





# QUARTERLY ACTIVITIES AND CASH FLOW REPORT QUARTER ENDED 30 JUNE 2023

#### Highlights:

- Orphan Drug Designation granted by FDA for Ga68-Trivehexin (RAD 301)
- Successful completion of pre-Investigational New Drug (IND) meeting with the FDA concerning F18-pivalate (RAD 101)
- Supply agreement announced with TerThera for the provision of the isotope Terbium-161 (Tb-161)
- Educational webinar hosted on Pivalate platform technology

**Sydney, Australia – 31 July 2023** – 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 June 2023.

#### **RAD 301 receives FDA Orphan Drug Designation**

In May, Radiopharm announced that the US Food and Drug Administration (FDA) had granted Orphan Drug Designation for Ga68-Trivehexin (RAD 301), a radiopharmaceutical technology for imaging patients with pancreatic ductal adenocarcinoma (PDAC).

Radiopharm is developing Trivehexin as a unique radiopharmaceutical for both imaging and treatment of pancreatic cancer. Trivehexin, a proprietary peptide-based molecule, targets  $\alpha\nu\beta6$ -integrin, a cellular indicator of tumour invasion and metastatic growth. Its expression correlates with decreased survival in several carcinomas, and it is found in high density on most pancreatic carcinoma cells, rendering it a valuable diagnostic and therapeutic target.

The Company currently holds two FDA Orphan Drug Designations, the other being the LRRC15 antibody DUNP19 for treating patients with osteosarcoma. The designation is awarded to a drug or biologic product that has potential to diagnose, prevent, or treat rare diseases and conditions. Those granted the designation receive benefits and incentives such as tax credits for qualifying clinical trials, exemption from user fees, and potential seven-year market exclusivity if the drug is approved.

Radiopharm signed an exclusive licensing agreement with TRIMT GmbH for the development and commercialisation of RAD 301 in the USA, Australia, China, Hong Kong, and Japan.

#### FDA Pre-IND meeting supports an IND application for RAD 101

Radiopharm also announced the completion of a successful pre-Investigational New Drug (IND) meeting with the FDA concerning F18-pivalate (RAD 101), representing a significant milestone towards the IND application for the Company's late-stage clinical trials.

Following positive guidance from the FDA, Radiopharm will file an IND application to commence a multi-centre trial for imaging brain metastasis in Q3 2023, with plans to administer the first patient dose by the end of the year.

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RAD 101 is a proprietary imaging agent made of F18 radioisotope and pivalate, a small molecule that targets fatty acid synthetase. October 2022 saw encouraging data from the Imperial College of London's Phase IIa imaging trial of RAD 101 in patients with brain metastases, showing notable tumour uptake that was consistent with and independent from the tumour of origin, supporting pivalate's potential for monitoring cerebral metastasis.

Radiopharm holds an exclusive global license for the pivalate platform technology and maintains a collaboration with the Imperial College of London to develop a therapeutic candidate that leverages the same mechanism of action.

#### Pivalate (RAD-101) brain glioma imaging study published in prestigious peer reviewed journal

In a media release issued subsequent to the end of the quarter, Radiopharm announced that a report of the first study of F18-Pivalate (RAD 101) PET in patients with glioma was published in the prestigious, peer reviewed European Journal of Nuclear Medicine and Molecular Imaging.

The original article titled <u>"Feasibility of [18F]fluoropivalate hybrid PET/MRI for imaging lower and higher grade glioma: a prospective first-in-patient pilot study"</u> reported RAD 101 data and suggested potential for additional indications in Glioblastoma.

Data presented from ten adult glioma subjects showed significant tumor uptake in high grade gliomas, with safety and tolerability in all patients dosed. The results support further investigation of RAD 101 pivalate for PET/MRI brain tumor imaging in a larger patient population.

#### Agreement with TerThera to supply Terbium-161 isotope

In June, the Company announced a supply agreement with TerThera for the provision of the isotope Terbium-161 (Tb-161). This isotope will be combined with a unique peptide to create RAD 602, a radiotherapeutic agent designed by Radiopharm to target protein tyrosine phosphatase mu (PTP $\mu$ ), a protein primarily found in cancer cells. During Q4 2023 Radiopharm will initiate a Phase I trial of RAD 602 for the treatment of brain cancer patients.

Terbium-161 has been identified as a promising isotope for targeted cancer therapy, due to its radiation characteristics, which include both Auger electrons and short-range beta particles. The isotope's bioequivalence shows promise for comparable biodistribution to existing radiolanthanides and potential superiority over Lutetium-177 (Lu-177), due to its enhanced potency and efficacy in destroying tumour cells while sparing healthy tissue.

The costs of acquiring Tb-161 are not significant to RAD's annual budget and will be covered from existing funds. Preclinical use orders were completed in April 2023, and clinical use orders are expected in October 2023. The supply agreement, effective as of 17 April 2023, spans three years, with a potential two-year extension, unless otherwise agreed.

Radiopharm will retain all data and discoveries from its clinical trials.

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#### **Financial Update**

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

As detailed in the attached Appendix 4C, the Company had \$11.7 million in cash equivalents as at 30 June 2023, decreasing from \$19.3 million at 31 March 2023. 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 \$7.7 million with direct Research and Development expenditure and Staff costs accounting for 87% 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.

Use of Funds under Prospectus	Funds allocated under Prospectus	Funds expected allocation between admission and 30 June 2023	Funds expended between admission and 30 June 2023	Variance	
Offer Costs - IPO1	\$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>2</sup>	\$2,835,962	\$2,363,851	\$4,752,244	(\$2,388,393)	(101%)
Employment <sup>2</sup>	\$9,543,591	\$7,787,690	\$10,284,145	(\$2,496,455)	(32%)
Sponsored research agreements <sup>2</sup>	\$3,951,266	\$3,960,717	\$4,886,800	(\$926,083)	(23%)
Milestones <sup>1</sup>	\$6,172,980	\$0	\$0	\$0	0%
Phase 1 clinical trials and manufacturing <sup>3</sup>	\$10,700,502	\$10,700,502	\$9,663,943	\$1,036,559	10%
Total	\$50,000,000	\$41,608,459	\$46,480,926	(\$4,872,467)	(12%)

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

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 or the November 2022 entitlement offer.

<sup>&</sup>lt;sup>2</sup> Increased expenditure relating to hiring additional employees and engaging in additional corporate and research activities.

<sup>&</sup>lt;sup>3</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.

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#### **Educational webinar**

During the quarter the Company hosted an educational webinar on its Pivalate platform technology for shareholders and interested parties.

Radiopharm CEO and Managing Director Riccardo Canevari provided an overview on the encouraging pre-IND meeting with FDA, Pivalate late-stage development plan and market opportunity.<sup>2</sup>

#### **About Radiopharm Theranostics**

Radiopharm Theranostics is a clinical stage radiotherapeutics company developing a world-class platform of innovative radiopharmaceutical products for diagnostic and therapeutic applications in areas of high unmet medical need. Radiopharm has been listed on ASX (RAD) since November 2021. The company has a pipeline of six distinct and highly differentiated platform technologies spanning peptides, small molecules and monoclonal antibodies for use in cancer, in pre-clinical and clinical stages of development from some of the world's leading universities and institutes. The pipeline has been built based on the potential to be first to market or best in class. The clinical program includes one Phase II and three Phase I trials in a variety of solid tumour cancers including breast, kidney and brain. Learn more at RadiopharmTheranostics.com.

Authorised on behalf of the Radiopharm Theranostics board of directors by Executive 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/

<sup>&</sup>lt;sup>2</sup> The replay can be viewed at: https://youtu.be/e0J7aphfyig

## **Appendix 4C**

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

#### Name of entity

Radiopharm Theranostics Limited

Quarter ended ("current quarter")

### ABN

57 647 877 889 30 June 2023

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (12 months) \$A'000
1.	Cash flows from operating activities		
1.1	Receipts from customers	-	292
1.2	Payments for		
	(a) research and development	(4,585)	(13,371)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(114)	(575)
	(d) leased assets	-	-
	(e) staff costs	(2,062)	(7,858)
	(f) administration and corporate costs	(1,021)	(3,787)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	36	144
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	1,555
1.8	Other – GST refunded	91	397
1.9	Net cash from / (used in) operating activities	(7,655)	(23,203)

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

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (12 months) \$A'000
2.	Cash flows from investing activities		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	(45)
	(d) investments	-	(1,485)
	(e) intellectual property	-	-
	(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	-	(1,530)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	10,073
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	-	(855)
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	-	9,218

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (12 months) \$A'000
4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	19,268	26,979
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(7,655)	(23,203)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	(1,530)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	9,218
4.5	Effect of movement in exchange rates on cash held	86	235
4.6	Cash and cash equivalents at end of period	11,699	11,699

5.	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	11,699	19,268
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)	11,699	19,268

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	452
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 nation 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 quarter 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)	(7,655)
8.2	Cash and cash equivalents at quarter end (item 4.6)	11,699
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	11,699
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	1.5
	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: The Company anticipates maintaining a similar level of net operating cash flows for the time being and management continue to evaluate the use of funds based on available capacity and priorities.

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: The Board believe that the Company can raise sufficient capital on the basis of past success and current interest in the company and its projects. The Board continues to evaluate alternative sources of capital.

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: Yes, the Board expects to be able to continue its operations and to meet its business objectives. The Board believe that the Company can raise sufficient capital on the basis of past success and current interest in the company and its projects. The Board continues to evaluate alternative sources of capital.

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: 31 July 2023

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".
- 5. 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 June 2023



