

# Initiation Report

RADIOPHARM THERANOSTICS LTD.



Company Sponsored Research  
01/10/22  
Initiation of Coverage

# RADIOPHARM THERANOSTICS LTD. (ASX: RAD)

## Diversified Portfolio of Radiation Targeted Cancer Therapies

### Investment Highlights

- Diversified Radiopharmaceutical Therapy Pipeline** - Radiopharm has licensed a diversified pipeline of Radiopharmaceutical Therapies (RPTs) spanning from peptides, humanized monoclonal antibodies, and small molecules addressing roughly 75% of the causes of death from cancer. The therapies will be tested as both diagnostic and therapeutic treatments, while the company's advanced pipeline of RPTs currently includes its diagnostic research and clinical trial currently in phase 1/2. The cancer targets range from brain metastases, mRCC, breast cancer, glioma to pancreatic ductal adenocarcinoma (PDAC). The diversified pipeline in our view considerably lowers risk from competition within the RPT market. Published data from the phase 1 and preclinical trials for various therapies under development have demonstrated robust safety and potential efficacy profiles of RPTs as a diagnostic and therapeutic treatment.
- Experienced Management Team** - Radiopharm Theranostics was founded by Paul Hopper who is also the current Executive Chairman of the company. With twenty-five years of experience within the biotechnology, healthcare, and the life sciences sectors, he has been successful identifying and leveraging emerging technologies within the sector. Paul has served as Executive Chairman, Non-Executive Director, and/or CEO for various biotech companies in the U.S. and Australia and was instrumental in the success of Viralytics which was acquired by Merck for roughly \$400 million. The Managing Director and CEO Riccardo Canevari previously served as Chief Commercial Officer (CCO) of Novartis company Advanced Accelerator Applications, one of the leading nuclear medicine companies globally. He has extensive experience within oncology and radiopharmaceuticals more specifically. Radiopharm has been further supported by the scientific team with profound knowledge and experience in the development of RPTs.
- Expanding RPT Market** - The radiopharmaceutical market was valued at \$4.86 billion in 2018 and is projected to grow at a CAGR of 9.2% to reach a market value of \$9.67 billion by 2026. With the advancement in technology, there has been an increasing number of potential radioisotopes and increased demand for radiopharmaceutical therapies (RPT). The future growth of radiopharmaceuticals is expected to be supported by the continued discovery of more-specific targets, improvements in radiochemistry, and the increased and low-cost availability of radionuclides. The current pipeline of RPTs under development by Radiopharm target various cancers, few of which like prostate cancer are researched by other companies, while others including breast cancer and kidney cancer are currently not extensively researched. Even with more competitors entering the market, we believe that the company's diversified portfolio and strong team considerably reduces any competitive risk.
- Valuation** - We have valued Radiopharm Theranostics based on seven indications currently under development. We have assumed a 10-15% probability of success depending on the clinical phase. Based on our assumptions, we have valued at A\$0.84 contingent on successful execution by the company. We view RAD as a suitable investment for institutional and high-risk-tolerant retail investors given the unique high risk-reward opportunity.

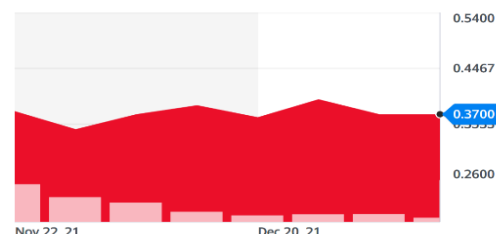
### Company Description

Radiopharm Theranostics is a biotechnology company that has recently licensed four radiopharmaceutical candidates with therapeutic and diagnostic focuses in early development phases. The portfolio includes differentiated platforms, spanning peptides, small molecules, and monoclonal antibodies that address various oncological conditions.

### Biotechnology

Hunter Diamond, CFA  
[research@diamondequityresearch.com](mailto:research@diamondequityresearch.com)  
1441 Broadway 3rd Floor, New York, NY 10018

### Price- Volume History



Source: Yahoo! Finance

### Key Statistics

Closing Price (As of 01/07/2022)	A\$0.37
52 Week Range	A\$0.295-\$0.410
Average Volume (10 days)	2,999.86K
Shares Outstanding (M)	253.3
Market Capitalization (M)	A\$93.73
Number of Analysts Covering	2
Valuation Per Share	A\$0.84
Enterprise Value/Revenue	N/A

### Revenue(A\$ in millions)

Dec. FY	2020A	2021A	2022E
1Q	n/a	n/a	n/a
2Q	n/a	n/a	n/a
3Q	n/a	n/a	n/a
4Q	n/a	n/a	n/a
FY	n/a	n/a	n/a

### EPS(A\$)

Dec. FY	2020A	2021A	2022E
1Q	n/a	n/a	n/a
2Q	n/a	n/a	n/a
3Q	n/a	n/a	n/a
4Q	n/a	n/a	n/a
FY	n/a	(0.09)	(0.11)

## Company Overview

Radiopharm Theranostics (ASX: RAD) is a clinical-stage radiopharmaceutical company that was incorporated in Australia in February 2021. The company is focused on developing and commercializing radiopharmaceutical products and nuclear medicines for both therapeutic and diagnostic applications in precision oncology. The company in our view is working to commercialize its pipeline for a possible licensing and distribution agreement, or possible sale to a leading global pharmaceutical company. It has secured the licenses of four platform technologies, which it is seeking to develop for the diagnosis and treatment of a range of cancers. Radiopharmaceuticals are drugs that contain medical quality radioisotopes designed to take radiation directly to cancer cells, where they can be used to diagnose and treat cancers. These radiopharmaceuticals can be categorized in two distinct methods of operation: ‘Diagnostic’ in which low energy radiation is used to evaluate disease within the body. ‘Therapeutic’ is a method that involves the usage of high-energy particle emitters, isotopes that attack and destroy malignant tumors and targeted cancers. There has been growing interest in the radiopharmaceutical industry and, in particular, therapeutic uses of the technology, due to advancements made in radiopharmaceutical drug development.

*Radiopharm Theranostics has licensed a diversified range of candidates targeting various cancers*

The Company has a pipeline of four licensed platform technologies, with diagnostic and therapeutic applications in both pre-clinical and clinical stages of development, from some of the world’s leading universities and institutes such as Imperial College London and Memorial Sloan Kettering. The company’s product portfolio targets the high unmet medical needs in oncology indications, tumor types that can be considered radiosensitive, and target expression with clear theranostic potential. Radiopharm’s portfolio includes four distinct and highly differentiated platforms, which include peptides, small molecules, and monoclonal antibodies that address roughly 75% of the causes of death from cancer.<sup>1</sup>

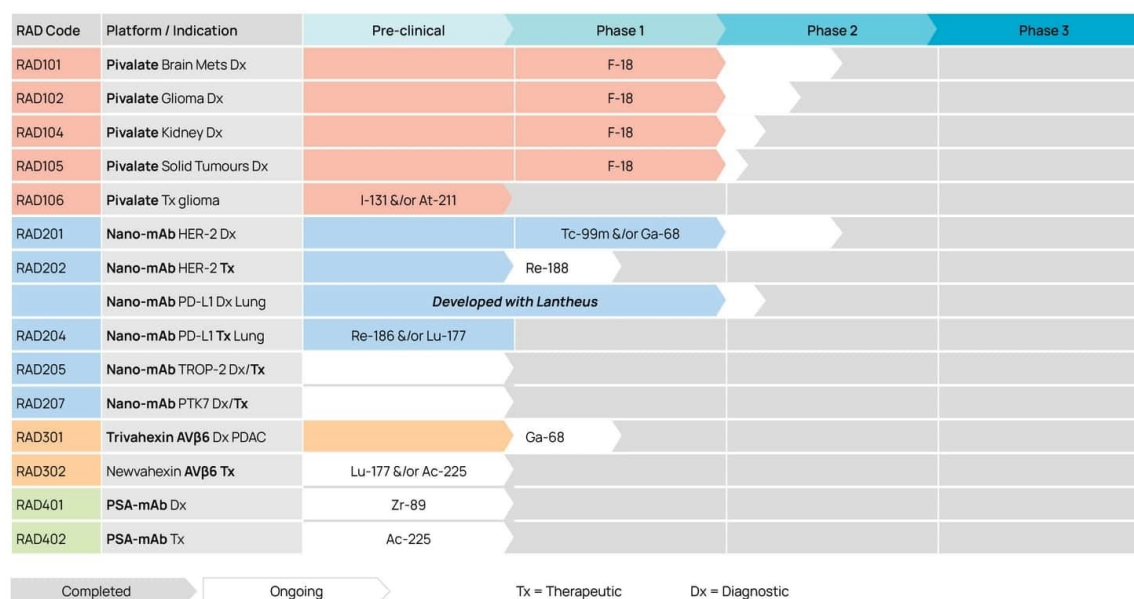
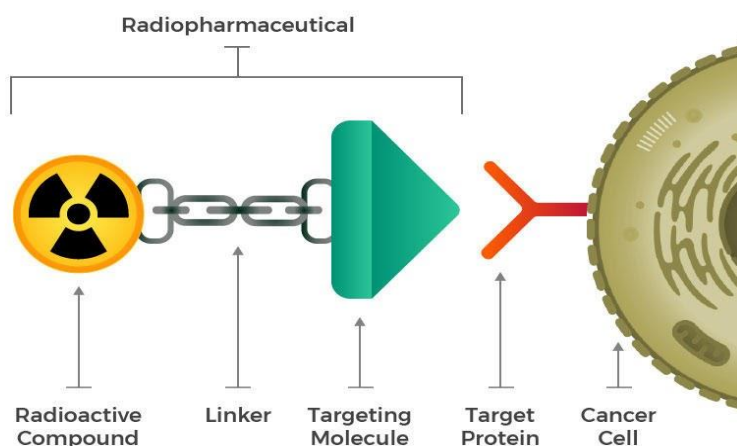


Exhibit 1: Product Pipeline, Source: Company Website

<sup>1</sup> Radiopharm Theranostics Newsletter, December 2021

## Radiopharmaceuticals - An Emerging Targeted Therapy

The past two decades have brought a paradigm shift in the way various types of cancer are treated. In targeted therapies, monoclonal antibodies help to shut down specific proteins in cancer cells or tumors that help them grow, divide, and spread. Immunotherapies work in a way where the body's own immune system gets stimulated or suppressed, which helps to fight cancer. However, common treatment methods like surgery, chemotherapy, and radiation still remain the backbone for cancer treatment. The applications of radiation therapy date back to more than 100 years ago, which is still prevalent even today, as almost half of the patients diagnosed with cancer receive such treatment at some point in time. It is delivered in a way, where the tumor inside the body gets killed using external radiation beams which although effective can also cause serious side effects. The resulting side effects of radiation therapy depend on the area of the body being treated but can include loss of taste, skin changes, hair loss, diarrhea, and sexual problems.



*Radiopharmaceutical Therapy (RPT) holds tremendous potential as a safe and targeted approach to treating cancer*

Exhibit 2: Radiopharmaceuticals Mechanism of Action, Source: National Cancer Institute

Researchers are working on the development of a new class of drugs called radiopharmaceuticals, which helps to overcome the limitations faced using radiation therapy in terms of minimizing severe side effects. These drugs are often referred to as medicinal radio compounds, which contain radioactive isotopes and can be used as both diagnostic and therapeutic agents. Lately, oncologists are showing an increased inclination towards using radiopharmaceuticals that contain radioactive particles, which are attached to drugs that precisely target and kill cancer cells. In this case, radiation therapy is delivered directly and specifically to cancer cells, which helps to reduce the potential risk of both short and long-term side effects of the treatment. Over the last few years, there has been an increasing trend in the number of clinical trials and research & development using radiopharmaceutical products.

Radiopharmaceutical Therapy (RPT) is evolving as a safe and effective targeted approach to treating various types of cancer.<sup>2</sup> In RPT, radiation is systemically or locally delivered using pharmaceuticals that either bind preferentially to cancer cells or accumulate by physiological

mechanisms.<sup>2</sup> RPT has shown strong efficacy with minimal toxicity in comparison to all other systemic cancer treatment options. Technetium-99m (Tc-99m) is the most widely used radioisotope in radiopharmaceuticals which is the decay product of Molybdenum-99 (Mo-99) and is mainly generated in research reactors. The radiopharmaceuticals approved by the U.S. FDA for cancer treatment are as follows:

### US-FDA Approved Radiopharmaceuticals

**Radium-223 dichloride (Xofigo®) for metastatic prostate cancer in the bones**

**Sodium iodide I-131 (Hicon®) for thyroid cancer**

**Iobenguane iodine-131 (Azedra®) for adrenal gland tumors**

**Lutetium-177 (Lutathera®) for neuroendocrine tumors of the digestive tract**

**Yttrium-90 (Zevalin®) for non-Hodgkin lymphoma**

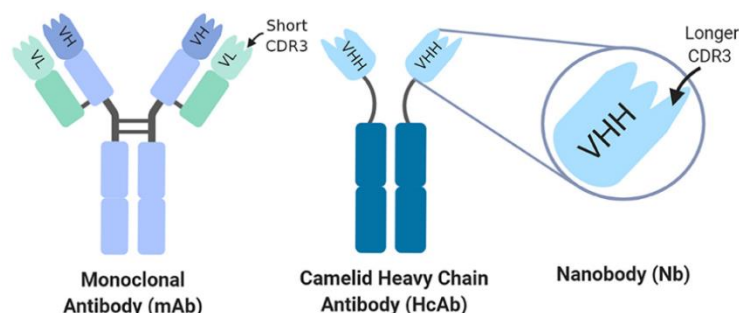
**Samarium-153 lexidronam (Quadramet®) has been approved for its pain-killing properties for metastatic bone lesions in breast cancer, prostate cancer, and other cancers**

*There are more than 300 radionuclides relevant for medicine with just a few of them extensively researched*

Exhibit 3: US-FDA Approved Radiopharmaceuticals (Cancer Treatment). Source: [Cancercenter](https://www.cancercenter.org/)

### Nano-mAbs

Radiopharm Theranostics' pipeline of licensed theranostics includes a novel radiopharmaceutical platform invented by Dr. Hong Hoi Ting, founder and CEO of NanoMab Technology Limited. The development of targeted medicine has led to the creation of various therapies with monoclonal antibodies (mAbs) emerging as the prevalent treatment in recent years. However, nanobodies have been gaining traction both in cancer imaging and treatment as a more effective and efficient drug delivery mechanism.



*Heavy Chain Antibodies or Affibodies holds various advantages in terms of structure, MoA compared to that of mAb*

Exhibit 4: monoclonal antibody (mAb) vs. heavy chain antibody (HcAb), Source: [Nanobodies: Next Generation of Cancer Diagnostics and Therapeutics](https://www.nature.com/articles/nrn3888)

The NanoMab platform is a unique technology based on a single-domain antibody that can be genetically engineered and labeled with radioisotopes to diagnose and treat cancers expressing HER-2 TROP-2, PD-L1, and PTK7 antigens. Single chain antibodies or nanobodies are produced

<sup>2</sup> Sgouros, G., Bodei, L., McDevitt, M.R. et al. Radiopharmaceutical therapy in cancer: clinical advances and challenges. Nat Rev Drug Discov 19, 589–608 (2020). <https://doi.org/10.1038/s41573-020-0073-9>

mainly by camelid species (camels, llamas) that lack the structural feature of light chains generally seen in conventional antibodies. In comparison to conventional antibodies, nanobodies have lighter weight and are smaller in size. The innate properties of nanobodies provide various advantages over conventional antibodies making them an ideal drug delivery vehicle. Nanobodies exhibit better pharmacokinetics with better circulation time, deeper penetration, and high specificity to the target. From a manufacturing standpoint, nanobodies are simple and inexpensive to produce. Lacking post-translational modifications, nanobodies can be synthesized through microbial systems, with the additional benefit of generating homogeneous products.<sup>3</sup>

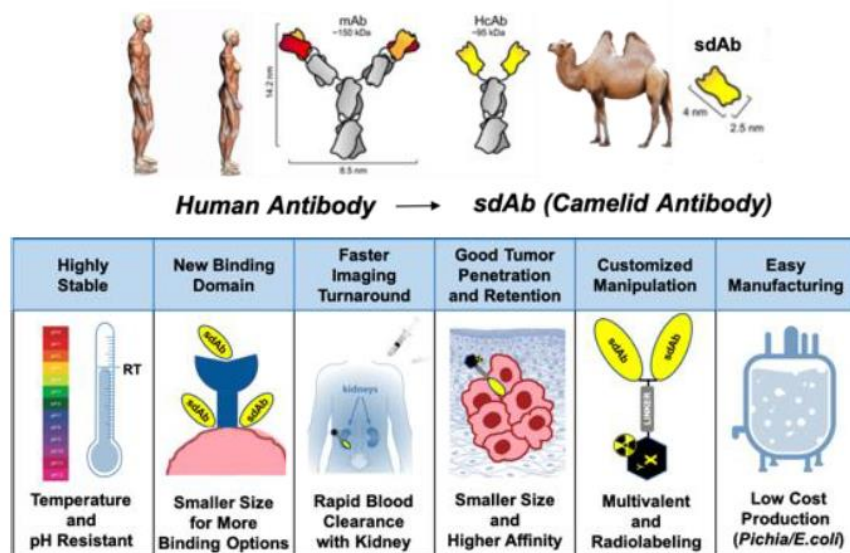


Exhibit 5: sdAb Platform Source: Investor Presentation

## Clinical Development and Clinical Study Results

RAD is evaluating Technetium 99m single domain antibody targeting HER 2 for breast cancer, PD L1 for Non-Small Cell Lung Cancer & TROP 2 for Triple Negative Breast Cancer. A phase 1 imaging trial has been completed on 40 patients using 99M TC-NM-02, a diagnostic nanobody recognizing HER-2 positive breast. While the company has concluded the phase 1 diagnostic trial, the phase 1 therapeutic study is about to launch in late-stage HER2+ breast cancer in the U.S. with Re-188.

### RAD201 - Phase 1 Diagnostic Study for HER2+ Breast Cancer

The company recently announced the completion of a phase 1 imaging study evaluating the safety, dosimetry, and efficacy of RAD201 in HER2+ breast cancer subjects. Human Epidermal Growth Factor Receptor 2 (HER2) protein promotes the growth of cancer cells found in about 15-30% of breast cancer cases. HER2 serves as a prognostic and predictive biomarker, overexpression of which is often associated with aggressive disease and poor prognosis. The

*Overexpression of  
HER2+  
biomarker has  
also been  
observed in  
Gastric,  
Esophageal and  
Ovarian Cancer  
regulating cell  
growth, survival,  
and cellular  
proliferation*

<sup>3</sup> Yang Emily Y., Shah Khalid, Nanobodies: Next Generation of Cancer Diagnostics and Therapeutics, *Frontiers in Oncology*, 10, 2020, 1182, <https://www.frontiersin.org/article/10.3389/fonc.2020.01182>, 10.3389/fonc.2020.01182, 2234-943X



phase 1 procedure involved injecting the HER2+ subjects with RAD201, allowing for nanobodies to localize at HER2+ cancer. Single Photo Emission Computed Tomography (SPECT) imaging is used to identify HER2+ areas that were localized using RAD201. The results demonstrated good binding characteristics with an outstanding target to the background making quantification of the disease straightforward. RAD201 SPECT imaging non-invasively visualizes cancer while displaying a clear delineation of active tumor manifestation. RAD201 provided more accurate and detailed information in comparison to Immunohistochemistry (IHC) and fluorescence in situ hybridization (FISH) detection from biopsy samples. Aside from one minor grade adverse event reported as unrelated to RAD201/99mTc-NM-02 tracer, the drug and dosage exhibited robust safety and efficacy profile, albeit at an early stage.

### **RAD202 - Phase 1 Therapeutic Study for HER2+ Breast Cancer**

Radiopharm has begun the Phase 1 therapeutics trials in late-stage HER2+ breast cancer. The therapeutics study utilizes the same targeting mechanism of action, just using different targeting agents (Tc 99m to Re 188). 188Re-NM-02 will be tested in 11 patients in phase 1 trial as a radionuclide therapy for HER2+ metastatic breast cancer, with dose escalation to determine the right dosage and understand the safety profile for the subsequent trial phases.

### **Nano-mAb PD-L1 Diagnostic for Non-Small Cell Lung Cancer**

NanoMab has licensed the diagnostic uses of 99mTc-NM-01 (PD-L1) independently of RAD to Lantheus Holdings, Inc., which is currently in clinical trials. A phase 1 diagnostic/imaging trial was completed in 2019 with a focus on subjects with Non-Small Cell Lung Cancer (NSCLC). Programmed death ligand 1 (PD-L1) biomarkers have improved survival in a subset of patients with advanced lung cancer and are found in 24%-60% of the patient population with NSCLC<sup>4</sup>. The detection of PD-L1 expression has been the primary predictive biomarker for response to anti-PD-L1 immunotherapy. The phase 1 study involved administration of single domain antibody NM-01 genetically engineered and radiolabelled with 99Tc radioisotope against PD - L1 in 16 subjects with homeopathically proven NSCLC. No drug-related adverse events were observed in the study. The two-hour tumor to blood pool ratio (T: BP) was lower in tumors with PD-L1 expression and correlated with PD-L1 immunohistochemistry results. Tracer uptake was observed in the kidneys, spleen, liver, and bone marrow. 99mTc-labeled anti-PD-L1-sdAb SPECT/CT using 99mTc-NM-01 have proven to be a safe diagnostic procedure presenting favorable blood distribution and imaging characteristics. The results efficacy and safety results were promising that correlated with immunohistochemistry results - the gold standard in diagnostic for NSCLC. The company has received approval for Phase 2 clinical trial by MHRA and Drug Master Files have been filed with the U.S. FDA.

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<sup>4</sup> Hui Yu, Theresa A. Boyle, Caicun Zhou, David L. Rimm, Fred R. Hirsch, PD-L1 Expression in Lung Cancer, Journal of Thoracic Oncology, Volume 11, Issue 7, 2016, Pages 964-975, ISSN 1556-0864, <https://www.sciencedirect.com/science/article/pii/S1556086416303409>, <https://doi.org/10.1016/j.jtho.2016.04.014>

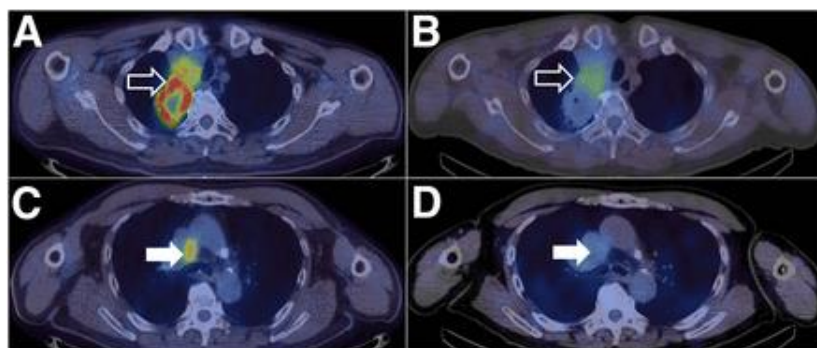


Exhibit 6: SPECT/CT, Source: [Phase I Study](#)

## Market Opportunity - Breast and Lung Cancer

Breast cancer most commonly occurs in women and is the second most common cancer type globally with an estimated 2.3 million new cases diagnosed annually. Reviews generally report that approximately 15% to 30% of breast carcinomas show an overexpression of the oncoprotein HER2. The breast cancer therapy market stood at \$20.20 billion in 2020 which is projected to grow at a CAGR of 8.3% to reach a market value of \$32.60 billion by 2026.<sup>5</sup> This growth is attributed to the increased incidence rate, high prevalence of breast cancer across the globe, and a strong product pipeline that provides effective and upgraded treatment options along with the development of alternative therapies. Currently, the treatment option depends on the stage of breast cancer and most often includes radiation, chemotherapy, hormone therapy, and surgery. Breast cancer is the most common cancer in women in the WHO Europe region with an estimated incidence of 576,300 cases in 2020. According to breastcancer.org, an estimated 281,550 new cases of invasive breast cancer are expected to be diagnosed in 2021 in the U.S., along with 49,290 new cases of non-invasive breast cancer.<sup>6</sup>

The global lung cancer therapeutics market stood at \$18.32 billion in 2018 which is projected to grow at a CAGR of 13% to attain a market value of \$48.72 billion by 2026.<sup>7</sup> It occurs due to uncontrolled cell growth in the lungs which spreads innumerable causing cough, chest pain, weight loss, and shortness of breath. On the basis of disease type, it is classified into non-small cell lung cancer (NSCLC) and small cell lung cancer (SCLC), where the former cancer type dominates the market and accounts for 80%-85% of all lung cancer cases globally. Currently, the treatment options include chemotherapy, surgery, targeted therapies, radiation therapy, and immunotherapy. The treatment for lung cancer provides lucrative opportunities for the existing companies and attracts new ones into the market due to the huge addressable patient population. As per National Cancer Institute (NIH), lung and bronchus cancer represent 12.4% of all new cancer cases in the U.S. The rate of new cases of lung and bronchus cancer was 53.1 per 100,000 men and women per year and the death rate was estimated to be around 36.7 per 100,000 men and women per year.<sup>8</sup>

<sup>5</sup> Breast Cancer Therapy Market - Growth, Trends, Covid-19 Impact, And Forecasts (2021 - 2026), Mordor Intelligence

<sup>6</sup> U.S. Breast Cancer Statistics, [https://www.breastcancer.org/symptoms/understand\\_bc/statistics](https://www.breastcancer.org/symptoms/understand_bc/statistics)

<sup>7</sup> Global Lung Cancer Therapeutics Market, Fortune Business Insights

<sup>8</sup> Cancer Stat Facts: Lung and Bronchus Cancer, <https://seer.cancer.gov/statfacts/html/lungb.html>



## Pivalate

Radiopharm licensed 18F-FPIA imaging agent developed as the result of research undertaken at Imperial College London by Professor Eric Aboagye. Pivalate is an artificial fatty acid that binds the enzyme fatty acid synthetase and is very stable. Glucose and fatty acids dominate as energy sources required for normal cellular homeostasis. Short-chain fatty acids (SCFAs) such as acetate, propionate, butyrate, and pivalate are rapidly taken up by tumors. For example, in tumor models of malignant glioma, acetate contributes over half of oxidative activity, while glucose contributes only a third.<sup>9</sup> SCFA's use early steps of the oxidation pathway, but unlike acetate pivalate cannot be oxidized to carbon dioxide in mammalian cells.<sup>10</sup> Post the esterification of Pivalate, the resulting ester plasma is rapidly eliminated in urine. Pivalate aims at detection and progression monitoring of Glioma, Kidney Cancer, Brain Mets, and Solid Tumors using the novel agent Fluoropivalate (FPIA), tagged with the radioisotope Fluorine-18 (18F-FPIA).

### Clinical Development and Clinical Study Results

Pivalate is the most advanced candidate under RAD's diversified pipeline with a diagnostic agent currently under phase 2 clinical trials. RAD is progressing its Pivalate candidate with a number of indications under the diagnostic application.

The phase 1 diagnostic study included the administration of 18F-FPIA in 24 healthy volunteers to understand the safety, dosimetry, and biodistribution profile of the diagnostic agent.<sup>10</sup> Trial participants were divided into two groups of 12 each - fed group and fasted group. The phase 1 study results showed promising results with over 90% of radiotracer present in plasma at 60 minutes post-injection. The study also demonstrated benefits over 18F-FDG Imaging. 18F-FDG is an analog of glucose and, as such, a versatile radiopharmaceutical with major applications in oncology, neurology, and cardiology. Compared to 18F-FDG, very low uptake was observed within the brain, suggesting the potential use of 18F-FPIA in future brain tumor imaging efforts. In addition to the biodistribution profile, the radiation dosimetry profile was also favorable with mean ED at  $0.0154 \pm 0.0010$  mSv/MBq, lower than the ED of 18F-FDG (0.019 mSv/MBq). No adverse events were reported in all 24 patients. The benefits were also visible with Pivalate delaying urinary excretion patterns. The optimistic safety and efficacy profile indicates the potential for future cancer imaging and treatment in both CNS and pelvic malignancies. Over 90% of radiotracers were present in plasma 60 minutes post-administration.

*The phase 1  
diagnostic study  
demonstrated the  
superiority of 18F-  
FPIA PET  
Imaging over 18F-  
FDG PET/CT  
imaging*

<sup>9</sup> Strickland Marie, Stoll Elizabeth A., Metabolic Reprogramming in Glioma, Frontiers in Cell and Developmental Biology, 5, 2017, 43, <https://www.frontiersin.org/article/10.3389/fcell.2017.00043>, 10.3389/fcell.2017.00043

<sup>10</sup> Dubash, S.R., Keat, N., Kozlowski, K. et al. Clinical translation of 18F-fluoropivalate – a PET tracer for imaging short-chain fatty acid metabolism: safety, biodistribution, and dosimetry in fed and fasted healthy volunteers. Eur J Nucl Med Mol Imaging 47, 2549–2561 (2020). <https://doi.org/10.1007/s00259-020-04724-y>

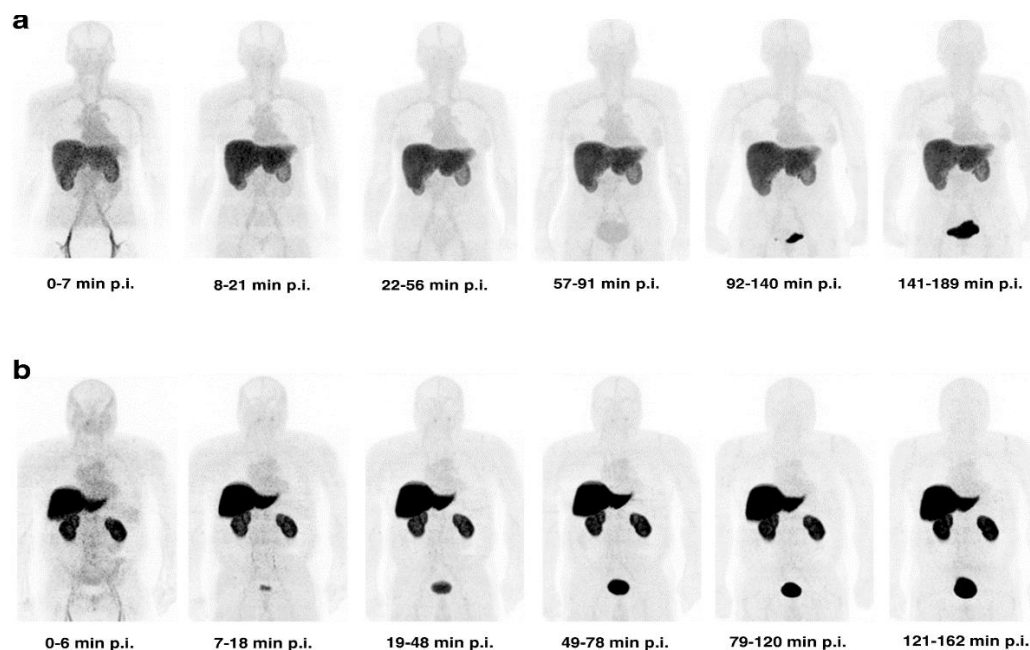


Exhibit 7: Biodistribution of 18F-FPIA in male and female healthy subjects Source: [Clinical translation of 18F-fluoropivalate](#)

- Single-dose 18F-FPIA (maximum, 370 MBq) IV will be administered under phase 2 diagnostic study targeting patients with glioma followed by a whole-brain dynamic PET/MRI scan. The primary outcome of the study is to measure 18F-FPIA uptake in 20 patients with glioma.
- The second indication under Pivalate targets patients with cerebral metastases. The study includes 24 patients with radiological evidence of cerebral metastases on MRI. Patients will be administered with a single dose of 18F-FPIA (maximum, 370 MBq) IV followed by a whole-brain dynamic PET/MRI scan over 66 minutes. The primary outcome of the study is to measure 18F-FPIA uptake within the cerebral metastases of treatment naïve patients and patients treated with stereotactic radiosurgery (SRS).
- A phase 2 diagnostic study targeting patients with metastatic renal cell cancer. 24 patients with radiological and/or histological evidence of mRCC are administered with single dose 18F-FPIA (maximum 370 MBq) IV followed by whole-body PET/CT scanning from 60 minutes. Patients will have three imaging visits at baseline, 4-6 weeks, and 12 weeks post the commencement of treatment. The goal of the study is to measure the uptake of 18F-FPIA in mRCC at the baseline time frame of 4-6 weeks and 12 weeks post-commencement of treatment.
- The fourth indication currently under phase 2 diagnostic study targets solid tumors. The open-label phase 2 study will recruit 21 patients. The primary outcome of the study is to measure the 18F-FPIA uptake and its relation with tumor proliferation, to understand and determine which cancers are using fatty acids as an energy source and if they can be measured. Patients will undergo two PET/CT scans with the 18F-FPIA tracer on two separate visits.

## Market Opportunity - Glioma, Brain Metastases, and Kidney Cancer

According to Research & Markets, the global kidney cancer drugs market will grow from \$3.29 billion in 2021 to \$3.6 billion in 2025 at a CAGR of 2.3%.<sup>11</sup> Kidney cancer is also known as renal cancer, which occurs due to innumerable cell growth in the kidney. The two most common types of kidney cancer are renal cell carcinoma (RCC) and transition cell carcinoma (TCC) of the renal pelvis. RCC accounts for approximately 80% of primary renal cancers, whereas TCC accounts for the remaining 20% of the cases. As per the American Cancer Society's estimates, there were roughly around 73,820 new cases of kidney cancer that represent around 4.2% of all new cancer cases in the United States. This also led to the death of 14,770 patients in 2019.

Brain Metastases is a type of cancer that is caused when carcinoma cells spread innumerable from their original site to the brain. This may result in mortality and morbidity among cancer patients. As the tumor spreads and advances towards the brain it creates symptoms like edema, seizure, headache, memory loss, and many others. Lung, breast, colon, kidney, & melanoma cancer are most likely to lead towards brain metastasis. As per the American Association of Neurological Surgeons, about 0.2 million new cases of brain metastases are being diagnosed annually in the U.S. According to the WHO, globally, an estimated 245,000 cases of brain and nervous system tumors are reported annually.<sup>12</sup>

*Glioma, Brain Metastases and Kidney Cancer together represent a huge addressable market*

Glioma is a condition that covers a broad category of brain and spinal cord tumors that can be fatal depending on the location and severity of the tumor. According to the Atlas of Genetics and Cytogenetics in Oncology and Hematology, glioma comprises about 30% of the brain tumors and 70% of all the malignant tumors. Gliomas are categorized as rare diseases; however, in the last decade, the incidence rate and prevalence of gliomas have increased steadily. The global adult malignant glioma therapeutics market was valued at \$14.59 billion in 2018 which is projected to grow at a CAGR of 9.3% and will reach a market value of \$29.64 billion by 2026.<sup>13</sup>

## AVβ6 - Integrin

Trivehexin (AVβ6 Integrin) is a strong and selective ligand for a cell surface protein called αvβ6 integrin. The technology was developed at TRIMT GmbH (Germany) for imaging and diagnosis of tumors overexpressing αvβ6-integrin expression. The novel compound when labeled with 68Ga radionuclide has potential as an imaging agent. αvβ6-integrin is over-expressed in many cancers such as pancreatic carcinoma, cervical, head-and-neck, and lung cancers. Integrins are a family of cell surface receptors which primarily mediate the binding and physical attachment of cells to various insoluble strand proteins, such as collagen, laminin, fibronectin, vitronectin, and others, that constitute the extracellular matrix (ECM)<sup>14</sup>. Integrins regulate cellular growth, proliferation, migration, signalling, and cytokine activation and release and thereby play

<sup>11</sup> Kidney Cancer Drugs Global Market Report 2021: COVID-19 Impact and Recovery to 2030, Research and Markets

<sup>12</sup> Adult Malignant Glioma Therapeutics Market, Mordor Intelligence

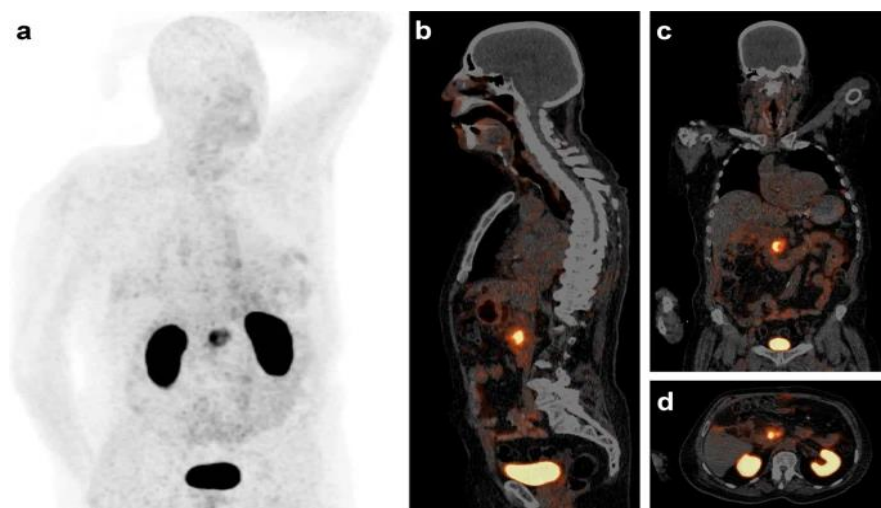
<sup>13</sup> Adult Malignant Glioma Therapeutics Market, Fortune Business Insights

<sup>14</sup> Kossatz S, Beer AJ, Notni J. It's Time to Shift the Paradigm: Translation and Clinical Application of Non-αvβ3 Integrin Targeting Radiopharmaceuticals. *Cancers*. 2021; 13(23):5958. <https://doi.org/10.3390/cancers13235958>

important roles in cell proliferation and migration, apoptosis, tissue repair, as well as in all processes critical to inflammation, infection, and angiogenesis.<sup>15</sup>

### Clinical Development and Clinical Study Results

The image below shows the <sup>68</sup>Ga-Trivehexin PET/CT of a male patient with histologically confirmed Pancreatic ductal adenocarcinoma (PDAC). Apart from pancreatic head prominent signals are observed in kidneys and urinary bladder due to renal excretion. No relevant uptake was observed in the liver, stomachs, intestines. The company is in the process to begin the phase 1 clinical trial which is expected to include patients with histologically confirmed PDAC. The primary outcome of the phase 1 trial will be to observe the uptake and to compare the trial imaging results with immunohistochemistry results.



*αvβ6 Integrin has been demonstrated to modulate tumor cells and promotes carcinoma progression*

Exhibit 8: PET/CT imaging of pancreatic carcinoma targeting the “cancer integrin” αvβ6, Source: [European Journal of Nuclear Medicine and Molecular Imaging](#)

### Market Opportunity

According to Market Data Forecast, The Global Pancreatic Cancer Therapeutics Market is valued at \$2.59 billion in 2021 which is projected to grow at a CAGR of 7.54% to reach a \$3.73 billion market value in 2026. In comparison to women, men are more prone to get diagnosed with pancreatic cancer, and as per SEER estimates, it accounts for around 7% of the total deaths caused by cancer in the U.S. annually. Adenocarcinoma accounts for more than 90% of pancreatic cancer diagnoses.

Pancreatic ductal adenocarcinoma (PDAC) is a highly devastating disease with a poor prognosis and rising incidence<sup>16</sup>. According to The American Cancer Society’s estimates, about 60,430 people will be diagnosed with pancreatic cancer in 2021 leading to the deaths of roughly around

<sup>15</sup> Mezu-Ndubuisi, O.J., Maheshwari, A. The role of integrins in inflammation and angiogenesis. *Pediatr Res* 89, 1619–1626 (2021). <https://doi.org/10.1038/s41390-020-01177-9>

<sup>16</sup> Orth, M., Metzger, P., Gerum, S. et al. Pancreatic ductal adenocarcinoma: biological hallmarks, current status, and future perspectives of combined modality treatment approaches. *Radiat Oncol* 14, 141 (2019). <https://doi.org/10.1186/s13014-019-1345-6>

48,220 patients. The incidence of PDAC is projected to increase two-folds in the coming decade with the rising number of cases and 5-year overall survival of less than 8%. There are various imaging techniques being used for diagnosing pancreatic cancer which include CT scan, MRI, and ultrasound. Current treatment options include surgery, radiation therapy, targeted therapies (growth factor inhibitors & anti-angiogenesis factors), immunotherapy, and amongst all the other procedures, chemotherapy is the most common treatment option adopted by medical practitioners and oncologists.

## PSA-mAb

Radiopharm has sublicensed its fourth theranostic platform from Diaprost AB that targets prostate cancer for use as a diagnostic and therapeutic. Diaprost AB licensed the platform and patents related to it from Memorial Sloan Kettering Cancer Center in 2020. The humanized mAb that is PSA-mAb has been developed to specifically bind to human kallikrein 3 (“hK3”) also known as Prostate Specific Antigen (PSA). hK3/PSA is a 33 kDa single-chain glycoprotein synthesized in the epithelial cells of the prostate gland. With chymotrypsin-like enzymatic activity, hK3 is, directly and indirectly, involved in a number of diverse biological functions including male fertility, the regulation of cell proliferation, and the inhibition of angiogenesis.<sup>17</sup> PSA is generally found in small quantities in the serum of men with healthy prostate, while it is elevated in the presence of prostate cancer.

*Recently it has become widely accepted that Prostate Specific Antigen (PSA) or hK3 is also present in many non-prostatic sources*

## Clinical Development and Preclinical Study Results

Independent studies were conducted at Memorial Sloan Kettering Cancer Center, New York using two murine models (i) LNCaP-AR xenografts in NSG mice (ii) PSA expressing transgenic mice. The animal subjects were treated with 89Zr- or treated with 90Y- or 225Ac- labeled PSA.

The study results indicated that treatment with 90Y/225Ac-PSA-mAb effectively reduced tumor burden and prolonged survival. Complete responses were observed in 7 of 18 mice infused with 225Ac-PSA-mAb and 1 of 9 mice infused with 90Y-PSA-mAb.<sup>18</sup> Effects of beta-emitting 90Y-PSA-mAb were more immediate than 225Ac-PSA-mAb but less sustained.<sup>18</sup> The imaging agent 89Zr-PSA-mAb’s pharmacokinetics were consistent between mice and nonhuman primates (NHPs). Overall, the preclinical evaluation in both murine models demonstrated the ability of PSA-mAb as a theranostic for treating and diagnosing/imaging prostate cancer. The company is currently in the preclinical stages, while we expect the phase 1 clinical trials to begin within 18-24 months.

<sup>17</sup> Jeremy G. Stone, Raj K. Rolston, Masumi Ueda, Hyoung-Gon Lee, Sandy L. Richardson, Rudy J. Castellani, George Perry, Mark A. Smith, Evidence for the Novel Expression of Human Kallikrein-related Peptidase 3, Prostate-Specific Antigen, in the Brain, Int J Clin Exp Pathol. 2009; 2(3): 267–274. Published online 2008 Oct 20

<sup>18</sup> Immunotheranostics in Murine Prostate Cancer Models and Nonhuman Primates, Clin Cancer Res April 1 2021 (27) (7) 2050-2060; DOI: 10.1158/1078-0432.CCR-20-3614



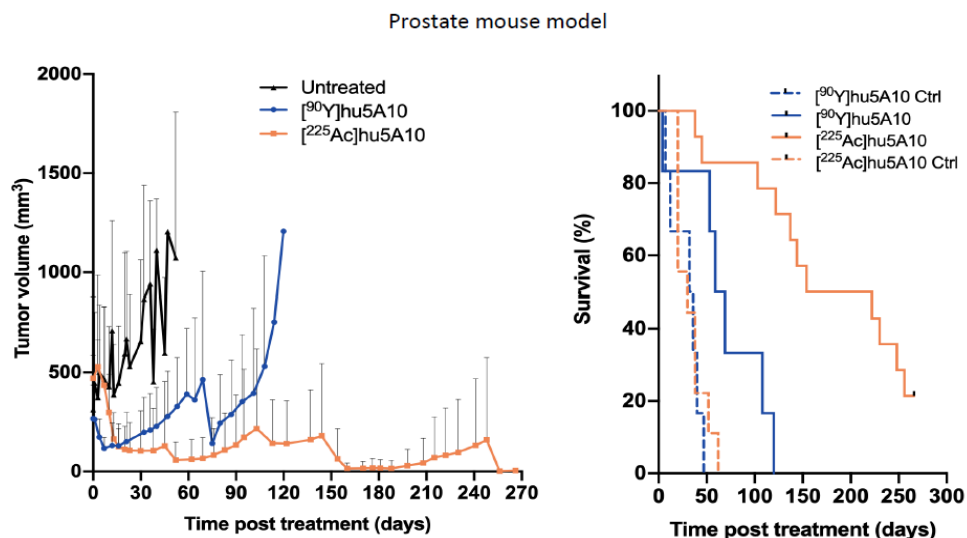


Exhibit 9: Prostate Mouse Model Source: Investor Presentation

## Market Opportunity

According to Allied Market Research, in 2018 the Global Prostate Cancer Market was valued at \$6.9 billion which is projected to grow at a CAGR of 4.6% and reach a market value of \$9.9 billion by 2026.<sup>19</sup> Prostate cancer is a type of cancer in which cells grow abnormally and invade the prostate gland in an uncontrolled manner. In terms of the severity of the disease, prostate cancer comes at the sixth position amongst the mortality related to cancer and eleventh in terms of loss of life from any disease.

In 2020 alone there were an estimated 1.4 million new cases of prostate cancer leading to the death of around 375,000 patients worldwide. The incidence rate of prostate cancer amongst men in higher HDI countries is 37.5 per 100,000 and in the lower HDI countries, it is 11.3 per 100,000. According to the American Cancer Society's estimates for 2021, there are approximately 248,530 new cases of prostate cancer in the U.S. alone.<sup>20</sup> The various treatment methods for Prostate Cancer include Radiation Therapy, Chemotherapy, Surgery, Biological Therapy, and Hormone Therapy, which are widely accepted standard treatments by medical practitioners and oncologists. There are various diagnostic and therapeutic products used in the treatment and management of prostate cancer such as prostatic adenocarcinoma, benign prostatic hyperplasia, small cell carcinoma, and others.

## Radiopharmaceutical Industry Dynamics

The development of cardiological, oncological, and neurological therapies has gained momentum in the last few decades because of the much-needed push attributed due to progress in immunology, biology, and genetics. In the past two decades, multiple radionuclide-based targeted therapies have gradually emerged as one of the most efficient and effective techniques for

<sup>19</sup> Prostate Cancer Treatment Market, Allied Market Research

<sup>20</sup> Key Statistics for Prostate Cancer, American Cancer Society, <https://www.cancer.org/cancer/prostate-cancer/about/key-statistics.html>

inflammatory lesions and cancer treatment.<sup>21</sup> New radiopharmaceuticals are emerging today as R&D activity intensifies and particularly  $\beta^-$  emitters are increasingly being used across clinical research or tested in ongoing clinical trials along with other therapeutic radionuclides. This gives a noteworthy push to the Radiopharmaceutical Industry as a whole which was valued at \$4.86 billion in 2018 and is projected to grow at a CAGR of 9.2% to attain a market value of \$9.67 billion by 2026.

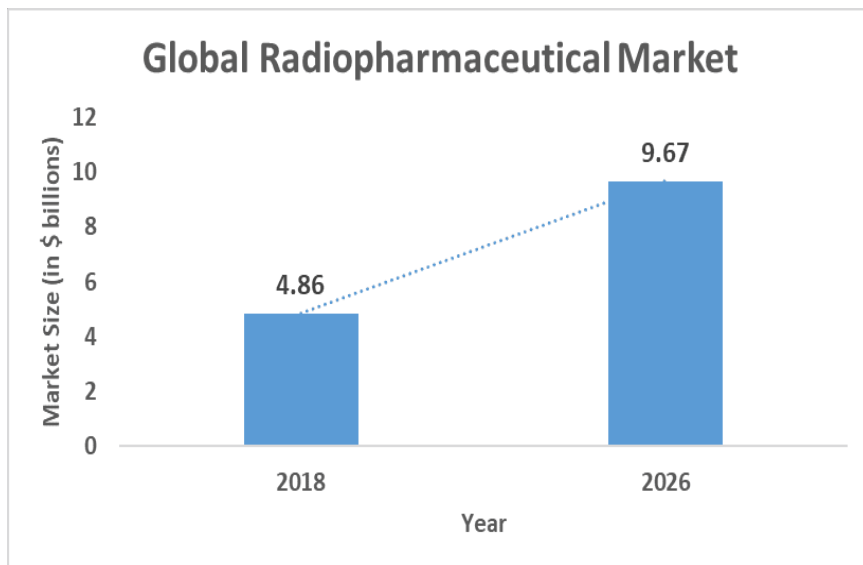


Exhibit 10: Global Radiopharmaceutical Market. Source: [Fortune Business Insights](#)

There are several promising factors currently providing significant impetus to the global radiopharmaceutical/nuclear medicine market and a necessary push to the various radiopharmaceutical product offerings. Nuclear medical imaging and the introduction of advanced technologies such as SPECT & Positron Emission Tomography (PET) often play a significant role in protecting health by diagnosing and managing serious chronic ailments well in time. There are various factors attributing to the growth of the radiopharmaceuticals market such as increased incidence rate of targeted diseases and rising prevalence of cancer cases, and initiatives to lessen the demand-supply gap of Mo-99.

In therapeutic radiopharmaceuticals, recent product launches such as Lutathera by Advanced Accelerator Applications, and anticipated product launches due to robust pipelines in upcoming years, are expected to drive the global market.<sup>22</sup> Radiopharmaceuticals are increasingly being used for the treatment of severe diseases like cancer, cardiovascular diseases, and neurological disorders. It is because of their characteristics of radioactive decay and ability of targeted therapeutic irradiation that radiopharmaceuticals are extensively being used for the treatment of such diseases. Companies are entering the radiopharmaceutical market by way of acquisitions, joint partnership agreements, and most significantly growing organically through product launches.

<sup>21</sup> Radiopharmaceutical Market Global Industry Analysis, Size, Share, Growth, Trends, and Forecast, 2021 - 2031, Transparency Market Research

<sup>22</sup> Nuclear Medicine/Radiopharmaceuticals Market Size, Share & Industry Analysis, Fortune Business Insights

Date	Companies Involved	Clinical Development Stage	Acquisition Value
Jan 2018	Novartis/Advanced Accelerator Application	Approved	US\$3.9b
Dec 2018	Novartis/Endocyte	Phase 3	US\$2.1b
June 2019	Bracco/Blue Earth Diagnostics	Approved	US\$450M+
March 2021	Point Biopharma/Research Alliance Corp.	Phase 3	US\$300M

Exhibit 11: Key Radiopharmaceutical Acquisitions. Source: Investor Presentation

For instance, earlier this year, Cardinal Health launched Navista™ TS to assist oncology practices in improving patient care, lowering costs, and achieving success in value-based care. Furthermore, additional investments by big pharmaceutical companies like Jubilant Radiopharma into SOFIE Biosciences Inc. also paves the way for other companies to enter and expand in this market. Other leading players in the radiopharmaceutical market include Siemens Healthineers, GE Healthcare, Bayer AG, Telix Pharmaceuticals, Avanos Medical Inc., etc.

Name	Company	Approval	Sales*	Dx/Tx
CERIANNA™	Zionexa	May-20	N/A	Dx
Vizamyl™	GE Healthcare	Oct-13	N/A	Dx
NETSPOT™	Advanced Accelerator Applications	Jun-16	\$90	Dx
LUTATHERA®	Advanced Accelerator Applications	Jan-18	\$445	Tx
AZEDRA®	Lantheus Medical Imaging	Jul-18	N/A	Tx
TAUVID™	Eli Lilly	May-20	N/A	Dx
Xofigo®	Bayer Healthcare Pharmaceuticals	May-13	\$296	Tx
Lymphoseek®	Cardinal Health	May-13	N/A	Dx
Axumin™	Blue Earth Diagnostics	May-16	N/A	Dx

Exhibit 12: Approved Radiopharmaceutical Therapies Source: Diamond Equity Research.  
2020 Sales in \$US Millions\*

## Competitive Landscape

The radiopharmaceutical market is emerging and competitive with a number of private and public companies developing radiopharmaceutical therapies (RPT) for various hematological malignancies and solid tumors. There are two other companies listed on ASX aside from RAD that are focused on developing RPTs. There are few large pharmaceutical companies like Novartis, Bayer, and J&J who have either gained exposure to RPTs through organic or through inorganic means. With these many small biotech companies have entered the theranostics market as well

The majority of the therapies that are currently being researched are targeting prostate cancer, hematological malignancies, Neuroendocrine tumors (NETs) while companies entering the market have started targeting other forms of cancer too. We believe that the RPT market still has huge room to accommodate more players and the research ongoing in RPTs is underpenetrated compared to other forms of treatment such as immunotherapies.




Company	Cancer Target	Clinical Phase
Clarity Pharmaceuticals	Prostate Cancer	Phase 1/2
Telix Pharmaceuticals	Prostate Cancer, Kidney Cancer	Illuccix® (US FDA approved), Phase 3
Advanced Accelerator Applications (Novartis)	NETS, Prostate Cancer	Lutathera®/NETSPOT (US FDA approved), Phase 3
Advanced Accelerator Applications (Novartis)	Multiple Solid Tumors, Glioblastoma	Phase 1/2
Fusion Pharmaceuticals	Solid Tumors	Phase 1
J&J/ Fusion Pharmaceuticals	NSCLC	Phase 1
Bayer	HER2+ tumors	Preclinical
Bayer	Lymphoma	Phase 1

Exhibit 13: Selected RPT agents under Development Source: Diamond Equity Research and [Radiopharmaceutical therapy in cancer](#)





Radiopharm Theranostics is well positioned given its diversified portfolio, targeting various cancers like prostate cancer, solid tumors, breast cancer, metastatic renal cell carcinoma (mRCC), and Lung Cancer. The competitive risk within RPTs is minimal, while the competition from other forms of emerging cancer treatment entering the market still exists.

## Management Team

Radiopharm Theranostics is led by a world-class management team of C-suite executives recruited from the most prestigious radiopharmaceutical companies who bring extensive educational qualifications and knowledge in the field of biotechnology. The board comprises experienced and seasoned life science-focused directors with prior radiopharmaceutical and biotechnology experience.

 <p><b>Riccardo Canevari</b> <b>M.D. &amp; C.E.O.</b></p>	<p>Riccardo Canevari serves as the Managing Director and Chief Executive Officer of Radiopharm Theranostics. He has rich and diverse experience in specialty pharma, oncology, and radiopharmaceuticals. He was most recently the Chief Commercial Officer of Novartis Company Advanced Accelerator Applications program, which is one of the leading radiopharmaceuticals and nuclear medicines companies globally. Previously, he has served in key management roles in companies including Novartis, Ethicon, and Johnson &amp; Johnson.</p>
 <p><b>Paul Hopper</b> <b>Executive Chairman</b></p>	<p>Paul Hopper is an Australian serial biotech entrepreneur and currently serves as the Executive Chairman of Radiopharm Theranostics. He has a rich experience of more than 25 years in the fields of biotechnology, healthcare, and life sciences. He brings experience serving on boards of companies like Imugene, Chimeric Therapeutics, Viralytics, Prescient Therapeutics, and Arovella Therapeutics. He has been a key person in various M&amp;A, and Biotechnology deals including Viralytics which was acquired for \$400 million by Merck.</p>
 <p><b>Professor David Mozley</b> <b>Chief Medical Officer &amp; Scientific Advisory Board Chair</b></p>	<p>David Mozley has extensive experience in the field of nuclear medicine and most recently he served as the Chief of Nuclear Medicine at Cornell University. He was also the principal investigator for first-in-human pharmaceutical industry contracts from three different companies using novel radiopharmaceuticals as major endpoints. He has practical experience in the development of novel radiopharmaceuticals with his active participation in over 60 clinical trials at Eli Lilly and over 100 trials at Merck during his career.</p>



 <p><b>Dr. Thom Tulip</b> Chief Technology Officer</p>	<p>Dr. Thom Tulip currently serves as the Chief Technology Officer at Radiopharm Theranostics and has spent over 25 years in the development and commercialization of radiopharmaceuticals and imaging agents. He has also served senior leadership roles at various biotech companies including Navidea, Alseres, Lantheus Medical Imaging, Bristol Myers Squibb, and DuPont.</p>
 <p><b>Dr. Gitasha Chand</b> Global Medical Director</p>	<p>Dr. Gitasha joined RAD on January 1<sup>st</sup>, 2022, as Global Medical Director. She will be responsible for monitoring early phase trials as Dr. Chand is a physician with special expertise in radiopharmaceutical drug development. She heads the clinical research department at NanoMab Technology Limited, where she was involved in planning and supervising the completion of two early Phase 1 studies in Shanghai. These studies involved targeting PD-L1 expression in non-small cell lung cancer and HER2 expression in breast cancer.</p>
 <p><b>Dr. Levente Meszaros</b> Global Director of Translational Science</p>	<p>Dr. Meszaros joined RAD on January 1<sup>st</sup>, 2022, as Global Director of Translational Science. He is an expert in molecular imaging and radioconjugate development. He serves as Technical Operations Director at NanoMab Technology Limited, where he is responsible for overlooking non-clinical tracer development, technology transfer, and GMP manufacturing of small molecules. Prior to joining RAD, he was a research scholar at King's College London focusing his research on radiolabeled peptide hormones.</p>
 <p><b>Dr. Scot Harper</b> Senior V.P. of Clinical Operations</p>	<p>Dr. Harper has extensive experience in drug development and joined RAD's management team on December 1<sup>st</sup>, 2021. He has served senior executive roles such as Vice President at companies like Eli Lilly, Novartis, and Parexel. He was also the SVP of Clinical Development at Endocyte, working on radiopharmaceutical imaging and therapies.</p>

## Valuation Outlook

We have valued Radiopharm Theranostics based on those candidates that are in clinical phase or will enter the clinical trials in the near term. We have assumed a probability of success of 10% for the candidates currently in phase 1 and 15% for those currently in phase 2 clinical trial. The revenue has been modeled in both the major geographies that are, US and Europe where the company has required licenses. Even with a number of diagnostic candidates under clinical development, a significant value is derived from its therapeutic candidate. Peak market penetration varies from indication and ranges from 13.5% - 16.5%.

We initiate coverage on Radiopharm Theranostics with our valuation model indicating a fair value of A\$0.84 using DCF as our preferred methodology, assuming successful execution by the company.

Drug/Therapy	Indication	Probability of Success	Status	Treatment Price (\$US)	Approval Year
Pivalate Diagnostic	Glioma	15%	Phase -2	\$10,900.00	2028
Pivalate Diagnostic	Brain Mets	15%	Phase -2	\$10,900.00	2027
Pivalate Diagnostic	Kidney Cancer	15%	Phase -2	\$10,900.00	2028
Nano-mAbs Diagnostic	HER2+ Breast Cancer	15%	Phase -2	\$10,900.00	2027
Nano-mAbs Diagnostic	Non Small Cell Lung Cancer	15%	Phase -2	\$10,900.00	2028
Nano-mAbs Therapeutic	HER2+ Breast Cancer	10%	Phase -1	\$215,000.00	2030
AVβ6 Integrin Diagnostic	PDAC	10%	Phase -1	\$10,900.00	2030

	Approaches (in \$ mm)	Value (AUD)	Weight	Wtd. Value (AUD)	
Calculated Equity Value (\$mm)	DCF	\$205.49	80%	\$164.39	
Enterprise Value	\$140.77	GPCM	\$242.29	20%	\$48.46
- Debt and Preferred Stock	\$0.00	GTM	-	0%	\$0.00
+ Cash	\$64.72	Wtd Avg. Equity Value (USD)			\$212.85
Net Debt	\$64.72	No of Shares			253.33
Equity Value	\$205.49	Intrinsic Value Per Share			\$0.84

Company Name	Ticker	Price	Currency	Exchange	Market Cap.	P/B	P/R&D
Clarity Pharmaceuticals	CU6	0.75	AUD	ASX	192.1 Million	7.02	19.85
CycloPharm Ltd.	CYC	1.63	AUD	ASX	152.20 Million	3.43	42.99
Telix Pharmaceuticals	TLX	7.88	AUD	ASX	2246.37 Million	46.3	79.80
OncoSil Medical Limited	OSL	0.04	AUD	ASX	34.07 Million	0.01	11.79
Actinium Pharmaceuticals	ATNM	6.43	USD	NYSE	146.73 Million	1.83	9.12
Clovis Oncology	CLVS	3.08	USD	NASDAQ	412.03 Million	0	1.99
Fusion Pharmaceuticals Inc.	FUSN	4.98	USD	NASDAQ	214.58 Million	5.72	4.33
Nanobiotix S.A.	NANO	7.18	EUR	ENXTPA	249.94 Million	6.03	10.27
Lantheus Holdings, Inc.	LNTH	29.91	USD	NASDAQ	1990.78 Million	7.38	42.99
Y-mAbs Therapeutics, Inc.	YMAB	16.99	USD	NASDAQ	770.32 Million	4.83	8.70
Pliant Therapeutics, Inc.	PLRX	14.68	USD	NASDAQ	553.56 Million	6.13	7.22
Cellectar BioSciences, Inc.	CLRB	0.68	USD	NASDAQ	42.77 Million	0.61	2.71
Median						5.28	9.70
Mean						7.44	20.15

Exhibit 14: Valuation and Comps Snapshot, Source: Diamond Equity Research

## Financial Position of the Company

After the recent IPO raising A\$50 million, Radiopharm Theranostics has a cash balance of over A\$60 million. The company is currently in the early stages of clinical development, and thus model no revenue for next 5-6 years. We expect the cash burn rate to be at A\$25-A\$30 million for the short to medium term and increase as the company advances its pipeline to further clinical stages. The current cash balance at the expected cash burn rate would support the company's research and operational activities for the next 6-8 quarters. The company will have to go through additional rounds of funding to progress its pipeline and for commercialization activities later in the future. Radiopharm does not have any debt on its balance sheet, which we expect to stay constant.

RADIOPHARM THERANOSTICS												
Income Statement												
(in AUD except per share amounts or otherwise stated)												
Income Statement	FY2020 A	FY2021 A	FY2022 E	FY2023 E	FY2024 E	FY2025 E	FY2026 E	FY2027 E	FY2028 E	FY2029 E	FY2030 E	FY2031 E
Net sales	-	-	-	-	-	-	-	9,130,193.0	25,751,857.4	48,170,363.2	144,686,476.1	241,488,407.6
Cost of sales	-	-	-	-	-	-	-	(2,282,548.2)	(6,437,964.3)	(12,042,590.8)	(36,171,619.0)	(60,372,101.9)
Gross profit	-	-	-	-	-	-	-	6,847,644.7	19,313,893.0	36,127,772.4	108,514,857.1	181,116,305.7
Operating expenses												
General and Administrative Expenses	-	(125,266.0)	(5,542,479.0)	(5,819,603.0)	(6,110,583.1)	(6,232,794.8)	(6,357,450.7)	(4,108,586.8)	(10,300,743.0)	(19,268,145.3)	(50,640,266.6)	(84,520,942.7)
Marketing Expense	-	-	-	-	-	-	-	(730,415.4)	(2,060,148.6)	(3,853,629.1)	(7,234,323.8)	(12,074,420.4)
Research and Development	-	-	(12,500,000.0)	(16,250,000.0)	(22,750,000.0)	(31,850,000.0)	(28,665,000.0)	(31,531,500.0)	(3,090,222.9)	(4,817,036.3)	(14,468,647.6)	(16,904,188.5)
Share Based Payments	-	(359,487.0)	-	-	-	-	-	-	-	-	-	-
EBITDA	-	(484,753.0)	(18,042,479.0)	(22,069,603.0)	(28,860,583.1)	(38,082,794.8)	(35,022,450.7)	(29,522,857.5)	3,862,778.6	8,188,961.7	36,171,619.0	67,616,754.1
Depreciation and amortization expenses	-	-	(5,731,351.0)	(5,761,351.0)	(5,806,351.0)	(5,866,351.0)	(5,926,351.0)	(6,002,001.9)	(6,145,509.9)	(6,426,414.4)	(7,159,270.4)	(8,626,734.9)
Other income/ (expense)	-	-	-	-	-	(1,188,645.1)	(7,062,063.4)	-	(185,335.0)	(6,063,005.2)	(1,131,687.3)	(1,635,380.6)
License Agreement Payments	-	-	-	-	-	-	-	-	-	-	-	-
Other non operating expenses	-	(437.0)	-	-	-	-	-	-	-	-	-	-
EBIT	-	(485,190.0)	(23,773,830.0)	(27,830,953.9)	(34,666,934.1)	(45,137,790.8)	(48,010,865.0)	(35,524,859.5)	(2,468,066.3)	(4,300,457.9)	27,880,661.4	57,354,638.6
Interest Income	-	-	135.5	276,903.4	152,927.5	21,320.6	136,946.3	89,661.1	(24,215.7)	(58,125.0)	(59,964.9)	42,007.4
Interest Expense	-	-	-	-	-	-	-	-	-	-	-	-
Profit before exceptional items, extraordinary items and tax	-	(485,190.0)	(23,773,694.5)	(27,554,050.6)	(34,514,006.6)	(45,116,470.2)	(47,873,918.7)	(35,435,198.4)	(2,492,282.0)	(4,358,582.9)	27,820,696.5	57,396,646.0
Exchange loss (net)	-	-	-	-	-	-	-	-	-	-	-	-
Provision for costs associated with closure of operations and impairment of intangible	-	-	-	-	-	-	-	-	-	-	-	-
Employee separation cost	-	-	-	-	-	-	-	-	-	-	-	-
Profit before tax from continuing operations	-	(485,190.0)	(23,773,694.5)	(27,554,050.6)	(34,514,006.6)	(45,116,470.2)	(47,873,918.7)	(35,435,198.4)	(2,492,282.0)	(4,358,582.9)	27,820,696.5	57,396,646.0
Income tax (expense) benefit	-	-	-	-	-	-	-	-	-	-	7,233,381.1	(14,923,128.0)
Net earnings including noncontrolling interests	-	(485,190.0)	(23,773,694.5)	(27,554,050.6)	(34,514,006.6)	(45,116,470.2)	(47,873,918.7)	(35,435,198.4)	(2,492,282.0)	(4,358,582.9)	20,587,315.4	42,473,518.1
Share of profit / (loss) of associates (net)	-	-	-	-	-	-	-	-	-	-	-	-
Minority interest	-	-	-	-	-	-	-	-	-	-	-	-
Net earnings attributable to RadioPharm Theranostics	-	(485,190.0)	(23,773,694.5)	(27,554,050.6)	(34,514,006.6)	(45,116,470.2)	(47,873,918.7)	(35,435,198.4)	(2,492,282.0)	(4,358,582.9)	20,587,315.4	42,473,518.1
Adjusted Net Income	-	(485,190.0)	(23,773,694.5)	(27,554,050.6)	(34,514,006.6)	(45,116,470.2)	(47,873,918.7)	(35,435,198.4)	(2,492,282.0)	(4,358,582.9)	20,587,315.4	42,473,518.1

Exhibit 15: Income Statement Snapshot, Source: Diamond Equity Research

## Risk Profile

- **Dependence upon license agreements** - Radiopharm is reliant on the continuing operation of the license agreements. Any failure of the licensor or inability of the company to comply with the terms of the agreement could have a material adverse impact on business performance, financial condition, and may also affect any future commitments.
- **Third-party collaboration risk** - The company may work jointly with pharmaceutical and life science companies and collaborate with academic institutions for carrying out further research & development activities. If the company is unable to collaborate with a third party it would affect the financial position of the company as all the R&D and commercialization expenses will need to be borne by the company itself.
- **Ability to raise capital:** The company will likely be required to raise additional equity or debt capital in the future which might lead to further dilution of equity. There is no assurance a raise will be successful when required and/or at attractive terms.
- **Dilution risk:** The company is still in the developmental stage and does not generate a regular income currently. The company is heavily dependent on external capital for continuing its research and developmental activities leading to dilution of the stake of the current shareholders.
- **Delay in approval and commercialization:** The company might encounter hurdles in the development process given the novel nature of therapies. Any delays in approval or additional or unanticipated clinical trials will affect the cash burn and valuations of the company
- **Small Business Risk:** Given the smaller size and limited history of operations, the company faces various small business risks including strategic risk, liability risk, and security risk which might lead to permanent loss of capital.

*These risk factors are not comprehensive. For a full list of risk factors, please read Radiopharm Theranostics' latest prospectus and/or annual filings*

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