

Radiopharm Theranostics Ltd. – Multiple Pipeline Candidates Progressing Towards Clinical Trials

Radiopharm Theranostics Ltd. (ASX: RAD)



Key Statistics

52 Week Range	A\$0.13 - A\$0.50
Avg. Volume (3 months)	366.74K
Shares Outstanding	255.43M
Market Capitalization	A\$56.19M
EV/Revenue	n/a
Cash Balance*	\$26.97M
Analyst Coverage	3

*Cash balance as of June 2022

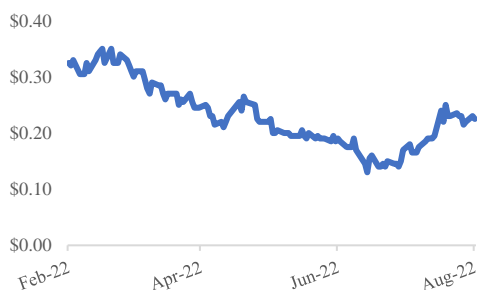
Revenue (in A\$mm)

June - FY	2021A	2022E	2023E
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 (in A\$)

June - FY	2021A	2022E	2023E
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	(0.12)	(0.09)

Stock Price Chart (in A\$)



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Share Price: A\$0.22

Valuation: A\$0.88

Investment Highlights

- Key partnerships aiding progress in clinical trials** - Radiopharm Theranostics engaged in multiple partnerships in the past few months that are expected to advance the company's pipeline of radiopharmaceutical therapies. The company entered into a supply agreement with Isotopia Molecular Imaging to supply high-quality Lutetium - 177 N.C.A for the purpose of conducting research, clinical trials, development, and early-stage commercialization of Radiopharm's diagnostic and therapeutic products. Lutetium - 177(Lu- 177) has been widely discussed and proven to be one of the promising radioisotopes. Radiopharmaceuticals based on Lu-177 have gained prominence due to their excellent therapeutic performance for certain cancer treatments. [Novartis](#) recently gained the approval of lutetium Lu 177 vipivotide tetraxetan for the treatment of adult patients with prostate cancer. Additionally, Radiopharm extended its [previous agreement](#) with GenesisCare to support a second Radiopharm clinical trial in Australia. The trial will use Radiopharm's PSA targeting antibody to start a therapeutic Phase 1 in prostate cancer. A global oncology provider GenesisCare aims to bring novel therapies and precision medicine to more cancer patients through its global innovation programs.
- Strong financial position and lower than expected burn rate** - The company ended the quarter and year with an operating cash burn of \$3.7 million and \$9.9 million, respectively. Research and staff expenditure accounted for 83% and 78% of the total operating cash burn for the quarter and year ended June 2022. The operating cash burn was reported lower than our expectations of \$15.1 million for the year. The company reported cash and cash equivalents of \$26.9 million as of June 2022. We expect the company's operating cash burn to steadily increase as both therapeutic and diagnostic candidate advances toward clinical trials.
- Valuation** - Radiopharm has a diversified pipeline of therapeutic and diagnostic candidates targeting diseases with high unmet needs. Five new candidates are expected to enter the phase 1 clinical trial during the second half of 2022. We have updated our valuation methodology, reducing our estimates for the near-term operating cash burn. Even though we have reduced our near-term estimates, we expect the operating cash burn to increase significantly as more candidates enter clinical trials. Updating the discount rates and the comparable company analysis, our valuation methodology yielded a value of \$224.19 million or \$0.88 per share, 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 licensed four radiopharmaceutical candidates with therapeutic and diagnostic focuses in the early development phases. The portfolio includes differentiated platforms, spanning across peptides, small molecules, and monoclonal antibodies that address various oncological conditions.

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.¹

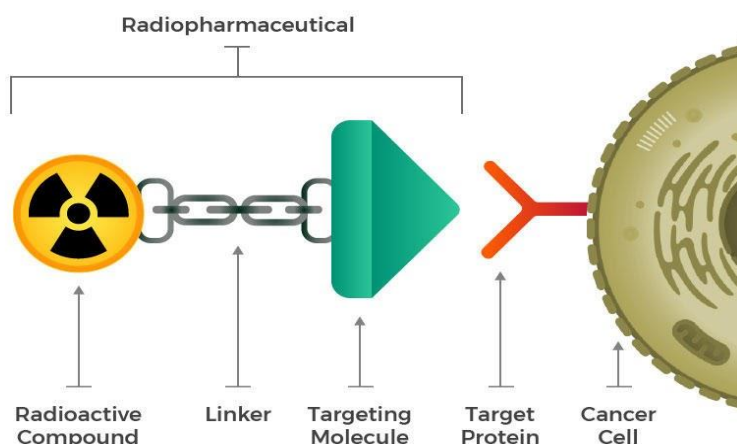
RAD Code	Platform / Indication	Isotope	Country	Pre-clinical	Phase 1	Phase 2	Notes
RAD101	Pivalate Brain Mets Dx	F18	UK				Phase II read out 2H 2022
RAD101	Pivalate Glioma Dx	F18	UK				
RAD101	Pivalate Kidney Dx	F18	UK				
RAD101	Pivalate Solid Tumours Dx	F18	UK				
RAD102	Pivalate Glioblastoma Tx	I131	UK				
RAD201	Nanobody HER2 Breast Dx	Tc99	USA				
RAD202	Nanobody HER2 Breast Tx	Re188	USA				Phase I planned 2H 2022
RAD204	Nanobody PDL1 NSCLC Tx	Re188	AUS				Phase I planned 2H 2022
RAD205	Nanobody TROP2 TNBC Tx	Ga68					
RAD206	Nanobody TROP2 TNBC Tx	Lu177					
RAD207	Nanobody PTK7 Ovarian Dx	Ga68					
RAD208	Nanobody PTK7 Ovarian Tx	Lu177					
RAD301	Integrin αVβ6 Pancreatic Dx	Ga68	USA				Phase I planned 2H 2022
RAD302	Integrin αVβ6 Pancreatic Tx	Lu177	USA				
RAD401	PSA-mAb Prostate Dx	Zr89	AUS				Phase I planned 2H 2022
RAD402	PSA-mAb Prostate Tx	Ac225	AUS				Phase I planned 2H 2022
RAD501	Dunp19 Osteosarcoma Dx	Cu64	USA				
RAD502	Dunp19 Osteosarcoma Dx	Lu177	USA				
RAD601	PTPμ Glioblastoma Dx	Ga68					
RAD602	PTPμ Glioblastoma Tx	Lu177					

Exhibit 1: Product Pipeline, Source: Company Website

¹ 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.² In RPT, radiation is systemically or locally delivered using pharmaceuticals that either bind preferentially to cancer cells or accumulate by physiological

mechanisms.² 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.com)

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 inflammatory lesions and cancer treatment.³ New radiopharmaceuticals are emerging today as R&D activity intensifies and particularly β^- 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.

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

² Sgouros, G., Bodej, 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>

³ Radiopharmaceutical Market Global Industry Analysis, Size, Share, Growth, Trends, and Forecast, 2021 - 2031, Transparency Market Research

market.⁴ 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.

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 4: 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 5: Approved Radiopharmaceutical Therapies Source: Diamond Equity Research.
2020 Sales in \$US Millions*

⁴ Nuclear Medicine/Radiopharmaceuticals Market Size, Share & Industry Analysis, Fortune Business Insights

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® (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 5: 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.

Appendix

Income Statement	FY2020 A	FY2021 A	FY2022 E	FY2023 E	FY2024 E	FY2025 E	FY2026 E	FY2027 E	FY2028 E	FY2029 E
Net sales	-	-	-	-	-	-	-	9,130,193.0	25,751,857.4	48,170,363.2
Cost of sales	-	-	-	-	-	-	-	(2,282,548.2)	(6,437,964.3)	(12,042,590.8)
Gross profit	-	-	-	-	-	-	-	6,847,644.7	19,313,893.0	36,127,772.4
Operating expenses										
General and Administrative Expenses	-	(125,266.0)	(6,917,364.0)	(7,263,232.2)	(7,626,393.8)	(7,778,921.7)	(7,934,500.1)	(8,673,683.3)	(16,738,707.3)	(21,676,663.4)
Marketing Expense	-	-	-	-	-	-	-	(730,415.4)	(2,060,148.6)	(3,853,629.1)
Research and Development	-	-	(6,022,271.0)	(5,735,496.2)	(7,456,145.0)	(10,438,603.1)	(9,394,742.8)	(14,151,799.1)	(16,738,707.3)	(19,268,145.3)
Share Based Payments	-	(359,487.0)	(4,705,444.0)	(4,940,716.2)	(5,187,752.0)	(5,447,139.6)	(5,719,496.6)	(4,108,586.8)	(5,150,371.5)	(3,853,629.1)
EBITDA	-	(484,753.0)	(17,645,079.0)	(17,939,444.6)	(20,270,290.9)	(23,664,664.4)	(23,048,739.5)	(20,816,840.0)	(21,374,041.6)	(12,524,294.4)
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)
Other income/ (expense)										
License Agreement Payments	-	-	-	-	-	(1,188,645.1)	(7,062,063.4)	-	(185,335.0)	(6,063,005.2)
Other non operating expenses	-	(437.0)	-	-	-	-	-	-	-	-
EBIT	-	(485,190.0)	(23,376,430.0)	(23,700,795.6)	(26,076,641.8)	(30,719,660.4)	(36,037,153.8)	(26,818,841.9)	(27,704,886.5)	(25,013,714.1)
Interest Income	-	-	135.5	98,399.8	148,197.5	65,841.4	307,852.1	330,486.1	306,897.5	218,541.5
Interest Expense	-	-	(8,518,320.0)	-	-	-	-	-	-	-
Profit before exceptional items, extraordinary items and tax	-	(485,190.0)	(31,894,614.5)	(23,602,395.8)	(25,928,444.3)	(30,653,819.0)	(35,729,301.7)	(26,488,355.8)	(27,397,989.0)	(24,795,172.6)
Exchange loss (net)	-	-	(12,512.0)	-	-	-	-	-	-	-
Provision for costs associated with closure of operations and impairment of	-	-	-	-	-	-	-	-	-	-
Employee separation cost	-	-	-	-	-	-	-	-	-	-
Profit before tax from continuing operations	-	(485,190.0)	(31,907,126.5)	(23,602,395.8)	(25,928,444.3)	(30,653,819.0)	(35,729,301.7)	(26,488,355.8)	(27,397,989.0)	(24,795,172.6)
Income tax (expense) benefit	-	-	-	-	-	-	-	-	-	-
Net earnings including noncontrolling interests	-	(485,190.0)	(31,907,126.5)	(23,602,395.8)	(25,928,444.3)	(30,653,819.0)	(35,729,301.7)	(26,488,355.8)	(27,397,989.0)	(24,795,172.6)

Exhibit 6: Income Statement

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, and 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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