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Radiopharm Theranostics Limited (RADX - NASDAQ)

RADX: Prostate Cancer KOL Summary

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 (9/5/2025)	$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)	**28,506**
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

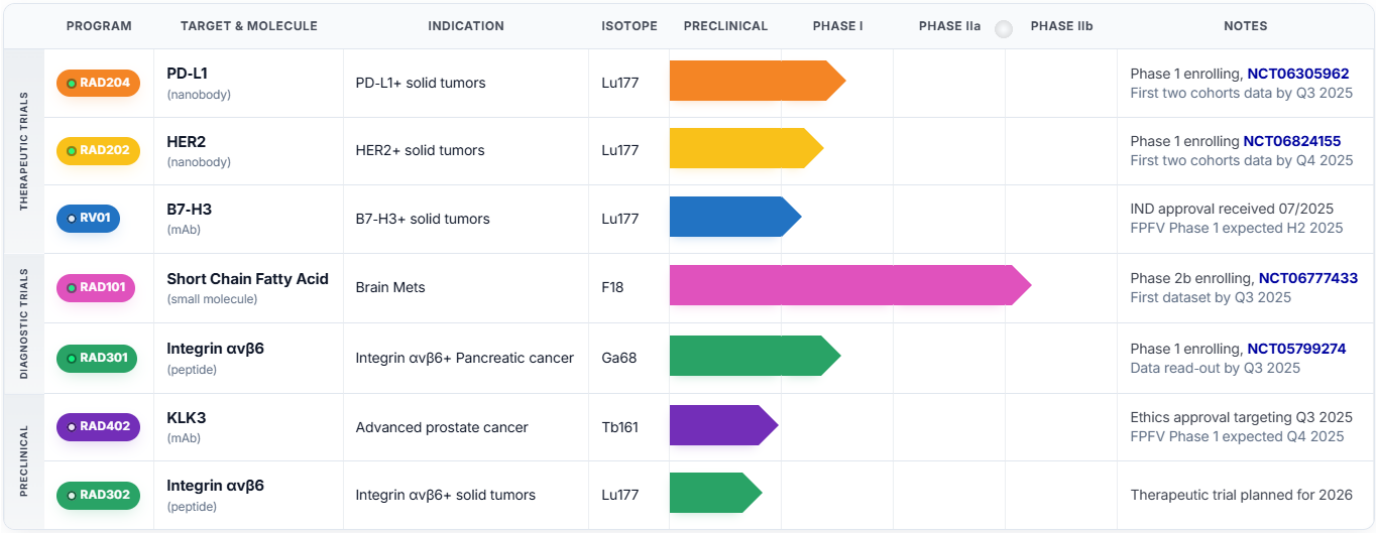
Earnings per Share

	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

WHAT'S NEW

Radiopharm Theranostics Limited (NASDAQ: RADX) held two key opinion leader (KOL) events: one at the end of August and the other at the beginning of September. The events highlighted the company's work in prostate cancer pursuing both the B7-H3 and KLK3 targets, which are used by Radiopharm's RV01 and RAD402 radiopharmaceutical candidates, respectively. Both of the presentations were hosted by Radiopharm's Chief Medical Officer, Dr. Dimitris Voliotis and began with an introduction of the speakers. The first event was held on August 27th and featured Dr. Oliver Sartor and Dr. David R. Piwnica-Worms while the second event was held on September 2nd and featured Dr. Hans David Ulmert and Radiopharm CEO Riccardo Canevari.

Exhibit I – Radiopharm Theranostics' Pipeline



Source: Radiopharm Theranostics' Website

B7-H3 Targeted Radiotherapy

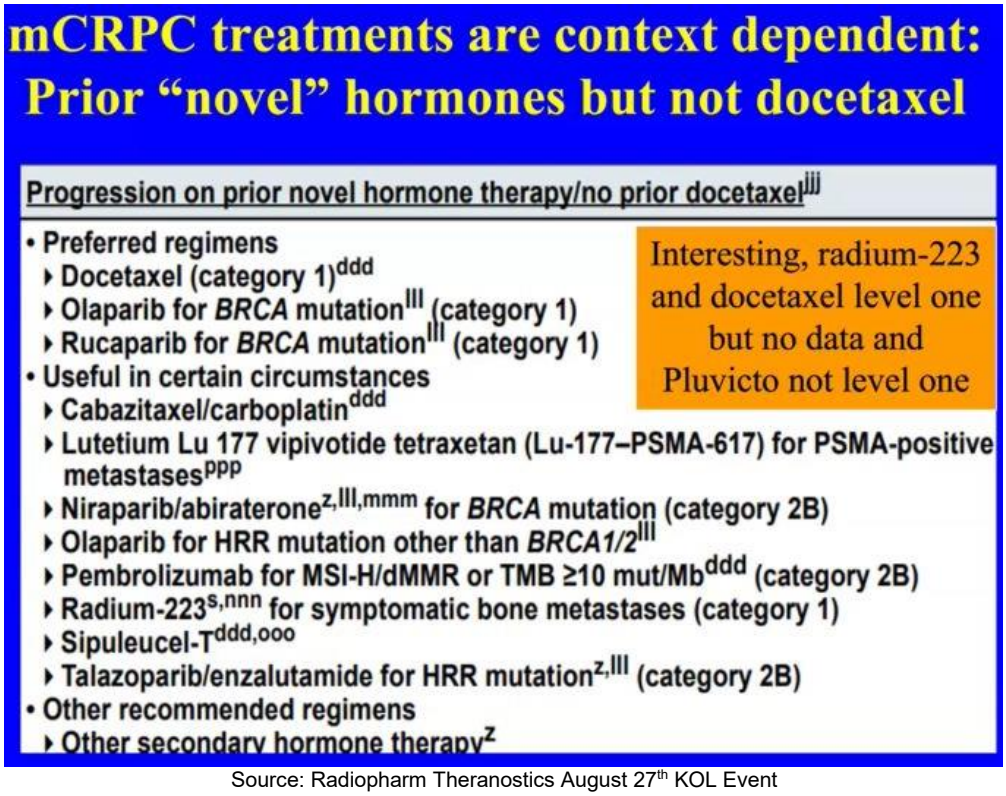
The August 27th KOL event featured Dr. Oliver Sartor of Tulane University among other prestigious affiliations and Dr. David Piwnica-Worms of the MD Anderson Cancer Center. The presentation began with a review of prostate cancer treatment. It traced its evolution from treatments centered on surgery, radiation and chemotherapy to more modern approaches using targeted therapy, immunotherapy and molecularly targeted radiation.

Prostate cancer is divided into two main groups: castrate sensitive and castrate resistant. The former is responsive to hormonal therapy while the latter is not. Further divisions include metastatic and non-metastatic disease, each of which calls for a different treatment approach.

Metastatic castrate resistant prostate cancer (mCRPC) represents a diverse disease with more than 30 subtypes. Because of this variability, a single precision therapy can only benefit a subset of patients. Broadly expressed targets like B7-H3 are therefore especially valuable in developing effective treatments and can be used in a wider array of patients.

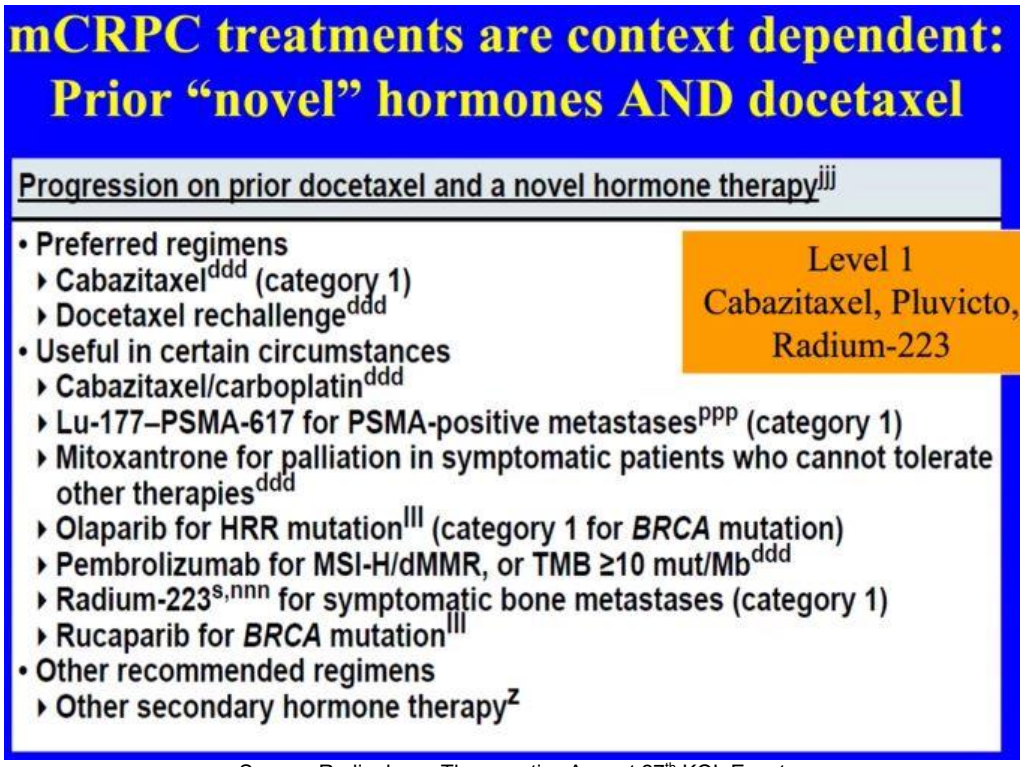
Dr. Sartor reviewed several Phase III trials in mCRPC evaluating products including docetaxel, Sipuleucel-T, abiraterone and enzalutamide among others. Each showed an overall survival benefit over the control ranging from 2.4 months to 8.8 months. However, the benefit did not dramatically improve survival, leaving an unmet need. Dr. Sartor noted that "...everybody with mCRPC is going to progress and die from their disease" under existing treatment modalities bringing into relief the need for dramatically improved therapies. He also pointed out that the sequence of mCRPC treatment is important for determining what is administered in later lines of therapy. This is illustrated in the following slides.

Exhibit II - mCRPC Treatments are Context Dependent (No Prior Docetaxel)



Source: Radiopharm Theranostics August 27th KOL Event

Exhibit III - mCRPC Treatments are Context Dependent (Novel Hormones + Prior Docetaxel)



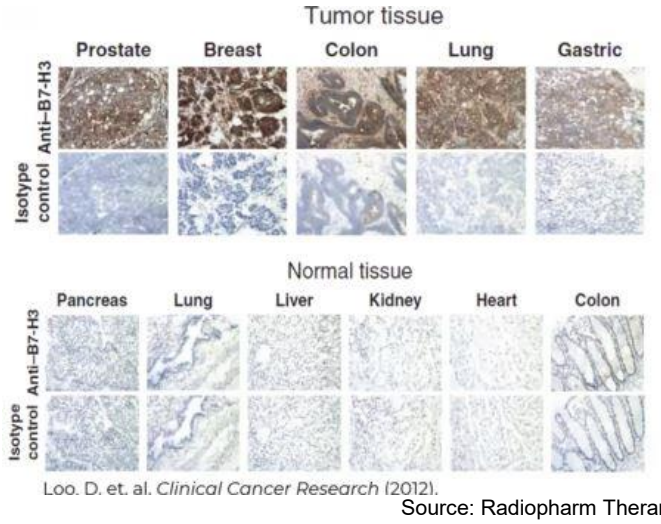
Source: Radiopharm Theranostics August 27th KOL Event

Following an explanation of the radioisotope design, Dr. Sartor reviewed the PEACE III trial which evaluated the combination of enzalutamide plus radium-223 versus enzalutamide alone in men with mCRPC and bone metastases. Interim data for the trial showed an overall survival (OS) benefit of 7.3 months. This was cited to show the efficacy of using a radioisotope as part of the treatment regimen.

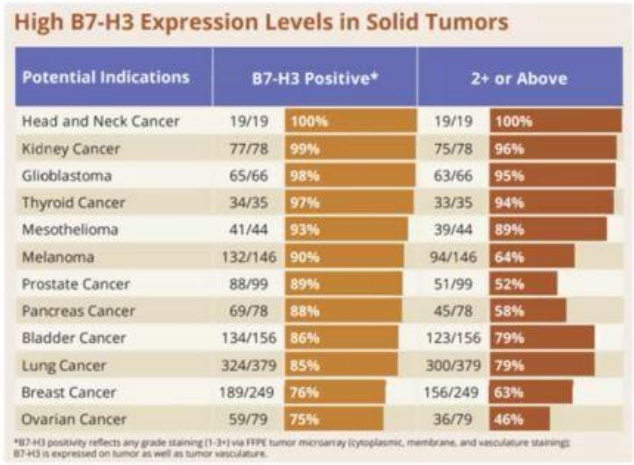
Dr. Sartor authored the New England Journal of Medicine article entitled Lutetium-177-PSMA-617 for mCRPC. The product referenced in the article, better known as Pluvicto, was first approved in March 2022 based on data from the VISION trial. The VISION study met both primary endpoints of OS and progression free survival (PFS) adding four months of life for the average patient. Pluvicto received an expanded approval by the FDA in March 2025 to include adults with PSMA-positive mCRPC who have had androgen receptor (AR) pathway inhibitor therapy and are appropriate candidates to delay taxane chemotherapy. These interim results were generated from the PSMAfore trial. Based on the data in these trials, Dr. Sartor believes that there is a significant unmet need for better therapies in mCRPC and that radiopharmaceuticals provide an attractive modality. He identifies the primary unmet needs as OS limited to two years post-treatment, difficult side effect profile for chemotherapy and castration and lack of other approved drugs post-Pluvicto.

After his 15-minute presentation, Dr. Sartor handed the baton to the second KOL guest, Dr. Piwnica-Worms, who introduced the B7-H3 immune checkpoint target and Radiopharm's Lu-177 Betabart candidate designated RV01. B7-H3 is an attractive pan-tumor target and is expressed in prostate, breast, colon, lung and gastric tumor tissue. Staining work shows that the target is not expressed in normal tissue in these sites.

Exhibit IV - B7-H3 Expression in Different Tissues



Loo. D. et. al. *Clinical Cancer Research* (2012).



High B7-H3 Expression Levels in Solid Tumors

Potential Indications	B7-H3 Positive*		2+ or Above	
Head and Neck Cancer	19/19	100%	19/19	100%
Kidney Cancer	77/78	99%	75/78	96%
Glioblastoma	65/66	98%	63/66	95%
Thyroid Cancer	34/35	97%	33/35	94%
Mesothelioma	41/44	93%	39/44	89%
Melanoma	132/146	90%	94/146	64%
Prostate Cancer	88/99	89%	51/99	52%
Pancreas Cancer	69/78	88%	45/78	58%
Bladder Cancer	134/156	86%	123/156	79%
Lung Cancer	324/379	85%	300/379	79%
Breast Cancer	189/249	76%	156/249	63%
Ovarian Cancer	59/79	75%	36/79	46%

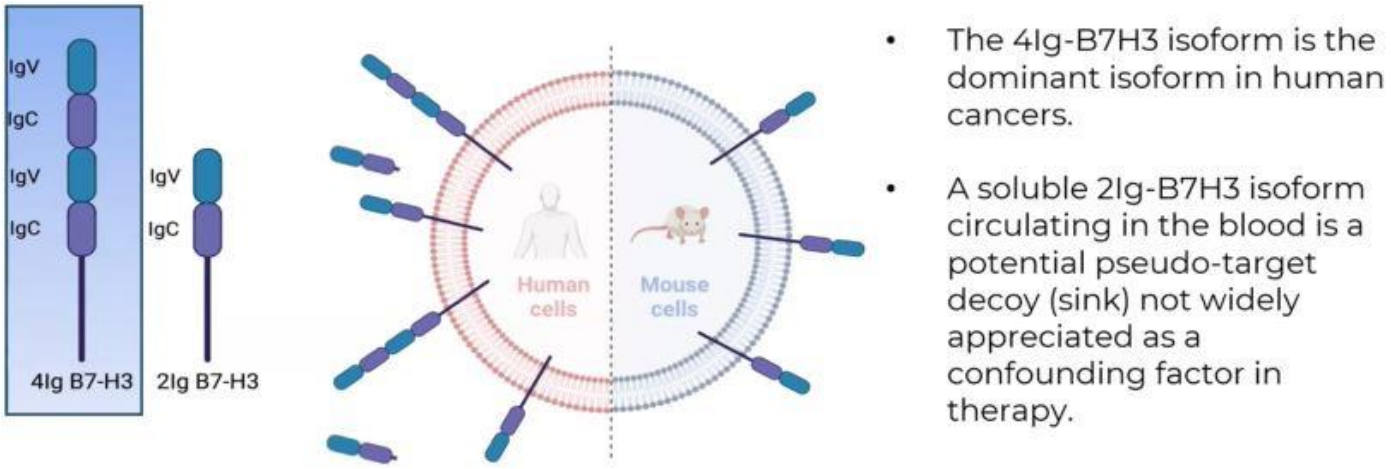
*B7-H3 positivity reflects any grade staining (1-3+) via FFPE tumor microarray (cytoplasmic, membrane, and vasculature staining); B7-H3 is expressed on tumor as well as tumor vasculature.

Source: Radiopharm Theranostics August 27th KOL Event

B7-H3 is an alternative target when prostate-specific membrane antigen (PSMA) targeting therapies fail. The rationale behind its attractiveness is that B7-H3 is expressed very early in the evolution of the disease and its expression is consistent between primary and metastatic sites. The checkpoint's expression is also consistent between castrate-sensitive and castrate resistant tissue. Other features of the immune response regulator are its overexpression in prostate cancers with defective DNA repair genes and negative correlation with mismatch repair defect (MMRd) status. In his presentation, Dr. Piwnica-Worms referenced 11 Phase I or II active or completed clinical trials that are evaluating the B7-H3 target.

One of the features of B7-H3 is that it is expressed as multiple isoforms: 4Ig and 2Ig. The 4Ig isoform is dominant and is membrane bound while the 2Ig form is soluble and circulates through the blood. This has implications for the design of a binding ligand. If a therapeutic targeting agent binds to the 2Ig isoform, very high doses will be needed to deliver sufficient B7-H3 to the target tumor tissue. If the targeting agent can only bind to the 4Ig isoform which only appears on tumors and within the tumor microenvironment, then lower doses of the treatment can be used, reducing side effects and radiation exposure in the case of RV01.

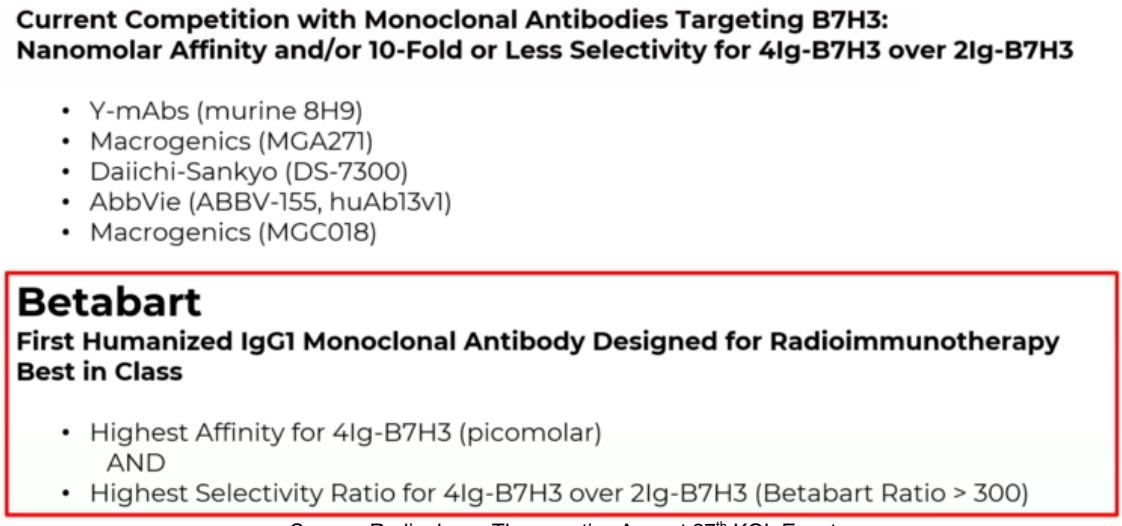
Exhibit V - B7-H3 4Ig and 2Ig Isoforms



Source: Radiopharm Theranostics August 27th KOL Event

The event continued with Dr. Piwnica-Worms providing an overview of prostate cancer treatment highlighting the unmet needs in metastatic castrate resistant prostate cancer (mCRPC). Despite the double-digit number of early studies, none of them employed radioisotopes for treatment although other monoclonal antibodies targeting B7-H3 exist. Betabart, Radiopharms B7-H3 binding monoclonal antibody, sought to improve on the characteristics of these candidates by achieving picomolar affinity vs nanomolar affinity to the target and selectivity for the 4Ig isoform over the 2Ig isoform.

Exhibit VI – Competing B7-H3 Targeting Antibodies

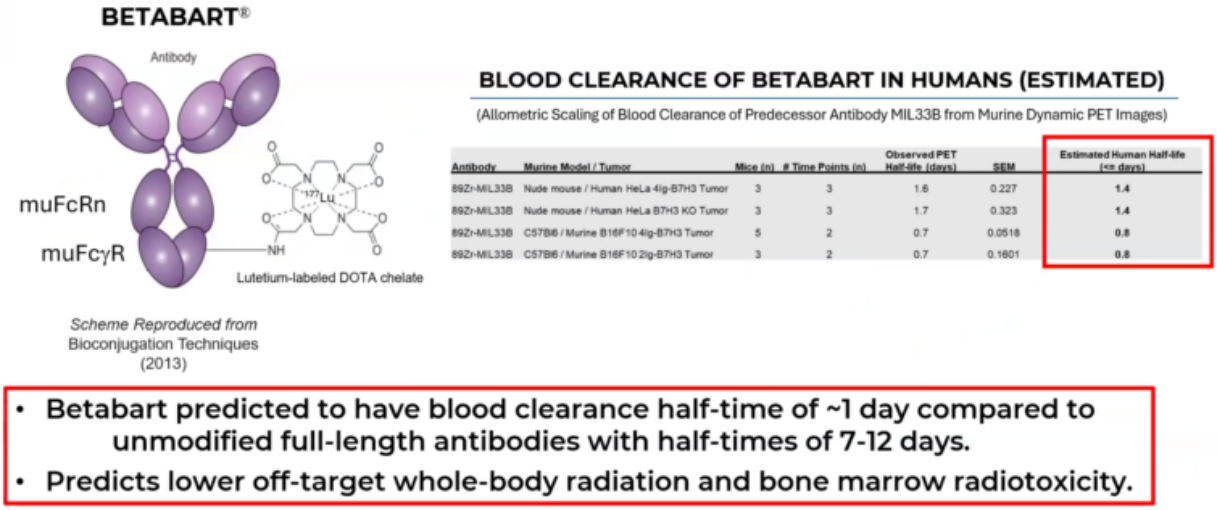


Source: Radiopharm Theranostics August 27th KOL Event

Betabart has broader applicability and multi-indication potential in B7-H3 positive tumors and has shown early evidence of efficacy in prostate, pancreatic, hepatocellular, colorectal, triple negative breast, lung, ovarian and endometrial cancers.

Further modifications of Betabart include the introduction of mutations into the FC domain of the antibody. This change will accelerate its clearance from circulation and decrease marrow binding where the B7-H3 receptors are present. These changes will reduce off-target radiation exposure as demonstrated in a mouse model.

Exhibit VII – Betabart's Other Features



Source: Radiopharm Theranostics August 27th KOL Event

Following the discussion of his slides, Dr. Piwnica-Worms summarized Betabart's features:

- Represents a best-in-class, high affinity humanized IgG1 antibody
- Demonstrates 300x greater selectivity for the 4Ig isoform compared to the 2Ig form
- Engineered with Fc mutations to increase blood clearance and liver extraction rate with reduced bone marrow affinity
- Provides PET/SPECT imaging properties *in vivo*
- Supported by mouse model data

The Betabart candidate will be the subject of a basket study looking at a variety of tumors beginning later this year.

KLK3 Targeted Radiotherapy

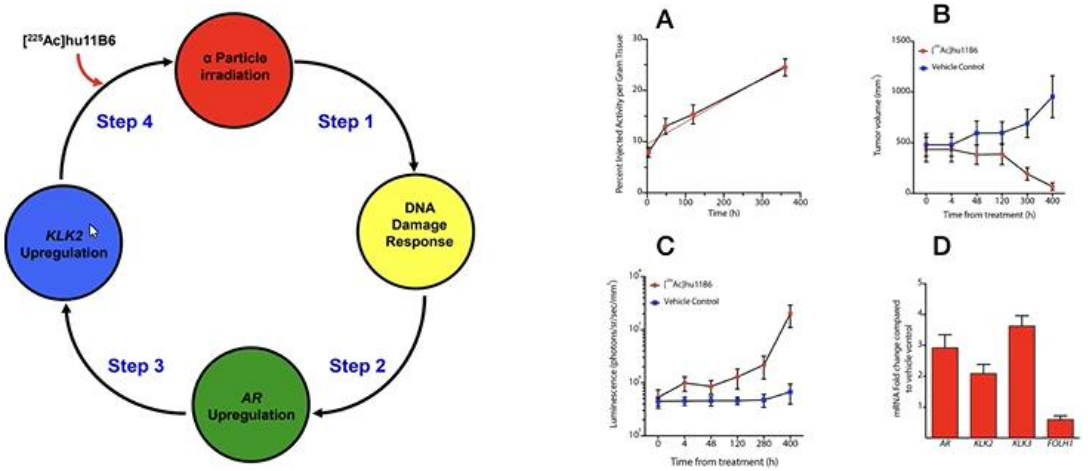
The second KOL event was held on September 2nd and featured Dr. H. David S. Ulmert from UCLA. He was joined by hosts, Dr. Dimitris Voliotis and Radiopharm CEO Riccardo Canevari. Dr. Ulmert presented the prostate kallikrein (hK2/PSA) targeted radioimmunotheranostic RAD402 and its surrounding framework.

The guest began with a background on the human kallikrein related peptidase 2 (KLK2) and prostate specific antigen (PSA or KLK3) noting that it is only found in a few species and is specifically expressed in prostate tissues. This is in contrast to prostate-specific membrane antigen (PSMA) which, in addition to the prostate is also found in salivary glands, lacrimal glands and kidneys among other sites. While minute levels of the two kallikreins (KLK2 and KLK3) circulate in the blood, they are rapidly inactivated by protease inhibitors. An exhibit provided in the slide deck illustrated over 100 different tissues where material levels of PSMA appear. KLK2 and KLK3 only appear in high levels in the prostate. This localized expression is expected to limit off target effects and reduce side effects.

KLK2 and KLK3 are closely related members of the kallikrein family of serine proteases. Studies are conducted using the KLK2 target because the two genes and their protein products are similar in structure, function and regulation. Both KLK2 and KLK3 have genomic proximity, high homology (80% sequence similarity with active sites highly conserved) and are both strongly driven by AR signaling. Murine models lack a functional KLK3 gene which directs investigators to use the KLK2 ortholog in conducting preclinical studies in these animal models.

The presentation referenced a mouse study to evaluate KLK2-expressing tumors treated with a radioisotope. Dr. Ulmert observed that as the DNA damage repair mechanism increases, the expression of androgen receptors (ARs), KLK2 and KLK3 are also upregulated. This produces more targets for the antibody, thereby increasing the effect of the drug. The study demonstrated tumor uptake in the prostate tissue of the mouse and that late and enzalutamide-resistant disease can be targeted.

Exhibit VIII – Ac-225 hK2-Radioimmunotherapy Feed-Forward Therapeutic Mechanism



Source: Radiopharm Theranostics September 2nd KOL Event

The upregulation of AR expression in PSMA treatment as its efficacy declines makes KLK3 targeting therapy an attractive approach in post-Pluvicto settings. This is due to elevated KLK3 levels in the prostate following treatment.

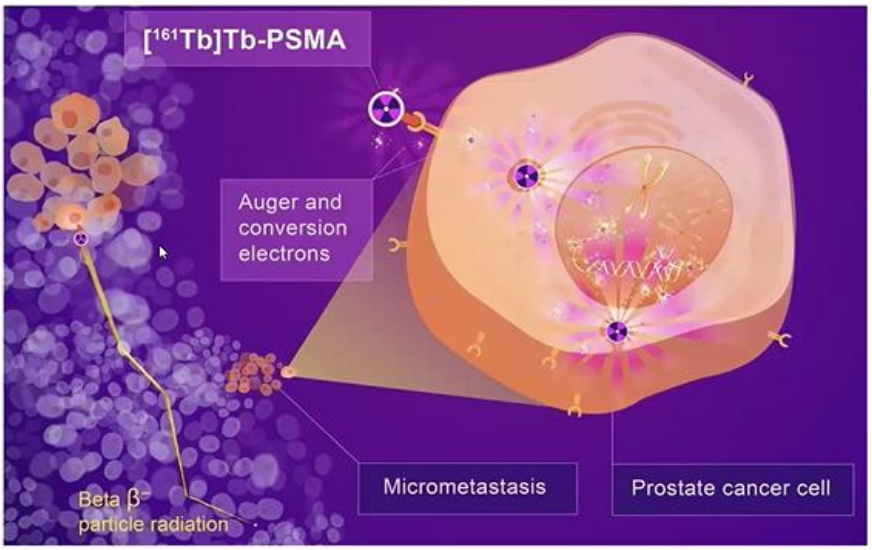
Johnson & Johnson (J&J) has conducted work on this target using an Indium-111 radioisotope. Its human imaging study found tumor uptake and limited off-target accumulation in dose-limiting organs such as the salivary glands and kidneys. The radiotracing study also demonstrated that the KLK2 target was co-located with the PSMA target in tumor tissue, thereby allowing for more specificity than can be achieved with the latter. This work supported J&J's later launch of an ongoing Phase I study to measure therapeutic response. The J&J studies have shown that the KLK2 radioisotope can precisely target tumors in patients with mCRPC and can deliver deep and durable reduction in cancer markers for patients with mCRPC who do not respond to other treatments.

This background work has set the stage for moving forward with a kallikrein-targeting isotope because:

- It is expressed at higher levels than KLK2 enabling better targeting and delivery to tumors
- It has been studied extensively with over 27,000 publications and in multiple Phase I/II trials, providing vital background that lowers development risks and accelerates clinical progress
- It is a reliable biomarker for screening, diagnosing and monitoring prostate cancer

Radiopharm is using the Terbium-161 radioisotope for its warhead linked to the KLK3 antibody. This radioisotope has several attractive features including the emission of both beta particles and Auger electrons which can improve its killing ability.

Exhibit IX – Advantage of Terbium-161 Radiotherapy



Source: Radiopharm Theranostics September 2nd KOL Event

Dr. Ulmert continued his discussion by describing the mechanism of action for the KLK3 binding antibody. When the antibody binds to the KLK3 epitope on the surface of the serine protease, the radioisotope is internalized and is able to target its Auger, alpha or beta radiation precisely. Radiopharm's Tb-161 radioisotope is particularly appropriate given its emissions. Tb-161's beta particles and Auger electrons have medium and short-range reach respectively. Auger electrons are only effective if they are very close to the nucleus, which is effective since the KLK3 targeting monoclonal antibody and its associated Tb-161 radioisotope are internalized.

Radiopharm plans to run its first RAD402 study in Australia early next year.

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 interim data – 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

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 two KOL events featuring its B7-H3 and KLK3 targeting assets. The KOLs who participated are luminaries in the field and provided prostate cancer's background and framework to better understand Radiopharm's new candidates. The guests informed viewers of the types of prostate cancer, the limitations of existing therapies, the unmet needs addressed by the B7-H3 and KLK3 targeting candidates and anticipated start dates for clinical trials for each

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.

[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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