

## Radiopharm Theranostics Limited (RADX - NASDAQ)

### **RADX: Initiating Coverage – Adding a Radio-isotope to Precision Oncology**

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 (5/9/2025) **\$4.18**  
**Valuation** **\$12.50**

### INITIATION

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 <sup>18</sup>F radioisotope imaging brain metastases is the most advanced asset. It has advanced to Phase II clinical trials. Other candidates include RAD 202 (HER2) & RAD204 (anti-PD-L1) which are both nanobodies conjugated to <sup>177</sup>Lu for treatment. The pipeline further includes RAD301/302, a theranostic pair targeting  $\alpha$ V $\beta$ 6 & 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	<b>50.82</b>
52-Week Low	<b>3.50</b>
One-Year Return (%)	<b>-25.4</b>
Beta	<b>0.8</b>
Average Daily Volume (sh)	<b>184,483</b>
Shares Outstanding (mil)	<b>11.7</b>
Market Capitalization (\$mil)	<b>48.9</b>
Short Interest Ratio (days)	<b>1.1</b>
Institutional Ownership (%)	<b>16.2</b>
Insider Ownership (%)	<b>25.4</b>
Annual Cash Dividend	<b>\$0.00</b>
Dividend Yield (%)	<b>0.00</b>
5-Yr. Historical Growth Rates	
Sales (%)	<b>N/A</b>
Earnings Per Share (%)	<b>N/A</b>
Dividend (%)	<b>N/A</b>
P/E using TTM EPS	<b>N/A</b>
P/E using 2025 Estimate	<b>N/A</b>
P/E using 2026 Estimate	<b>N/A</b>
Zacks Rank	<b>N/A</b>

### 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	\$0.0 E	\$1.4 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	-\$0.01 E	-\$0.02 E
2026					-\$0.01 E
2027					

## INITIATION

We are initiating coverage of Radiopharm Theranostics Limited (NASDAQ: RADX) and assign a valuation of \$12.50 per American Depository Receipt (ADR). This valuation is based on our estimates for successful development, approval and commercialization of RAD101, RAD202 and RAD204 in the United States and developed world. Radiopharm is a clinical stage biopharmaceutical company developing radiopharmaceuticals for both diagnostic and therapeutic applications in oncology. Radiopharm's imaging products are intended for use in Positron Emission Tomography (PET) and PET-computed tomography (PET-CT). Radiopharm's therapeutic agents can be imaged using Single Photon Emission Computed Tomography (SPECT) and SPECT-CT imaging.



# RADIOPHARM THERANOSTICS

Source: Radiopharm Theranostics Website

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 Programmed Death-Ligand 1 (PD-L1) and Human Epidermal Growth Factor Receptor 2 (HER2) as well as other emerging targets such as short chain fatty acids, B7H3, Kallikrein-related peptidase 3 (KLK3) and integrin  $\alpha V\beta 6$ . The most advanced candidate in the company's pipeline is RAD101. It is the subject of Phase II studies for imaging brain metastases. The radiopharmaceutical targets short chain fatty acids that are unique to primary brain tumors and metastases in the brain. It may address a large unmet need as many common cancers frequently metastasize into the brain, but oncologists lack tools to identify the distribution and extent of these metastases after treatment with interventional therapies such as stereotactic radiosurgery (SRS). Interim data from the study are expected to be available before year end 2025. RAD202 and RAD204 leverage Radiopharm's nanobody construct offering a more versatile approach compared to full size antibodies along with the Lutetium-177 radioisotope. Both are the subject of Phase I trials. RAD202 targets HER2, which is a common protein expressed in breast, gastric and gastroesophageal cancer. We see almost 90,000 cases of cancers with the HER2 marker in the U.S. and many more globally. RAD204 employs one of the most important targets in oncology, PD-L1, and is pursuing multiple solid tumor types. Other programs in Radiopharm's portfolio are in earlier stages of development and we anticipate as more advanced programs are either partnered or approved, their earlier stage siblings will move forward.

Based on the candidates' advanced status, management intent and capital resources 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.

Radiopharm may pursue many development and commercialization pathways which could include partnerships. However, our valuation model assumes that the company will develop all of its assets to the point of regulatory approval and pass them on to established partners for commercialization. In return, we estimate royalties that represent the economic value coming from the customary upfront, milestone and royalty packages offered to sponsors.

Radiopharmaceuticals are an important tool for both diagnostic and therapeutic applications in oncology. They play a vital role in identifying, staging and treating the disease. These drugs aid in detecting cancer early, identifying metastases, localizing tumors and determining the extent of the disease for further treatment. Radiopharmaceuticals can also serve as cancer therapy where targeted radiation is delivered to cancer cells.

The company's most advanced program features the imaging agent RAD101 designed to identify suspected relapsed brain metastases after SRS. Identifying these micro-tumors is difficult due to their size, difficulty in transporting imaging agents behind the blood brain barrier and difficulty reaching this sensitive organ. RAD101 is able to tar-

get short chain fatty acids (SCFAs) that are metabolized by metastasized cancer cells in the brain and do not appear endogenously. RAD101 binds fluoropivalate to F-18 and has demonstrated uptake in cerebral metastases.

Beyond these primary candidates, Radiopharm has other assets that may rise to relevance as more advanced programs are partnered or are approved. This includes the theranostic pair RAD301 and 302 which is pursuing integrin  $\alpha V\beta 6$  expressing tumors, RV01, a B7-H3 monoclonal antibody also bound to Lu-177 pursuing multiple solid tumors and RAD402, introducing terbium-161, which is linked to KLK3 to treat prostate cancer.

Radiopharm has an important relationship with Lantheus Holdings and has received a sizable investment in the company from it. As of April 2025, Lantheus holds 12.16% of the company's shares. It has also acquired two assets from Radiopharm which the former is developing internally. These are a TROP2 targeting nanobody and an LRRC15 targeting monoclonal antibody.

Key reasons to own Radiopharm Theranostics shares:

- **Pursuing validated yet unexploited immuno-oncology radiopharmaceutical targets**
  - **Expanding radiopharmaceutical use into non-traditional cancers**
  - **Developing differentiated targeting molecules in underdeveloped areas**
- **Management offers significant radiopharmaceuticals experience**
  - **CEO Canevari from Novartis Oncology & Advanced Accelerator Applications**
  - **CMO Voliotis from Convergent, Zentalis, Eisai and Bayer**
- **Infrastructure in place to support existing and new products**
  - **Contract research organization partners experienced in radiopharmaceutical development**
  - **Established radioisotope supply chain**
  - **Lantheus serves as valuable development partner**
- **Partnership with M.D. Anderson to develop novel target vectors**
  - **75% ownership**
  - **RV01**
- **Pipeline of in-development clinical assets**
  - **RAD101**
  - **RAD202**
  - **RAD204**

The initiation report provides an introduction to radiopharmaceuticals, defining the industry and discussing the different types of radiation and particles involved. We start with a brief history, then describe the diagnostic and therapeutic categories including details regarding the important subcategories of the therapeutic modality. Radiopharmaceuticals require advanced logistics, management and care compared to other health care products. We describe the considerations required for their regulation, transportation and disposal. The report provides an industry review tracing the recent commercial history of the drug class, including new company formation and merger and acquisition activity.

The next section examines the primary end markets for Radiopharm's products. Products and pipeline are next, as we review assets in Radiopharm's portfolio including RAD101, RAD202 and RAD204. Peers and competitors are reviewed including a summary of their focus. We list historical milestones and background on Radiopharm followed by a summary of recent financial performance. Key members of senior management are introduced and risks related to life sciences companies in general and for Radiopharm specifically are discussed. The report winds down with valuation work and a presentation of the assumptions supporting our model. The target price relies on a discounted cash flow model that estimates contributions from RAD101, RAD202 and RAD204 in both the U.S. and developed countries. We initiate on Radiopharm Theranostics Limited with a valuation of \$12.50 per share.

## Radiopharmaceuticals

Radiopharmaceuticals are radioactive medicines or radioisotopes that are used to diagnose and/or treat disease. They are used to image a variety of conditions from cancer to cardiovascular disease to kidney dysfunction and neurodegenerative disease. In the treatment realm, this class of drug is predominantly used in cancer. Radionuclides are radioactive forms of elements that can either occur naturally or be manufactured. The radioactive element contains an unstable nucleus which emits radiation as it decays. The particles and rays that it emits can either be detected by a variety of diagnostic devices or they can bombard tumors which causes DNA strand breaks and cancer cell death.

The agents can be further categorized depending upon what type of radiation they emit. These include products that emit alpha particles, beta particles, gamma radiation, positrons and neutrons among others. The emissions support applications in medicine, scientific research, industrial processes and energy production. Some of the most common radionuclides, which are also known as radioisotopes, are listed below.

**Exhibit I – Common Isotopes Used in Radiomedicine**

Technetium-99m	Thallium-201	Indium-111	Yttrium-90
Samarium-153	Radium-223	Gallium-67	Carbon-11
Lutetium-177	Fluorine-18	Iodine-131	Cobalt-60

Compiled by Zacks Analyst

The physical half-life<sup>1</sup> of radioactive isotopes is critically important to radiopharmaceuticals' use, safety and efficacy. The biological half-life, or the time it takes for half of the drug to be eliminated through biological processes is another important consideration which determines how rapidly the diagnostics and medicines must be used. The rapid decay of radionuclides imposes certain constraints. This is an important consideration for manufacturers and nuclear medicine physicians who must find the balance between a short half life which limits delivery flexibility and a long half-life which may expose patients to excessive radiation.

Other features important to success include low cost and availability. The agent must specifically target the desired tissue but must either not accumulate in or clear quickly from non-target tissues in order to minimize background noise and organ radiation exposure. The radionuclide should emit the proper type of radiation for its purpose, such as gamma rays for imaging and alpha or beta particles for therapy. Favorable pharmacokinetic properties are also essential such as effective targeting, stable labeling, predictable biodistribution, rapid clearance from non-target tissue and chemical stability.

### Types of Radiation

Radiomedicine is associated with many types of radiation including X-rays, gamma radiation, alpha and beta particles, positrons and Auger electrons. The most widely used type of radiation used in modern medicine is the X-ray which is used for body imaging, mammography, dental imaging and fluoroscopy. Also commonly used are gamma rays which are important for nuclear medicine imaging, positron emission tomography (PET) scans and stereotactic radiosurgery (SRS) for treatment of brain tumors. Beta radiation is commonly used to treat certain types of cancer, eye conditions and to alleviate pain in bone metastases. Proton beam therapy is a radiation treatment that precisely delivers a beam of protons to disrupt and destroy tumor cells while ultraviolet radiation can be used to treat skin conditions like psoriasis and as phototherapy for babies with jaundice.

Auger electrons are another type of particle that is used in therapy. The advantage of Auger electron therapy is high linear energy transfer. They deliver intense radiation damage within an extremely short range, potentially minimizing damage to surrounding healthy tissues when properly targeted to cancer cells.

Imaging typically uses gamma emitters or positron emitters which show up on scans while therapy often uses beta or alpha emitters which offer tissue-damaging properties. Some radioisotopes emit multiple types of radiation, allowing for the combination of therapy and diagnostic imaging. These are known as theranostic applications.

<sup>1</sup> The half-life is the time it takes for half of any given amount of a radioactive isotope to decay into its daughter products. This rate remains constant regardless of the sample size.

## A Condensed History of Radiopharmaceuticals

Radiation has been associated with medicine for over a century with X-rays producing some of its earliest benefits. X-rays were used to image and treat cancer in the late 19th century in Germany.<sup>2</sup> In 1928, head and neck cancers were cured with fractionated X-rays and a decade later the first patient was treated with neutron beams.<sup>3</sup> As the science advanced, the first radiopharmaceuticals were developed that could serve as either diagnostic tracers or therapeutic agents.

Other mentions of radiopharmaceuticals in the early twentieth century relate to radiotracers and their use to conduct diagnostic procedures. The first true use of a radiotracer is often credited to George de Hevesy in the 1920s. He used radioactive lead to study lead metabolism in plants, which is considered one of the pioneering experiments in nuclear medicine and radiotracer technology.<sup>4</sup> In 1925, at the Beth Israel Hospital in Boston, Hermann Blumgart measured circulation using radium C to generate vapor trails in a modified Wilson cloud chamber.<sup>5</sup> In the 1930s, Emilio Segre and Carlo Perrier isolated technetium, which was the first synthetic element and now widely used in medical imaging as technetium-99m.<sup>6</sup> After World War II, the Atomic Energy Commission began to regulate how radioactive materials were used. One of the early radioactive substances purchased from the US government's national laboratories was iodine-131, which was employed as a radiotracer to diagnose thyroid cancer. Abbott Laboratories established a radiopharmaceutical laboratory in the mid-1950s which provided early products to researchers. Soon after, competitor E.R. Squibb emerged on the scene providing more flexible timing for radiopharmaceutical product availability which allowed scheduling of patient imaging any day of the week.

The FDA first began to regulate radiopharmaceuticals in the 1970s preceding their wider use in oncology imaging and therapy in the 1980s. During the 1970s, the FDA withdrew the exemptions granted to radioactive products used in medicine and began regulating them as drugs in a process completed in 1977. With the realization that technetium-based products were effective for imaging, their use expanded substantially during the following years. The 1980s saw the development of several new oncology agents such as I-meta-iodobenzylguanidine which could be used for imaging and treatment. The 1990s produced the first monoclonal antibody bound to a radionuclide for tumor imaging called In-satumomab pendetide. PET imaging was also evolving during the 1990s & 2000s as 3-D PET scanning was introduced and improved detector designs allowed for better resolution. The use of this modality also became more widespread for cancer staging and monitoring along with growing applications in neurology. PET/CT hybrid systems also were deployed beginning a multimodal imaging approach that improved accuracy and combined anatomical and functional information.

## Imaging and Diagnostics

Nuclear medicine imaging is a diagnostic technique that provides spatial, functional and metabolic information about various organs and systems in the body. A selected radionuclide attached to a biologically active molecule is infused into the circulation where it distributes throughout the system. As it circulates, the active molecules concentrate in specific organs or tissues based on the biological properties or receptors that appear on the agent and target tissue or cell.

Various agents can be used to conduct a variety of studies including thyroid, infection, cancer and heart imaging. They are used in different types of detectors that identify alpha, beta, gamma and other types of radiation. SPECT provides three dimensional images of the distribution of the radioisotope. PET uses positron-emitting radionuclides for high-resolution functional imaging. Planar imaging generates two dimensional images; while simpler and less expensive, it lacks the detail found in SPECT or PET. Hybrid imaging is an emerging approach that combines nuclear medicine techniques with cross-sectional imaging modalities. Examples include PET/CT which combines functional PET with anatomical CT imaging, SPECT/ CT which integrates SPECT with CT for better localization and PET/MRI which joins PET with MRI for superior soft tissue contrast. Imaging with radiopharmaceuticals continues to evolve, offering valuable diagnostic information across various medical specialties. This approach provides functional information that complements other imaging modalities, making it a valuable diagnostic tool.

<sup>2</sup> On November 8, 1895, physicist Wilhelm Conrad Röntgen (1845-1923) became the first person to observe X-rays, a significant scientific advancement that would ultimately benefit a variety of fields, most of all medicine. In 1896 Röntgen presented a lecture on the X-ray. Within months, systems were being devised to use x-rays for diagnosis, and within three years radiation was used to treat cancer. American Cancer Society, [History of Cancer Treatments, Radiation Therapy](#).

<sup>3</sup> Connell, P.P., Hellman, S. [Advances in Radiotherapy and Implications for the Next Century: A Historical Perspective](#). Cancer Research. January 2009.

<sup>4</sup> Hevesy, G. [The Absorption and Translocation of Lead by Plants: A Contribution to the Application of the Method of Radioactive Indicators in the Investigation of the Change of Substance in Plants](#). The Biochemical Journal, 1923.

<sup>5</sup> Patton, D.D. [The Birth of Nuclear Medicine Instrumentation: Blumgart and Yens](#), 1925. The Journal of Nuclear Medicine. 2003.

<sup>6</sup> [1937, Palermo: the discovery of technetium](#).

## Radiotherapy

While many radiopharmaceuticals are used for diagnostics, some are used for treatment. Most of the therapies are directed towards hematological, solid organ cancers or blood dyscrasias. The autoimmune disorder Graves' disease is responsive to radioactive iodine (I-131) therapy, which gradually shrinks the thyroid. Oncology related uses include I-131 for treating thyroid cancer and hyperthyroidism, lutetium-177 for treating neuroendocrine tumors and prostate cancer and yttrium-90 microsphere for liver cancer to name a few.

### *Radioligand Therapy*

An emerging subcategory of radiopharmaceuticals is radioligand therapy (RLT). It is a form of targeted cancer treatment that combines molecular targeting with the killing ability of radiation. RLT employs a ligand that targets cancer cells expressing a specific biomarker which is bound to a therapeutic radionuclide to deliver cytotoxic radiation. The compound provides both diagnostic features and therapy. Examples of RLTs include Lutathera and Pluvic- to which were approved in 2018 and 2022 respectively.

Some of the more common ligands used are the prostate-specific membrane antigen (PSMA), somatostatin receptor ligands (SSTR2 for example) and CXCR4 ligands. The ligands are usually conjugated with chelators that can bind radioactive isotopes such as lutetium-177, actinium-225 or yttrium-90 for therapeutic purposes. The specific isotope chosen depends on the specific cancer type, target expression and treatment goals. Radiopharm is working on several RLTs including RAD204 which targets PD-L1, RV01 which binds to B7H3 and RAD301/302 which employs integrin  $\alpha$ V $\beta$ 6 as the targeting vector.

An important feature of RLT is the chemical structure of the attachment between the ligand and the radioisotope. For elements that are metals, a chelator is used to bind the two parts of the RLT. The chelator securely holds the radioisotope to prevent its early release into the body and to maintain the stability of the radioligand complex while the RLT is in the patient's circulation. The choice of a chelator can affect the pharmacokinetics and biodistribution of the radioligand. Other types of connections can be used including covalent bonding, encapsulation or nanoparticles.

Yet another domain of RLT uses monoclonal antibodies (mAbs) for molecular targeting in a discipline called radioimmunotherapy. The related medicines are called radioimmunoconjugates (RICs) and can be used for both imaging and therapy. This technology labels mAbs with a radionuclide directed against tumor-associated antigens that is specific to a certain biomarker. This approach increases the dose delivered to tumor cells and avoids off-target binding to normal tissues.<sup>7</sup> Some of the common radioisotopes used with RICs include iodine-131, yttrium-90 and indium-111.<sup>8</sup> One example of an approved RIC is [Zevalin](#), which is indicated for non-Hodgkin's lymphoma and uses a mAb that targets the CD20 receptor. Antibody-bound complexes such as Zevalin are also called radioconjugates and are discussed further in the next paragraph.

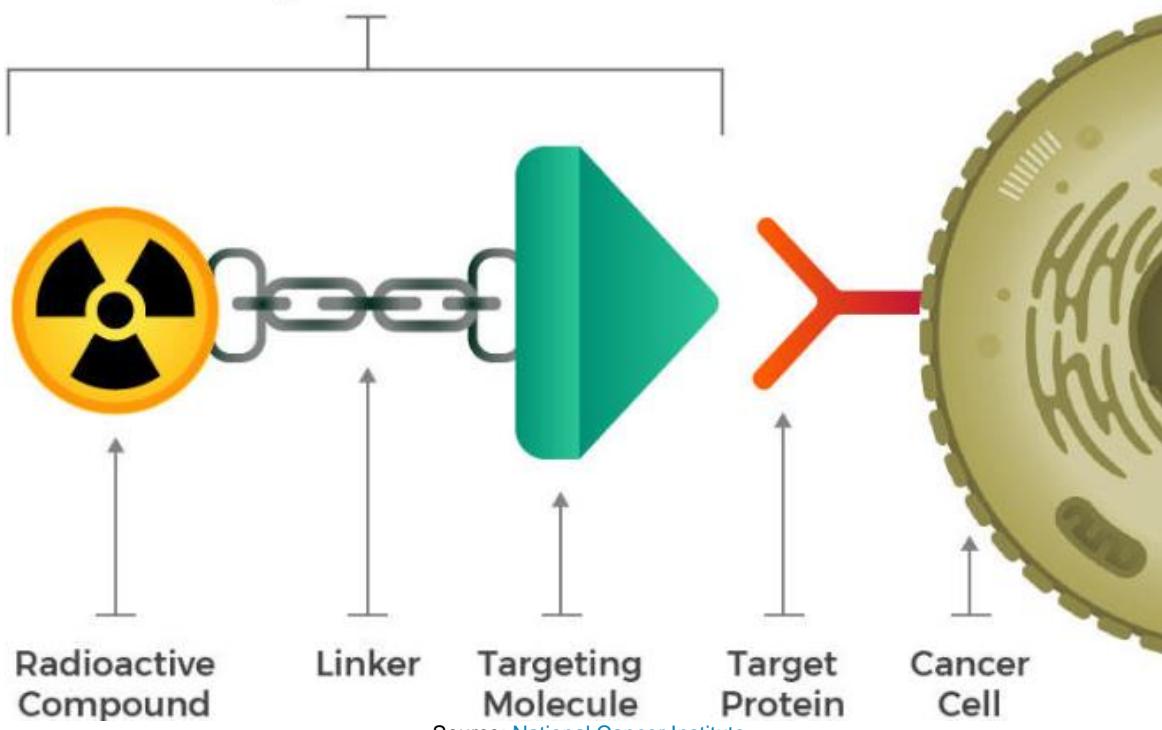
### *Radiopharmaceutical Structure*

Diagnostic and therapeutic radiopharmaceuticals are frequently designed with a targeting molecule-linker-radioisotope construct to bind selectively to specific receptors on or within target cells and deliver cytotoxic radioisotopes. This is illustrated in the following exhibit.

<sup>7</sup> Yeong, C.H., et al. [Therapeutic radionuclides in nuclear medicine: current and future prospects](#). Journal of Zhejiang University. 2014

<sup>8</sup> Parakh, S. et al. [Radiolabeled Antibodies for Cancer Imaging and Therapy](#). Cancers. March 2022.

**Exhibit II – Structure of a Radiopharmaceutical  
Radiopharmaceutical**



Source: National Cancer Institute

Traditional radiation therapy can damage nearby healthy tissue. Radiopharmaceuticals can sidestep this side effect through direct delivery of the radionuclide to the diseased cell. The structure of many radiopharmaceuticals includes a radioactive compound that is bound to a targeting molecule with a linker, quite similar to the structure of an antibody drug conjugate (ADC). In some cases, a diagnostic can be combined with a therapeutic to measure and treat simultaneously. This class of product falls into the radiotheranostic domain.

### Radiotheranostics

Theranostics is the integration of diagnostics and therapeutics in support of precision medicine. The approach can include the use of isotope-based methods that represent the category of radiotheranostics. The use of radiopharmaceuticals allows for the imaging of target tissue that illustrates the distribution of the cancer, justifying the use of targeted radiotherapy for treatment. Patient progress can be monitored by measuring the change in receptor-mediated uptake of the radiodiagnostic probe in tumor at different time points during treatment and to optimize the therapeutic index to ensure the best dose of the therapy is being used.<sup>9</sup> This branch of medicine relies on the combination of disease-related biomarkers with the delivery of a radioisotope that can be imaged.

One of the earliest applications of theranostics was the use of Iodine-131 to both image and treat thyroid cancer in the 1940s. Thyroid cells readily absorb I-131, which, once inside the cells, emits gamma radiation which can be detected by gamma cameras and kills cells that naturally absorb iodine. This allows clinicians to assess the extent of the disease, treat it and monitor treatment response.

Two examples of approvals in the theranostics category include the theranostic pairs Lu-177 Dotatate + Ga-68 Dotatate and Lu-177 PSMA-617 + Ga-68 PSMA-11. These combinations are used to respectively treat and detect neuroendocrine tumors and prostate cancer. Radiotheranostic agents improve diagnostic accuracy, where similar targeting vectors are used for both imaging and therapy ensuring that treatment only binds to specific molecular markers or receptors and monitors activity in real time which provides oncologists feedback for optimizing therapy among other benefits.

<sup>9</sup> Aboagye, E.O., Barwick, T.D. Radiotheranostics in Oncology: Making Precision Medicine Possible. Cancer Journal for Clinicians. January 2023.

### Exhibit III – Common Radiotheranostic Pairs

Indication	Diagnostic	Therapeutic	FDA Approved
Neuroendocrine	Ga-68 Dotatace	Lu-177 Dotatace	2018
PSMA+ mCRPC	Ga-68 PSMA-11	Lu-177 PSMA-617	2022
Thyroid Cancer	I-123	I-131	

Source: Analyst work

## Radiopharmaceutical Considerations

Radiopharmaceuticals require additional considerations compared to biologic or chemical molecules with respect to inventory, shelf life, product safety, storing, handling, licensing and disposing among other factors. These requirements create barriers to entry that limit competition. These products are classified as specialty medicines containing radionuclides whose half-lives range from a few minutes to several days. This short product life requires efficient transportation timelines and protocols as well as local manufacturing.

### *Handling*

Substances containing radioactive isotopes used for medical imaging or therapy require strict handling procedures to protect both healthcare personnel and patients from radiation exposure. Lead shielding is used to protect individuals transporting and manufacturing the nuclear medicines and products are clearly labeled. The International Atomic Energy Agency (IAEA) sets regulations for radioactive materials. Shipments must be meticulously documented, identifying the radioactive material and its properties. Transport security and emergency response plans must be in place.

### *Transportation*

Time is of the essence when transporting radiopharmaceuticals. Air transport is frequently the most effective method to deliver these ephemeral products to their final destination. Radionuclides with short half-lives must be produced locally to allow for rapid delivery. For products with medium-term half-lives, transportation between distant cities is possible, but radioactive decay must be considered. This requires expedited shipping and tightly coordinated logistics to avoid product loss. Type A packaging, which is durable against water and impact damage, is required during transport.

### *Regulation*

In the United States, the primary regulators of radiopharmaceuticals are the NRC and the FDA. In Europe, the European Medicines Agency (EMA) oversees regulation of the class. The radioactive products must be manufactured in nuclear research reactors or cyclotrons which are approved by the US Nuclear Regulatory Commission (NRC) or its designated stage agency. In the United States, F-18 radiolabeled products are made on a cyclotron at a site which must be approved by the FDA. For a license from the NRC, a sponsor must apply for a license to manufacture and distribute the products. The Application for Materials License requires information about the radioactive materials to be used, their purpose, individuals responsible for the radiation safety program, training, facilities, radiation safety procedures and waste management practices. Following inspections and a review, a license may be granted for a specific type and quantity of radioactive material to be allowed and any limitations or conditions imposed are listed. The license must be renewed every ten years.

### *Waste Disposal*

Radioactive material waste disposal is another consideration. Waste can either be short or long lived with each category requiring different treatment. Waste with a short half-life can be stored on site until it has reached radiological clearance. Generally, waste with a half-life of less than 120 days falls into this category. After radiation levels reach background levels, it can be disposed of as regular medical refuse. Longer lived waste may be sent to specialized long-term storage facilities. It is stored in special shielded containers and can be transferred to a licensed disposal facility. Liquid waste from either the fluids used in the laboratory or urine or feces from a treated patient are many times placed into a separate septic system where it is held in tanks until it decays to background levels and is then placed into the regular sewer system.<sup>10</sup>

### *Finished Product*

In contrast to other medical products, radiopharmaceuticals are decaying radioisotopes with half-lives ranging from a few hours to several days. Therefore, they are almost exclusively produced on demand with minimal lead time which requires an efficient production and distribution mechanism. Finished goods, such as doses of F-18 FDG and

<sup>10</sup> Tas, A., Ozer, A.Y. [Waste Disposal and Management in Radiopharmaceuticals](#). Journal of Pharmaceutical Science. 2020.

technetium generators cannot sit in inventory because of their rapid decay. These products are produced using just-in-time manufacturing, processing and distribution. Supply chains define the limitations that determine which products can be used and where.

## Industry Review

After the dawn of the nuclear age, many new uses were found for radioisotopes and radionuclides. As we have discussed, substantial progress was made from the 1930s to the 1980s in imaging disease and treating cancer. However, the pace of advancement slowed in the 1990s and 2000s with attention shifting towards new imaging technologies and biologics. However, over the last decade, the industry has reemerged as an area driven by new scientific advancements in PET imaging including Amyvid, Vizamyl and Neuraceq in the neuroimaging space, and Axumin, Xofigo, Netspot and Lutathera for both imaging and treatment of cancer. This resurgence in radiopharmaceuticals has led to new company formation and merger and acquisition activity over the last several years. Medical professionals have begun to recognize the benefits of better radioisotopes to more clearly and precisely image disease and the use of precision medicine used to deliver radiation directly to cancerous cells, without some of the side effects that come with beamed or implanted radiation.

Some of the radiopharmaceutical startups launched in recent years include the Germany-based [Isotopen Technologien Munchen](#) (ITM) developing its Peptide Receptor Radionuclide Therapy, Boston-based [Aktis Oncology](#) developing  $\alpha$ -emitting agents for cancer treatment and [Arizona Isotope Science Research Corporation](#) producing medical grade isotopes with strontium-82, germanium-68, iodine-123 and actinium-225.

Merger and acquisition activity has been vigorous. The first multi-billion-dollar deal that took place in the industry occurred over 10 years ago. Bayer bought Algeta in March 2014 for \$2.9 billion and was eventually able to take its candidate through regulatory approval to market [Xofigo](#) for prostate cancer that has spread to the bones. Transaction activity slowed until 2017 when Novartis bought out Advanced Accelerator Applications (AAA) for Lutathera, the Lu-177 dotatacept radionuclide for the treatment of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs). The product was subsequently approved by the FDA in January 2018.

Novartis went to bat again for another radiopharmaceutical asset with its \$2.1 billion acquisition for Endocyte in December 2018. It recognized the value of Pluvicto for metastatic castration resistant prostate cancer, which was later approved in 2022. Novartis continued its radiopharma buying spree in 2024 with Mariana Oncology in May picking up a portfolio of radioligand therapies including MC-330 for small cell lung cancer.

Another prolific acquiror in recent years has been the Australia-based Telix Pharmaceuticals which bought QSAM Biosciences ( $^{153}\text{Sm}$ -DOTMP) in 2023. In 2024 it picked up ATRMS (cyclotron-based isotope production) in March and RLS Radiopharma (31 US-based radiopharmacies) in September to further integrate its supply chain, manufacturing and distribution capabilities.

There are several other billion-dollar plus acquisitions that have taken place since 2023. This includes Eli Lilly and its buy of POINT BioPharma, which had previously partnered its lutetium-177 portfolio of SSTR2 and PSMA targeting molecules with Radiopharm's investor Lantheus. Bristol Myers picked up Rayze Bio only months after its IPO for \$4.1 billion in December 2023, gaining its SSTR2 receptor product for GEP-NETs and small cell lung cancer. AstraZeneca also got in on the action absorbing the Canadian Fusion Pharma for \$2.4 billion. Fusion is developing novel linker technology that can be used with alpha emitters to improve safety and reduce off target effects.

2025 began with several radiopharmaceutical acquisitions including two by Lantheus and one by Telix. Lantheus made a \$750 million bid for Life Molecular Imaging in mid-January. The deal includes the globally approved asset NeuraCeq and a pipeline of other neurodegenerative and cardiovascular imaging assets. The deal complements Lantheus' own neurodegenerative pipeline and is expected to help advance the commercialization of its in-development assets by one to two years. Lantheus' other acquisition took place in late January in a deal that offered over \$1 billion for Evergreen Theragnostics. Evergreen has submitted the diagnostic agent Octevy for approval and offers other pipeline assets as well as manufacturing infrastructure. The Evergreen acquisition was completed in April 2025. Telix has continued its acquisition streak into 2025 with its \$45 million bid for ImagineAb. ImagineAb is a cancer imaging purveyor featuring its pipeline of CD8-targeting ImmunoPET agents.

**Exhibit IV – Recent Merger & Acquisition Activity**

Date	Acquiror	Target	Amount (\$MM)	Comment
1/28/25	Lantheus	Evergreen Theragnostics	\$1,003	Octevy, manufacturing assets & pipeline
1/13/25	Telix Pharmaceuticals	ImaginAb	\$45	PET imaging platform & protein research facility
1/13/25	Lantheus	Life Molecular Imaging	\$750	Novel PET diagnostics
1/7/25	BWX Technologies	Kinectrics	\$525	Isotopes for the radiopharmaceutical industry
10/17/24	Sanofi	Orano Med	\$325	Next-gen radioligand therapies: <sup>212</sup> Pb $\alpha$ isotopes
9/23/24	Telix Pharmaceuticals	RLS Radiopharma	\$250	31 radiopharmacies & radiometals production
8/24/24	Siemens	Novartis Mfg Network	\$223	47 radiopharmacies in US & EU
5/2/24	Novartis	Mariana Oncology	\$1,750	Radioligand therapies for cancer
3/19/24	AstraZeneca	Fusion Pharma	\$2,400	Actinium based radioconjugates
3/5/24	Telix Pharmaceuticals	ATRMS	\$82	Isotope production platform & manufacturing
12/26/23	Bristol Myers	Rayze Bio	\$4,100	Actinium RP therapies in GEP-NETs & SCLC
11/13/23	Telix Pharmaceuticals	QSAM Biosciences	\$125	<sup>153</sup> Sm-DOTMP for bone cancer
10/3/23	Eli Lilly	POINT BioPharm	\$1,400	Lu-177 RP targeting PSMA & SSTR2
11/28/22	Full-Life Tech	Tocus-X Tx	\$245	RP based on peptides for cancer
3/28/22	PeptiDream	Toyama RP Biz	\$177	PDPS platform for SPECT/PET
10/18/18	Novartis	Endocyte	\$2,100	<sup>177</sup> Lu-PSMA-617 in mCRPC
10/30/17	Novartis	AAA	\$3,900	Lutathera for NETs
12/19/13	Bayer	Algeta	\$2,900	Xofigo for mCRPC w/ abnormal bone

Source: Compiled by Zacks Analysts

The radiopharmaceutical industry has become more dynamic in recent years with increased attention and activity around new ways of reimbursing these medicines and innovating novel products. CMS promulgated its [final rule](#) for reimbursement of high-cost diagnostic radiopharmaceuticals in November 2024. The rule states that diagnostic radiopharmaceuticals above a threshold of \$630 per scan will be reimbursed separately. We expect this rule to include RAD101. The change benefits fee for service (FFS) Medicare outpatients who are reimbursed with a bundled payment. Shifting reimbursement paradigms have generated optimism that growth for radiopharmaceutical products will endure longer than previously expected. All qualifying products will be paid separately at their mean unit cost (MUC), which is a payment rate derived from hospital claims data. The rule would eliminate the transitional pass-through (TPT) regime which provided temporary special pricing. Prior to the change, the pricing premium expired after two or three years, reducing access for Medicare patients after it ended. The final rule will align these diagnostics to be reimbursed in a manner similar to how drugs and biologics are reimbursed for Medicare beneficiaries. The space is also benefiting from the increased precision of radiopharmaceuticals and the advancement of other therapeutic categories. There are many products with improved targeting, treatment and imaging features that can provide improved safety and efficacy for patients especially in areas that are underpenetrated such as novel targets for radiopharmaceuticals including PL-L1, HER2, KLK3 and B7H3.

## Indications & End Uses

Radiopharm Theranostics is developing products addressing a wide variety of cancers including solid tumors, brain metastases, breast, gastric, pancreas and prostate. It is also pursuing molecular targets PD-L1, HER2, short chain fatty acids, integrin  $\alpha$ V $\beta$ 6, B7H3 and KLK3. Radiopharm's imaging and therapeutic candidates also offer a theranostic pair able to image and treat with the same targeting vector.

The most important indications for Radiopharm are brain metastases, PD-L1 positive and HER2 positive cancers. These approaches are expected to initially focus on specific sites, but if successful in clinical trials may be site agnostic and target cancers exhibiting a specific biologic marker.

### Brain Metastases

Brain metastases occur when tumor cells move or metastasize from a primary location in the body and spread to the brain. Metastasis is the most common cause of cancer in the brain as cancers that originate in the brain such as gliomas and other tumors are rare. Brain metastases occur in 15-40% of patients with cancer and may initially be asymptomatic.<sup>11,12</sup> The most common types of malignancies that can metastasize into the brain include lung, breast, melanoma, kidney or colorectal cancer. However, any type of cancer may spread here. Detection of brain metastases is usually achieved using radiological imaging such as magnetic resonance imaging (MRI) and computed tomography (CT) as it is difficult to obtain biopsy in the brain.

Imaging brain metastases allows providers to distinguish neurological symptoms from other conditions, determine the extent and location of disease when present and predict outcomes. The imaging can show the size and distribution of metastases which can guide therapy towards surgical resection, radiation therapy or other precision approach. Imaging studies can also monitor the treatment response and detect recurrence or progression.

Brain metastases affect hundreds of thousands of patients annually in the United States and a multiple of that around the globe. These secondary tumors adapt to the unique brain microenvironment and reprogram their metabolism to survive. Cancer cells that have metastasized to the brain specifically leverage fatty acid metabolism to thrive, enabling their proliferation and survival in this setting. The brain environment is scarce in native fatty acids which are necessary for brain metastases to form and grow. To survive, the metastases require a metabolic change in the tumor microenvironment that allows them to proliferate in the brain.<sup>13,14</sup> Metastatic cells may also modify the blood brain barrier (BBB) to allow various nutrients, including the necessary lipids, to breach the boundary.

The dependence of brain metastases on fatty acid metabolism offers actionable therapeutic targets for both imaging and treatment. Some transcription factors that impact lipid metabolism are peroxisome proliferator-activated receptor  $\gamma$  (PPAR $\gamma$ ), sterol regulatory element-binding protein 1 (SREBP1) and tumor protein (P53).

#### Prevalence

Brain metastases occur in 20% to 40% of cancer patients, which is equivalent to about 400,000 to 800,000 cases per year in the United States.<sup>15,16,17</sup> Their prevalence varies by cancer origin with the highest proportion coming from lung cancer and melanoma. Breast cancer is also a notable contributor with 10 to 30% of cases producing brain metastases, especially HER2 and triple negative subtypes.

#### Diagnosis

Brain metastases are diagnosed using clinical evaluation, advanced imaging and, in some cases tissue sampling. A neurological exam allows physicians to assess cognitive function as well as sensory and motor skills to identify deficits related to brain lesions. Imaging tests are also performed which include magnetic resonance imaging (MRI), computed tomography (CT) and positron emission tomography (PET) scans. Other diagnostics including blood work and tumor marker tests may be administered to evaluate the malignancy. In rare cases a biopsy may be performed if there is an uncertain diagnosis relying on imaging or there is no known primary cancer.

<sup>11</sup> Fink, K.R., Fink, J.R. [Imaging of Brain Metastases](#). *Surgical Neurology International*. May 2013.

<sup>12</sup> Tyagi, A., et al. [Metabolism in the progression and metastasis of brain tumors](#). *Cancer Letters*. May 2022.

<sup>13</sup> Cheng, Y., et al. [Lipid metabolism in malignant tumor brain metastasis: reprogramming and therapeutic potential](#). *Expert Opinion on Therapeutic Targets*. September 2023.

<sup>14</sup> Tyagi, A., et al. [Metabolism in the progression and metastasis of brain tumors](#). *Cancer Letters*. May 2022.

<sup>15</sup> Wong, J. et al. [Quality of life in brain metastases radiation trials: a literature review](#). *Journal of Current Oncology*. October 2008.

<sup>16</sup> Cleveland Clinic website. [Brain Metastases](#).

<sup>17</sup> Bertolini, F. et al. [Brain Metastases: An Overview](#). *CNS Oncology*. January 2015.

### *Treatment*

Treatment is highly dependent on the metastases' characteristics such as their number and size, migration site, patient overall health and other factors. Patients with higher performance status generally tolerate more aggressive interventions. Surgical resection is appropriate when the tumor is of significant mass and there are few metastases; however, surgery alone is rarely curative and additional therapies are required to address residual disease. Radiation therapy is also considered and provides an approach that can address micro metastases. This can include whole-brain radiation therapy and stereotactic radiosurgery. Other systemic approaches may be used including chemotherapy, targeted therapy which may latch onto specific genetic signatures such as EGFR mutations, ALK rearrangements or HER2-positive disease. Immunotherapy can be used, specifically PD-1 or PD-L1 inhibitors in disease that presents these markers.<sup>18</sup> Stereotactic radiosurgery (SRS) is a radiation delivery technique that precisely emits radiation from multiple directions, centering on a tumor to destroy it. One type of SRS is the Gamma Knife which emits gamma radiation toward a target point in the patient's brain. The Gamma Knife can treat small, well-defined brain metastases, especially those in deep brain areas where surgical access is challenging. Linear accelerator-based methods emit X-rays and proton beam therapy emits protons to treat tumors in the brain.

### *Prognosis*

The prognosis of patients with brain metastases is poor and survival is typically estimated to be a matter of months after diagnosis. Patients with limited metastases have a better prognosis than those with more extensive disease. Some of the factors that affect the prognosis depend on the severity of the primary tumor and whether or not it is controlled, the number of metastases and the patient's age and performance status. Untreated brain metastases may have a median survival of as little as one to two months. With treatment, survival can be from three months to over a year depending on specific tumor type, disease severity and treatment.

## **Programmed Death-Ligand 1 (PD-L1) Positive Cancers**

PD-L1 positive tumors are cancers in which tumor cells express high levels of PD-L1, a protein that plays a critical role in immune evasion. PD-L1 binds to the PD-1 receptor on T-cells, effectively suppressing their ability to attack cancer cells. This mechanism allows tumors to grow and spread by avoiding detection and destruction by the immune system. A PD-L1 vector works through a dual mechanism that combines targeted immunotherapy with radiation therapy. The radiopharmaceutical contains a targeting molecule (antibody, peptide or small molecule) that specifically binds to PD-L1 expressed on cancer cells and immune cells in the tumor microenvironment. This allows precise delivery of the radioisotope to PD-L1-overexpressing tumors.

When bound to the PD-L1 ligand, the radioisotope is precisely transported allowing it to deliver localized radiation. This causes DNA damage, triggers apoptosis and disrupts cellular processes leading to cell death. Blocking PD-L1 also allows the body's natural immune response to be more effective as T cells are free to attack malignant cells and are no longer inhibited by the checkpoint. A third mechanism is also activated as the tumor cells are destroyed. Tumor antigens are released, absorbed and presented to antigen presenting cells. When a CD8 cytotoxic T cell recognizes an antigen, it becomes activated and differentiates into a cytotoxic T lymphocyte (CTL). These CTLs are now specifically armed to recognize and kill other cancer cells displaying the same antigens.

### *Prevalence*

PD-L1 expression is common across cancer types with prevalence varying by cancer site, disease stage and lines of treatment. Lung cancer<sup>19</sup> is one of the most common cancers to express PD-L1 with anywhere from 25% to 60% of cases presenting the marker and higher rates in squamous cell carcinomas. PD-L1 expression in melanoma is also frequent with 40% - 60% of cases positive for PD-L1. Other cancers that have high rates of PD-L1 expression are head and neck squamous cell carcinoma and triple negative breast cancer with just above half of all patients expressing the marker. Hodgkin lymphoma is regarded as having the highest prevalence rates. Based on search results, other cancers expressing the PD-L1 protein include hepatocellular carcinoma, bladder cancer, cervical cancer and colorectal cancer among others. One meta study that examined 59 studies capturing data for over 20,000 patients found that about 30% of tumors were PD-L1 positive.<sup>20</sup>

<sup>18</sup> Bettegowda, C., MD, PhD. Johns Hopkins Medicine. [Metastatic Brain Tumors](#).

<sup>19</sup> Fakhri, G., et al. Prevalence of programmed death ligand-1 in patients diagnosed with non-small cell lung cancer in Lebanon.

<sup>20</sup> Xiang, X., et al. [Prognostic value of PD –L1 expression in patients with primary solid tumors](#). Oncotarget. December 2017.

## Diagnosis

A biomarker test can be used to measure the percentage of tumor cells expressing PD-L1 and identify if the patient is a candidate for PD-L1 therapy. Tumors with higher expression levels (e.g.,  $\geq 50\%$ ) are often termed "PD-L1 positive" and may respond better to immune checkpoint inhibitors.

## Treatment

Treatment for PD-L1 positive cancers varies depending upon the site of the cancer and its stage. Triple negative breast cancer (TNBC), head and neck squamous cell carcinoma (HNSCC), non-small cell lung cancer (NSCLC) should receive pembrolizumab plus chemotherapy as first line therapy.<sup>21</sup>

## Human Epidermal Growth Factor Receptor 2 (HER2)

Human epidermal growth factor receptor 2 (HER2) is a protein that can promote the growth of cancer cells. The HER2 marker is most common in breast cancer but also appears in gastric, uterine, ovarian and other cancers. It is a receptor tyrosine kinase that regulates cell proliferation and survival. In HER2-positive cancers overexpression or amplification of the HER2 gene leads to excessive HER2 protein on cell surfaces, promoting uncontrolled growth and survival. HER2 activation disrupts normal epithelial organization, enhances cell motility, and reduces apoptosis.<sup>22,23</sup> Interactions with other signaling pathways further drive tumor progression and early metastasis of cancer cells.

HER2-based radiopharmaceuticals are designed to selectively deliver cytotoxic radiation to cancer cells that over-express HER2. Their mechanism of action involves a combination of targeted delivery and radiation-induced cell damage. This class of drug could be used after first line therapy using trastuzumab, pertuzumab or docetaxel. In order to overcome any resistance that developed from these drugs, a new formulation of a HER2 targeting moiety would likely provide improved results. From this perspective, a nanobody, antibody fragment or another HER2-binding molecule could be used to bind to a different epitope. Combined with the addition of a radioisotope, this approach may be appropriate for patients that have failed first line therapy. Over half of patients fail first line HER2-targeted therapy due to primary and acquired resistance.<sup>24</sup>

## Prevalence

From 15 to 20% of breast cancers are HER2 positive according to the American Cancer Society (ACS). Stomach cancer is also highly positive. A study examined almost 12,000 patients with cancers other than breast and stomach cancer and found HER2 overexpression in 2.7% of samples.<sup>25</sup> Of this group, epithelial cancers showed the highest frequency of HER2 overexpression. According to the ACS, there are just over 2 million cancer cases in the United States, with 320,000 breast cancer cases and 30,000 stomach cancer cases. If we apply the midpoint of prevalence of breast and stomach cancer to its totals and 2.7% to the remaining cancers, we get about 89,400 HER2 positive cases of cancer in the US per year.

## Diagnosis

HER2 positive cancers are diagnosed by immunohistochemistry (IHC) which is able to measure HER2 protein levels. A tissue sample is taken and the test is run. IHC is frequently conducted first because it is fast and inexpensive. However, if the IHC test is ambiguous, then a more precise test known as *in situ* hybridization may be performed which is able to confirm the presence of the HER2 gene. Other tests such as fluorescence *in situ* hybridization (FISH) and dual ISH (DISH) detect HER2 gene amplification in the tumor DNA and INFORM HER2 Dual ISH uses a different technology to visualize HER2 gene copies with a standard light microscope. Another ISH variant employed is the chromogenic *in situ* hybridization (CISH).

## Treatment

After diagnosis, HER2 positive cancers are treated with a variety of drug classes including monoclonal antibodies (mAbs), tyrosine kinase inhibitors (TKIs) and antibody drug conjugates (ADCs). Two mAbs that are used include trastuzumab (Herceptin) and pertuzumab (Perjeta). TKIs commonly used include lapatinib (Tykerb) and neratinib (Nerlynx). Finally, ado-trastuzumab emtansine (Kadcyla) and fam-trastuzumab deruxtecan (Enhertu) are ADCs that treat HER2+ disease.

<sup>21</sup> National Comprehensive Cancer Network guidelines, 2024.

<sup>22</sup> American Cancer Society. [Breast Cancer HER2 Status](#).

<sup>23</sup> Freudenberg, J.A., et al. [The role of HER2 in early breast cancer metastasis and the origins of resistance to HER2-targeted therapies. Experimental and Molecular Pathology](#). August 2010.

<sup>24</sup> Sharial, M., et al. [Overcoming resistance and restoring sensitivity to HER2-targeted therapies in breast cancer](#). Annals of Oncology. August 2012.

<sup>25</sup> Yan, M., et al. [HER2 expression status in diverse cancers: review of results from 37,992 patients](#). Cancer Metastasis Review. February 2015.

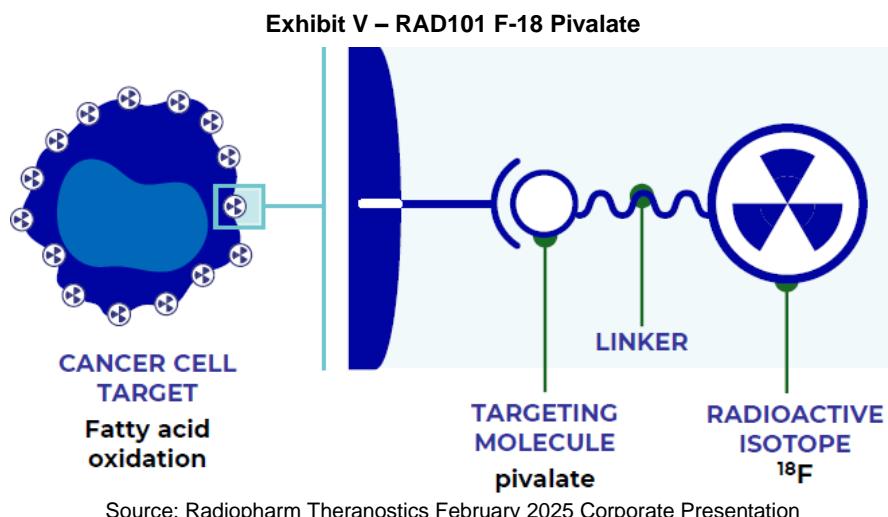
## Products and Pipeline

### Development Pipeline

#### RAD101 (F-18 Pivalate)

RAD101, also known as F-18 fluoro-pivalic acid (F-18 FPIA), is an investigational PET imaging radiotracer developed by Radiopharm Theranostics to target fatty acid metabolism in tumors. As a fluorine-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, F-18 FPIA does not undergo defluorination *in vivo*, making it particularly suitable for clinical imaging applications. It can be synthesized using automated radiosynthesis platforms, facilitating broader clinical adoption.

RAD101 is specifically designed to target fatty acid synthase (FASN), a multi-enzyme protein responsible for *de novo* fatty acid synthesis and overexpressed in numerous malignancies, including gliomas, breast, oral, prostate, and ovarian cancers.<sup>26,27,28</sup> FASN is especially relevant in brain metastases, where the lipid-poor microenvironment requires increased fatty acid synthesis for tumor survival and growth. Studies such as Ferraro *et al.* (2021) have demonstrated elevated FASN expression in brain metastases relative to primary tumors, supporting its relevance as an imaging biomarker.<sup>29</sup>



The utility of RAD101 lies in its irreversible uptake by tumors via monocarboxylate transporters, independent of blood-brain barrier permeability. This allows the compound to accumulate in brain tumors, offering a distinct advantage over other imaging agents that are subject to renal clearance, bone uptake or confounding interactions with healthy tissues. Additionally, because RAD101 is not oxidized, it alters cell membrane permeability and provides enhanced tumor-to-background contrast in imaging.<sup>30</sup>

Radiopharm has integrated RAD101 into a hybrid imaging modality—PET combined with multiparametric MRI (PET-mpMRI)—to improve the detection and characterization of brain metastases. Standard imaging approaches often fail to capture the metabolic nuances of tumor progression, highlighting the need for advanced tracers like RAD101.

In October 2024, Radiopharm announced a strategic partnership with BAMF Health to manufacture and administer RAD101 for clinical evaluation. The Phase IIb study ([NCT06777433](#)), which began dosing in April 2025, is an open-label, single-arm trial designed to assess the imaging performance of RAD101 in patients with suspected recurrent

<sup>26</sup> Xu, S., *et al.* Fatty acid synthase promotes breast cancer metastasis by mediating changes in fatty acid metabolism. *Oncology Letters*. November 2020.

<sup>27</sup> Agostini, M. *et al.* Fatty acid synthase is required for the proliferation of human oral squamous carcinoma cells. *Oral Oncology*. August 2004.

<sup>28</sup> Nguyen, P.L. *et al.* Fatty Acid Synthase Polymorphisms, Tumor Expression, Body Mass Index, Prostate Cancer Risk, and Survival. *Journal of Clinical Oncology*. August 2010.

<sup>29</sup> Ferraro, G.B., *et al.* Fatty Acid Synthesis is Required for Breast Cancer Brain Metastasis. *Nature Cancer*. October 2021.

<sup>30</sup> Pisaneschi, F., *et al.* Synthesis of [<sup>18</sup>F] fluoro-pivalic acid: an improved PET imaging probe for the fatty acid synthesis pathway in tumors. *Medicinal Chemistry Communications*. 2013.

brain metastases from various primary tumors. Conducted near BAMF's Grand Rapids, Michigan headquarters, the study anticipates enrolling 30 patients.

#### Exhibit VI – RAD101 Clinical Development

PRECLINICAL	PHASE I	PHASE IIa	PHASE IIb	PHASE III
	UK	UK		USA
	24 pts	17 pts	30 pts	150 pts
✓	✓	✓	2H 2024-2H2025	1H2026 – 2H 2027

Source: Radiopharm Theranostics February 2025 Corporate Presentation

This Phase IIb trial builds upon earlier findings from a clinical study conducted at Imperial College London and summarized by Islam *et al.* (2025).<sup>31</sup> In that study, 22 patients with intracranial metastatic disease (IMD) were imaged using FPIA-PET. 12 of the patients were treatment-naïve and 10 were previously treated with stereotactic radiosurgery (SRS). The tracer demonstrated high tumor-to-background uptake across all lesions, independent of extracranial disease origin. FPIA-PET volumes exceeded contrast-enhanced MRI volumes in treatment-naïve cases and showed prognostic value. Patients with a maximum Standardized Uptake Value (SUV)  $\geq 2.0$  had significantly shorter median overall survival (4 months vs. 15 months,  $p = 0.0136$ ), whereas MRI alone provided limited prognostic insight.

Overall, RAD101 offers a promising approach for visualizing brain metastases through metabolic imaging, with the potential to improve diagnosis, guide treatment planning and stratify patient prognosis.

#### Exhibit VII – RAD101 Milestones

PROGRAM	TARGET & MOLECULE	INDICATION	Dx/Tx	ISOTOPE	1ST HALF 2024	2ND HALF 2024	1ST HALF 2025	2ND HALF 2025
RAD101	Short Chain Fatty Acid (Small Molecule)	BRAIN METS	Imaging	F18		IND Approval Phase 2b N=30	First Patient Ph 2b First patient data	Phase 2 Top Line data

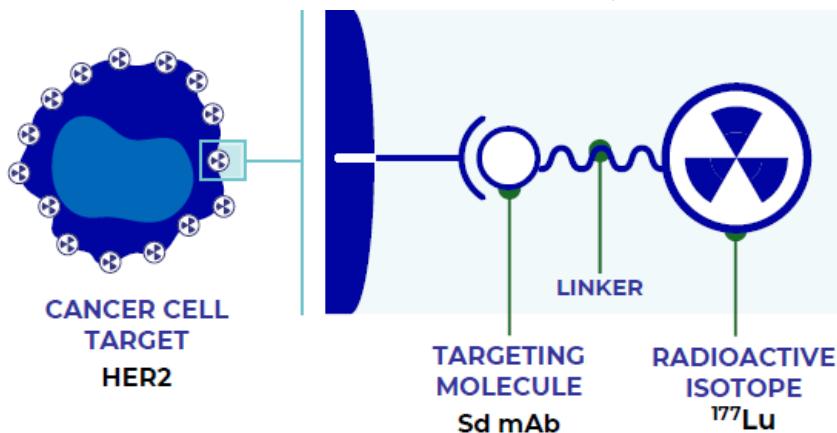
Source: Radiopharm Theranostics February 2025 Corporate Presentation

#### 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  $\beta$  particles and  $\gamma$  rays, offering a half-life of 6.73 days. Lu-177 can be used for both diagnostic ( $\gamma$  rays) and therapeutic ( $\beta$  particles) purposes.

<sup>31</sup> Islam, S. *et al.* A hybrid [<sup>18</sup>F]fluoropivalate PET-multiparametric MRI to detect and characterise brain tumour metastases based on a permissive environment for monocarboxylate transport. European Journal of Nuclear Medicine and Molecular Imaging. February 2025.

Exhibit VIII – RAD202 HER2 Nanobody



Source: Radiopharm Theranostics February 2025 Corporate Presentation

RAD202 is the subject of a Phase I basket trial (designated HEAT) 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 (HER2 Antibody Therapy with Lutetium-177). Ga-68 RAD202 provides imaging for the targeted tumor while Lu-177 RAD202 represents the treatment component.

Radiopharm received approval from the ethics board in December to initiate the Phase I therapeutic trial of RAD202 in HER2 positive breast and gastric cancers. RAD202 is a Lu-177 radionuclide bound to a single-domain monoclonal antibody (mAb) targeting HER2 positive tumors. The study will evaluate safety and tolerability of RAD202 in these patients. The multicenter study will have multiple sites in Australia and will be managed by GenesisCare CRO.

Two imaging studies were conducted and later discussed in journal articles (Zhao 2021 and Zhao 2024)<sup>32,33</sup> which demonstrated that a predecessor to RAD202 is able to successfully target HER2 breast cancer providing a proof of concept for the nanobody. The referenced studies employed a <sup>99m</sup>Tc-labeled anti-HER2 single-domain antibody to measure detection of HER2 expression and investigated its safety, radiation dosimetry, biodistribution and tumor-targeting potential. In the 2021 study, tracer uptake was visually observed in the primary tumors and metastases. Patients with confirmed breast cancer were investigated in the 2024 study and imaged with both <sup>99m</sup>Tc-NM-02 SPECT/computed tomography (CT) and <sup>18</sup>F-fluorodeoxyglucose (<sup>18</sup>F-FDG) positron emission tomography (PET)/CT. <sup>18</sup>F-FDG imaging is a widely recognized and clinically established modality for identifying the presence of metastases and is recommended for this use by the European Association of Nuclear Medicine (EANM) and the Society of Nuclear Medicine and Molecular Imaging (SNMMI). The 2024 study demonstrated that uptake of the <sup>99m</sup>Tc-bound HER2 nanobody was positively correlated with HER2 expression in the newly diagnosed breast cancer group and that this radiolabeled compound has the potential for visualizing whole-body HER2 overexpression in untreated patients, making it a promising method for HER2 assessment in patients with these types of cancers.

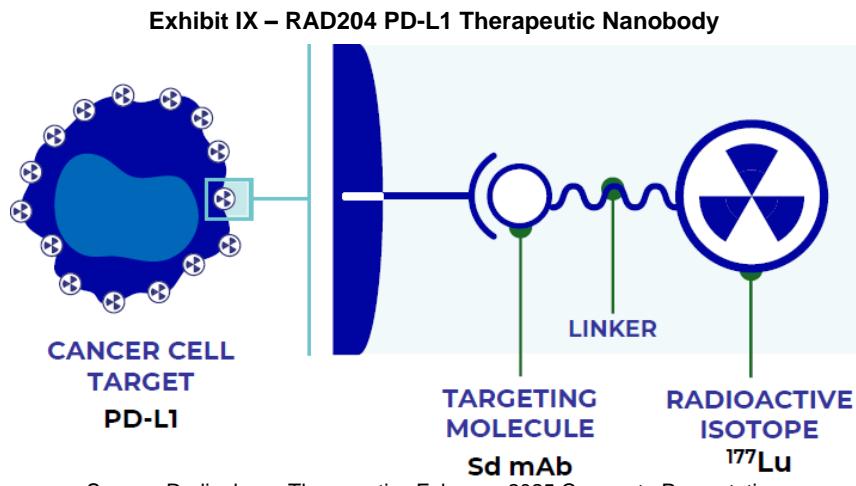
Radiopharm further [presented](#) a poster containing RAD202 data at the European Molecular Imaging Meeting (EMIM) that was held March 11<sup>th</sup> to 14<sup>th</sup>, 2025. It was entitled: Clinical utility of imaging and therapy with <sup>68</sup>Ga-RAD202 and <sup>177</sup>Lu-RAD202 in HER2-positive tumors; validation of optimized dosing in preclinical models. Imaging data, which used Ga-68 RAD202 demonstrated that it binds to the HER2 receptor with a high tumor to background ratio. The removal of a His-tag from the RAD202 nanobody, a modification which impacts biodistribution and tumor targeting, was shown to be superior for PET imaging due to the higher tumor-to-organ ratio. In preclinical studies, therapy with Lu-177 RAD202 was well tolerated and led to prolonged survival. Fractionated dosing produced improved inhibition of tumor growth compared to single-dose therapy. Treatment with the radioligand therapy produced a reduction in tumor volume and a survival benefit which supports continuation of the trial.

<sup>32</sup> Zhao, L., et al. Development of a <sup>99m</sup>Tc-Labeled Single-Domain Antibody for SPECT/CT Assessment of HER2 Expression in Breast Cancer. Molecular Pharmaceutics. July 2021.

<sup>33</sup> Zhao, L. et al. Detection of HER2 expression using <sup>99m</sup>Tc-NM-02 nanobody in patients with breast cancer: a non-randomized, non-blinded clinical trial

## 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 program is in Phase I studies evaluating the safety of using the candidate in treating non-small cell lung cancer (NSCLC) and other solid tumors.



Source: Radiopharm Theranostics February 2025 Corporate Presentation

The 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 on clinicaltrials.gov under the designator [NCT06305962](#). 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 ongoing and recruiting at four sites in Australia with trials managed by the contract research organization (CRO) GenesisCare.

## Exhibit X – RAD204 Study Dosages Measured

<b>Phase 0 (Imaging Period with <math>^{177}\text{Lu-RAD204}_{\text{im}}</math>)</b>	<b>Dose Level<sup>1</sup></b>	<b>Dose</b>
	<b>Imaging dose</b>	10 (0.36 GBq)
<b>Phase I (Treatment Period with <math>^{177}\text{Lu-RAD204}_{\text{tr}}</math>)</b>	<b>Dose Level<sup>2</sup></b>	<b>Dose (mCi)</b>
	<b>DL1</b>	30 mCi (1.1 GBq)
	<b>DL2</b>	40 mCi (1.5 GBq)
	<b>DL3+</b>	TBD

Source: Radiopharm Theranostics February 2025 Corporate Presentation

In November 2024, Radiopharm was [granted](#) approval to expand the Phase I clinical trial to additional indications beyond NSCLC by the Australian Ethics Committee. This includes other tumors that express PD-L1, such as small cell lung cancer (SCLC), triple negative breast cancer (TNBC), melanoma, head and neck cancer and endometrial cancer. The goal is to obtain approval for PD-L1 expressing cancers so that RAD204 will receive a tumor agnostic approval based on a pan-tumor predictive biomarker. In May 2025, the Data Safety and Monitoring Committee (DSMC) [approved](#) the study to move on to the next higher dose cohort in the Phase I study in PD-L1 positive advanced cancers. This will advance the treatment dose from 30 mCi of Lu-177-RAD204 to 60 mCi. The 60 mCi group

is expected to be fully enrolled by mid-2025 and data from the first two cohorts is expected later this year. The DSMC further concluded that the study may continue as planned without any modifications.

#### Exhibit XI – RAD204 Upcoming Milestones

PROGRAM	TARGET & MOLECULE	INDICATION	Dx/Tx	ISOTOPE	1ST HALF 2024	2ND HALF 2024	1ST HALF 2025	2ND HALF 2025
RAD204	PD-L1 (Nanobody)	MULTIPLE SOLID TUMORS	Therapy	Lu177	▲ Ethics Approval received	▲ First Patient treated ▲ Approval for Trial expansion in six tumor types	▲ 2 Cohorts completed & data release	▲ Phase 1 Top Line data

Source: Radiopharm Theranostics February 2025 Corporate Presentation

#### RAD402 (Tb-161 KLK3 mAB)

RAD402 is being developed to treat advanced prostate cancer. It links a Terbium-161 isotope to a monoclonal antibody raised to target the Kallikrein Related Peptidase 3 (KLK3) gene. KLK3 encodes for the prostate-specific antigen and is highly expressed in prostate cancer cells and limited expression in sites outside of the prostate. Another distinct feature of RAD402 is that it uses the Tb-161 radioisotope which emits both short-range Auger electrons and short-range beta particles. These emissions allow for targeted delivery of radiation, selective cell destruction and minimize damage to surrounding tissue. KLK3 is almost exclusively expressed in the prostate, unlike PSMA which appears throughout the organs of the body. PSMA, is prostate specific in name only as it is also expressed in other tissues such as the parotid and salivary glands and kidneys. 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.

#### Exhibit XII – RAD402 Milestones

PROGRAM	TARGET & MOLECULE	INDICATION	Dx/Tx	ISOTOPE	1ST HALF 2024	2ND HALF 2024	1ST HALF 2025	2ND HALF 2025	1ST HALF 2026
RAD402	KLK3 (mAb)	PROSTATE	Therapy	Lu177		▲ BioD & Tox studies completed	▲ CMC completion	▲ Ethics Committee Approval	▲ First Patient Dosed

Source: Radiopharm Theranostics February 2025 Corporate Presentation

#### *Terbium-161<sup>34</sup>*

We outlined some of the most widely used radioisotopes used in medicine at the beginning of our report. Radiopharm is moving in a new direction by using a less well-known radioisotope called Terbium-161 (Tb-161). Terbium is a rare earth metal with the atomic number 65. It is not found in nature as a free element but is contained in other minerals. Terbium-161 has a half-life of 6.89 days. In addition to emitting  $\beta$  particles, Tb-161 also radiates Auger electrons, which have very short ranges, high linear energy transfer and can cause high local damage.

<sup>34</sup> Terbium-161 has an atomic number of 65, meaning it has 65 protons. The mass number of 161 means that it has 96 neutrons (161-65=96)

### *Auger Electrons*

Auger electrons are low-energy electrons emitted from atoms through a non-radiative process following inner-shell ionization. Discovered by Lise Meitner in 1922 and Pierre Auger in 1923, these electrons play critical roles in material analysis, surface science and, most importantly, targeted cancer therapies. The mechanism of Auger electron emission is achieved through the removal of an inner-shell electron causing a higher-energy electron to fill the vacancy, thereby releasing energy. Typically emitted with energies between 50 eV and 2.5 keV, their short travel range (<500 nm) results in high linear energy transfer and thereby limits damage to immediate surroundings, reducing exposure to non-targeted tissue.

Late last year, Radiopharm announced that it had completed preclinical studies of RAD402 generating data that support advancing the candidate into Phase I studies. The company expects to receive ethics approval in 3Q:25 and begin the Phase I in 4Q:25

### **RAD301 and RAD302 (Integrin $\alpha$ V $\beta$ 6)**

Radiopharm's RAD301 employs trivehexin which targets integrin  $\alpha$ V $\beta$ 6 bound to the radioactive tracer Gallium-68 (Ga-68). When injected into a patient, Ga-68 trivehexin accumulates in tissues where  $\alpha$ V $\beta$ 6 integrin is present, generating an image using a PET scan. This helps in cancer diagnosis, staging, and monitoring treatment response. RAD302 or Lu-177 trivehexin has been designed as a therapeutic and also targets the  $\alpha$ V $\beta$ 6 cell surface receptor.

$\alpha$ V $\beta$ 6-integrin is overexpressed in several cancers including pancreatic ductal adenocarcinoma (PDAC) non-small cell lung cancer (NSCLC) and squamous cell carcinoma of the head and neck (SCCHN). Integrin  $\alpha$ V $\beta$ 6 is a type of cell surface receptor that mediates cell adhesion to the extracellular matrix, wound healing and activation of transforming growth factor-beta 1 (TGF- $\beta$ 1), which is involved in various cellular processes, including cell growth and differentiation. The receptor also plays a role in cancer and fibrosis. In healthy adult tissues, its expression is generally low or absent, but it becomes upregulated during tissue injury, inflammation and in various disease states.  $\alpha$ V $\beta$ 6 expression is frequently greater in various epithelial cancers. This upregulation is often associated with more aggressive tumor behavior and poor prognosis.<sup>35</sup>

RAD302 is radiolabeled with Lutetium-177, a beta-emitting radionuclide. The Lu-177 radiation selectively destroys integrin-expressing tumor cells while sparing normal tissues due to limited expression of  $\alpha$ V $\beta$ 6-integrin outside tumors. Since  $\alpha$ V $\beta$ 6-integrin is expressed on many types of tumors, it has potential in multiple indications. RAD302 will be used in combination with the imaging candidate RAD301, which together creates a theranostic pair. Ga-68 is an appropriate radionuclide for medical imaging because of its short half life of about 68 minutes, high positron emission fraction of 89% which is detected by the PET scan and mean positron energy of 890 keV which finds a favorable balance between tissue penetration and spatial resolution for clear imaging. Combining Ga-68 and Lu-177 for diagnosis and therapy is a common diagnostic pairing.<sup>36</sup>

### *$\alpha$ V $\beta$ 6 Integrin*

$\alpha$ V $\beta$ 6 integrin is an epithelial-specific cell surface receptor that belongs to the integrin family, which plays a key role in cell adhesion, migration and signaling. It is a heterodimer made up of  $\alpha$ v (alpha-v) and  $\beta$ 6 (beta-6) subunits. Unlike many other integrins,  $\alpha$ V $\beta$ 6 is not widely expressed in normal adult tissues but is upregulated in diseases, particularly cancer and fibrosis. Pathways promoted by integrin  $\alpha$ V $\beta$ 6 expression include TGF- $\beta$  activation, matrix metalloproteinase regulation, signaling pathway modulation and immune microenvironment alteration. Cancers that commonly express integrin  $\alpha$ V $\beta$ 6 are colorectal, gastric, pancreaticobiliary, lung and others. Integrin  $\alpha$ V $\beta$ 6's role as a driver of metastasis and immune evasion makes it an important target for precision oncology.

### **RV01 (Lu-177 B7-H3 mAb)**

RV01 is a radiopharmaceutical candidate targeting B7-H3 (also known as CD276) using a monoclonal antibody conjugated to the  $\beta$ -emitting lutetium-177. B7-H3 is expressed in multiple cancers including prostate, lung, hepatocellular carcinoma, pancreatic, colorectal, head & neck and breast.

<sup>35</sup> Brzozowska, E., Deshmukh, S. [Integrin Alpha v Beta 6 \( \$\alpha\$ V \$\beta\$ 6\) and Its Implications in Cancer Treatment](#). International Journal of Molecular Sciences. October 2022.

<sup>36</sup> Barca, C., et al. [Expanding Theranostic Radiopharmaceuticals for Tumor Diagnosis and Therapy](#). Pharmaceuticals. December 2021.

**Exhibit XIII – 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 [Corporate Presentation](#)

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 included 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 slated to be launched in 2025. Conclusions from preclinical mouse studies identified a high affinity antibody specific to the B7-H3 receptor, complete regression of established solid tumors with treatment and promising evidence of immune system stimulation and ability to confer immune memory.

#### *B7-H3 Monoclonal Antibody*

The B7-H3 monoclonal antibody (mAb) is designed to target various solid tumors that express the B7-H3 protein (also known as CD276). This protein is highly expressed on many cancer cells but has limited expression on normal tissue. High expression of this target is associated with a poor prognosis in many cancer types.

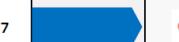
#### Assets Transferred to Lantheus

Along with a strategic investment from Lantheus Holdings, Radiopharm transferred rights to two early preclinical assets to Lantheus for A\$3 million (US\$2.0 million) as part of a transfer and development agreement in 2024. Its structure consisted of a sub-license assignment of a TROP2 targeting nanobody and an LRRC15 targeting monoclonal antibody. Details of the transaction were included in a June 2024 [press release](#). The assets were renamed LNTH-2404 and LNTH-2403 respectively and are summarized below.

LNTH-2404 is a Trophoblast cell surface antigen 2 (TROP-2) targeted radiotherapeutic. TROP-2 is over-expressed in triple negative breast, urothelial/bladder, ovarian epithelial, gastric and pancreatic cancers. LNTH-2404 has the potential to improve patient selection and therapeutic index relative to approved TROP-2 targeted antibody drug conjugates (ADCs).

LNTH-2403 is a LRRC15 targeted radiotherapeutic which may be appropriate for several cancers including osteosarcoma, non-small cell lung cancer, triple negative breast cancer, glioblastoma, and head & neck cancer. This asset is a potential first-in-class, highly specific monoclonal antibody radio-conjugate with Orphan Drug and Rare Pediatric Disease designations from the FDA for the treatment of osteosarcoma.

### Exhibit XIV – Radiopharm's Pipeline

	PROGRAM	TARGET & MOLECULE	INDICATION	ISOTOPE	PRECLINICAL	PHASE I	PHASE II	COUNTRY	NOTES
THERAPEUTIC TRIALS	RAD204	PD-L1 (Nanobody)	Multiple Solid Tumors	Lu177				AUS	Phase 1 enrolling, NCT06305962 First two cohorts' patients' data by mid-2025
	RAD202	HER 2 (Nanobody)	BREAST & GASTRIC	Lu177				AUS	Approval for Phase 1 (Dec 2024) First two cohorts' patients' data by Q4 2025
IMAGING TRIALS	RAD 101	Short Chain Fatty Acid (Small molecule)	BRAIN METS	F18			Phase 2a Phase 2b	USA	IND approved Phase 2b (n=30); enrollment started in Jan 2025 First patients' dataset by mid-2025
	RAD301	Integrin $\alpha V \beta 6$ (peptide)	PANCREAS	Ga68				USA	Phase 1 Imaging enrolling Data read-out by mid 2025
PRECLINICAL THERAPEUTIC MOLECULES	RV01	B7H3 (mAb)	Multiple Solid Tumors	Lu177				USA	IND approval expected mid-2025 PPFV Phase 1 in Q3 2025
	RAD402	KLK3 (mAb)	PROSTATE	Tb161				AUS	Ethics approval in Q3 2025 PPFV Phase 1 in Q4 2025
	RAD302	Integrin $\alpha V \beta 6$ (peptide)	Multiple Solid Tumors	Lu177				tbd	Phase 1 Therapeutic planned for late 2025

Source: Radiopharm Theranostics February 2025 Corporate Presentation

## Peers and Competitors

Radiopharm Theranostics' peers, competitors and competing technologies are focused on radiopharmaceuticals. There has been substantial merger and acquisition activity over the last several years with deals between Bristol Myers & RayzeBio, AstraZeneca & Fusion Pharma, Eli Lilly and POINT Biopharma and, most recently, Lantheus acquisition of Evergreen Theragnostics. Collaborations and partnerships have been another area of activity such as Lilly's [partnership](#) with Aktis and Radiopharm's relationship with Lantheus. In the following section we summarize some of the more important players in the radiopharmaceutical space.

### *Radiopharmaceutical Companies*

Actinium is focused on developing antibody radiation conjugates. It offers a hematology focus with nine pipeline assets. Its Iomab-B asset for acute myeloid leukemia (AML) has completed Phase III pivotal studies. AstraZeneca acquired the Canadian Fusion Pharmaceuticals in March of this year which is developing a novel linker technology, for use with alpha-emitters, to improve the safety of radiopharmaceuticals (RP) and reduce off-target effects on healthy tissue. Blue Earth Diagnostics is a UK-based firm that offers an F-18 PET imaging agent that competes with Pylarify in prostate cancer. Bristol Myers acquired RayzeBio last year which has an actinium-based radiopharmaceuticals development platform. Its current pipeline programs are targeting the treatment of solid tumors, including gastroenteropancreatic neuroendocrine tumors (GEP-NETs), small cell lung cancer, hepatocellular carcinoma and other cancers. Cardinal Health is a dominant provider of radiopharmaceuticals in the United States, with a network of over 130 nuclear pharmacies and distribution of PET and SPECT products.

Curium Pharma is a developer, manufacturer and distributor of RPs with a portfolio of products that includes generators, cold kits, hot products and auxiliary products used in the diagnosis and treatment of a wide range of diseases affecting the thyroid, lungs, liver, bones, brain, heart, glands, kidneys and joints. Curium commercializes Pylclar<sup>37</sup> in Europe. Eli Lilly is another recent acquiror, picking up Lantheus' partner POINT Biopharma. Point has development programs for Lutetium-based radiopharmaceuticals targeting PSMA and SSTR2, both in Phase III. GE Healthcare is another dominant player in the space which offers not only the imaging equipment which detects the radiotracers but also markets cERianna, DaTscan, Vizamyl, technetium products and other nuclear imaging agents. ITM Radio-pharma offers targeted radionuclide diagnostics and therapies in precision oncology. Theranostic agents for neuroendocrine tumors (NETs). TOCscan is the diagnostic companion to non-carrier added <sup>177</sup>Lu-Edotreotide and a ready to use radiopharmaceutical which ensures high-quality PET images. ITM also provides a GMP radiolabeling service. Jubilant Pharmova is an India-headquartered firm with numerous business segments including a US radiopharmacy presence and radiopharmaceutical products including the Rubidium <sup>82</sup>Rb Generator and Elution System. Life Molecular Imaging, soon to be acquired by Lantheus, develops neurodegenerative imaging assets with a PET RP for Alzheimer's disease (AD) and cardiovascular disease.

Novartis' buy of Mariana Oncology added a portfolio of radioligand therapy programs from lead optimization to early development across a range of solid tumor indications in breast, prostate and lung cancer. This includes development candidate MC-339, an actinium-based RLT being investigated in small cell lung cancer. Novartis also offers a <sup>68</sup>Ga-based PSMA PET imaging agent. Precirix is a private company focused on developing precision radiopharmaceuticals in oncology, using camelid single-domain antibodies labeled with radioisotopes. CAM-H2, a HER2-directed single domain antibody combined with iodine-131 recently completed a Phase I clinical study. The company's Fibroblast Activation Protein (FAP)-targeting program is transitioning into the clinic. Research on multiple isotopes, linker technology and combination therapies further expand the platform. Precirix' technology allows for a theranostic approach, where patients can be selected using an imaging version of the product, followed by a therapeutic dose for treatment.

Telix Pharma and RLS Radiopharma recently announced a combination between the two where the former will expand its North American manufacturing and distribution platform with the latter. Telix will engage RLS' 31 licensed radiopharmacies to build a radiometal production and distribution network for key therapeutic and diagnostic isotopes along with last-mile delivery of finished unit doses. Sofie Biosciences licensed quinoline-based PET tracers, developed by the team at Heidelberg University, that act as FAP inhibitors (FAPI). The company is also developing a gallium 68 product (<sup>[68]Ga</sup>FAPI-46) along with a fluorine 18 product (<sup>[18]F</sup>FAPI-74) in Phase II clinical studies. Sofie also works with GE Healthcare and has entered a licensing agreement to develop, manufacture and commercialize <sup>[68]Ga</sup>FAPI-46 and <sup>[18]F</sup>FAPI-74 for diagnostic and companion diagnostic use. Another Australia-based company, Clarity Pharmaceuticals, uses the SARTATE platform. It supports a theranostic approach pursuing prostate cancer, neuroblastoma, NETs and other cancers using a variety of targeting molecules and copper isotopes (Cu-64

<sup>37</sup> Pylclar is the branded name for piflulofolastat F-18 or Pylarify in Europe.

and Cu-64). Clarity has multiple Phase II and Phase III trials underway in the US and Australia. Georgia-based UPI manages a commercial nuclear and PET pharmacy network and represents over 80 institutional and independent sites throughout the United States. It serves as a group purchasing organization (GPO) for its client companies.

**Exhibit XV – Peers and Competitors<sup>38</sup>**

Ticker	Company	Price	MktCap (MM)	EV (MM)	Therapeutic Area
ATNM	Actinium	\$1.48	\$46	(\$27)	R&D for Antibody Radiation-Conjugates; AML lead indication
AZN	AstraZeneca	\$67.57	\$209,551	\$230,848	Acquired Fusion Pharma: PSMA radioconjugates (FPI2265)
BMY	Bristol Myers	\$46.45	\$94,530	\$128,905	Acq RayzeBio, radiotherapeutics, solid tumors
BWXT	BWXT Medical	\$108.37	\$9,901	\$11,028	Manufactures radioisotopes, radiopharmaceuticals & medical devices
CAH	Cardinal Health	\$148.22	\$35,377	\$39,187	Full suite of PET/SPECT products, nuclear pharmacy, distribution
CATX	Perspective Tx	\$2.35	\$174	(\$51)	Precision $\alpha$ (Pb212-VMT- $\alpha$ -NET) & $\beta$ (Lutathera) therapies
CLRPF	Clarity Pharma	A\$1.55	A\$498.0	A\$430.7	SARTATE theranostic for SSTR2. Cu-67 isotope & HER2 targets
GEHC	GE Healthcare	\$69.87	\$31,992	\$36,276	PET imaging agents, cyclotrons, Optison, PET/CT & SPECT equipment
JUBLPHA	Jubilant Pharmova	INR867.9	INR137,572	INR157,650	Radiopharmaceuticals & radiopharmacy
LLY	Eli Lilly	\$734.57	\$696,178	\$727,457	Acq Point Biopharma: PSMA, GEP-NET radioligands, LNTH partner
LNTH	Lantheus	\$81.74	\$5,655	\$5,283	RP & microbubble franchises with AD imaging & radiotherapeutics
NVS	Novartis	\$108.70	\$229,620	\$244,090	Ga-68-based PSMA PET imaging, acq Mariana Oncology
TLPPF	Telix Pharma	A\$17.88	A\$5,983	A\$5,650	Ga-68-based PSMA PET imaging agents
pvt	Abdera				Targeted $\alpha$ therapies with mAbs/ $\Delta$ -like ligand 3, NSCLC
pvt	Aktis Oncology				Precision $\alpha$ therapy for breast, lung, colorectal, bladder & liver
pvt	Blue Earth Diag				F18 PSMA & brain metastases PET imaging agent
pvt	Bracco				Imaging agents, nuclear medicine. Lumason microspheres.
pvt	CarThera				Ultrasound, microbubble; Alzheimer's indication
pvt	Cerevast				Ultrasound & microsphere technologies
pvt	Convergent Tx				$^{225}\text{Ac}$ in PSMA mAbs in Ph1 (CONV01- $\alpha$ )
pvt	Curium Pharma				Develop, manufacture & distribute RPs.
pvt	Insightec				Ultrasound platform for treatment of neurological disease
pvt	Isotopen Munchen				Diagnostic & therapeutic RP & radionuclides for cancer treatment
pvt	ITM Radiopharma				RP precision therapeutics & diagnostics for hard-to-treat tumors
pvt	Life Molecular Imaging				PET RP for neurodegen (AD) & cardiovascular disease imaging
pvt	PharmaLogic				CDMO for PMF F18 production, SPECT & PET radiopharmacy
pvt	Precirix				Developing radio-immunotherapeutic drugs for cancer patients
pvt	RadioMedix				RP products & services + pipeline of diagnostics & treatments
pvt	RLS Radiopharm				Commercial radiopharmacy, distribution, compounding
pvt	Sofie Biosciences				Molecular PET imaging, 18F FAPI-74
pvt	SonoThera				Non-viral genetic therapies/ultrasound microbubbles/sonoporation
pvt	UPPI				Commercial nuclear & PET pharmacy network
RADX	Radiopharm Thera	\$4.18	\$49	\$12	Biologically validated targets for RLT in imaging & treatment

Source: Analyst Own Work

<sup>38</sup> Price and market capitalization data is as of May 9, 2025

## Milestones, History and Review of Financial Results

### Corporate Milestones

- Launch of Radiopharm Theranostics – 2021
- Riccardo Canevari appointed CEO – September 2021
- Letter of Intent with GenesisCare to perform as CRO for RAD204 – March 2022
- Collaboration with Lantheus – August 2022
- Joint venture with MD Anderson (Radiopharm Ventures) – September 2022
- First patient dosed in the RAD301 imaging trial – February 2024
- Strategic investment from Lantheus – June 2024
- Transfer of two preclinical assets to Lantheus – June 2024
- Dr. Dimitris Voliotis appointed Chief Medical Officer – August 2024
- Ownership increase in Radiopharm Ventures to 75% - August 2024
- 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

### Background

Radiopharm Theranostics was founded by Paul Hopper in September 2021 and listed on the Australian Securities Exchange shortly after under the ticker RAD. Paul recognized the acceleration in activity in the radiopharmaceuticals space specifically noting the listing of Telix in Australia and Novartis' purchase of Advanced Accelerator and Endocyte which prompted him and his associates to launch Radiopharm. The company initially sought clinical stage assets developed at leading universities with a reputation for quality science. It started with three clinical platforms including pivalate, nano-mAbs and av $\beta$ 6 integrin. The genesis of the company came from the realization that there was a material opportunity in the next generation of radiopharmaceuticals that is able to combine a radioactive payload to validated vector molecules to take advantage of advancements in precision oncology and radioisotopes.

### Fiscal Year 2025 Financial and Operational Results

Radiopharm Theranostics released its fiscal year 2025 [third quarter cash flow statement](#) on April 28<sup>th</sup>, 2025. The company has a June 30 fiscal year end and reports audited financial statements semiannually. The company also provides quarterly updates of its cash use and cash balance. The most recent update captures company cash sources and uses for the first nine months of fiscal year 2025 and summarizes important milestones. Radiopharm presented RAD202 data at the 2025 European Molecular Imaging Meeting (EMIM). It also generated data showing that it was able to successfully detect brain metastases using RAD101 as reported in a 22-patient multiparametric imaging methodology study. During the reporting period, the company attended scientific and investor conferences, dosed the first patient in the RAD301 trial and announced that its cash runway guidance for the year would remain the same.

In terms of cash flows, Radiopharm consumed (\$29.6) million and (\$7.4) million in operating activities for the nine- and three-month periods ending March 31<sup>st</sup>, 2025. Cash from financing activities was \$44.7 million and \$8.1 million for the same nine- and three-month periods.<sup>39</sup>

<sup>39</sup> Note that results are reported in Australian Dollars. The most recent exchange rate between Australian Dollars and U.S. Dollars is \$1.56 AUD to \$1.00 USD.

For the first nine months of the reporting period ending March 31<sup>st</sup>, 2025 and compared to the same prior year period:

- Receipts from customers were \$4.5 million related to proceeds received from Lantheus for managing partnered clinical trials vs. \$291,000;
- Research and development consumed (\$23.6) million related to the management of multiple clinical trials vs. (\$12.5) million;
- Staff costs consumed (\$8.1) million vs. (\$6.7) million;
- Administration and corporate costs were (\$3.5) million vs. (\$1.9) million;
- Other miscellaneous cash operating expenses include (\$157,000) for advertising and marketing, \$607,000 for interest income and \$614,000 from a tax refund;
- Cash from financing was \$44.7 million from the issuance of equity securities related to Lantheus' investment offset by transaction costs and the repayment of borrowings compared to \$7.2 million also related to issuance of equity securities and net borrowings partially offset by transaction costs;

As of March 31<sup>st</sup>, 2025, Radiopharm held \$36.9 million in cash compared to \$18.6 million at the end of FY:24. Cash burn for the first nine months of FY:25 was (\$29.6) million vs. (\$16.0) million same prior year period. The company has indicated that it has sufficient cash to support operations until June 2026.

**Exhibit XVI – Quarterly Cash and Cash Flows, Actual**

Radiopharm Theranostics Ltd	Q1 A	Q2 A	Q3 A	Q4 A	2024 A	Q1 A	Q2 A	Q3 A
<b>Cash and Cash Equivalents</b>	<b>\$1,834</b>	<b>\$1,894</b>	<b>\$2,938</b>	<b>\$18,575</b>	<b>\$18,575</b>	<b>\$46,431</b>	<b>\$36,437</b>	<b>\$36,864</b>
Operating & Cap-X	(\$9,868)	(\$1,905)	(\$4,200)	(\$7,003)	(\$22,976)	(\$13,477)	(\$8,739)	(\$7,430)
Financing	\$0	\$1,979	\$5,180	\$22,718	\$29,877	\$38,749	(\$2,140)	\$8,067

Source: Radiopharm Theranostics Quarterly Activities and Cash Flow Report

## MANAGEMENT PROFILES

### **Riccardo Canevari, Chief Executive Officer**

Riccardo has broad and deep experience across specialty pharma, oncology and radiopharmaceuticals. He was most recently Chief Commercial Officer of Novartis company Advanced Accelerator Applications, one of the leading radiopharmaceutical and nuclear medicine companies globally. He was responsible for global commercial strategy and country organizations in near 20 countries across North America, Europe and Asia. He was lead for Lutathera's in-market growth strategy and execution to build a blockbuster asset and lead on the prelaunch plan for Lu-PSMA 617 in metastatic prostate cancer. He assessed Go To Market Models for each priority country and access to other markets. Prior to this Riccardo was Senior Vice President and Global Head, Breast Cancer Franchise for Novartis Oncology since 2017, overseeing the launch of major breast cancer products including KISQALI and PIQRAY. He has also held various management roles with Novartis Pharma and Ethicon/Johnson & Johnson.

### **Dimitris Voliotis, M.D., Chief Medical Officer**

Dr. Voliotis has 20 years of experience in the pharmaceutical and biotechnology sector in the US and Europe, with an emphasis on radiopharmaceuticals, and 12 years' experience in academic preclinical and clinical research. He has held global drug development roles in large and medium sized pharmaceutical companies and start-up phase companies. He has designed and executed multiple registrational trials in numerous oncology indications, multiple investigational new drug applications, preclinical through to first in human trials and has overseen numerous regulatory submissions which have resulted in approvals for four drugs in eight different oncology indications. He was most recently Senior Vice President, Head of Clinical Development of radiopharmaceutical business Convergent Therapeutics. Prior to this he held the same role at oncology company Zentalis Pharmaceuticals (NASDAQ: ZNTL). He previously held a range of development roles with major German multinational pharma company Bayer AG as well as at Japanese company Eisai Inc. Dr. Voliotis also recently acted as a Consultant in Oncology Drug Development with Magnesia Partners Consulting LLC, advising on clinical development and regulatory strategy.

## Risks

All investments contain an element of risk which reflects business uncertainty and opportunity. Some investments offer greater predictability, with current cash flows and established sales. These enterprises will have a lower level of perceived risk while other companies that are developing an undefined, new technology have a much higher level. Radiopharm is commercializing a portfolio of radiopharmaceuticals that image and treat a broad range of cancers. The company also supports the development of new products, many of them through partnerships and licensing arrangements. Radiopharm is exposed to geographical, partner and development risks. It is also exposed to risks specific to radioactive products. These include additional layers of regulation and time constraints related to the radiation and half-lives of the products it is developing. We review the principal risk categories faced by Radiopharm Theranostics below.

### Financing

Even if a company has a strong, experienced team that is developing a product with a high likelihood of success and a large addressable market, securing funding may be difficult. Access to financing comes and goes in cycles. During periods of improving confidence, capital may be easy to obtain; however, during a liquidity crisis or a period of heightened risk perception, even companies with bright prospects may be in trouble if they are dependent on the financial markets to fund their work. If capital is needed to sustain operations and it is not readily available, the company may be forced to suspend research and development, sell equity at a substantial discount to previous valuations and dilute earlier shareholders. A lack of funding may leave potentially promising therapies without a viable route forward or force a company to accept onerous terms.

Increases in cost of capital can make previously attractive investments less so. Interest rates have been volatile over the last two years, materially changing the net present value and reward to risk ratio for many investments, especially those in higher risk categories such as preclinical assets. As a development stage company, Radiopharm is more exposed to these risks. The company is consuming substantial free cash flow and has almost one year of cash burn on its balance sheet.

### Regulatory Environment

All drugs and devices must navigate the regulatory approval process in the US, EU, Japan and other countries before commercialization. Success is uncertain and may take years to achieve depending upon the needs and desires of the determining authority. Substantial expense is undertaken to bring a device, molecule or compound through clinical trials and address all of the regulatory agencies' concerns. Companies with a long history of research success in product development, with opinion leaders and experts in the field, are in a stronger position to mitigate this risk. Companies that have achieved previous success with the FDA or other regulatory agencies also are more attractive than those who may be new to the process.

### Competitive Environment

While there are many technologies that are used for disease imaging and cancer treatment, radiopharmaceuticals have emerged as an area of innovation. Targeting specific cells, enzymes, antigens and proteins, carrier molecules such as antibodies, glucose analogs, hormone analogs, nanoparticles or peptides has become more precise, allowing for improved safety and efficacy while delivering the desired radionuclide. The use of different radionuclides along with new imaging technologies have delivered clearer images that improve diagnosis and localization of target tissue and help physicians change the treatment plan for the better.

There have been a number of high-profile radiopharmaceutical acquisitions in recent years demonstrating the value perceived in the space. We anticipate that the market will grow and that competition will increase as the field continues to advance into new imaging modalities and oncology indications. Radiopharm is in the enviable position of having a broad portfolio of novel radiopharmaceuticals and it has a strong relationship with industry leader Lantheus which allows it to more efficiently develop its products and potentially provide an avenue for commercialization. On the other hand, many of the acquired radiopharmaceutical players are now part of larger and more financially dominant biopharmaceutical companies that can now compete from a position of greater strength against peers.

## **Partners & Collaborators**

Partners represent both a risk and an opportunity. Radiopharm has relied upon research and development partners for the innovation that exists in its development portfolio. This approach reduces the cost and risk of any one development project and allows the company to hold a broader pipeline of assets that can contribute to future revenues. Radiopharm has invested in the next generation of imaging and therapy with its pipeline of assets working with M.D. Anderson, Lantheus, GenesisCare, MedPace and others. While these relationships may provide financial benefit, they may also divert company resources and distract from other investments that could be more profitable. Partners may withdraw their participation in the collaboration or refuse to advance work resulting in a loss for the efforts and funds invested so far.

Collaborators also include service providers who may have competing demands that can adversely affect the work they are managing on behalf of the firm. CROs and subcontractors must abide by strict execution and trial parameters that if violated can jeopardize trial execution or data validity. Patient recruitment may be difficult. Subcontractors supervise and execute research, biometrics and pharmacovigilance, which are complex tasks. Trial sites require sufficient capacity to enroll subjects and the candidate drug needs to be manufactured in compliance with current Good Manufacturing Practices (cGMP) and be available to administer. Finally, the data itself needs to achieve statistical significance to justify regulatory approval. Radiopharm's pipeline consists of three pre-clinical assets and four clinical assets that must complete necessary investigatory trials before they can be marketed.

## **Management**

Corporations are highly reliant on attracting and maintaining experienced and talented executives to advance their objectives. For small companies with management teams of only a few people, the impact of each individual is greater, increasing the risk that the company faces with the loss of an executive. Radiopharm has a small senior executive team which includes a Chief Executive Officer and Chief Medical Officer. The duties of a Chief Financial Officer are outsourced to an organization called CFO Solutions. This organization provides Radiopharm a professional with skills and experience in back-office support, financial reporting, and compliance systems management services. Radiopharm's board is closely involved with the operations of the company which can offset some of this risk. Some of the board members include the founder Paul Hopper, the fractional CFO, Phillip Hains and the CEO Riccardo Canevari.

## **Manufacturing**

Manufacturing to align with precise and time-sensitive constraints is the *sine qua non* of radiopharmaceutical companies. In addition to the demands to produce in compliance with current Good Manufacturing Practices, the company must also conform to the demands of the Nuclear Regulatory Commission (NRC) in the United States and recognize the time sensitive nature of its product. Many of the demands of these requirements are handled by CRO and hospital partners. Radiopharm contracts with a number of providers for radioisotopes including Isotopia, Shine and Australia's Nuclear Science and Technology Organisation (ANSTO).

## **Intellectual Property**

Despite the existence of patents, exclusivity, trademarks and trade secrets, infringement of intellectual property is a risk. At its inception, Radiopharm sought late preclinical or early clinical radiopharmaceutical assets that had been developed by distinguished research hospitals and universities, then license the rights to develop and commercialize these assets. Radiopharm has licensing agreements with several entities that grant the use of their intellectual property in return for license fees. Two examples are the  $\alpha$ V $\beta$ 6 integrin with TRIMT GmbH and nanomab assets (including PD-L1 and HER2) with NanoMab technology Limited. Radiopharm also recognizes intellectual property through Radiopharm Ventures (RV01) and Cancer Research Technologies (RAD101). Other licenses held by Radiopharm are with NeoIndicate and the University of California Los Angeles (UCLA).

## **Market Risk**

Successful marketing of approved candidates relies on adoption by patients and providers. An approved product must have convincing clinical trial data and maintain a favorable reputation with prescribers. Marketing is expensive and requires an experienced sales force and a presence in the marketing region. Products remain under surveillance and any unexpected adverse effects may lead to regulatory authorities revoking marketing authorization. Inclusion of the drug in insurance plan offerings is also important. Rapidly obtaining a preferred position on health plan and payor formularies is critical to achieving target penetration rates. If health plans, formularies and payors cannot agree on appropriate pricing for the product and it fails to offer a significant benefit above standard of care,

sales may be limited. All of Radiopharm's products are in development and we anticipate that the company will work with partners to commercialize its approved assets.

### **Geopolitical**

Trade tensions and the imposition of tariffs by the United States have negatively impacted the global economy, slowed cross-border commerce and limited technology transfer. The conflict may add an additional layer of cost to cross-border distribution of medical products and reduce the availability of capital. It may also limit the formation of partnerships and future development and commercialization deals between countries around the globe. The UK withdrew from the European Union in 2020, creating additional trade, transportation and other barriers between the UK and mainland Europe. Conflict between Ukraine and Russia and in Israel has led to disruptions in these countries. Sanctions have been imposed on many Russian businesses which may lead to product shortages. Refugees fleeing the war in Ukraine may also impact nearby nations and their productivity which could affect clinical trials and commercialization in the region. Radiopharm is reliant on source material for its radioisotopes which are sourced from around the globe. Given the time sensitive nature of distributing radiopharmaceuticals, development is highly reliant on stable and reliable governments that allow efficient transportation.

### **Inflation**

Drug price inflation has gained attention as it and other healthcare costs have risen at a materially faster pace than overall prices. As new therapies have been approved, drug prices have increased to reflect higher development costs and improved pricing power of pharmaceutical and biotech companies. On the demand side, deductibles and co-pays have steadily risen over the last decades, and in some cases, individuals and families must cover several thousand dollars in costs before the benefits of insurance begin. Cost sharing or co-insurance is another component of insurance plans that directly increases a patient's burden. This has resulted in greater elasticity in demand for drugs than was previously the case. Individuals with high deductibles or no insurance may be very sensitive to price and avoid treatments with high cost.

While we have discussed a broad variety of risks above, we believe that our forecast parameters, discount rates, success probabilities and valuation metrics address these potential outcomes and our target price reflects an assumption of these risks faced by life sciences companies in general and Radiopharm Theranostics.

## VALUATION

Radiopharm offers a pipeline of both diagnostic and therapeutic radiopharmaceuticals that are in clinical and pre-clinical stages. The most advanced asset is RAD101, a Phase II imaging asset for brain metastases. Other candidates in the pipeline include RAD202 and RAD204, both nanobody constructs that target HER2 and PD-L1 respectively. These candidates are subjects of Phase I studies. Our work evaluates these assets to generate the valuation. Market size assumptions are based on the overall number of patients with the identified therapeutic targets. However, we anticipate that Radiopharm will pursue the market based on the initial site of the cancer and expand to other sites after achieving success in the first indications.

### RAD101

Brain metastases occur in 20% to 40% of cancer patients and are far more common than primary brain cancers. The appropriate individual for RAD101 is a cancer patient that has received SRS and can no longer provide useful images due to the necrotic tumor tissue. These patients require imaging that can detect recurrence associated with short chain fatty acids which are found in brain metastases. Based upon the number of cancer cases in the US and developed world we estimate the addressable market for this diagnostic to be about 300,000 in the United States growing at 20 basis points per annum. RAD101 is now in Phase II development for imaging brain metastases. We anticipate that pivotal trials will start next year and that a new drug application will be submitted in early 2028.

Approval and first sales for RAD101 are forecasted for the US in 2029 where we estimate a 33-basis point penetration in year one rising to 533 basis points by year seven (2035). Each patient is expected to be administered a total of three scans that occur prior, during and after treatment. This equates to about 3,000 scans in 2029, rising to about 49,000 scans in 2035 after which we see about 2% volume growth. Revenue is expected to be \$4,730<sup>40</sup> per scan in 2025 based on our research validating third party work commissioned by Radiopharm. Price inflation is estimated to be 2.5% per annum. These assumptions generate product revenues of about \$16 million in 2029 rising to \$89 million by year seven.

Outside of the US, our assumptions for RAD101 anticipate international approval and first sales in 2030. The addressable market for the developed world is estimated to be about three times the size of that in the United States growing at 1% per annum. First year penetration is estimated at 3 basis points rising to 53 basis points by year seven. As we do for the U.S., we assume three scans per patient on average. This generates about 950 scans in 2030 rising to just over 16,000 scans by 2036. Revenue per scan is estimated to be about 40% of U.S. levels or \$2,000 in 2025 inflating at 1% per year. These assumptions generate revenues of about \$2 million in 2030 rising to almost \$36 million by 2036.

### RAD204

PD-L1 positive patients comprise anywhere from 20% to 60% of patients depending upon the cancer type. We referenced a meta-study in this report that found that about 30% of all tumors were PD-L1 positive. This equates to a prevalence of about 600,000 in the United States. We have this growing at 0.2% per year. Our forecasts call for Phase I studies to transition to Phase II studies in 2027 and Phase III studies in 2029. Pivotal studies will complete and a new drug application will be submitted producing first sales in 2032. First year penetration is estimated at 7 basis points generating 432 treatments. This is expected to rise to 45 basis points of penetration by year seven (2038) which is equivalent to about 2,800 treatments. Pricing for a radioimmunotherapy is forecast at \$180,000 per course of treatment inflating at 2.5% per year. These assumptions produce product revenue of \$92 million in year one rising to \$690 million by year seven.

Outside of the US, our assumptions for RAD204 recognize an addressable market of 1.8 million PD-L1 positive patients. We anticipate a delay of one year for commercialization to begin outside the U.S. and first year penetration of 1 basis point or 260 treatments. Growth is expected to average about 30% per year resulting in 9 basis points of penetration by year 2039 and 1,675 patients treated. Pricing for a course of treatment is estimated to be about 40% of US levels or \$72,000 per course of treatment growing at 1% per year. This produces year one revenue of \$20 million (2033) and \$139 million by year seven (2039).

### RAD202

HER2 appears in about 2.7% of all cancers yielding an addressable market of about 89,000 in the United States growing at a 0.4% rate. We anticipate that the RAD202 program will follow a similar development path to RAD204 with Phase I studies moving to Phase II studies in 2027 and Phase III studies beginning in 2029. The biologic li-

<sup>40</sup> All currency amounts in the valuation section are denominated in US Dollars.

cence application (BLA) is expected to be submitted and approved by 2032. Revenues are forecast to begin in 2032 with 15 basis points of penetration moving to nearly 300 basis points of penetration by year seven (2038). This equates to 135 patients in 2032 rising to over 2,700 in 2038. Revenue per course of therapy is expected to match that of RAD204 starting at \$180,000 and rising at 3% per year. Product revenue in year one is forecast to be \$30 million increasing to over \$700 million by year seven (2039).

Outside of the U.S., we see an addressable market of 267,000 patients growing at a 1% rate per year. First revenues are anticipated in 2033 driven by 3 basis points of penetration. This is forecast to grow to 59 basis points of penetration by 2039. Similar to RAD204, international pricing begins at 40% of the amount in the United States or \$72,000 per course of therapy. Price inflation is set at 1% per annum. These assumptions generate product revenues of \$6.8 million in year one rising to \$151 million by year seven (2039).

We expect Radiopharm Theranostics to sign a deal with an established pharmaceutical company for commercialization of its approved products. Deals of this type customarily propose upfronts, milestones and royalties. We simplify this approach and accrue all of the expected value in a royalty. Based on the novelty of, complexity of and expected demand for the assets in development, we forecast a 30% royalty rate to be paid on product revenues.

We assume cash costs for operating Radiopharm's research and development functions to be \$24.1 million in 2025, rising to \$24.8 million in 2026 and fluctuating with the anticipation of clinical trial work for RAD101, RAD204 and RAD202. After approvals begin in 2028, we forecast a decline in research and development expenditure. General and Administrative expenses are forecast at \$8.4 million in 2025 and \$8.9 million in 2026. Over the following years the amount fluctuates but generally increases at a mid-single digit inflation rate until 2033 after which it declines as we forecast RAD101, RAD204 and RAD202 are commercialized by partners. As Radiopharm advances new programs that merit our valuation, we will adjust the costs and benefits to reflect this. Note that we convert Australian dollars to U.S. dollars from the income statement to our discounted cash flow model to show estimated expenses.

Taxes will be assessed at a 25% rate and will be subtracted after net operating losses (NOL) are consumed. After-tax cash flows to the company are discounted at a 15% rate with a terminal growth rate of -10%. We apply a blended 25% probability of regulatory and commercial success for the RAD101, RAD204 and RAD202 programs. Our probability of success is guided by historical rates of approval at the various stages of development and the previous approval of the underlying mechanisms and radioisotopes.

Options and warrants with exercise prices below our target price are assumed executed with proceeds added to cash and exercised shares added to shares outstanding. The share price valuation also includes the issuance of sufficient shares to cover anticipated capital raises over the succeeding year. Based on the assumptions identified in our discounted cash flow model, we generate a valuation of \$12.50 per share.

## PROJECTED FINANCIALS

### Radiopharm Theranostics Limited - Income Statement

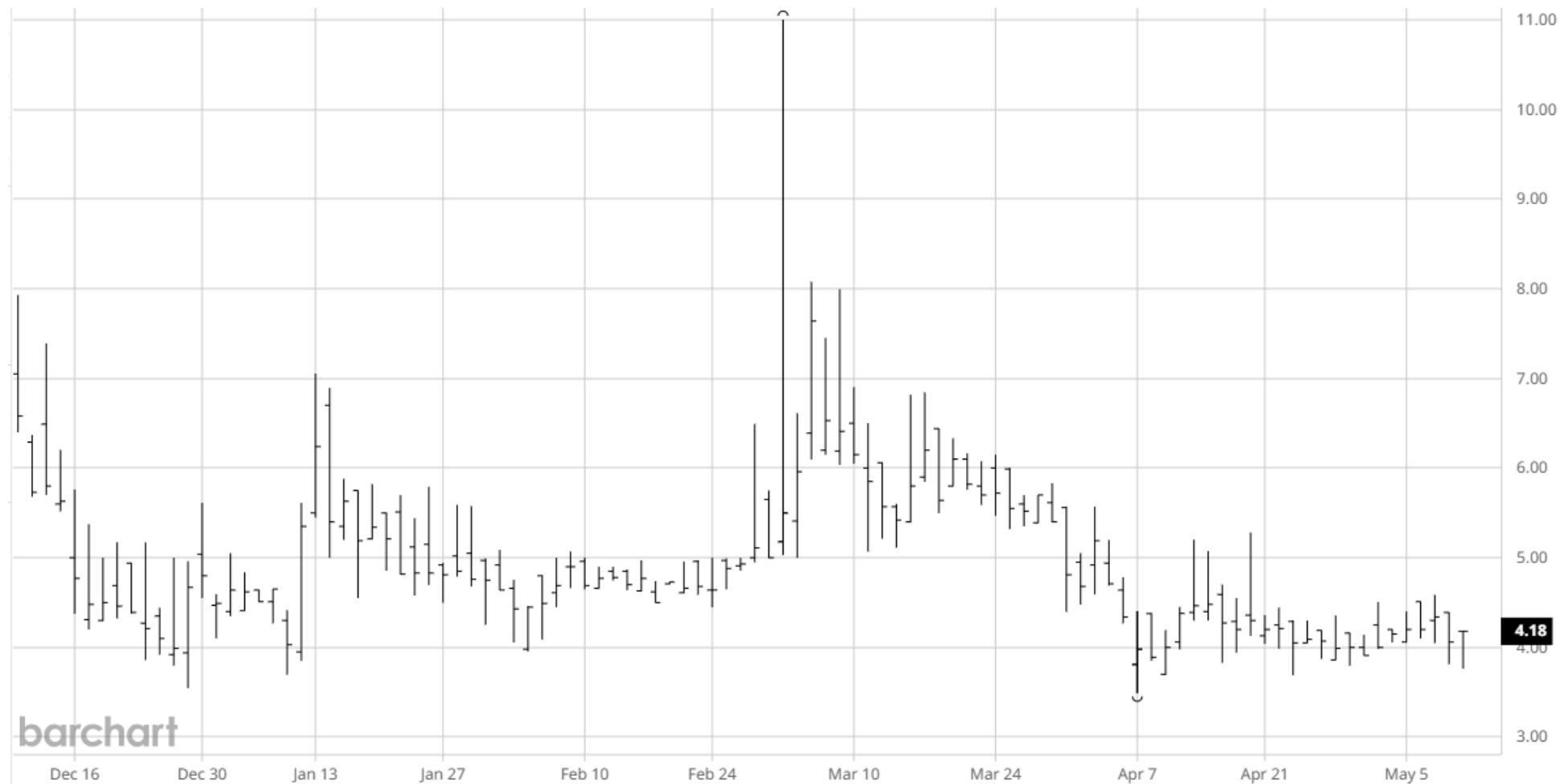
Radiopharm Theranostics Ltd	2024 A	H1 A	H2 E	2025 E	2026 E	2027 E
<b>Customer Contract Rev (A\$'000)</b>	<b>\$299</b>	<b>\$1,384</b>	<b>\$0</b>	<b>\$1,384</b>	<b>\$0</b>	<b>\$0</b>
Cost of Sales	\$0	(\$1,615)	\$0	(\$1,615)	\$0	\$0
Gross Margin		-16.7%				
Other Income	\$1,343	\$1,054	\$0	\$1,054	\$0	\$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)	(\$19,052)	(\$38,594)	(\$38,775)	(\$40,398)
Operating Margin						
Finance Expenses	(\$643)	\$0	\$0	\$0	\$0	
Pre-Tax Income	(\$47,853)	(\$19,542)	(\$19,052)	(\$38,594)	(\$38,775)	(\$40,398)
Provision for Income Tax	(\$96)	(\$101)	(\$38)	(\$139)	(\$155)	(\$162)
Tax Rate	0.2%	0.5%	0.2%	0.4%	0.4%	0.4%
<b>Net Income</b>	<b>(\$47,949)</b>	<b>(\$19,643)</b>	<b>(\$19,090)</b>	<b>(\$38,733)</b>	<b>(\$38,930)</b>	<b>(\$40,560)</b>
Net Margin						
Comprehensive Income	\$203	\$376	\$0	\$0	\$0	\$0
Non-controlling Interest	(\$1,964)	(\$918)	(\$764)	(\$1,681)	(\$1,557)	(\$1,622)
<b>Total Comprehensive Income</b>	<b>(\$45,782)</b>	<b>(\$18,350)</b>	<b>(\$18,326)</b>	<b>(\$37,052)</b>	<b>(\$37,373)</b>	<b>(\$38,937)</b>
<b>Reported EPS</b>	<b>(\$0.12)</b>	<b>(\$0.0109)</b>	<b>(\$0.01)</b>	<b>(\$0.02)</b>	<b>(\$0.02)</b>	<b>(\$0.01)</b>
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
<b>Adjusted EPS</b>	<b>(\$0.1241)</b>	<b>(\$0.0102)</b>	<b>(\$0.0082)</b>	<b>(\$0.0188)</b>	<b>(\$0.0152)</b>	<b>(\$0.0141)</b>

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

Radiopharm Theranostics Ltd	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	2037	2038	2039	
<b>RAD101 - US: Brain Metastases</b>																
Addressable market	300,000	300,600	301,201	301,804	302,407	303,012	303,618	304,225	304,834	305,443	306,054	306,666	307,280	307,894	308,510	
Penetration	Ph2b	Ph3	Ph3	NDA	0.33%	1.33%	3.00%	4.00%	4.67%	5.00%	5.33%	5.50%	5.60%	5.67%	5.72%	
Patient scans (3x)					3,024	12,120	27,326	36,507	42,677	45,817	48,969	50,600	51,623	52,342	52,909	
Price per scan (\$,000)	\$4.730	\$4.848	\$4.969	\$5.094	\$5.221	\$5.352	\$5.485	\$5.622	\$5.763	\$5.907	\$6.055	\$6.206	\$6.361	\$6.520	\$6.683	
Revenues					\$15,789	\$64,863	\$149,891	\$205,260	\$245,948	\$270,644	\$296,496	\$314,032	\$328,391	\$341,289	\$353,613	
Royalty Revenues (30%)	\$0	\$0	\$0	\$0	\$4,737	\$19,459	\$44,967	\$61,578	\$73,784	\$81,193	\$88,949	\$94,210	\$98,517	\$102,387	\$106,084	
<b>RAD101 - Ex-US: Brain Metastases</b>																
Addressable market	900,000	909,000	918,090	927,271	936,544	945,909	955,368	964,922	974,571	984,317	994,160	1,004,102	1,014,143	1,024,284	1,034,527	
Penetration	Ph2b	Ph3	Ph3	NDA	Pricing	0.03%	0.13%	0.30%	0.40%	0.47%	0.50%	0.53%	0.55%	0.57%	0.60%	
Patient scans (3x)					946	3,821	8,684	11,695	13,780	14,912	16,066	16,733	17,746	19,733	19,733	
Price per scan (\$,000)	\$2,000	\$2,020	\$2,040	\$2,061	\$2,081	\$2,102	\$2,123	\$2,144	\$2,166	\$2,187	\$2,209	\$2,231	\$2,254	\$2,276	\$2,299	
Revenues					\$1,988	\$8,113	\$18,621	\$25,328	\$30,143	\$32,945	\$35,848	\$37,711	\$43,079	\$45,536		
Royalty Revenues (30%)	\$0	\$0	\$0	\$0	\$0	\$596	\$2,434	\$5,586	\$7,598	\$9,043	\$9,884	\$10,754	\$11,313	\$13,924	\$13,361	
<b>RAD204 - US (PD-L1): Therapy</b>																
Addressable market	600,000	601,200	602,402	603,607	604,814	606,024	607,236	608,451	609,667	610,887	612,109	613,333	614,559	615,789	617,020	
Penetration	Ph1	Ph1	Ph2	Ph2	Ph3	Ph3	BLA	0.07%	0.17%	0.26%	0.34%	0.37%	0.41%	0.45%	0.50%	
Patients								432	1,050	1,572	2,081	2,294	2,528	2,787	3,071	
Price per course of therapy (\$,000)	\$180.0	\$184.5	\$189.1	\$193.8	\$198.7	\$203.7	\$208.7	\$214.0	\$219.3	\$224.8	\$230.4	\$236.2	\$242.1	\$248.1	\$254.3	
Revenues						\$0	\$0	\$92,432	\$230,245	\$353,336	\$479,533	\$541,755	\$612,050	\$691,467	\$781,188	
Royalty Revenues (30%)	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$27,730	\$69,073	\$106,001	\$143,860	\$162,526	\$183,615	\$207,440	\$234,356	
<b>RAD204 - ex-US (PD-L1): Therapy</b>																
Addressable market	1,800,000	1,803,600	1,807,207	1,810,822	1,814,443	1,818,072	1,821,708	1,825,352	1,829,002	1,832,660	1,836,326	1,839,998	1,843,678	1,847,366	1,851,060	
Penetration	Ph1	Ph1	Ph2	Ph2	Ph3	Ph3	BLA	Pricing	0.01%	0.03%	0.05%	0.07%	0.07%	0.08%	0.09%	
Patients								260	631	945	1,251	1,379	1,520	1,675		
Price per course of therapy (\$,000)	\$72	\$72.7	\$73.4	\$74.2	\$74.9	\$75.7	\$76.4	\$77.2	\$78.0	\$78.7	\$79.5	\$80.3	\$81.1	\$81.9	\$82.8	
Revenues								\$20,249	\$49,702	\$75,156	\$100,506	\$111,886	\$124,554	\$138,656		
Royalty Revenues (30%)	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$8,991	\$46,396	\$95,768	\$123,548	\$153,010	\$189,499	\$215,132	\$244,232	
<b>RAD202 - US: HER2: Therapy</b>																
Addressable market	89,000	89,178	89,356	89,535	89,714	89,894	90,073	90,254	90,434	90,615	90,796	90,978	91,160	91,342	91,525	
Penetration	Ph1	Ph1	Ph2	Ph2	Ph3	Ph3	BLA	0.15%	0.75%	1.50%	1.88%	2.25%	2.70%	2.97%	3.27%	
Patients								135	678	1,359	1,702	2,047	2,461	2,713	2,990	
Price per course of therapy (\$,000)	\$180	\$185.4	\$191.0	\$196.7	\$202.6	\$208.7	\$214.9	\$221.4	\$228.0	\$234.9	\$241.9	\$249.2	\$256.6	\$264.3	\$272.3	
Revenues								\$29,970	\$154,655	\$319,226	\$411,826	\$510,034	\$631,663	\$717,106	\$814,106	
Royalty Revenues (30%)	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$8,991	\$46,396	\$95,768	\$123,548	\$153,010	\$189,499	\$215,132	\$244,232	
<b>RAD202 - ex-US: HER2: Therapy</b>																
Addressable market	267,000	269,670	272,367	275,090	277,841	280,620	283,426	286,260	289,123	292,014	294,934	297,883	300,862	303,671	306,910	
Penetration	Ph1	Ph1	Ph2	Ph2	Ph3	Ph3	BLA	Pricing	0.03%	0.15%	0.30%	0.38%	0.45%	0.54%	0.59%	
Patients								87	438	885	1,117	1,354	1,641	1,823		
Price per course of therapy (\$,000)	\$72	\$72.7	\$73.4	\$74.2	\$74.9	\$75.7	\$76.4	\$77.2	\$78.0	\$78.7	\$79.5	\$80.3	\$81.1	\$81.9	\$82.8	
Revenues								-	6,762	34,492	70,371	89,732	109,842	134,460	150,879	
Royalty Revenues (30%)	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$2,029	\$10,348	\$21,111	\$26,919	\$32,953	\$40,338	\$45,264		
Total Revenues (\$USD for RADx)	\$0	\$0	\$0	\$0	\$4,737	\$20,056	\$47,401	\$103,885	\$204,956	\$317,263	\$409,898	\$477,572	\$549,463	\$606,586	\$672,894	
R&D (\$USD for RADx)	\$15,667	\$15,904	\$15,904	\$16,000	\$16,480	\$14,080	\$14,784	\$13,440	\$3,200	\$2,400	\$1,800	\$1,350	\$0	\$0	\$0	
G&A (\$USD for RADx)	\$8,448	\$8,912	\$8,912	\$9,600	\$9,888	\$10,185	\$10,490	\$10,805	\$11,129	\$8,903	\$7,123	\$5,698	\$5,869	\$6,045	\$6,226	
Total Cash Costs (\$USD for RADx)	\$24,115	\$24,816	\$24,816	\$25,600	\$26,368	\$24,265	\$25,274	\$24,245	\$14,329	\$8,923	\$7,048	\$5,869	\$6,045	\$6,226		
Net Operating Cash Flow to the Firm	-\$24,115	-\$24,816	-\$24,816	-\$25,600	-\$21,631	-\$4,209	\$22,127	\$79,640	\$190,627	\$305,959	\$400,975	\$470,524	\$543,594	\$600,541	\$666,667	
Pre Tax Cash Flow Margin	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	-456.7%	-21.0%	46.7%	76.7%	93.0%	96.4%	97.8%	98.5%	98.9%	99.0%	99.1%	
Taxes								NOL	NOL	NOL	\$76,490	\$100,244	\$117,631	\$135,899	\$150,135	\$166,667
Tax Rate	25.0%	25.0%	25.0%	25.0%	25.0%	25.0%	25.0%	25.0%	25.0%	25.0%	25.0%	25.0%	25.0%	25.0%	25.0%	
Free Cash Flow to the Firm	-\$24,115	-\$24,816	-\$24,816	-\$25,600	-\$21,631	-\$4,209	\$22,127	\$79,640	\$190,627	\$229,470	\$300,732	\$352,893	\$407,696	\$450,406	\$500,000	

## HISTORICAL STOCK PRICE

Radiopharm Theranostics Limited – Share Price Chart<sup>41</sup>



<sup>41</sup> 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 view expressed in this research report accurately reflects 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.