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August 4, 2025
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Radiopharm Theranostics Limited (RADX - NASDAQ)

RADX: July 2025 Update

We use a discounted cash flow (DCF) model and apply a 25% probability of success to our forecasts for RAD101, RAD202 & RAD204 in both domestic and international markets to generate our valuation. The DCF employs a 15% discount rate and terminal growth of -10%. Our model extends until 2046.

Current Price (8/1/2025)	$5.35
Valuation	**$12.50**

OUTLOOK

Radiopharm Theranostics is advancing a portfolio of imaging and therapeutic radiopharmaceutical candidates in oncology. Its approach recognizes the opportunities in tumors beyond prostate, thyroid & neuroendocrine targets originated by precision oncology & validated by clinical trials & regulatory approval.

RAD101, an ^{18}F radioisotope developed to image brain metastases is the most advanced asset. It has advanced to Phase II clinical trials. Other candidates and their target include RAD 202 (HER2) & RAD204 (anti-PD-L1) which are both nanobodies conjugated to ^{177}Lu for treatment. The pipeline further contains RAD301/302, a theranostic pair targeting αVβ6 & preclinical assets targeting B7H3 (RV01) & KLK3 (RAD402).

The company is developing candidates both in the US & developed global markets. It collaborates with Lantheus Holdings, MD Anderson (Radiopharm Ventures) & with CROs GenesisCare and MedPace.

SUMMARY DATA

52-Week High	**50.82**
52-Week Low	**3.50**
One-Year Return (%)	**-4.5**
Beta	**0.8**
Average Daily Volume (sh)	**20,596**
Shares Outstanding (mil)	**7.8**
Market Capitalization ($mil)	**41.6**
Short Interest Ratio (days)	**0.7**
Institutional Ownership (%)	**16.2**
Insider Ownership (%)	**25.4**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2025 Estimate	**N/A**
P/E using 2026 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Products**

ZACKS ESTIMATES

Revenue

(In millions of AUD)

	Q1 (Sep)	Q2 (Dec)	Q3 (Mar)	Q4 (Jun)	Year (Jun)
2024	$0.0 A	$0.0 A	$0.0 A	$0.3 A	$0.3 A
2025	$0.0 A	$1.4 A	$0.0 A	$4.0 E	$5.4 E
2026					$0.0 E
2027					$0.0 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
2024	$0.00 A	-$0.07 A	$0.00 A	-$0.05 A	-$0.12 A
2025	$0.00 A	-$0.01 A	$0.00 A	$0.00 E	-$0.02 E
2026					-$0.02 E
2027					-$0.01 E

WHAT'S NEW

Since our May initiation of Radiopharm Theranostics Limited (NASDAQ: RADX), the company has provided several progress updates. Two radionuclide supply agreements were signed, the RAD204, RAD202 and RAD101 studies have advanced, the RV01 trial reported preclinical data and received investigational new drug (IND) clearance, a research and development (R&D) tax credit was paid and Dr. Sartor was appointed to the Scientific Advisory Board (SAB). By far, the most impactful of the announcements relates to the forward movement of the clinical trials. We saw the RAD204 trial cleared to move to the next dose in its Phase I trial, the first patient dosed in the RAD202 Phase I study and the grant of the Fast Track designation for the RAD101 program for imaging brain metastases by targeting fatty acid synthase (FASN). Radiopharm also filed its quarterly cash flow and activities report for the final quarter of its 2025 fiscal year.

Quarterly Activities and Cash Report, Fiscal Year 2025

In addition to a number of business updates which we discuss below in further detail, Radiopharm Theranostics provided a financial update reviewing cash balances and allocation of cash expenditures for the period ending June 30th, 2025. The details are included in the Quarterly Activities & Cash Report.

As of June 30, 2025, the company's cash balance was A$29.1 million, an increase from A$18.6 million a year earlier. Cash inflows rose to A$5.4 million related to the Lantheus investment while research and development cash expense was A$28.4 million. Total cash used in operating activities for FY:25 was A$36.7 million. Financing cash flows were A$44.2 million, with proceeds from issue of equity securities only partially offset by transaction costs, repayment of borrowings and other finance related expenses. Following the end of the reporting period, Radiopharm announced that it had received A$4.58 million from the Australian government related to its research and development tax incentive. We expect the annual report with audited financial statements for fiscal year 2025 next month.

Supply Agreements

ITM and Lu-177
Over the years, Radiopharm has signed several supply agreements for the radioisotopes used in its portfolio of assets. Agreements go back several years including several in 2022 for Actinium-225 and Lutetium-177. The most recent agreements were announced in the second quarter including one for non-carrier added (n.c.a.) Lutetium-177 with ITM Isotope Technologies Munich. ITM holds a US Drug Master File with the FDA for n.c.a. Lu-177 and has marketing authorization in the EU with EndolucinBeta. As described in a press release, Radiopharm will use the supply for its pipeline of Lu-177 candidates. In all, Radiopharm has four agreements for Lu-177 which further include ANSTO in Australia, SHINE in the United States and Isotopia in Israel. The agreements are expected to provide uninterrupted access to the radioisotope.

Non-carrier added Lu-177 is a highly pure form of Lu-177 which contains little to no stable lutetium resulting in higher specific activity. This allows for better binding, less competition from inactive isotopes and more effective therapy using lower doses. Radiopharm will use the Lu-177 across its clinical pipeline including RAD 204, the PD-L1 targeting nanobody, RAD 202, the HER2 targeting nanobody and RV01, a B7-H3 targeting monoclonal antibody.

Cyclotek and Tb-161
Terbium-161 is a less well-known radioisotope that emits β particles and Auger electrons. Linked with the anti-Kallikrein Related Peptidase 3 (KLK3), it is the radioligand component of RAD 402. In late June, Radiopharm signed a supply agreement with Cyclotek, a radiopharmaceutical manufacturer in Australia. The execution of the agreement is the final step required prior to requesting approval from the ethics board and launching the Phase I clinical trial in prostate cancer.

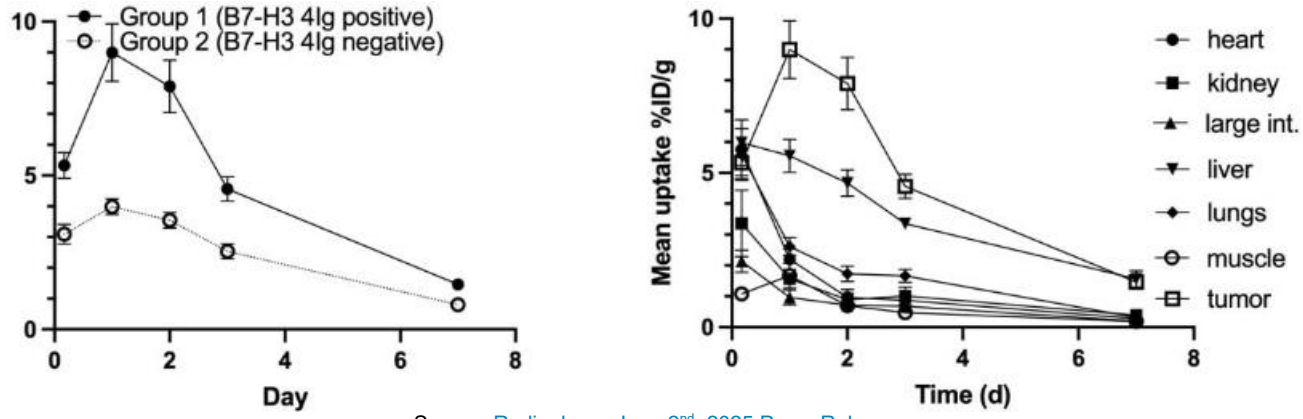
RAD 402 (Tb-161 KLK3 monoclonal antibody)
RAD 402 is in development to treat advanced prostate cancer. It links a Terbium-161 isotope to a monoclonal antibody raised to target the KLK3 gene. KLK3 encodes for this prostate-specific antigen and is highly expressed in prostate cancer cells with limited expression outside of the prostate. Another distinct feature of RAD402 is its combination with Tb-161 which emits both short-range Auger electrons and short-range β particles. These emissions allow for targeted delivery of radiation, selective cell destruction and minimal damage to surrounding tissue. KLK3 is almost exclusively expressed in the prostate, unlike PSMA which appears throughout the body. This PSMA off-target expression is responsible for some of the toxicities associated with PSMA targeting agents including Pluvicto. The goal with RAD402 targeting KLK3 is to reduce this off-target effect.

RV01 Clinical Trial

In early June, Radiopharm announced that it had compiled its preclinical data for RV01 in order to submit an investigational new drug (IND) application with the FDA. In late July, the FDA cleared the IND, allowing the trial to start. RV01 is a radiopharmaceutical candidate targeting B7-H3 (also known as CD276) using a monoclonal antibody conjugated to the β-emitting lutetium-177. B7-H3 is expressed in multiple cancers including prostate, lung, hepatocellular carcinoma, pancreatic, colorectal, head & neck and breast.

The data from the study validated earlier preclinical work that showed strong affinity to the B7-H3 target without the extensive circulation time of other monoclonal antibodies (mAbs). Compared with the half life of other mAbs which can be over one week, RV01 peaks within one or two days. The antibody is excreted by the liver more quickly which allows the radioligand to target the desired tissues, potentially without the associated toxicities that would be present with a longer duration of exposure. Biodistribution and clearance details over a week-long period for RV01 in B7-H3 positive and negative tissue and for major organs is provided in the following exhibit.

Exhibit I – RV01 Biodistribution



Source: Radiopharm June 2nd, 2025 Press Release

Radiopharm submitted its IND in June and announced that the FDA had cleared it on July 28th. The company plans to initiate the Phase I study for RV01 in solid tumors in 4Q:25. The company also indicated that the compound RV01 would be referenced as Betabart and further refined the description of the mAb indicating that it was designed with a strong affinity for the 4Ig isoform of B7-H3. This isoform is highly expressed in tumors but not in healthy tissues. It is further expressed on stationary tumor cells, avoiding distraction from circulating 2Ig isoforms that are shed from tumors and which may sequester the drug.

RV01 is being developed in a joint venture with MD Anderson called Radiopharm Ventures, which was created in 4Q:22. Details of the program were in a presentation included in the following press release. The effort will combine funding and executive leadership from Radiopharm and scientists from MD Anderson. Preclinical work took place in 2024 and a Phase I basket trial is expected to start in 2025.

Asset Advancement

Radiopharm has achieved several milestones for its RAD204, RAD202 and RAD101 programs. RAD204 received a positive recommendation from the data safety and monitoring committee (DSMC) allowing the associated Phase I study to continue. The first patient in the RAD202 trial was dosed in advanced HER2+ solid tumors and the FDA granted Fast Track status to RAD101 in brain metastases imaging, allowing for increased communication with the FDA and a greater opportunity for expedited treatment.

RAD204 (Lu-177 PD-L1 Nanobody)
RAD204 is a drug conjugate linking a single domain monoclonal antibody that targets programmed cell death ligand 1 (PD-L1) and the radioactive isotope Lutetium 177. The Phase I program is evaluating RAD204's safety in treating non-small cell lung cancer (NSCLC) and other solid tumors. The recent DSMC recommendation allows the trial to move to the next highest dose. The first cohort of four patients were treated with 30mCi of RAD204 and the DSMC confirmed that there was positive safety, pharmacokinetic and biodistribution data supporting the move to the next dose level. The subsequent cohort will be treated with 60mCi of Lu-177 and should be fully enrolled in the middle part of 2025. This cohort will include patients with multiple tumor types including NSCLC, SCLC, TNBC, cutaneous melanoma, head and neck squamous cell carcinoma and endometrial cancer.

The RAD204 Phase I trial design seeks to assess safety and tolerability of Lu-177 RAD204 and to find a recommended dose for the anticipated Phase II study. The trial is listed under the designator NCT06305962 on clinicaltrials.gov. It uses a Bayesian Optimal Interval (BOIN) design for escalation and de-escalation. The Phase I was designed based on preclinical work examining biodistribution, dosimetry and pharmacokinetics with low dose Lu-177 RAD204 in organs of interest and tumors. The trial initially targeted enrollment of 23 patients to assess the safety and tolerability of RAD204 and will expand to address additional PD-L1 expressing tumors. The trial is active and recruiting at four sites in Australia, managed by the contract research organization (CRO) GenesisCare.

RAD202 (Lu-177 HER2 Nanobody)
RAD202 is a radiopharmaceutical targeting Human Epidermal Growth Factor Receptor 2 (HER2)-expressing cancers. It combines a single-domain monoclonal antibody with the radioactive isotope Lu-177 to deliver targeted radiation to cancer cells. The isotope emits β particles and γ rays, offering a half-life of 6.73 days. Lu-177 can be used for both diagnostic (γ rays) and therapeutic (β particles) purposes.

RAD202 is the subject of a Phase I basket trial evaluating safety and tolerability in HER2-positive cancers, including breast, gastric and other solid tumors. Details of the trial are available on the clinicaltrials.gov website under the designator NCT06824155. It is referred to as the HEAT trial (**HE**R2 **A**ntibody **T**herapy with Lutetium-177). Ga-68 RAD202 provides imaging for the targeted tumor while Lu-177 RAD202 represents the treatment component. The first patient was dosed this spring, as announced in a June 4th press release at the St. John of God Murdoch Hospital. The goal of the trial is to determine the recommended Phase II dose and to evaluate safety and efficacy of the candidate in HER2-expression advanced cancers.

RAD101 (F-18 Pivalate)
RAD101, also known as F-18 fluoro-pivalic acid (F-18 FPIA), is an investigational PET imaging radiotracer developed to target fatty acid metabolism in tumors. As an F-18 labeled derivative of pivalic acid, it is structurally related to fluoroacetate but incorporates a gem-dimethyl group at the C-2 position, enhancing its metabolic stability. Unlike many conventional tracers, it does not undergo defluorination *in vivo*, making it particularly suitable for clinical imaging applications. It can be synthesized using automated radiosynthesis platforms, facilitating broad clinical adoption.

RAD101 is specifically designed to target fatty acid synthase (FASN), a multi-enzyme protein responsible for *de novo* fatty acid synthesis. It is overexpressed in numerous malignancies, including gliomas, breast, oral, prostate, and ovarian cancers. FASN is especially relevant in brain metastases, where the lipid-poor microenvironment requires increased fatty acid synthesis for tumor survival and growth. A June 11th press release announced the FDA's Fast Track designation for RAD101. Fast Track is a program offered by the FDA that allows for more frequent and earlier communication with the agency, earlier guidance on trial design, data collection and avoiding pitfalls relative to a non-Fast Track candidate. It can also allow for rolling review of a drug application and eligibility for accelerated approval and priority review. Fast Track candidates address serious or life-threatening conditions and address an unmet need. The press release continued with a target of topline results from the trial in the second half of 2025.

Exhibit II – Radiopharm Theranostics Pipeline

	PROGRAM	TARGET & MOLECULE	INDICATION	ISOTOPE	PRECLINICAL	PHASE I	PHASE IIa	PHASE IIb	NOTES
THERAPEUTIC TRIALS	RAD204	PD-L1 (nanobody)	PD-L1+ solid tumors	Lu177					Phase 1 enrolling, NCT06305962 First two cohorts' data by Q3 2025
	RAD202	HER2 (nanobody)	HER2+ solid tumors	Lu177					Phase 1 enrolling NCT06824155 First two cohorts' data by Q4 2025
DIAGNOSTIC TRIALS	RAD101	Short Chain Fatty Acid (small molecule)	Brain Mets	F18					Phase 2b enrolling, NCT06777433 First dataset by Q3 2025
	RAD301	Integrin $\alpha V\beta 6$ (peptide)	Integrin $\alpha V\beta 6$+ Pancreatic cancer	Ga68					Phase 1 enrolling, NCT05799274 Data read-out by Q3 2025
THERAPEUTIC MOLECULES (PRECLINICAL)	RV01	B7-H3 (mAb)	B7-H3+ solid tumors	Lu177					IND approval expected mid-2025 FPFV Phase 1 expected H2 2025
	RAD402	KLK3 (mAb)	Advanced prostate cancer	Tb161					Ethics approval targeting Q3 2025 FPFV Phase 1 expected Q4 2025
	RAD302	Integrin $\alpha V\beta 6$ (peptide)	Integrin $\alpha V\beta 6$+ solid tumors	Lu177					Therapeutic trial planned for 2026

Source: Radiopharm June 2025 Corporate Presentation

Corporate Milestones[1]

- Dosing of first patient in Phase I RAD204 trial – 4Q:24
- ADS listed on NASDAQ – November 2024
- First patient dosed in the Phase IIb imaging study for brain metastases – April 2025
- DSMC clears RAD204 for 60 mCi dose – May 2025
- Supply agreement signed with ITM for n.c.a. Lu-177 – May 2025
- RV01 preclinical data reported – June 2025
- First patient dosed in RAD202 (HEAT) trial – June 2025
- RAD101 receives Fast Track designation from FDA – June 2025
- Supply agreement signed with Cyclotek for Tb-161 – June 2025
- Australian government awards A$4.5 million tax incentive – July 2025
- Dr. Oliver Sartor appointed to Scientific Advisory Board – July 2025
- FDA clears IND for Phase I RV01 study – July 2025
- Request for ethics approval for Phase I RAD402 trial - 3Q:25
- Filing of FY:25 Annual Report – September 2025
- RAD204 data from first two cohorts – 2H:25
- RAD101 interim data – 2H:25
- Launch of Phase I RV01 trial – 4Q:25
- Begin dosing patients in Phase I RAD402 trial – 4Q:25
- RAD202 data from first two cohorts - end of 2025

Summary

Radiopharm reported fiscal year 2025 cash flows and, over the last few months, announced a number of achievements. The RAD204, RAD202 and RAD101 trials are all advancing to the next dose, initiating dosing and obtaining FDA recognition. We expect to see readouts from each over the next few quarters. RV01 shared preclinical data that shows the radioconjugate's favorable biodistribution in tumor cells and fast clearance from sensitive organs. Management continued to bolster its supply of radioisotopes with an arrangement for an additional supply of Lu-177 with ITM and Tb-161 with Cyclotek.

Radiopharm offers a broad pipeline of both imaging and therapeutic assets that are aligned with many of the most important targets in oncology. This includes PD-L1 and HER2 as well as other emerging targets such as short chain fatty acids, B7H3, KLK3 and integrin αVβ6. The most advanced candidate in the company's pipeline is RAD101. We value Radiopharm's RAD101, RAD202 and RAD204 in our model. We expect RAD101 to traverse the development and regulatory process over the next several years resulting in FDA approval and first sales in 2029 in the United States and first sales in the rest of the developed world the following year. We see RAD202 and RAD204 as receiving FDA approval and launching sales in 2032 in the U.S. trailed by sales the following year outside of the U.S.

Our investment thesis identifies Radiopharm's pursuit of validated yet unexploited immuno-oncology radiopharmaceutical targets that will benefit from the infrastructure and relationships in place to support development. Partners such as Lantheus and M.D. Anderson are established allies that can help this development company realize its potential. We maintain our valuation of $12.50 per share.

[1] Quarters and halves listed in the milestones section are calendar quarters and halves in contrast to Radiopharm's June 30 fiscal year end.

PROJECTED FINANCIALS

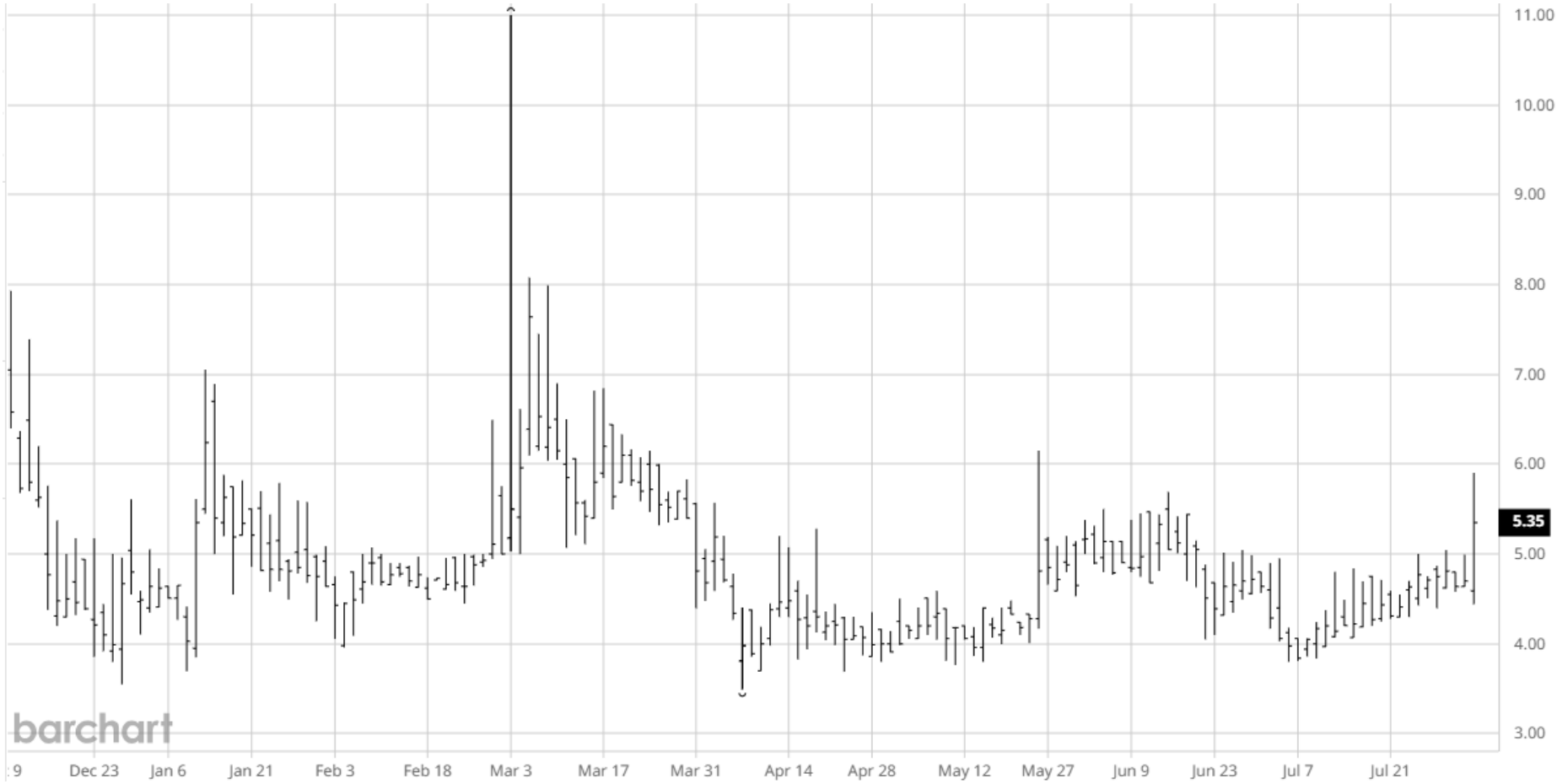
Radiopharm Theranostics Limited - Income Statement

Radiopharm Theranostics Ltd	2024 A	H1 A	H2 A	2025 A	2026 E	2027 E
Customer Contract Rev (A$'000)	**$299**	**$1,384**	**$3,982**	**$5,366**	**$0**	**$0**
Cost of Sales	$0	($1,615)	$0	($1,615)	$0	$0
Gross Margin		-16.7%		69.9%		
Other Income	$1,343	$1,054	$0	$1,054	$0	$0
Other Losses	($1,226)	$235	$0	$235	$0	$0
General & Administrative	($13,039)	($6,342)	($6,858)	($13,200)	($13,925)	($14,458)
Research & Development	($23,086)	($13,593)	($10,887)	($24,480)	($24,850)	($25,940)
Share Based Payments	($2,640)	($693)	($1,307)	($2,000)	$0	$0
Change in Fair Value, Contingent Cons	($8,860)	$28	$0	$28	$0	$0
Income from operations	($47,210)	($19,542)	($15,070)	($34,612)	($38,775)	($40,398)
Operating Margin						
Finance Expenses	($643)	$0	$0	$0	$0	
Pre-Tax Income	($47,853)	($19,542)	($15,070)	($34,612)	($38,775)	($40,398)
Provision for Income Tax	($96)	($101)	($30)	($131)	($155)	($162)
Tax Rate	0.2%	0.5%	0.2%	0.4%	0.4%	0.4%
Net Income	**($47,949)**	**($19,643)**	**($15,100)**	**($34,743)**	**($38,930)**	**($40,560)**
Net Margin						
Comprehensive Income	$203	$376	$0	$0	$0	$0
Non-controlling Interest	($1,964)	($918)	($604)	($1,522)	($1,557)	($1,622)
Total Comprehensive Income	**($45,782)**	**($18,350)**	**($14,496)**	**($33,222)**	**($37,373)**	**($38,937)**
Reported EPS	**($0.12)**	**($0.0109)**	**($0.01)**	**($0.02)**	**($0.02)**	**($0.01)**
YOY Growth						
Fully Diluted Shares	386,460	1,798,972	2,330,150	2,064,561	2,555,210	2,875,110
Adjustments	$0.00	$0.00	$0.00	$0.00	$0.00	$0
Adjusted EPS	**($0.1241)**	**($0.0102)**	**($0.0065)**	**($0.0168)**	**($0.0152)**	**($0.0141)**

Source: Company Filing // Zacks Investment Research, Inc. Estimates

HISTORICAL STOCK PRICE

Radiopharm Theranostics Limited – Share Price Chart[2]



[2] Source: Barchart.com, Inc.

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