





# QUARTERLY ACTIVITIES AND CASH FLOW REPORT QUARTER ENDED 30 SEPTEMBER 2022

#### **HIGHLIGHTS:**

- Pivalate achieves positive Phase 2a data in brain mets trial
- Joint venture with MD Anderson to develop novel pharmaceuticals
- FDA grants orphan drug status and rare pediatric disease designation for DUNP19 treatment for osteosarcoma
- Entitlement offer raising \$10m
- Strategic agreements with Lantheus and NanoMab
- GenesisCare agreements extended to prostate cancer trial
- Clinical supply agreement announced with SHINE Technologies

Radiopharm Theranostics (ASX:RAD, "Radiopharm" or the "Company"), a developer of a world-class platform of radiopharmaceutical products for both diagnostic and therapeutic uses, is pleased to provide a summary of its activities for the quarter ended 30 September 2022.

#### Pivalate phase II data presented at 34th EORTC/AACR/NCI Symposium in Barcelona

Recently interim data from Imperial College London's F-18 Pivalate phase 2a imaging trial in brain metastases, funded by the Medical Research Council was presented at the 34<sup>th</sup> EORTC/AACR/NCI symposium in Barcelona (26-28 October 2022). It is also expected to be published in a peer-reviewed journal.

The positive Phase 2a data in patients with brain metastases demonstrated that F-18 Pivalate PET showed high uptake regardless of the origin of the primary tumor and can also be used to monitor cerebral metastases.

The Company held an investor webinar on Tuesday 18 October 2022, regarding the positive data. A replay can be viewed at: https://youtu.be/WbkfvOqsbms

Radiopharm holds the exclusive worldwide licence for the Pivalate platform technology and has a Sponsored Research Agreement on new analogues with its inventor Professor Eric Aboagye.

#### Joint venture launched with MD Anderson to develop novel radiopharmaceuticals

In September, Radiopharm and The University of Texas MD Anderson Cancer Center announced the launch of Radiopharm Ventures, LLC, a joint venture company created to develop novel radiopharmaceutical therapeutic products for cancer.

The joint venture brings together Radiopharm's expertise in the development of radiopharmaceutical products and MD Anderson's innovative and proprietary technologies in antigen discovery and molecular imaging. The initial focus of the venture will be on developing at least four therapeutic products based on MD Anderson intellectual products.



The first potential therapeutic candidate is a humanised immunoglobulin G (IgG) antibody against the tumor-specific antigen B7-H3, also known as CD276, which is highly expressed in several common tumors but not in healthy cells. Pre-clinical studies suggest the candidate radiotherapeutic antibody is effective in eliminating resistant colorectal cancers in laboratory models.

### Orphan drug status and rare pediatric disease designation granted by FDA to RAD's DUNP19 for osteosarcoma

Radiopharm announced that the US Food and Drug Administration (FDA) granted Orphan Drug Designation for its DUNP19 technology for the treatment of osteosarcoma, a rare bone cancer that primarily affects children, adolescents and young adults. Currently only surgery and chemotherapy are the only treatments available.

This designation can be granted for a drug or biologic product with the potential to diagnose, prevent or treat rare diseases and conditions. Recipients of this designation are typically entitled to benefits and incentives including tax credits for qualified clinical trials, exemption from user fees and a potential seven years of market exclusivity following the drug's approval.

Later in the quarter the FDA also granted Rare Pediatric Disease (RPD) designation for the Company's DUNP technology. This program is aimed at advancing the development of drugs with the potential to treat serious, rare pediatric diseases.

The designation allows companies to receive a priority review voucher (PRV) from the FDA when a marketing authorization is granted. This can be used to expedite approval or can be sold/transferred to other companies for use in the same manner. The price of two recent examples of PRVs sales have ranged from US\$105m¹ to US\$110m².

#### Institutional and retail entitlement offer to raise \$10m

Following the end of the quarter Radiopharm undertook a capital raising, comprised of an institutional and retail entitlement offer, to raise a total of \$10m. The 1 for 3.55 accelerated non-renounceable entitlement offer was conducted at A\$0.14 per New Share, with participants receiving 1 new option for every New Share issued under the offer (exercise price of A\$0.20, expiry 30 November 2026).

Radiopharm Chairman, Paul Hopper, committed to subscribe for A\$500,000 under the Offer and CEO, Riccardo Canevari, subscribed for approximately A\$170,000.

The capital raising provides the Company with runway until at least the end of FY 2023, including for the three new assets acquired since IPO.

As at 20 October 2022, Radiopharm confirmed the successful completion of the institutional component of the offer, raising approximately \$5.5m. The retail component of the entitlement offer opened on 25 October 2022, with a maximum of approximately \$4.5m to be raised to fill the \$10m overall raise.

Bell Potter Securities Limited has committed to fully underwrite the retail component of the Entitlement Offer of approximately \$4.5m, providing certainty that approximately \$10.0 million will be raised.

<sup>&</sup>lt;sup>1</sup>7 Sep 2021, https://ir.albireopharma.com/news-releases/news-release-details/albireo-sells-priority-review-voucher-prv-105-million <sup>2</sup> 9 Feb 2022, https://investors.biomarin.com/2022-02-09-BioMarin-Sells-Priority-Review-Voucher-for-110-Million#:~:text=SAN%20RAFAEL%2C%20Calif.%2C%20Feb,lump%20sum%20payment%20of%20%24110%2C000%2C000



#### Strategic agreements with Lantheus and NanoMab

In August, Radiopharm announced it had entered into a collaboration agreement with Lantheus for the mutually beneficial development of NM-01, a nanobody made using genetically engineered camelid derived single domain antibodies that can be labelled with radioisotopes for the potential diagnosis and treatment of multiple tumor types.

Lantheus will provide the diagnostic product candidate of NM-01 to Radiopharm for use in therapeutic clinical trials to assess PD-L1 expression during patient selection. Radiopharm and Lantheus will also have the option to expand their collaboration to additional assets and potential licencing opportunities in Radiopharm's pipeline under the agreement.

Separately, in a concurrent agreement, Radiopharm acquired the imaging rights of NM-01 from NanoMab for the strategic Chinese market and worldwide IP rights for any therapeutic use.

#### GenesisCare agreements extended to prostate cancer trial

In July, the Company announced that it had extended its agreement with global oncology provider GenesisCare to support a second Radiopharm clinical trial. The trial will use Radiopharm's PSA targeting antibody to start a therapeutic Phase 1 in prostate cancer, the innovative approach and novel mode of action compared with other treatments currently under development make Radiopharm's technology highly prospective.

With more than 440 locations across Australia, the UK, US and Spain, GenesisCare is a leading provider of integrated oncology care globally.

#### Clinical supply agreement announced with SHINE Technologies for cancer-fighting medical isotope

Late in the quarter, Radiopharm and SHINE Technologies, a next generation fusion technology company, announced a clinical supply agreement where SHINE will supply Radiopharm with isotope non-carrier-added lutetium-177 (Lu-177).

The isotope will be used in Radiopharm's clinical pipeline development of diagnostic and therapeutic radiopharmaceutical products. Lu-177 is an important isotope utilised in multiple programs across the Company's portfolio and is an important step in de-risking its business plan.

#### Ga68-Integrin (RAD301) selected for presentation at EANM

In September, the Company announced with TRIMT GmbH that is Ga68-Integrin (RAD301) was selected for an oral presentation at the 35<sup>th</sup> Annual Congress of the European Association of Nuclear Medicine (EANM).

Dr. Jana Rehm (University Hospital Carl Gustav Carus Dresden, Nuclear Medicine Dpt.) presented "PET/CT and PET/MR imaging with 68Ga-TVH in patients with pancreatic cancer - First clinical experience" within one of the top-rated oral presentation sessions of the Scientific Program of EANM on Tuesday 18 October.

The clinical evaluation of Ga68-Integrin in PDAC by the team of Prof. Dr. Jörg Kotzerke was also selected for the Congress Highlights.



#### NATURE publishes encouraging data on DUNP19 receptors role in cancer growth

In October, the Company announced that Dr. Shannon J. Turley and her team of over 30 scientists published an authoritative analysis of the role of LRRC15 in cancer growth in prestigious scientific journal Nature.

The article demonstrated that key role that TGF $\beta$ -dependent LRRC15+ plays in cancer growth, with LRRC15 proteins on cancer associated fibroblasts showed to be essential for protecting tumour cells from the immune system, and are thus essential for allowing tumours to grow.

Radiopharm's DUNP19 targets LRRC15 on cancer cells and the surrounding fibroblasts.

#### **Financials**

An Appendix 4C Quarterly Cash Flow Report is attached to this announcement.

As detailed in the attached ASX Appendix 4C, the Company had \$21.3 million in cash and equivalents as at 30 September 2022, down from \$27.0 million at 30 June 2022. This will support the Company's activities to progress the clinical trials that are underway.

The net cash used in operating activities during the quarter was \$6.0 million with direct Research and Development expenditure and Staff costs account for over 90% of the operating expenditure.

In accordance with Listing Rule 4.7C, payments made to related parties and their associates included in items 6.1 of the Appendix 4C includes sign on payment, payments for directors' fees and remuneration in the normal course of business at commercial rates, excluding reimbursements of out-of-pocket expenses.

Pursuant to Listing Rule 4.7C.2, the Company confirms that for the period since listing on the ASX, it has incurred expenditure largely in line with the Use of Proceeds set out in its Prospectus, as detailed below.

Use of Funds under Prospectus	Funds allocated under Prospectus	Prospectus Funds to 30 Sep 2022	Actual Funds expended from admission to 30 Sep 2022	Varian	ce
Offer Costs - IPO <sup>1</sup>	\$4,035,282	\$4,035,282	\$3,643,845	\$391,437	10%
License fees1	\$12,760,417	\$12,760,417	\$13,249,949	(\$489,532)	(4%)
Admin/corporate and general working <sup>1</sup>	\$2,835,962	\$1,554,301	\$1,208,204	\$346,097	22%
Employment <sup>1</sup>	\$9,543,591	\$4,874,763	\$4,777,012	\$97,751	2%
Sponsored research agreements <sup>1</sup>	\$3,951,266	\$2,309,958	\$2,191,738	\$118,220	5%
Milestones <sup>1</sup>	\$6,172,980	\$0	\$0	\$0	0%
Phase 1 clinical trials and manufacturing <sup>2</sup>	\$10,700,502	\$5,117,380	\$3,377,059	\$1,740,321	34%
Total	\$50,000,000	\$30,652,101	\$28,447,807	\$2,204,294	7%

<sup>&</sup>lt;sup>1</sup>Costs remain largely In line with expected use of funds.

<sup>&</sup>lt;sup>2</sup> Costs incurred are lower compared to funds allocated under prospectus as a result to lower Manufacturing and Preclinical spending requirements and the payment scheduling.



Expenditure in the above table relates only to the \$50 million raised during the Initial Public Offering and does not include the expenditure of the funds raised during the Convertible Note raise.

Authorised on behalf of the Radiopharm Theranostics board of directors by Chairman Paul Hopper.

#### For more information:

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#### **Follow Radiopharm Theranostics:**

Website – https://radiopharmtheranostics.com/ Twitter – https://twitter.com/TeamRadiopharm Linked In – https://www.linkedin.com/company/radiopharm-theranostics/

### **Appendix 4C**

## Quarterly cash flow report for entities subject to Listing Rule 4.7B

#### Name of entity

Radiopharm Theranostics Limited

## ABN Quarter ended ("current quarter") 57 647 877 889 30 September 2022

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (3 months) \$A'000
1.	Cash flows from operating activities		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(3,203)	(3,203)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(84)	(84)
	(d) leased assets	-	-
	(e) staff costs	(2,252)	(2,252)
	(f) administration and corporate costs	(572)	(572)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	18	18
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	-
1.8	Other – GST refunded	56	56
1.9	Net cash from / (used in) operating activities	(6,037)	(6,037)

2.	Cash flows from investing activities
2.1	Payments to acquire or for:
	(a) entities -
	(b) businesses -
	(c) property, plant and equipment -
	(d) investments -
	(e) intellectual property -

ASX Listing Rules Appendix 4C (17/07/20)

Cons	solidated statement of cash flows	Current quarter \$A'000	Year to date (3 months) \$A'000
	(f) other non-current assets	-	-
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
2.6	Net cash from / (used in) investing activities	-	-

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	-
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	-
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other	-	-
3.10	Net cash from / (used in) financing activities	-	
4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	26,979	26,979
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(6,037)	(6,037)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (3 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	-
4.5	Effect of movement in exchange rates on cash held	396	396
4.6	Cash and cash equivalents at end of period	21,338	21,338

<b>5.</b>	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter \$A'000	Previous quarter \$A'000
5.1	Bank balances	21,338	26,979
5.2	Call deposits		-
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	21,338	26,979

6.	Payments to related parties of the entity and their associates	Current quarter \$A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	860
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
	if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must includ ation for, such payments.	le a description of, and an

In accordance with Listing Rule 4.7C, payments made to related parties and their associates included in items 6.1 of the Appendix 4C includes compensation and director fee related payments in the normal course of business at commercial rates, excluding reimbursements of out-of-pocket expenses.

7.	Financing facilities  Note: the term "facility' includes all forms of financing arrangements available to the entity.  Add notes as necessary for an understanding of the sources of finance available to the entity.	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
7.1	Loan facilities	-	-
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	Total financing facilities	-	-
7.5	Unused financing facilities available at qu	arter end	-
7.6	Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.		
	N/A		

8.	Estimated cash available for future operating activities	\$A'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(6,037)
8.2	Cash and cash equivalents at quarter end (item 4.6)	21,338
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	21,338
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	3.5
	Note: if the entity has reported positive net operating cash flows in item 1.9, answer item figure for the estimated quarters of funding available must be included in item 8.5.	8.5 as "N/A". Otherwise, a

8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:

8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer: N/A

8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer: N/A

8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer: N/A

Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.

#### **Compliance statement**

- This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

Date: 26 October 2022

Authorised by: The Board

(Name of body or officer authorising release – see note 4)

#### **Notes**

- 1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.
- 2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.
- 3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.
- 4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [name of board committee eg Audit and Risk Committee]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".
- If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.



Quarterly Activities & Cash Report and 4C for the quarter ended 30 September 2022



