Zacks Small-Cap Research
Sponsored – Impartial – Comprehensive

September 29, 2025
John D. Vandermosten, CFA
312-265-9588 / jvandermosten@zacks.com

scr.zacks.com
101 N. Wacker Drive, Chicago, IL 60606

Radiopharm Theranostics Limited (RADX - NASDAQ)

RADX: RAD101: Imaging Recurring Brain Metastases

We use a discounted cash flow (DCF) model and apply a 25% 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 (9/26/2025)	$5.75
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 (%)	**2.7**
Beta	**0.9**
Average Daily Volume (sh)	**30,060**
Shares Outstanding (mil)	**7.8**
Market Capitalization ($mil)	**44.9**
Short Interest Ratio (days)	**1.9**
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

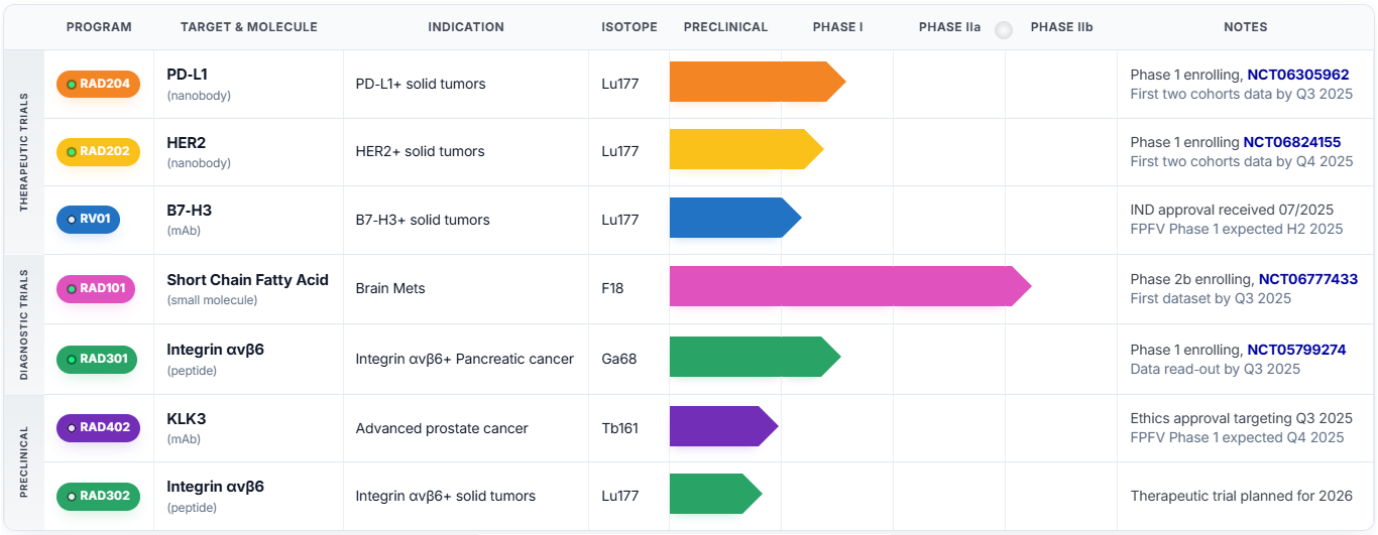
	Q1	Q2	Q3	Q4	Year
2024	$0.00 A	-$0.07 A	$0.00 A	-$0.05 A	-$0.12 A
2025	$0.00 A	-$0.01 A	$0.00 A	$0.00 E	-$0.02 E
2026					-$0.02 E
2027					-$0.01 E

© Copyright 2025, Zacks Investment Research. All Rights Reserved.

WHAT'S NEW

Radiopharm Theranostics Limited (NASDAQ: RADX) held another key opinion leader (KOL) event in late September. This episode's topic was treatment and imaging of brain metastases as an introduction to discussions about Radiopharm's lead candidate RAD101. RAD101 targets fatty acid synthase (FASN), which is expressed in many brain metastases. The KOL event covered treatment of brain metastases using Gamma Knife, also known as stereotactic radiosurgery (SRS). It further reviewed the company's pivalate technology and its targeting mechanism. The presentation summarized the data seen to date and the unmet need in brain metastases. Further discussion highlighted active and anticipated clinical trials evaluating the imaging agent. The presentation was hosted by Radiopharm's Chief Medical Officer, Dr. Dimitris Voliotis and began with an introduction of the featured speaker, Dr. Ramji Rajendran.

Exhibit I – Radiopharm Theranostics' Pipeline



Source: Radiopharm Theranostics' Website

Fatty Acid Synthase (FASN) Radioimaging Agent

The September 24th KOL event featured Dr. Ramji Rajendran of the Alexian Brothers Medical Center in Chicago. He completed his M.D. and Ph.D. in a combined program at the University of Illinois at Urbana-Champaign and is board certified in Radiation Oncology. He serves as the Medical Director of the Department of Radiation Oncology and Illinois Gamma Knife Center at Ascension Alexian Brothers Medical Center. Dr. Rajendran's expertise spans a wide range of advanced radiation therapy techniques, including Intensity-Modulated Radiation Therapy (IMRT), Stereotactic Body Radiation Therapy (SBRT) and Gamma Knife radiosurgery. His research contributions include work in prostate organ motion, proton radiation therapy and radiation therapy for breast and thoracic tumors.

Dr. Rajendran's presentation began with a review of brain metastases which are becoming more common as patients live longer. This gives the disease more time to spread. Detection is also improving, as more sensitive diagnostic tools can detect brain metastases that were previously too small to be found. Greater cancer incidence also contributes to the likelihood of brain metastases. While all cancers can spread to the brain, the types most likely to do so are lung, breast, colon, kidney and melanoma.

Dr. Rajendran then introduced stereotactic radiosurgery (SRS) which, despite its name, is a non-surgical radiation therapy technique. It is used to treat abnormalities, small tumors, and certain functional disorders in the brain and, in some cases, the spine or other parts of the body. It is commonly used to treat brain tumors, vascular malformations and other functional disorders and tumors. In Dr. Rajendran's practice, the Leksell Gamma Knife is used.

Exhibit II – Gamma Knife (SRS)



Source: Radiopharm Theranostics RAD101 KOL Event Presentation

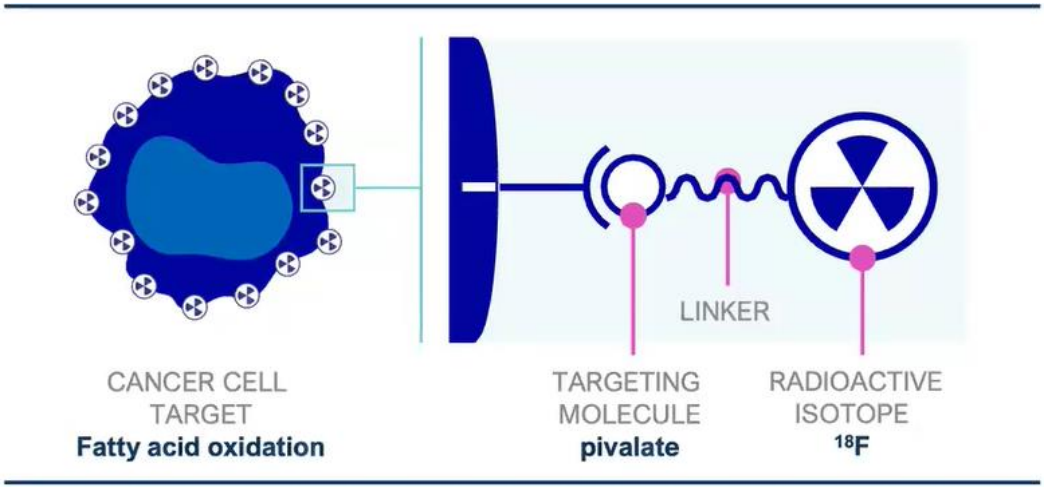
Radiopharm's guest speaker proceeded to share several examples of successes using SRS targeting brain metastases with the primary cancer of non-small cell lung cancer and melanoma. In both cases, the procedure was able to shrink the tumor leaving only a small scar. Patients with large tumors would not initially receive SRS. Rather the metastasis would be resected and then SRS would be used to address the tumor bed to prevent recurrence. A patient with several brain metastases may require whole brain radiotherapy and systemic treatments.

In the months following SRS treatment, the area the tumor originally occupied may expand in size. The necrotic tissue in the center of the tumor mass does not allow imaging making it difficult to determine if the tumor is again growing or that the area is inflamed and swelling as the body tries to clear the mass. At this point, the tools that are now available are insufficient to guide the optimal treatment. Providers must wait and see if the swelling subsides or the tumor expands to determine the best course forward. Waiting may also allow the tumors to grow and spread. In this case, the availability of an imaging agent that can discern between tumor necrosis and tumor progression would dramatically improve clinical care.

RAD101

In an effort to help these patients who have received SRS treatment Radiopharm is developing RAD101. The agent may clarify whether or not the cancer 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

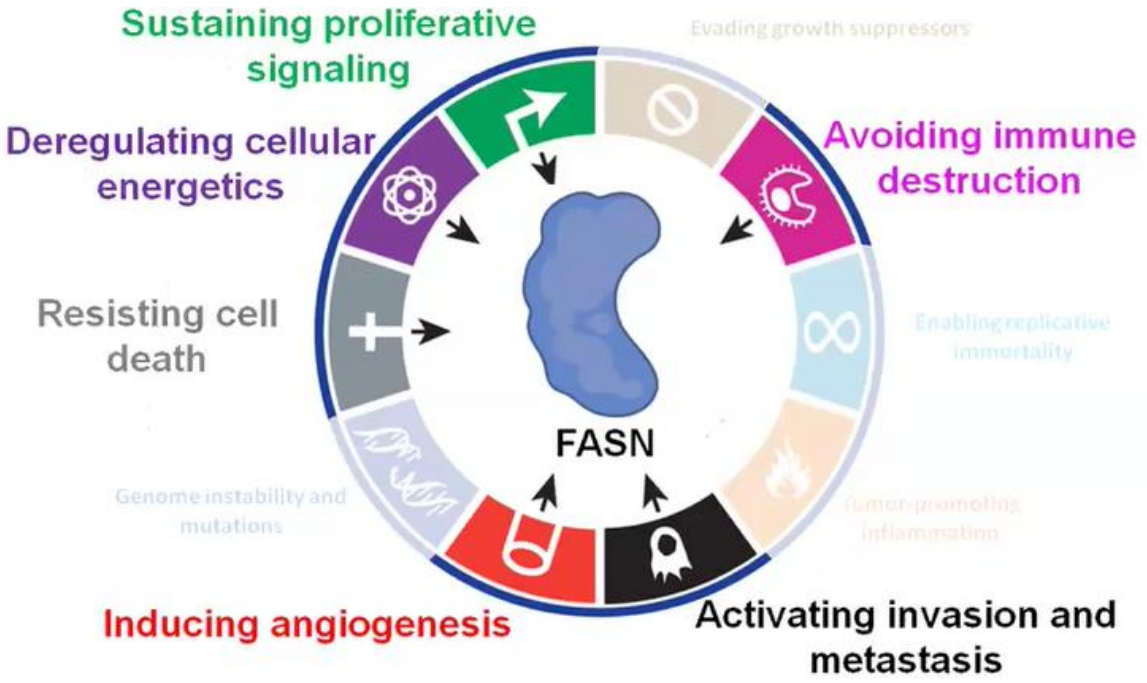


Source: Radiopharm Theranostics RAD101 KOL Event Presentation

Radiopharm's Chief Medical Officer, Dimitris Voliotis, took the reins from Dr. Rajendran to introduce RAD101. He identified approximately 300,000 new subjects that are diagnosed with brain metastases in the United States every year which comprise a material market size. Dr. Voliotis introduced data from the company's ongoing Phase IIb study, where an interim readout has demonstrated high tracer uptake in all brain metastases subjects irrespective of primary tumor origin.

The reason why this imaging approach is effective is related 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 synthesize their own fats to survive in a process called *de novo* lipogenesis. This adaptation can make brain metastases 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.

Exhibit IV – The Pro-Oncogenic Impact of FASN



Source: Radiopharm Theranostics RAD101 KOL Event Presentation

Preclinical work with RAD101 demonstrated uptake in implanted murine and human breast adenocarcinoma cells, which allows for localization of metastases. The most common types of cancers that produce brain metastases are non-small cell lung cancer (NSCLC), triple-negative breast cancer (TNBC), HER2-positive breast cancer, HR positive breast cancer and melanoma.

RAD101 has been the subject of preclinical work, Phase I and Phase II clinical trials. A Phase III study is planned and would be a global study evaluating 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. Early interim data and full enrollment are expected in 2H:25 with a Phase II read out in 1H:26.

CEO Summary
Radiopharm's CEO, Riccardo Canevari, provided additional detail on Radiopharm's Phase IIa RAD101 study. The work was conducted in 22 patients, and only half of them were evaluated after SRS. The Phase IIb is evaluating 30 patients in 5 different centers. He expects the trial to be fully recruited before year end 2025 and to read out in 2Q:26. Given the positive data generated to date, Radiopharm is in the process of planning its Phase III trial for RAD101 and believes that it can start it by late 2026. The trial should enroll about 150 patients and take 12 – 15 months to fully enroll. If the trial is able to maintain this timeline, Radiopharm could submit its new drug application in 2028. The following exhibit provides the company's anticipated timelines.

Exhibit V – RAD101 Clinical Milestones

▲ ACHIEVED

PROGRAM	2ND HALF 2024	1ST HALF 2025	2ND HALF 2025	Q1 2026	Q2 2026	Q3 2026				
RAD101 Phase 2b	▲ IND Approval	▲ First Patient dosed	~20 pts recruited	Last Patient dosed (30/30 pts)	Primary Objective data read-out	Long-term follow-up secondary objective read-out				

PROGRAM	2ND HALF 2024	1ST HALF 2025	2ND HALF 2025	Q1 2026	Q2 2026	Q3 2026	Q4 2026	1ST HALF 2027	2ND HALF 2027	2028
RAD101 Phase III			preparation for Phase III	preparation for Phase III	REGULATORY FDA meeting CLINICAL Expanding # clinical sites	FINAL PROTOCOL & CMC PACKAGE	PHASE III start	RECRUTING	RECRUTING	NDA SUBMISSION

Source: Radiopharm Theranostics RAD101 KOL Event 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
- 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 patient recruitment – 2H:25
- Launch of Phase I RV01 (Betabart) trial – 4Q:25
- Begin dosing patients in Phase I RAD402 trial – 4Q:25
- RAD202 data from first two cohorts - end of 2025
- RAD101 trial launch – 4Q:26
- RAD101 NDA submission - 2028

Summary

Radiopharm offers a broad portfolio of radiopharmaceuticals that both image and treat a variety of cancers. Radiopharm's goal has been to tread new ground in the space, seeking new targets and underappreciated radioisotopes to improve on-target activity and efficacy. The company recently held another KOL event this time featuring its RAD101 imaging asset. The radiation oncologist Dr. Ramji Rajendran served as the KOLs and provided an important perspective from a practicing physician treating patients using SRS. RAD101 is Radiopharm's lead asset and is the subject of a Phase IIb study and is in the planning stages for a pivotal Phase III study which is expected to begin next year.

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

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 ex-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.

PROJECTED FINANCIALS

Radiopharm Theranostics Limited - Income Statement

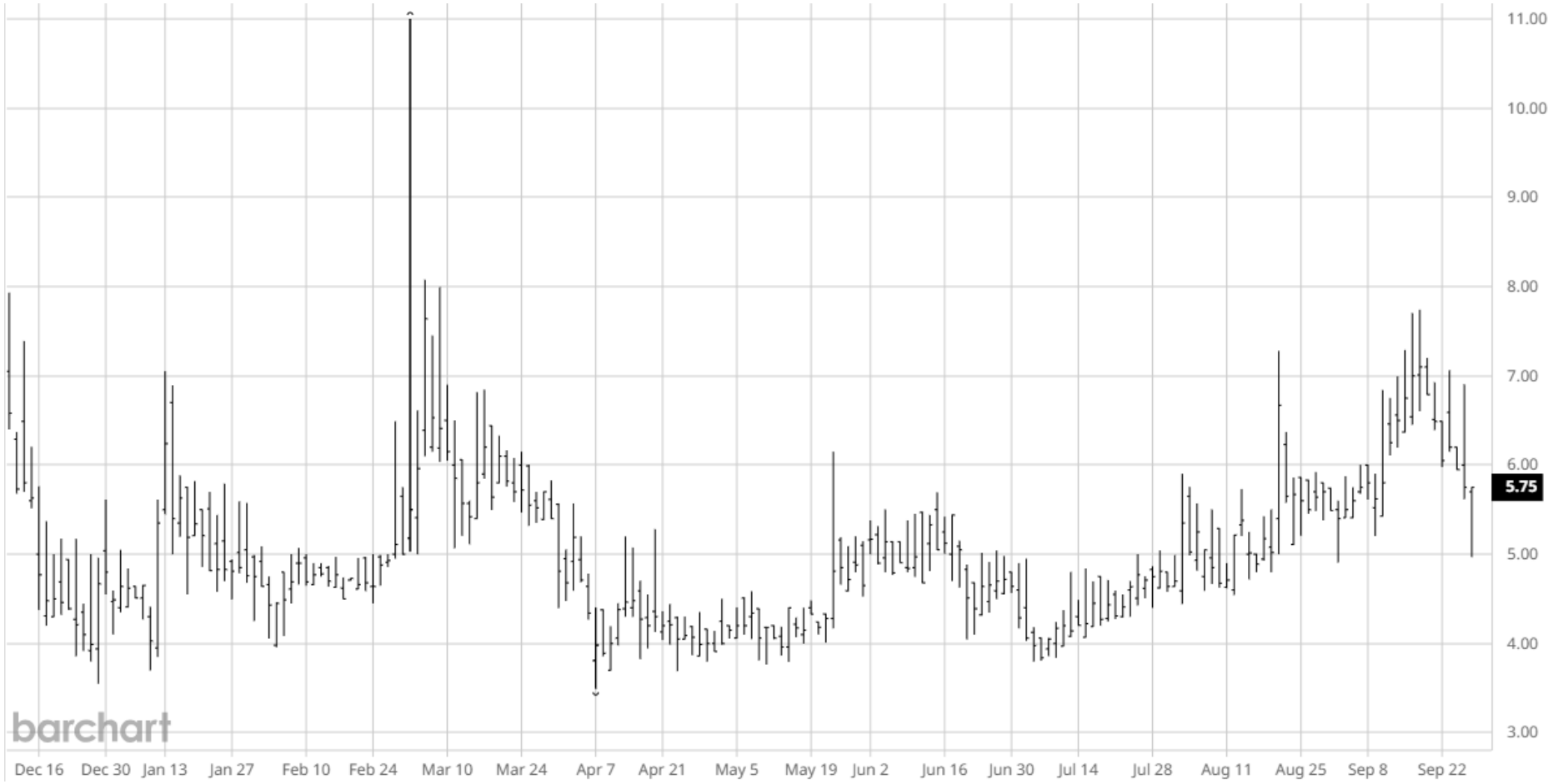
Radiopharm Theranostics Ltd	2024 A	H1 A	H2 A	2025 A	2026 E	2027 E
Customer Contract Rev (A$'000)	**$299**	**$1,384**	**$3,982**	**$5,366**	**$0**	**$0**
Cost of Sales	$0	($1,615)	$0	($1,615)	$0	$0
Gross Margin		-16.7%		69.9%		
Other Income	$1,343	$1,054	$0	$1,054	$0	$0
Other Losses	($1,226)	$235	$0	$235	$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

© Copyright 2025, Zacks Investment Research. All Rights Reserved.

HISTORICAL STOCK PRICE

Radiopharm Theranostics Limited – Share Price Chart[2]



[2] Source: Barchart.com, Inc.

DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

I, John Vandermosten, hereby certify that the views expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESTMENT BANKING AND FEES FOR SERVICES

Zacks SCR does not provide investment banking services nor has it received compensation for investment banking services from the issuers of the securities covered in this report or article.

Zacks SCR has received compensation from the issuer directly or from an investor relations consulting firm engaged by the issuer for providing non-investment banking services to this issuer and expects to receive additional compensation for such non-investment banking services provided to this issuer. The non-investment banking services provided to the issuer includes the preparation of this report, investor relations services, investment software, financial database analysis, organization of non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per-client basis and are subject to the number and types of services contracted.

POLICY DISCLOSURES

This report provides an objective valuation of the issuer today and expected valuations of the issuer at various future dates based on applying standard investment valuation methodologies to the revenue and EPS forecasts made by the SCR Analyst of the issuer's business.
SCR Analysts are restricted from holding or trading securities in the issuers that they cover. ZIR and Zacks SCR do not make a market in any security followed by SCR nor do they act as dealers in these securities. Each Zacks SCR Analyst has full discretion over the valuation of the issuer included in this report based on his or her own due diligence. SCR Analysts are paid based on the number of companies they cover. SCR Analyst compensation is not, was not, nor will be, directly or indirectly, related to the specific valuations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports and articles are based on data obtained from sources that it believes to be reliable, but are not guaranteed to be accurate nor do they purport to be complete. Because of individual financial or investment objectives and/or financial circumstances, this report or article should not be construed as advice designed to meet the particular investment needs of any investor. Investing involves risk. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports or articles or tweets are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.

© Copyright 2025, Zacks Investment Research. All Rights Reserved.