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Radiopharm Theranostics Limited (RADX - NASDAQ)

RADX: Interim Readout Achieves 92% Concordance

We use a discounted cash flow (DCF) model and apply a 28% probability of success to our RAD101, RAD202 and RAD204 forecasts 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 (12/19/2025)	$5.19
Valuation	**$13.50**

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 identified through precision oncology & validated by clinical trials & regulatory approval.

RAD101, an F-18 radioisotope developed to image brain metastases is the most advanced asset. It is the subject of Phase II clinical trials. Other candidates and paired targets include RAD202 (HER2) & RAD204 (anti-PD-L1) which are both nanobodies conjugated to Lu-177 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 in both the US & developed global markets. It collaborates with Lantheus Holdings, MD Anderson (Radiopharm Ventures) & with CROs GenesisCare and MedPace.

SUMMARY DATA

52-Week High	**16.25**
52-Week Low	**3.50**
One-Year Return (%)	**16.4**
Beta	**0.9**
Average Daily Volume (sh)	**678,393**
Shares Outstanding (mil)	**11.8**
Market Capitalization ($mil)	**61.2**
Short Interest Ratio (days)	**1.6**
Institutional Ownership (%)	**11.2**
Insider Ownership (%)	**20.9**
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	$2.3 A	$3.6 A
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	-$0.01 A	-$0.02 A
2026					-$0.02 E
2027					-$0.01 E

WHAT'S NEW

RAD101 Phase IIb Interim Analysis

Radiopharm Theranostics reported the primary endpoint for its RAD101 trial in an interim analysis on December 15th. Following the release, management held a webcast which featured the company's CEO Riccardo Canevari, Chief Medical Officer Dr. Dimitris Voliotis and the principal investigator on the RAD101 trial, Dr. Harshad Kulkarni.

Topline from the release indicated that 92% (11/12) of evaluated patients treated with RAD101 achieved concordance with Magnetic Resonance Imaging (MRI) imaging, which was the primary endpoint. RAD101 uptake was selective and significant in suspected or recurrent brain metastases.

Exhibit I – RAD101 Development

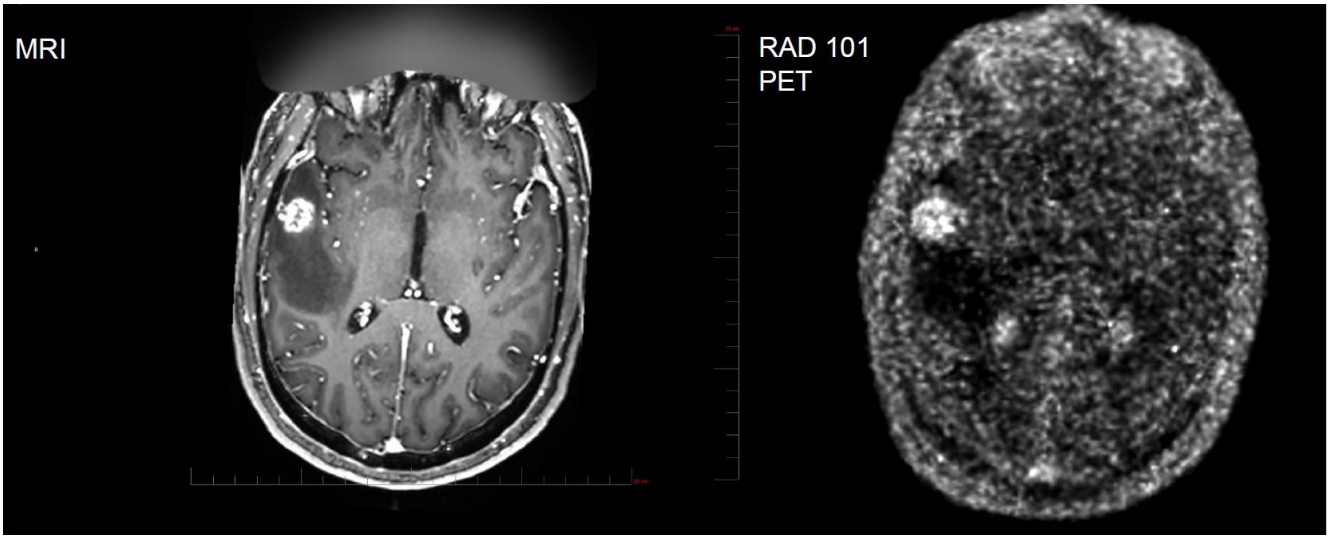
Source: Radiopharm Theranostics December 2025 Presentation

RAD101 Interim Topline Data Readout

The primary objective for the Phase IIa study evaluating RAD101 was to measure F-18 pivalate uptake in brain metastases and evaluate the impact of Stereotactic Radiosurgery (SRS) on F-18 pivalate uptake at 4 to 8 weeks. We include a summary of RAD101 in a later section of this report. The Phase IIb study for RAD101 is ongoing and recruiting subjects with an expected readout in 1H:26.

Interim results from the trial found that there was high uptake of F-18 pivalate, independent of primary tumor origin (lung, breast, melanoma and colorectal) observed in multiple brain tissues. Patients with high uptake suffered shorter overall survival (OS) (median 4 vs. 15 months with a p value of 0.0136) while MRI was uninformative. High uptake was considered to be a maximum PET Standardized Uptake Value $(SUV)_{MAX} \geq 2.0$. As an example, the following image shows agreement between the MRI scan and the PET scan. Note the bright area on the left side of each image along the horizontal centerline.

Exhibit II – Concordance Between MRI & PET



Source: Radiopharm Theranostics December 2025 Presentation

In the presentation, Dr. Kulkarni reviewed patients' MRI and Positron Emission Tomography (PET) scan tracer uptake. While reviewing sequential images, he noted that the MRI results were inconclusive; however, the RAD101 PET scan distinctly indicated active tumor. Another subject generated MRI images that were faint and inconclusive; however, when the PET with RAD101 was examined, the tumor region was very bright and easy to distinguish.

Dr. Kulkarni further noted that the PET scans can help quantify tumor volume. Monitoring tumor size enables the oncologist to determine if the treatment is working. The presenters also differentiated between MRI and PET noting that MRI is only an anatomical picture of the brain whereas PET can show metabolic and molecular features.

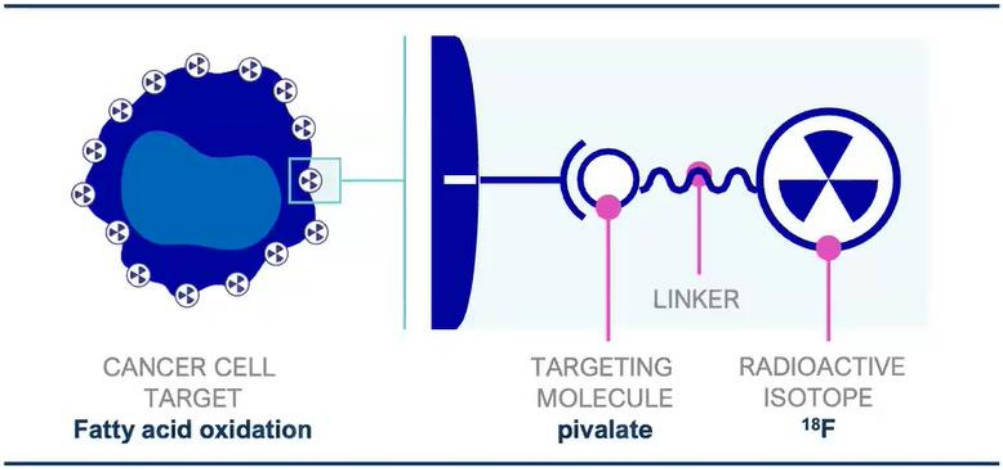
The last patient image that was shared was an example of a patient with no active tumor detected using PET and RAD101. This was an example of a patient who would not need further treatment at that point in time. Some of the risks of administering SRS include pressure effects, damage to healthy tissue, nausea, headache, vomiting, brain swelling, seizures and neurological deficits. Avoiding the use of SRS when not needed can eliminate these risks and the cost of additional treatment.

In summary, Radiopharm asserts that the study is recruiting well and site engagement is high. There is a high degree of positive correlation (concordance) between MRI and RAD101 PET imaging. The study continues with longitudinal scans underway to establish the standard of truth so that final data may be generated.

RAD101 (Fatty Acid Synthase) Background

In an effort to help SRS patients who may develop recurrent metastases, Radiopharm is developing RAD101. The agent may clarify whether or not the brain metastasis is in remission or is progressing. The radiopharmaceutical agent is a Fluorine-18 linked fluoropivalate alternatively called Pivalate which can be detected by PET or PET/MRI scanners. RAD101 targets short chain fatty acids in suspected recurrent brain metastases called fatty acid synthase (FASN) which rapidly accumulates in tumor cells due to its inability to be fully metabolized in the same way as natural fatty acids. The agent can help determine whether tissue in the brain is inflamed (pseudo-progression) or is a progressing tumor that requires additional treatments such as surgery or further SRS.

Exhibit III – RAD101 Construct



Source: Radiopharm Theranostics RAD101 KOL Event Presentation

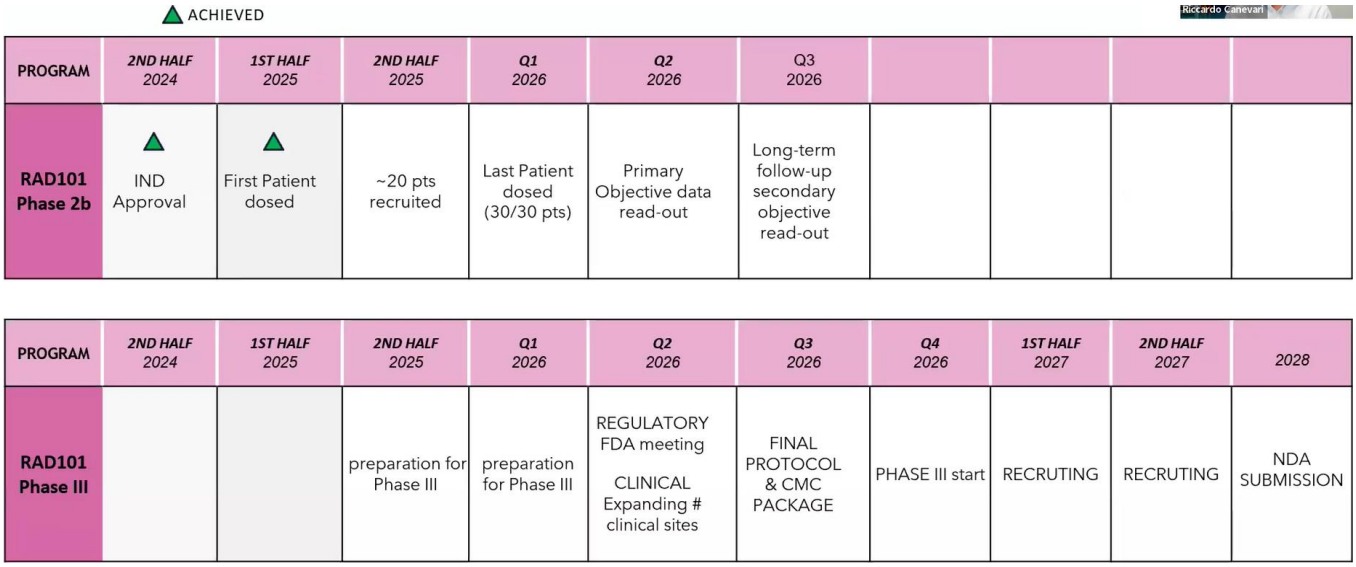
This imaging approach is effective due to the low lipid availability in the brain. When a tumor is not able to source the free fatty acid nutrients that it needs to survive, it synthesizes its own. Metabolic reprogramming in cancer cells enables them to manufacture their own fats to survive in a process called *de novo* lipogenesis. This adaptation can encourage brain metastases to be more aggressive and resistant to therapies that are effective against the primary tumor. FASN has a pro-oncogenic impact on the tumor microenvironment allowing cancer cells to avoid immune destruction, activating invasion and metastasis and inducing angiogenesis among other factors.

RAD101 has been the subject of preclinical work, Phase I and Phase II clinical trials. A Phase III study is planned, with global enrollment and planned enrollment of 150 patients. In research conducted to date, the trials have shown that high uptake of RAD101 is inversely correlated with survival and can act as an important biomarker for guiding treatment. The ongoing Phase IIb study is enrolling patients with a known history of brain metastases who are suspected of relapse or progression after SRS. The trial endpoint is agreement between PET and MRI lesion imaging and comparison with a six-month follow up after imaging. Full enrollment is expected in 1Q:26. In the company's re-

cent presentation, MRI and PET scans are provided (on slides 9, 10 and 11) which show the improved resolution for the latter in three patients. Results from MRI scans fail to show active tumor or necrosis after SRS. However, the PET scans differentiate high metabolic activity surrounding the necrotic area of the metastases, which is indicative of relapse. Images of these patients confirm metabolic activity in brain metastases compared to ambiguous MRI findings. The results are in line with reported Phase IIa results and, if confirmed by additional favorable results, Radiopharm will advance with a global Phase III registrational trial.

Radiopharm's CEO, Riccardo Canevari, believes that a Phase III trial can start by late 2026. It would take 12 to 15 months to fully enroll the targeted 150 patients. If the trial is able to maintain this timeline, Radiopharm could submit its new drug application to the FDA in 2028. The following exhibit provides the company's anticipated timelines.

Exhibit IV – RAD101 Clinical Milestones

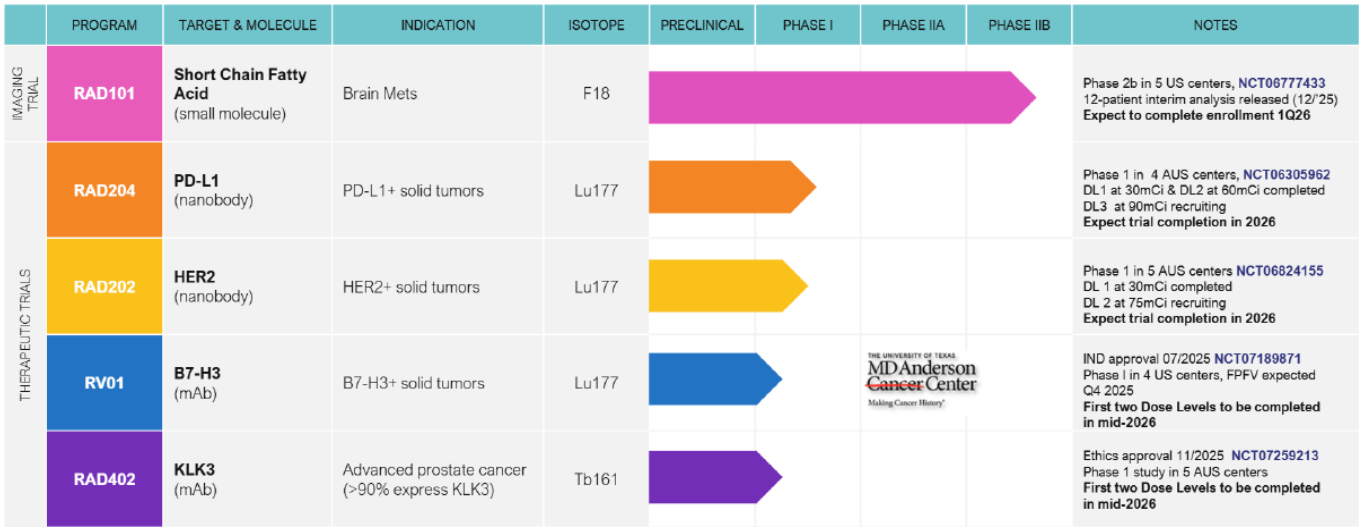


Source: Radiopharm Theranostics RAD101 KOL Event Presentation

Valuation

We adjust our valuation to reflect a higher probability of success for RAD101 based upon the strong data with 92% of evaluated patients achieving the primary endpoint. Our probability of success for the RAD101 program is increased to 38% bringing the blended probability of success for the portfolio to 28%. The result of this work generates a valuation of $13.50 per American Depositary Share (ADS).

Exhibit V – Radiopharm Theranostics Pipeline



Source: Radiopharm Theranostics December 2025 Presentation

Corporate Milestones[1]

- 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
- 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 patient recruitment – 2H:25
- Launch of Phase I RV01 (Betabart) trial – 4Q:25
- Begin dosing patients in Phase I RAD 402 trial – 4Q:25
- RAD301 Phase I last patient dosed – 4Q:25
- RAD202 report data from first two cohorts - end of 2025
- RAD101 Phase III trial launch – 2H:26
- RAD101 trial fully enrolled – February 2026
- RAD101 Phase II readout – 1H:26
- RAD202 Phase I data release (2 cohorts) – 1H:26
- RAD204 Phase I dose escalation complete – 1H:26
- RAD202 Phase I last patient dosed – 2H:26
- RAD301 Phase II trial start – 2H:26
- RAD101 Phase III launch – 2H:26
- RAD204 start Phase II study - 2027
- RAD301 Phase II trial complete – 2H:27
- RAD204 complete Phase II study – 4Q:27
- RAD101 NDA submission - 2028

Summary

Radiopharm provides an interim look at its Phase IIb RAD101 trial, generating impressive results for its primary endpoint. Results demonstrated a 92% concordance between F-18 pivalate measured by PET and MRI for the first twelve patients in its trial. While not final data, these results in 11 of 12 patients show that RAD101 in PET scans provides valuable information to oncologists that can be used to determine optimal treatment. In many cases, results from MRI are inconclusive and may delay necessary treatment or lead to further and unnecessary SRS treatment. As for next milestones, we expect to see a further readout for RAD101 in 1H:26 and the launch of a Phase III study in 2H:26. Based on the favorable data, we increase the probability of success for the RAD101 program which supports a rise in our valuation to $13.50 per ADS.

[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**	**$2,250**	**$3,633**	**$2,250**	**$2,333**
Cost of Sales	$0	($1,615)	($1,979)	($3,594)	($2,200)	($2,300)
Gross Margin		-16.7%	12.0%	1.1%	2.2%	1.4%
Other Income	$1,343	$1,054	$9,203	$10,257	$4,619	$0
Other Losses	($1,226)	$235	($587)	($352)	$0	$0
General & Administrative	($13,039)	($6,342)	($8,296)	($14,638)	($13,925)	($14,458)
Research & Development	($23,086)	($13,593)	($13,922)	($27,515)	($24,850)	($25,940)
Share Based Payments	($2,640)	($693)	($1,203)	($1,895)	$0	$0
Change in Fair Value, Contingent Cons	($8,860)	$28	($4,098)	($4,070)	$0	$0
Income from operations	($47,210)	($19,542)	($18,632)	($38,174)	($34,106)	($40,365)
Operating Margin						
Finance Expenses	($643)	$0	($66)	($65)	$0	
Pre-Tax Income	($47,853)	($19,542)	($18,697)	($38,239)	($34,106)	($40,365)
Provision for Income Tax	($96)	($101)	($2)	($103)	($136)	($161)
Tax Rate	0.2%	0.5%	0.0%	0.3%	0.4%	0.4%
Net Income	**($47,949)**	**($19,643)**	**($18,699)**	**($38,342)**	**($34,242)**	**($40,526)**
Net Margin						
Comprehensive Income	$203	$376	$88	$464	$0	$0
Non-controlling Interest	($1,964)	($918)	($722)	($1,639)	($1,370)	($1,621)
Total Comprehensive Income	**($45,782)**	**($18,350)**	**($17,890)**	**($36,239)**	**($32,873)**	**($38,905)**
Reported EPS	**($0.12)**	**($0.01)**	**($0.01)**	**($0.02)**	**($0.01)**	**($0.01)**
YOY Growth						
Fully Diluted Shares	386,460	1,798,972	2,364,949	2,081,058	3,755,210	4,275,110
Adjustments	$0.00	$0.00	$0.00	$0.00	$0.00	$0
Adjusted EPS	**($0.1241)**	**($0.0102)**	**($0.0079)**	**($0.0184)**	**($0.0091)**	**($0.0095)**

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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