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Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: Radiopharm Theranostics

By TIM BOREHAM

ASX code: RAD

Nasdaq code: RADX

Share price: 2.6 cents; **Shares on issue:** 2,364,949,502; **Market cap:** $61.5 million

Chief executive officer: Riccardo Canevari

Board: Paul Hopper (executive chair), Mr Canevari, Ian Turner, Hester Larkin, Dr Leila Alland, Phillip Hains, Noel Donnelly

Financials (June 2025 quarter): revenue nil, receipts $829,000 ($5.36 million for the year) from its Lantheus relationship, net operating cash outflows $7.03 million ($36.6 million for the year), cash balance $29.1 million.

Identifiable major holders: Lantheus 12.1%, Paul Hopper 6.3 %, Regal Funds 6.2%, OC Funds 4.1%, Nanomab Tech 2.7%

Radiopharm Theranostics pales in size relative to ASX peer Telix Pharmaceuticals and US nuclear medicine titan Lantheus, but CEO Riccardo Canevari is happy to walk in the shadow of giants.

Mr Canevari notes the duo's pioneering role in creating a $US1.5 billion-a-year-market for their prostate cancer imaging agents, Illuccix and Pylarify, respectively.

Previous to that, the biggest radiotherapy was the $US100 million a year Netspot, developed by Mr Canevari's former employer Novartis for neuro-endocrine tumors.

But the prostate cancer market now is crowded, with up to 40 agents targeting the common biomarker prostate specific membrane antigen (PSMA).

While Radiopharm has a prostate cancer agent in development, it's targeting the prostate specific antigen (PSA) and it's by no means the company's sole focus.

All up, the company has five programs at clinical stage in multiple indications and it should start a sixth by the end of the year.

The prostate cancer giants set the benchmark.

"What Telix and Lantheus have done has been transformational for the sector in that they have grown the market by 15 times," Mr Canevari says.

"I would be very happy to copy what they did, but just with a different product."

About Radiopharm

Radiopharm is about pairing diagnostic scans with companion radionuclide therapies, emphasizing precision, safety and novel oncology targets.

With a $59 million market valuation, Radiopharm might be a minnow, but its agenda spans multiple programs including peptides, small molecules and monoclonal antibodies.

"If nuclear medicine works well in prostate cancer, why shouldn't it work well in other solid tumors," Mr Canevari says.

A creation of biotech entrepreneur Paul Hopper, Radiopharm listed on the ASX on November 25, 2021, raising $50 million at 60 cents apiece.

The company listed on the Nasdaq in late November 2024.

In late December 2024, Radiopharm and the aforementioned, Nasdaq-listed Lantheus unveiled a "co-development" agreement, by which Lantheus would stump up for a phase I imaging trial in an area of unmet need.

Radiopharm is based on assets acquired from Imperial College London, New York's Sloan Kettering Memorial Hospital and the Technical University of Munich.

The New York City-dwelling Mr Canevari joined in September 2021, having spent 11 years at Novartis (including as head of the breast cancer franchise).

What's in a name?

The 'theranostics' in the company's name refers to developing both diagnostic and therapeutic radiopharmaceuticals for cancer.

The diagnostic leg involves the use of lower energy radioisotopes to allow physicians to ‘see’ and measure tumors. The treatment bit involves higher-energy particles.

The process involves attaching a radioactive isotope to a targeting agent, such as a small molecule or antibody.

“With the same molecule using different isotopes you can have an imaging agent to detect where the tumor is – both large tumors and small metastases,” Mr Canevari says.

“Then you switch isotopes to get the therapeutic model going to the same place the imaging agent went.”

RAD-101 takes flight

Radiopharm’s most advanced program, RAD-101, aims to develop an imaging tool for brain metastases.

It involves using the isotope F18 (not the fighter jet) and combining it with a radio-tracer called pivalate, for use in positive emission tomography (PET) imaging.

In the US, an open-label, single-arm, phase IIb, clinical trial is underway, enrolling 30 patients with confirmed recurrent brain metastases.

An earlier phase II trial showed the injected radio-tracers migrated to the tumors effectively.

Here's a fun fact: the US brain metastases (mets) market is bigger than that for prostate cancer, with 300,000 new patients a year compared with 270,000 to 280,000 for the latter.

“It’s a very large patient population and addressable market,” Mr Canevari says.

“All we need is good scientific data and good execution and keep going.”

The indication should not be confused with gliomas - primary brain tumors - which Telix is pursuing with a proposed agent the FDA has refused to approve (for the time being).

Radiopharm expects to announce interim data by the end of 2025.

Why hasn’t anyone else seized the opportunity?

“We are the only company with a phase II imaging trail for brain metastases,” Mr Canevari says.

Ok. But why?

“The answer is because it is difficult,” Mr Canevari says. “To image the brain, you need a molecule that is very small and able to cross the blood-brain barrier and have a selective uptake in the brain mass.”

He notes an Italian developer, Bracco Imaging abandoned a phase III imaging program.

“We thought six months ago we had a competitor ahead of us, but now officially they have dropped [off],” he says.

Mr Canevari says some agents have been glucose based, which is a problem because the brain contains a lot of sugar and thus the imaging contrast isn’t great.

RAD101 targets the fatty acid synthase, which is over-expressed in cancerous brain cells but not healthy ones.

Mr Canevari says standard-of-care magnetic resonance imaging (MRI) scans work quite well for assessing brain ‘mets’ initially.

But after treatment - typically with stereotactic radio-surgery (radiation beams) - there’s more dead brain tissue that makes imaging harder.

RAD204’s multi-tumor approach

RAD204 is subject to a first-in-human phase I therapy trial for advanced solid tumors expressing the PD-L1 antibody.

The nanobody is radio-labeled with Lutetium 177 (177-Lu-RAD204 to friends).

Following data and safety monitoring committee approval in May, the trial can dose a second cohort at one and a half times stronger than the initial delivery.

The trial enrolls patients with multiple tumor types, including non-small cell and small cell lung cancer, triple-negative breast cancer, cutaneous melanoma, head and neck squamous cell carcinoma and endometrial cancer.

Investors should see results from the first two cohorts by the end of 2025.

RAD202: the Heat is on

Also powered by lutetium, 177Lu-RAD202 targets HER-2 positive solid tumors.

(HER-2 stands for human epidermal growth factor receptor-2).

Mr Canevari says RAD202 is the only HER-2 breast radio-pharmaceutical therapy in clinical stage.

“We have the potential to be first to market with this product, assuming the science is nice to us.”

In June 2025, Radiopharm dosed the first patient in its phase I, open-label dose escalation trial, dubbed Heat.

The trial should determine the recommended dose for a phase II study and “evaluate the safety and preliminary clinical activity” for a variety of HER-2 cancers.

Covering 10 HER2-positive breast cancer patients, a previous phase I study showed “clinical proof-of-concept as well as the safety and distribution of RAD202”.

Once again, investors can expect clinical data from the first two cohorts by the time Santa arrives this year.

Crank up the RV and hit the road

In a joint venture, Radiopharm and the Houston, Texas MD Anderson Cancer Centre are running a program called RV-01 (Betabart).

In July 2025, the FDA granted assent for a first-in-human, phase I, therapeutic trial in solid tumors.

This is expected to kick off by the end of 2025.

RV refers not to recreational vehicles, but the joint venture vehicle Radiopharm Ventures.

A monoclonal antibody, RV-01 targets the B7-H3 antigen, a novel mechanism of action.

B7-H3 is highly expressed in tumors and “associated with poor prognosis in many cancer types”.

The company says RV-01 enables enough time for the agent to target the tumors, while the liver deals with monoclonal antibodies better than peptides or small molecules.

There’s more …

Radiopharm plans to submit for ethics approval to begin a phase I trial in prostate cancer, using 161Tb-RAD402.

161Tb-RAD402 what?

Okay - it’s an “anti-kallikrein related peptidase 3 monoclonal antibody radiotherapeutic labelled with Terbium 161”.

Crucially, the trial targets the prostate-specific antigen (PSA) rather than the prostate-specific membrane antigen (PSMA).

The difference is more than a case of the Judean Peoples’ Front versus the Peoples’ Front of Judea.

Found in the blood, PSA indicates potential prostate cancer. Found on the surface of cancerous cells, PSMA is more useful for imaging confirmed prostate cancer cases.

Mr Canevari says some patients don't respond to a PSMA-targeting agent and "could benefit from an additional line of therapy".

He doesn't believe the company would compete with Novartis' market-leading prostate cancer therapy, Pluvicto.

Also, Radiopharm has FDA approval for a pancreatic imaging trial, RAD301.

RAD301 road tests a gallium radio-labelled asset called Ga-68-RAD301, targeting the avBeta integrin antibody.

Integrins are cell surface receptors that play crucial roles in cell signaling, migration and survival.

An open-label, phase Ia study is evaluating "biodistribution" in subjects that include healthy volunteers and pancreatic cancer patients.

Finances and performance

A year ago, Radiopharm raised $70 million, consisting mainly of a $62.5 million institutional placement struck at four cents a share (an 18 percent premium).

In an "initial strategic investment", Lantheus chipped in $7.5 million at five cents a share (an almost 50 percent premium).

In January this year, Lantheus doubled down with a further $8 million placement, at six cents a share.

Lantheus is now Radiopharm's biggest holder with a stake of just under 7.0 percent. So, the Lantheus 'giant' is part of the Radiopharm 'shadow'.

Last month, Radiopharm reported June quarter receipts of $829,000, taking receipts for the year to $5.36 million, related to the Lantheus deal.

June quarter cash burn came in at $7 million for the quarter and $36.6 million for the year.

Radiopharm has cash of $29.1 million, enough to last until mid-2026.

"We are in a good position," Mr Canevari says.

"But we will remain opportunistic [about a further raising] and see if there is a right time to go to market."

While Clarity raised its $200 million locally, Radiopharm's Nasdaq listing enhances the prospect of tapping US investors.

Over the last 12 months Radiopharm shares have ranged between 4.2 cents (mid-January this year) and two cents (late July 2025).

Dr Boreham's diagnosis:

"Our molecules are well differentiated in areas where no other radio-pharmaceutical company is currently developing products," Mr Canevari says.

In soccer terms, Radiopharm has multiple shots at goal, but Mr Canevari acknowledges that not every 'ball' will hit the back of the net.

While Clarity recently ditched some second-string programs from its packed agenda, Mr Canevari reckons half a dozen programs - equally split between imaging and therapy - are about right.

"It's hard to think that all six will work perfectly - that's part of the risk - but there's a good probability that one or two will be the bright spot."

Mr Canevari says the company might only be a couple of years off commercializing the brain imaging RAD-101, which has FDA fast track designation.

He cites an US addressable market of $US500-600 million a year, "but it takes time to build".

Unlike Telix and Clarity holders, Radiopharm investors are yet to be rewarded for their patience. The shares have never recovered from listing day, when they tumbled by one third.

But would Lantheus waste time with an isotopic no-hoper that's a small shadow of itself?

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He has walked in the shadow of many journalistic greats – and some of them occasionally were sober.