RAD

RADIOPHARM THERANOSTICS

Radiopharm Theranostics (ASX "RAD") is a **clinical stage radiopharmaceutical company** developing **Therapeutic and Imaging products** using peptides, small molecules, nanobodies and antibodies.

November 2024

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INVESTMENT HIGHLIGHTS

3 Innovative clinical stage molecules

- Highly differentiated Imaging agent (Pivalate) for Brain Mets - large disease area with high unmet need-
- Potential first-in-class PD-L1 targeting radiopharmaceutical
- Potential best-in-class HER2 targeting radiopharmaceutical

3 Highly promising late stage-preclinical molecules

- Potential first-in-class B7H3 (*from Joint Venture / Strategic partnership with MD Anderson)*
- Potential first-in-class KLK3 targeting radiopharmaceutical
- Theranostic Pair targeting Integrin AvB6, with Imaging Phase I proof of concept ongoing

Solid financials

- Strong investment endorsement from Lantheus with ~7% ; Institutional Shareholders own 64%
- Cash runway to mid-2026

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COMPANY PIPELINE

PROGRAM	TARGET & MOLECULE	INDICATION	Dx/Tx	ISOTOPE	PRECLINICAL	PHASE I	PHASE II	NOTES
Clinical								
RAD 101	**Short Chain Fatty Acid** (Small molecule)	**BRAIN METS**	**Imaging**	**F18**			Phase 2a / Phase 2b	IND approval received for Phase 2b in US (n=30) FPFV expected in Dec 2024
RAD204	**PD-L1** (Nanobody)	**NON-SMALL CELL LUNG CANCER**	**Therapy**	**Lu177**				Phase 1 enrolling in Australia, NCT06305962 First two cohorts' patients' data by mid-2025
RAD202	**HER 2** (Nanobody)	**BREAST / GASTRIC CANCER**	**Therapy**	**Lu177**				Ethics approval for Phase 1 expected in Dec 2024 First two cohorts' patients' data by the end of 2025
Pre-Clinical								
RV01	B7H3 (mAb)	Multiple Solid Tumors	Therapy	Lu177				IND approval expected mid-2025 FPFV Phase 1 in Q3 2025
RAD402	KLK3 (mAb)	PROSTATE	Therapy	Tb161				Ethics approval in Q3 2025 FPFV Phase 1 in Q4 2025
RAD 301/302	Integrin *αVβ6* (peptide)	Multiple Solid Tumors	Therapy Imaging	Lu177 Ga68				Phase 1 Therapeutic planned for end of 2025 Phase 1 Imaging enrolling in USA

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Targeting MoA:

SHORT FATTY ACID CHAINS

Imaging for

BRAIN METASTASIS

Molecule: ***RAD101***

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RAD 101 Phase 2b Imaging: F18-PIVALATE

CLINICAL DEVELOPMENT & REGULATORY STRATEGY

- IND approval received for Phase IIb
- Only 1 expected competitor: Axumin (Bracco) currently in Phase III
- 300,000 new patients diagnosed every year (USA only)

PRECLINICAL	PHASE I	PHASE IIa	PHASE IIb	PHASE III
	UK	UK	USA	
	24 pts	17 pts	30 pts	150 pts
√	√	√	2H 2024-2H2025	1H2026 – 2H 2027

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RAD 101 Phase 2b – TRIAL DESIGN

Phase IIb imaging study in participants with suspected recurrent brain metastases from solid tumors

- **Primary Objective:** Concordance between RAD101 positive lesions and those seen in conventional imaging (MRI with gadolinium) in participants with suspected recurrent brain metastases

- **Population:** PTs with histopathologically confirmed advanced solid tumors with known history of brain metastases (lung, breast, colon, kidney, or melanoma), with SRS within 12 months prior to screening.

- **Design Methodology:** Single dose of RAD101, max 370 MBq (10 mCi), will be administered as IV followed by whole brain PET scan at 60 ± 10 min post-dose. High-resolution MRI will be performed in joint acquisition. 4-week screening period, 3-day imaging and safety follow-up, longitudinal imaging and data collection up to 6 months. N=30

- **Imaging:** Single dose of RAD101, at a maximum dose of 370 MBq (10 mCi)

UPCOMING MILESTONES

PROGRAM	TARGET & MOLECULE	INDICATION	Dx/Tx	ISOTOPE	*1ST HALF 2024*	*2ND HALF 2024*	*1ST HALF 2025*	*2ND HALF 2025*	*1ST HALF 2026*
RAD101	**Short Chain Fatty Acid** (Small Molecule)	**BRAIN METS**	***Imaging***	**F18**		▲ IND Approval Phase 2b received ▲ First Patient Ph 2b	▲ 10/30 patients' data to be released	▲ Phase 2 Top Line data	

▲ ACHIEVED

▲ Future Milestone

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Targeting MoA:
PDL1

Molecule: ***RAD204***

Therapeutic for
NON-SMALL CELL LUNG CANCER

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RAD 204 THERAPEUTIC: PD-L1 NANOBODY

CLINICAL DEVELOPMENT & REGULATORY STRATEGY

- Human pharmacokinetic and biodistribution proven with imaging agent (positive Phase I in 10pts in 2021, followed by IIT in Germany in additional 6 pts.
- Phase I therapeutic dose escalation in Lung Cancers started in Australia in H1 2024

PRECLINICAL	IMAGING PHASE I	THERAPEUTIC PHASE I in AUSTRALIA	THERAPEUTIC PHASE II In USA
		→	
	16pts	~25 pts	~50 pts
√	√	H1 2024 - H2 2025	H1 2026 – H1 2028

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RAD 204 – THERAPEUTIC PHASE 1 TRIAL DESIGN

^{177}Lu-ANTI-PD-L1 SINGLE DOMAIN AB IN METASTATIC NON-SMALL CELL LUNG CANCER

- Primary Objectives *(Phase 1, Treatment)*:
  - To assess the safety and tolerability of ^{177}Lu-RAD204$_{tr}$
  - To determine the recommended dose(s) of ^{177}Lu-RAD204$_{tr}$ for future exploration
- **Population:** ≥ 18 years of age with a documented history of PD-L1 positive (≥1%) metastatic NSCLC
- **Design Methodology:** BOIN for escalation / de-escalation.
- **Imaging:** Imaging and dosimetry with low dose ^{177}Lu-RAD204$_{im}$, consisting of ^{177}Lu-RAD204$_{im}$ Safety Lead-in, with or without dose escalation.
- **Therapeutic Dose:** ^{177}Lu-RAD204$_{tr}$ dose escalation. Treatment period of up to 3 cycles every 6 weeks.
- **Dosimetry *(Phase 0, Imaging)*:** To assess the biodistribution, pharmacokinetics and radiation dosimetry of ^{177}Lu-RAD204$_{im}$ in selected organs and tumor lesions.

Phase 0 (Imaging Period with ^{177}Lu-RAD204$_{im}$)	**Dose Level[1]**	**Dose (mCi)**	**Dose (GBq)**
	Imaging dose	10	0.37
Phase I (Treatment Period with ^{177}Lu-RAD204$_{tr}$)	**Dose Level[2]**	**Dose (mCi)**	**Dose (GBq)**
	DL1	30	1.1
	DL2	40	1.5
	DL3	TBD	TBD
	DL4	TBD	TBD

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RAD 204 – UPCOMING MILESTONES

PROGRAM	TARGET & MOLECULE	INDICATION	Dx/Tx	ISOTOPE	*1ST HALF 2024*	*2ND HALF 2024*	*1ST HALF 2025*	*2ND HALF 2025*	*1ST HALF 2026*
RAD204	**PD-L1** (Nanobody)	**NON-SMALL CELL LUNG CANCER**	**Therapy**	**Lu177**	▲ Ethics Approval received	▲ First Patient treated at Wollongong Hospital ▲ Nepean Hospital opened	△ 2 Cohorts completed & data release	△ Phase 1 Top Line data	

▲ ACHIEVED

△ Future Milestone

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Targeting MoA:
HER2

Molecule: ***RAD 202***

Therapeutic for
BREAST AND GASTRIC CANCER

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RAD 202 –THERAPEUTIC: HER-2 NANOBODY

CLINICAL DEVELOPMENT & REGULATORY STRATEGY

- Human pharmacokinetic and biodistribution proven with imaging agent
- Phase I therapeutic dose escalation in Breast / Gastric Cancers planned in Australia in Q4 2024

PRECLINICAL	IMAGING PHASE I	THERAPEUTIC PHASE I
	16pts	~25 pts
√	√	H2 2024-H1 2026

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RAD 202 – PHASE 1 TRIAL DESIGN

HEAT Trial (HER2 Antibody Therapy with Lutetium-177) in patients with HER2+ advanced solid tumors

- Primary Objectives *(Phase 1, Treatment):*
  - To assess the safety and tolerability of ^{177}Lu-RAD202$_{tr}$
  - To determine the recommended dose(s) of future exploration for ^{177}Lu-RAD202
- Population: Advanced solid tumours with HER2 amplification by local testing, including IHC,FISH and/ NGS
- Imaging: ^{177}Lu-RAD202$_{im}$, consisting of ^{177}Lu-RAD202$_{im}$ Safety Lead-in, with or without dose escalation.
- Therapeutic Dose: ^{177}Lu-RAD202$_{tr}$ dose escalation. Treatment period of up to 3 cycles every 6 weeks.
- Dosimetry *(Phase 0, Imaging):* To assess the biodistribution, pharmacokinetics and radiation dosimetry of ^{177}Lu-RAD202$_{im}$ in selected organs and tumour lesions.

Phase 0 (Imaging Period with ^{177}Lu-RAD202$_{im}$)	**Dose Level**	**Dose (mCi)**	
	Imaging dose	10 mCi	
Phase I (Treatment Period with ^{177}Lu-RAD202$_{tr}$)	**Dose Level[2]**	**Dose (mCi)**	**% Change in dose levels**
	DL1	~1.1 GBq (30 mCi)	+0%
	DL2	~2.2 GBq (60 mCi)	+100%
	DL3	~4.4 GBq (120mCi)	+100%
	DL4	~6.6 GBq (180 mCi)	+50%
	DL5	~8.8 GBq (240 mCi)	+33.33%

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RAD 202 – UPCOMING MILESTONES

PROGRAM	TARGET & MOLECULE	INDICATION	Dx/Tx	ISOTOPE	*1ST HALF 2024*	*2ND HALF 2024*	*1ST HALF 2025*	*2ND HALF 2025*	*1ST HALF 2026*
RAD202	**HER2** (Nanobody)	**BREAST & GASTRIC**	**Therapy**	**Lu177**		▲ Ethics Submission ▲ Ethics Approval	▲ First Patient dosed	▲ 2 Cohorts completed & data release	▲ Phase 1 Top Line data

▲ ACHIEVED

▲ Future Milestone

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CORPORATE SNAPSHOT

Stock Code: RAD

12-month trading range:

AUD$0.023(Oct24) – AUD$0.137(Oct 23)

Market Cap: AUD$52m

Shares on Issue: 2.17 billion

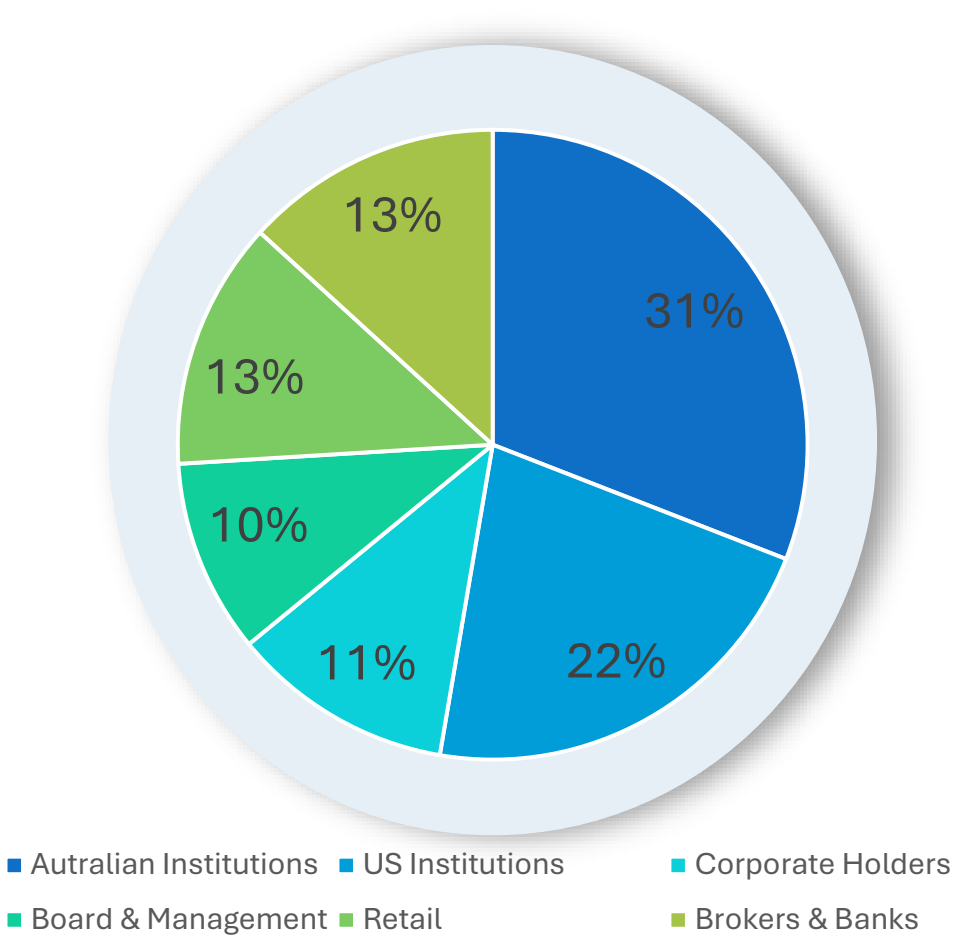
Options on Issue: 850m @ 6c / 2y

Cash at Bank: AUD$43M

No. of Shareholders: 2,300

FULLY FUNDED TO JUNE 2026

Shareholders: 64% Institutions + 10% Board



Top 20 Shareholders	2024, Oct 29th
JP Morgan (incl. Point72)	175.096.000
Deutsche Bank	157.420.000
Lantheus	149.625.000
Paul Hopper	149.221.000
Regal Funds	142.140.000
Octagon	93.703.000
OC Funds	88.500.000
Investors Mutual	75.000.000
Australian Ethical	57.633.000
Silverarc	56.221.888
Northstar	51.234.000
Affinity	46.851.574
Dellora	46.851.574
UBS Securities	44.182.000
NanoMab	43.295.000
Atlantis Fund	42.356.000
Thorney	40.502.000
Merril Lynch	31.459.000
Goldman Sachs	24.044.000
Scarlett Hopper	23.857.000

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THANK YOU