trends in Radiopharmaceuticals 2023 (ISTR-2023). EJNMMI Radiopharm. Chem. 8, 39 (2023)
2. Sgouros G. et. al. Radiopharmaceutical therapy in cancer: clinical advances and challenges. Nature Reviews Drug Discovery, 19:589–608 (2020)
3. Lapi, Suzanne E et al. Recent advances and impending challenges for the Radiopharmaceutical sciences in oncology. The Lancet Oncology 25(6): e236 - e249
4. Urbain, J. et al. Theranostic Radiopharmaceuticals: A Universal Challenging Educational Paradigm in Nuclear Medicine. Journal of Nuclear Medicine jnumed.123.265603 (2023)

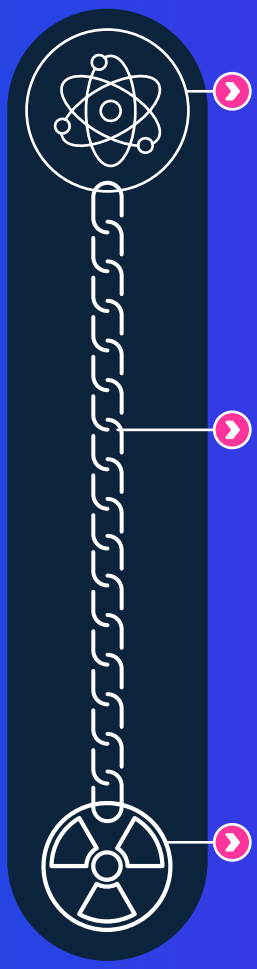
The advent of Radiopharmaceuticals as a precision medicine

The diagnostic use of Radiopharmaceuticals is well-established; advancements in healthcare technology have expanded their use as therapeutics, with precision oncology being the most mature application. Here, therapeutic Radiopharmaceuticals act as "magic bullets" leveraging ligands, small molecules, antibodies, nanoparticles, and others to deliver radiotherapy directly to target cells. This approach offers minimal toxicity and fewer treatment cycles when compared with more systemic cancer treatment options including traditional radiotherapy approaches (Figure 2).

From a clinical perspective, more recently developed Radiopharmaceuticals have demonstrated superior risk/benefit profiles over existing standards of care. For example, Novartis' PLUVICTO demonstrated a clinically meaningful and statistically significant benefit in progression-free survival in PSMA-positive metastatic castration-resistant prostate cancer and reduced the risk of progression or death by 60% compared to standard of care.

Despite somewhat of a false start in the space with early targeted Radiopharmaceuticals (e.g., Acrotech's ZEVALIN and GSK's BEXARR), more recent products XOFIGO (Bayer), LUTATHERA and PLUVICTO (Novartis) have proven more commercially successful (Table 1), with the latter expected to achieve blockbuster status in 2024 .This positive momentum is also reflected in the treatment pipeline, with several therapies in development across a range of oncology indications targeting the brain, heart, prostate and lung (Table 2).

Figure 2:
Anatomy of a radiotherapeutic



Targeting molecule

- Designed to specifically bind to a particular biological marker or receptor that is overexpressed on diseased cell or tissue
- Forms the precision element of radiotherapeutics, by helping to target radiation to the source of disease
- Several types of targeting molecules can be used for a Radiopharmaceutical including antibodies, ligands, nanoparticles and peptides

Linker / chelator

- Molecular "bridge" that connects the targeting molecule to the radioactive isotope
- Forms the stable attachment of the radioisotope to the targeting molecule and prevents the release of free radioisotope into the body
- Examples include EDTA, DOTA, bi functional chelators, cleavable linkers

Radioisotope payload

- A radioactive substance attached to the targeting moleculevia the linker/chelator, used to induce DNA damage through the targeted delivery of radiation to diseased cells through targeted DNA damage
- Beta emitters can target a larger surface area, but offer a less radiation, thereby requiring higher doses
- Alpha emitters deploy more radiation but have lower penetrating power and are therefore only hypothesised to work in highly localised targets
- Alpha: Ac-225, Ra-223, At-211, Th-227
- Beta: Lu 177, I 131, Y 90, Sr 89

Abbreviations:
Ac: Actinium; At: Astatine; I: Iodine; Lu: Lutetium; Ra: Radium; Th: Thorium; Sr: Strontium; Y: Yttrium

1. Radiopharmaceuticals: Radiation Therapy Enters the Molecular Age, National Cancer Institute (2020)
2. Radioisotopes in Medicine, World Nuclear Association (2024)
3. Novartis Pluvicto™ shows statistically significant and clinically meaningful radiographic progression-free survival benefit in patients with PSMA–positive metastatic castration-resistant prostate cancer, Novartis (2022)
4. GlaxoSmithKline LLC; Withdrawal of Approval of the Indication for Treatment of Patients With Relapsed or Refractory, Low Grade, Follicular, or Transformed CD20 Positive Non-Hodgkin's Lymphoma Who Have Not Received Prior Rituximab; BEXXAR, Federal Register (2013)
5. Bayer Receives U.S. FDA Approval for Xofigo® (radium Ra 223 dichloride) Injection as a New Treatment for Castration-Resistant Prostate Cancer with Bone Metastases, Bayer (2013)
6. Novartis 2023 Financial Results, Novartis (2023)

Radiopharmaceuticals Market Outlook

The targeted nature of Radiopharmaceuticals mixed with their relatively established value chains (at least compared to other modalities such as cell and gene therapies) have resulted in a more bullish outlook for the wider market. In 2023, the global Radiopharmaceuticals market was valued at ~$6 billion and is expected to reach nearly $14 billion by 2033 with a ten-year CAGR of 8%. While the diagnostic segment accounted for two-thirds of the overall market, the share of therapeutics is expected to increase.

The portfolio and future pipeline of Radiopharmaceutical products support the long-term growth story of the modality. At the time of writing, over 100 interventional trials are in progress (Figure 3). Although the early clinical development of Radiopharmaceuticals has been largely pioneered by specialist mid-size Pharma and Biotech, Big Pharma has been instrumental in bringing these therapies to market and expanding their use in hard-to-treat oncology conditions. For example, trials are currently underway in neuroendocrine tumours (NETs), a particularly challenging tumour type largely resistant to immunotherapies.

Tailwinds in the space include the rising prevalence across oncology conditions, technological advancements and growing expectations from payers and regulators for more targeted therapies with minimal impacts to safety and quality of life (e.g., the FDA's Project Optimus aims to reform dose selection to account for safety and tolerability as much as efficacy, essentially moving away from minimally tolerated dose). However, barriers to wider adoption and market penetration do exist including regulatory complexities, logistical expenses for secure handling and disposal, and the requirement for substantial up-front investment to develop production units.

1. Radiopharmaceuticals Market Size, Share and Trends 2024 to 2033, Precedence Research (2023)
2. Curbing the climb in cancer incidence, Lancet Oncology (2024)
3. Project Optimus, FDA (2024)
4. Scott, AM et al. Trends in nuclear medicine and the Radiopharmaceutical sciences in oncology: workforce challenges and training in the age of theragnostics. Lancet Oncology 25(6): e250-e259

Table 1:
Marketed Radiopharmaceutical products

Product	Company	Approved Indications	Pipeline Indications	Approval Year	Global Sales (USDm, 2023)
ZEVALIN	Acrotech Biopharma	NHL	-	2002 (US) 2004 (EU)	16[a]
BEXXAR	GSK	NHL	-	2003 (US)	Withdrawn[b]
XOFIGO	Bayer	PC, Bone metastasis	-	2013 (US and EU)	433[a]
LUTATHERA	Novartis	GEP-NET	Glioblastoma, SCLC, GEP-NET	2017 (EU) 2018 (US)	605
PLUVICTO	Novartis	PSMA-positive mCRPC	mHSPC, mCRPC, NEPC, OMPC	2022 (US and EU)	980

Sources:
Clinicaltrials.gov, EMA, FDA, BioMed Tracker

Abbreviations:
GEP-NET: Gastroenteropancreatic neuroendocrine tumours; mCRPC: Metastatic castration-resistant prostate cancer; mHSPC: Metastatic hormone-sensitive prostate cancer; NEPC: Neuroendocrine prostate cancer; NHL: Non-Hodgkin lymphoma; OMPC: Oligometastatic prostate cancer; PC: Prostate Cancer; PSMA: Prostate-specific membrane antigen; SCLC: Small cell lung cancer

Notes:
a. ZEVALIN and XOFIGO sales based on 2024 forecast data as 2023 actuals were not available
b. BEXXAR was withdrawn from market in 2013 owing to low sales (30% decline from peak in 2006

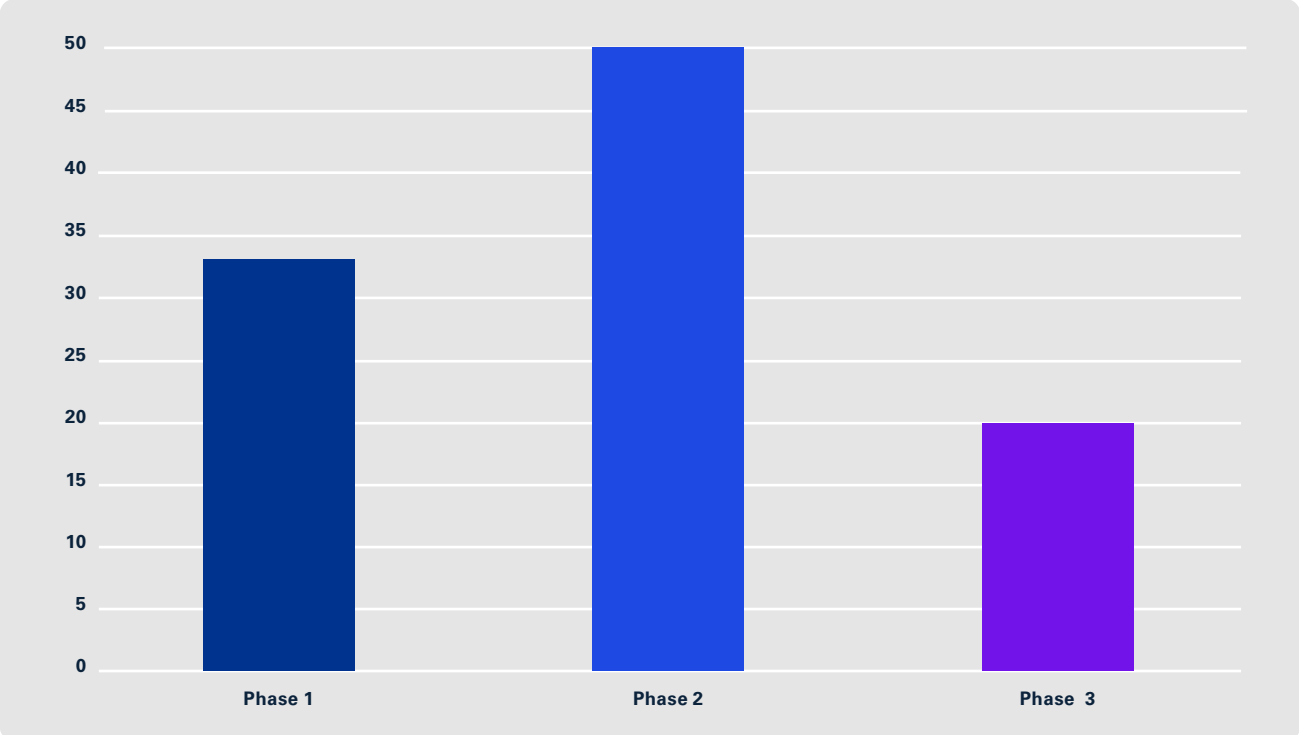
Table 2:
Examples of key assets in late-stage clinical development

	Asset	Study Sponsor	Clinical Phase	Indications
Oncology	FPI-2265	AstraZeneca	P2/3	PC
	RYZ101	BMS	P3	GEP-NET
	ITM-11T	ITM Radiopharma	P3	GEP-NET, Lung-NET
	177Lu-TLX591	Telix Pharma	P3	mCRPC
	177Lu-PSMA-I&T	Curium Pharma	P3	mCRPC
	TheraSphere Y-90Y glass microspheres	Boston Scientific	P3	HCC
Non-Oncology	**I-131**	**Johns Hopkins University**	**N/A**	**Hyperthyroidism**

Sources:
Clinicaltrials.gov

Abbreviations:
GEP-NET: Gastroenteropancreatic neuroendocrine tumours; HCC: Hepatocellular carcinoma; mCRPC: Metastatic castration-resistant prostate cancer; PC: Prostate Cancer

Figure 3:
Radiopharmaceuticals Clinical Development Pipeline



Source: Clinicaltrials.gov

Table 3:
Radiopharmaceuticals versus other therapeutic modalities

	Radiopharmaceuticals	Biologics	Cell & Gene Therapy
Mechanism of Action	**Targeted radiation** Deliver radiation directly to target tissues, either by selective uptake or being targeted through the use of specific biomarkers. The therapeutic effect is based on the radiation's ability to damage diseased cells	**Molecular pathway targeting** Target specific molecular pathways to inhibit or enhance immune responses, supress disease progression, or restore function. Usually involves substances derived from living organisms (e.g., proteins, antibodies, cytokines) that modulate or mimic natural biological processes	**Curative approach** Cell therapy focuses on introducing live cells into the body to replace damaged ones, while gene therapy involves correcting or replacing faulty genes responsible for disease progression. CGT is aimed at long-term correction by addressing the root causes of a condition
Development and Manufacturing	**Tightly regulated use of radioisotopes** Involves synthesis of radioactive isotopes which often requires nuclear reactors or particle accelerators. Short half-lives often make logistics and timely delivery crucial	**Standard biologics processes with some modifications** Development involves recombinant DNA technology where proteins or antibodies are produced by genetically modified cells in bioreactors. Requires complex manufacturing, purification, and validation processes to ensure the safety and effectiveness of end products	**Most complex, costly and time consuming** Significantly more complex compared to other modalities requiring ex-vivo manipulation of cells or genes. For cell therapy, cells are often collected from patient (autologous) or donors (allogeneic), expanded or modified in a lab. Gene therapy often involves viral vectors (e.g., AAV) to deliver therapeutic gene into patient's cells in-vivo or ex-vivo
Typical Applications	**Precision oncology** Primarily used in oncology for both diagnosis (e.g., PET) and treatment (e.g., radionuclide therapy for prostate cancer and NETs)	**Oncology, auto-immunity and infectious disease** Widely used in autoimmunity (e.g., monoclonal antibodies for rheumatoid arthritis), cancers (e.g., checkpoint inhibitors) and infections (e.g., vaccines)	**Rare and genetic conditions** Particularly transformative in rare and genetic disorders (e.g., hemophilia, muscular dystrophy), cancer (CAR-T) and regenerative medicine
Duration of Effect / Treatment Durability	**Short-term** Typically short-term, as their effects are tied to the decay of an isotope which can last from hours to days; repeated doses may be needed	**Variable** Duration of effect may vary, with longer term treatment needed for chronic conditions (e.g., insulin for diabetes), though treatments may be spaced over weeks or months	**Long-term / curative** Therapies are aimed for long-lasting and sometimes permanent effects; potential one-time cures aimed at providing sustained immune responses over months or years
Challenges	**Regulatory and safety arising from radiation exposure** Require "double" approval from both medical and nuclear bodies. Radiation exposure is also challenging from a patient safety and handling perspective	**Manufacturing complexity and immunogenicity** Variable treatment responses have been observed with potential immunogenicity. More complex manufacturing processes can be more costly and time-consuming	**High cost and "moving target" regulations** High cost of therapies and complexity in manufacturing have traditionally limited access. Patient-specific customisation (autologous CTx and *Ex vivo* GTx) can also limit scaling

Deal activity in the Radiopharmaceuticals space

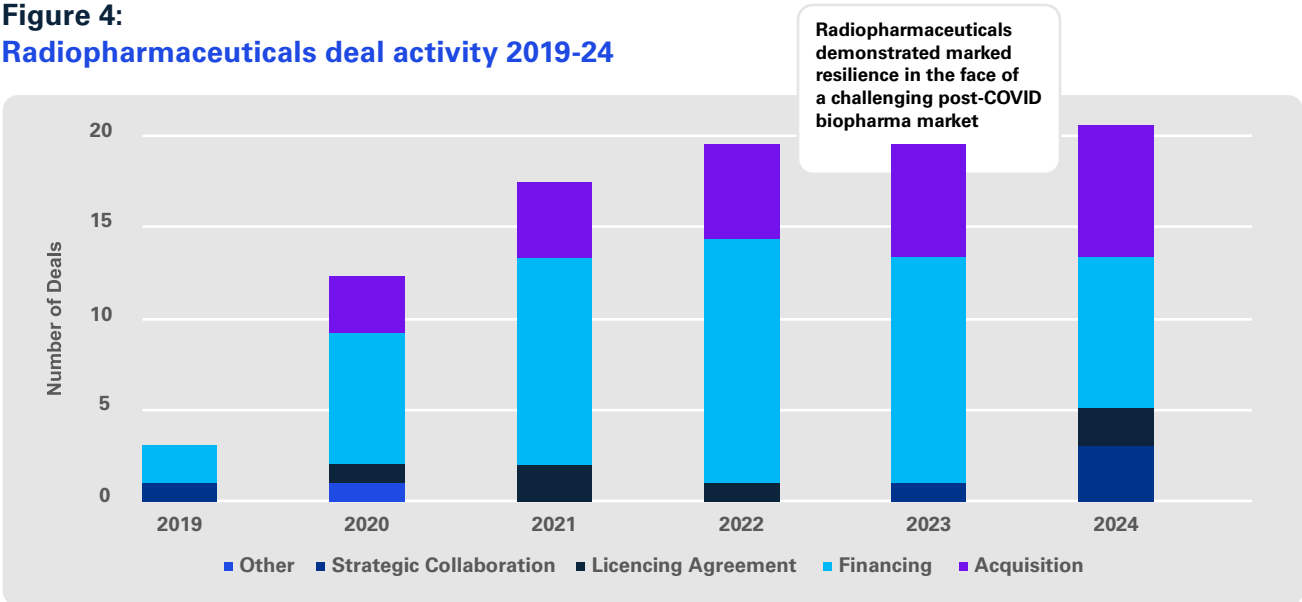
In a challenging post-COVID therapeutics environment, Radiopharmaceuticals have proven to be a relatively resilient asset class, having been cited as a key growth area at the 2024 JP Morgan Healthcare Conference. In the last three years alone, >90 deals have been made in the space including acquisitions, financing, and licensing deals (Figure 4).

Big Pharma has been especially active in Radiopharmaceuticals dealmaking evidenced by several acquisitions and licensing agreements, with six deals made so far in 2024. For example, AstraZeneca acquired Fusion Pharmaceuticals, bringing in four clinical-stage programmes targeting solid tumours into its pipeline. Lilly also entered a strategic collaboration with Aktis Oncology, aiming to leverage Aktis' proprietary miniprotein discovery platform to develop novel therapeutic Radiopharmaceuticals for a range of solid tumours.

From a capital markets perspective, IPO financing reached >$400m in the last 3 years with the offerings of Clarity Pharmaceuticals and RayzeBio, indicating strong growth potential on the therapeutics front (the latter was later acquired by BMS for $4.1 billion in 2023). In the last five years, >$3 billion was deployed in equity financing to fuel the growth of both the primary therapeutics market and its underlying tools and services, forecasting the range of future innovations to come (Table 3).

The space is also attracting attention from mid- and large-cap private equity owing to the channel protection, strong growth prospects and perception of lower risk compared to other therapeutic modalities. For example, Germany-based ITM Radiopharma announced a €255m equity investment with participation from Temasek Holdings, BlackRock and Carbyne. In the tools and services space, iCON Infrastructure purchased Mercurius Health, a full-service solutions provider for nuclear medicine and precision oncology.

Figure 4:
Radiopharmaceuticals deal activity 2019-24



Sources: Mergermarket, Biomedtracker, KPMG internal research

1. 2024 J.P. Morgan Healthcare Conference: key takeaways from the largest biotech gathering of the year, Labiotech (2024)
2. Deal tracking through Mergermarket, BioMed Tracker and KPMG Internal Research (2019-24)
3. AstraZeneca to acquire Fusion to accelerate the development of next-generation radioconjugates to treat cancer, AstraZeneca (2024)
4. Aktis oncology enters into strategic collaboration with Lilly to discover and develop novel anticancer Radiopharmaceuticals, Aktis Oncology (2024)
5. Clarity Pharmaceuticals lists on the ASX, Clarity Pharmaceuticals (2021)
6. RayzeBio, Inc. Announces Pricing of Upsized $311 Million Initial Public Offering, RayzeBio (2023)
7. Bristol Myers Squibb Adds Premier Radiopharmaceutical Platform with Acquisition of RayzeBio, BMS (2023)
8. ITM Announces €255m Investment Round, Plans to Advance Radiopharmaceutical Pipeline and to Expand Radioisotope Production Capacities, ITM Radiopharma (2023)
9. Nexxus Iberia sells Mercurius Health to iCON Infrastructure, Capital Riesgo (2023)

Table 4:
Select recent deals in Radiopharmaceuticals

Date	Company Name	Company Type	Lead Sponsor	Deal Type	Deal Value (USD, m)
Sep-24	Radiomedix	Biopharma	Sanofi	Strategic Collaboration	352
Jul-24	Radionetics Oncology	Biopharma	Eli Lilly	Acquisition	1,000
Jul-24	Glycotope	Pharma Services	Pentixapharm	Acquisition	Undisclosed
Jun-24	Nucleus Radiopharma	CDMO	AstraZeneca	Financing	Undisclosed
May-24	Aktis Oncology	Biopharma	Eli Lilly	Strategic Collaboration	1,160
May-24	Mariana Oncology	Biopharma	Novartis	Acquisition	1,750
Apr-24	Evergreen Theragnostics	CDMO	Petrichor Healthcare Capital	Financing	26
Mar-24	Fusion Pharmaceuticals	Biopharma	AstraZeneca	Acquisition	2,500
Mar-24	Clarity Pharmaceuticals	Biopharma	N/A	Financing (IPO; ASX)	121
Mar-24	Perspective Therapeutics	Biopharma	Undisclosed	Financing (PIPE)	87
Mar-24	ARTMS	Tools and Services	Telix Pharmaceuticals	Acquisition	43
Jan-24	Oncodesign	Pharma Services	Eurazeo	Financing	24
Dec-23	RayzeBio	Biopharma	BMS	Acquisition	3,100
Dec-23	Point BioPharma	Biopharma	Eli Lilly	Acquisition	1,400

Qualifying the opportunity in Radiopharmaceuticals

The Radiopharmaceuticals market is positioned to provide investment avenues for both financial sponsors (e.g., mid-to-large cap private equity) and strategic investors (e.g., Pharma and MedTech). For PE, the emergence of the secondary tools and services market, which supports and proliferates the adoption of Radiopharmaceuticals, may be especially interesting, as every aspect of this value chain undergoes innovation in the next few years (Figure 5).

Radiopharmaceuticals can be thought of as a "protected channel" owing to the complex manufacturing, distribution and disposal of radioisotopes. Scaling of these arduous logistics with growing demand can prove to be a critical bottleneck for commercialisation (e.g., the launch of PLUVICTO was hurdled by supply issues, resulting in widespread cancellations and delays).

Moreover, as the market is flooded with novel Radiopharmaceutical platforms (e.g., alpha emitters), investment in the secondary tools and services space can serve as a layer of protection from obsolescent platforms. Businesses providing local implementation support through innovations in digital services, education, or diagnostic solutions could also serve as attractive targets in the mid-market.

From the strategic perspective, several early and clinical-stage companies are innovating the modality to improve targeting, achieve better safety outcomes and target hard-to-treat disorders. Advancements in cell and tissue targeting through nanomedicine or ADCs and the use of novel radioisotopes with more favourable properties (i.e., alpha emitters) are key innovations that should be considered for scaling by a global strategic player. Incorporating Radiopharmaceuticals with novel combinations provide additional co-positioning opportunities, especially in targeted subpopulations who might better respond to those combinations. In essence, Radiopharmaceuticals can help Pharma to further ratify patient access in an increasingly differentiated oncology treatment landscape.

Figure 5:
Opportunities in the Radiopharmaceutical value chain

Radioisotope Production

- Nuclear reactors and cyclotron operators
- Isotope suppliers
- Dosimetry specialists
- Radioisotope clean rooms
- Radiation threat detection and security services
- PPE providers

Radiopharma -ceuticals R&D

- Discovery services
- Target molecule synthesis
- Linker synthesis
- *In vitro* or animal preclinical safety and toxicity services
- Specialised CROs
- Compliance and regulation advisory services
- Reagents, tools or equipment providers

Manufacturing and Distribution

- CDMOs
- Specialised distribution and logistics
- Nuclear waste management

Clinical Application and Services

- Hospitals and Diagnostic or imaging centres
- Digital oncology solutions
- Education and training of nuclear medicine professionals

Equipment and Maintenance

- Imaging equipment manufacturers
- Parts and maintenance for imaging technology
- Software solutions for analysis, interpretation or data management

The case for investment in Radiopharmaceuticals

Underlying growth in the primary therapeutics market	Big Pharma and capital markets have signalled interest in Radiopharmaceuticals, underpinned by the need for precision treatment in oncology and other disease areas. The modular nature of modern radioligand therapies greatly increases the number of diseases that can be targeted
Hedged risk compared to other emerging therapeutics	Next-generation Radiopharmaceuticals harness the longstanding clinical acceptance of radiation therapy and improve upon it through the power of precise molecular targeting. Thus, the value chain of Radiopharmaceuticals is more established, meaning investors can participate in a novel therapeutic modality without assuming the risk of a highly speculative platforms
Emerging auxiliary market	Increasing demand for Radiopharmaceutical products will give rise to the need for secondary products and services including CROs, CDMOs, raw materials, regulatory/compliance and cold chain logistics
Protected channel with specialist capabilities	Targets in the Radiopharmaceuticals ecosystem have specialist capabilities and regulatory clearances creating high barriers to entry for new players, which in turn can limit competition within the space
Scalable precision medicine	Radiopharmaceuticals can typically serve larger markets, through their applicability in a broader range of conditions. This leads to a higher commercial potential compared to CGT, which are often relegated to rare or orphan indications
Target hard-to-treat populations	The targeted nature of Radiopharmaceuticals can be leveraged to direct radiation to hard-to-reach cells and tissues, allowing patient populations previously refractory to other types of therapy access to new treatment options
Diversify oncology portfolio	As a distinct modality from immunotherapy, chemotherapy and CGT, Pharma can look to add Radiopharmaceutical products into their armamentarium of oncology portfolios, to provide more personalised options to patients

1. Dhoundiyal S. et. al. Radiopharmaceuticals: navigating the frontier of precision medicine and therapeutic innovation. Eur J Med Res 29:26 (2024)
2. Jalilian, A., Decristoforo, C., Denecke, M. et al. Proceedings of international symposium of trends in Radiopharmaceuticals 2023 (ISTR-2023). EJNMMI Radiopharm. Chem. 8, 39 (2023)
3. Novartis halts Pluvicto new patient starts, struggles with radiotherapy's supply amid manufacturing expansion, Fierce Pharma (2023)
4. Miederer M. et al. Alpha-Emitting Radionuclides: Current Status and Future Perspectives. Pharmaceuticals 17(1) (2024)

Remaining challenges in the space

Despite promising growth and significant potential in the Radiopharmaceuticals space, there are several remaining challenges that prospective investors should heed. Although Radiopharmaceuticals offer a more targeted approach, their curative potential is limited by the stage of disease and their use is often a part of comprehensive treatment strategy. Additionally, radiotherapeutics must comply with strict regulations not only from local medicines agencies, but also nuclear bodies, potentially prolonging development timelines and causing risking delays to launch or commercial scale-up. These can be further complicated by supply chain hurdles, including the inherent short half-lives of radioisotopes, leaving no room for error on timely delivery. Finally, with a marked increase in investment from strategics, prospective new investors in the space should expect more competition for quality assets.

1. The Regulatory Landscape of Radiopharmaceuticals: Ensuring Safety and Effectiveness, Regulink (2024)
2. Guideline on Radiopharmaceuticals, EMA (2008)
3. NICE consults on provisional decision to block NHS access to Pluvicto® (lutetium (177Lu) vipivotide tetraxetan) radioligand therapy for advanced prostate cancer, NICE (2022)

Concluding Remarks and Outlooks

In an increasingly challenging Life Sciences market, that demands better efficacy, safety and targeting, Radiopharmaceuticals have the potential to deliver on all three. Having already shown resilience in a biopharma down market, next generation radioligand therapies have an efficacy track record and adaptability that can be applied to a plethora of conditions. In turn, increased demand for Radiopharmaceuticals necessitates the creation of a secondary ecosystem of supporting tools and services to enable delivery at scale. From an investment standpoint, Radiopharmaceuticals present strategic and financial investors the opportunity to participate in an innovative therapeutics market without taking on onerous IP or obsolescence risk.

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