RAD

RADIOPHARM THERANOSTICS

Quarterly Activities & Cash Report and 4C for the quarter ended 30 September 2023

ASX ANNOUNCEMENT
31 OCTOBER 2023

QUARTERLY ACTIVITIES AND CASH FLOW REPORT
QUARTER ENDED 30 SEPTEMBER 2023

Highlights:

- ***FDA IND for Trivehexin (RAD 301) diagnostic Phase 1 pancreatic clinical trial***
- ***RAD 301 additional data on 33 patients presented at 2023 European Association of Nuclear Medicine Annual Meeting***
- ***Approval received for Phase 1 therapeutic study of PDL1 nanobody in non-small cell lung cancer***
- ***Supply agreement with TerThera expanded***
- ***F18-Pivalate brain glioma imaging study published in prestigious peer reviewed journal***

Sydney, Australia – 31 October 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 September 2023.

Overall, we experienced a very productive third quarter. The Company is continuing its transformation from preclinical to clinical stage with multiple assets. Two clinical trials have started screening patients with pancreatic cancer and non-small cell lung cancer, to assess their eligibility to start dosing. Engagement with FDA is active on multiple fronts, to prepare the next two trials. Several progresses have been made in production of high quality GMP material, that is at the core of our molecules. The Company's pipeline continues to be recognized as one of the most promising in the high potential radiopharmaceutical sector.
Listed below are some of the quarter highlights:

FDA IND for Trivehexin diagnostic Phase 1 pancreatic clinical trial

Subsequent to the end of the period, Radiopharm was pleased to announce that the FDA (Food and Drug Administration) accepted an amended the IND for the production and distribution of 68Ga-Trivehexin (RAD 301) in New York City, USA.

The New York State Board of Pharmacy also approved its distribution across the State. The upcoming Phase I study will evaluate 68Ga-Trivehexin (RAD 301) for the detection of lesions in patients with Pancreatic Ductal Adenocarcinoma (PDAC).

Trivehexin is a peptide-based molecule that targets αvβ6-integrin, a cellular marker for tumour invasion and metastatic growth, the expression of which correlates with decreased survival in several carcinomas. The αvβ6-integrin receptor is found in high density on most pancreatic carcinoma cells, making it an attractive diagnostic and therapeutic target.

The study will be conducted at the Montefiore Medical Center, Albert Eistein College of Medicine, NY, with patient screening commencing October 2023.

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Clinical data presentation for RAD 301 at 2023 European Association of Nuclear Medicine (EANM) Annual Meeting

Radiopharm was pleased to announce an oral presentation at EANM 2023 from Investigator-Initiated Research (IIR) conducted by the Fortis Memorial Research Institute, for clinical data of 68Ga-Trivehexin (RAD 301) for the imaging of Pancreatic Ductal Adenocarcinoma (PDAC) and Head and Neck Squamous Cell Carcinomas (H&N SCCs).

The current imaging standards of care for the detection of PDAC, F-fluoro-deoxy-glucose positron emission tomography (FDG PET), and Magnetic Resonance Imaging (MRI), have significant limitations. This pilot study demonstrated that 68Ga-Trivehexin PET/CT has higher accuracy than F18-FDG PET/CT, in the detection of primary and metastatic lesions in PDAC and H&N SCCs.

The results were presented during an oral session at the 2023 annual EANM congress in Vienna, Austria, highlighting the strong potential for 68Ga-Trivehexin as a promising molecular imaging agent for tumours expressing αvβ6 integrin. Furthermore, these findings serve to strengthen the current data set for Radiopharm's imaging technology for the detection of lesions in patients with PDAC.

Radiopharm has 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.

Approval for Phase 1 therapeutic study of PDL1-nanobody in non-small cell lung cancer

Radiopharm announced it was granted Human Research Ethics Committee (HREC) approval to commence its First-In-Human Phase I study in Australia for the Company's therapy for patients with PDL1-positive non-small cell lung cancer (NSCLC).

The dose escalation trial of RAD204, which targets PDL1-positive NSCLC, is designed to evaluate the safety and efficacy of this novel radiotherapeutic in eligible individuals with lung cancer. The study will be conducted at Princess Alexandra Hospital in Brisbane, Australia, with the support of leading oncology care provider GenesisCare.

The technology underpinning the trial is Radiopharm's proprietary nanobody from its NanoMab platform, which targets the PDL1 expression in NSCLC, the most common type of lung cancer. This is an area of high unmet need and there is potential for the treatment to be the "first in class" radiopharmaceutical therapy targeting PDL1.

Supply agreement expanded with TerThera for Terbium-161 isotope in prostate cancer

Following the initial supply agreement announced in June, Raidopharm announced an expanded supply agreement with TerThera for the provision of the isotope Terbium-161 (Tb-161).

The Tb-161 isotope will be linked to a proprietary monoclonal antibody (mAb) to form RAD 402, a radiotherapeutic that is being developed by Radiopharm to target KLK3 expression. KLK3 is highly expressed in prostate cancer cells but has limited expression in healthy tissue. Radiopharm will initiate a Phase I dose escalating trial evaluating the safety and efficacy of RAD 402 in patients with advanced prostate cancer, during the second half of 2024.

Terbium-161 is a highly promising isotope for targeted cancer treatment due to its unique characteristics of radiation emitted, which includes both Auger electrons and short-range beta particles. The beta radiation travels only a few millimeters and Auger electron emission has a higher linear energy transfer that travels less than the width of a single cell. Tb-161 has shown excellent bioequivalence presenting a biodistribution comparable to currently used radiolanthanides and is potentially superior to Lutetium-177 (Lu-177) due to Auger effect increasing potency and efficacy in selectively destroying tumor cells while leaving surrounding healthy tissue largely unaffected.

The costs associated with the purchase of Tb-161 are not material in relation to RAD's annual budgeted expenditure and will be met from existing funds. The initial order with TerThera is expected to occur during Q4 2023. The effective date of the supply agreement is 28 August 2023 and there are no material preconditions. The supply agreement is for an initial period of 3 years and may be extended for additional two years, unless agreed otherwise by either party. Cancellation provisions are at industry standard rates. Radiopharm will own all data generated and all inventions and discoveries made or conceived from its clinical trials.

F18-Pivalate brain glioma imaging study published in prestigious peer reviewed journal

During the quarter 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 *"Feasibility of [18F]fluoropivalate hybrid PET/MRI for imaging lower and higher grade glioma: a prospective first-in-patient pilot study"* reports new RAD 101 data and suggests 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 tumour imaging in a larger patient population.

RAD 101 is a proprietary radiopharmaceutical imaging agent composed of F18 radioisotope and pivalate, a small molecule that targets fatty acid synthetase. Radiopharm is filing an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) to initiate a multi-center trial for imaging brain metastasis during the third quarter of 2023 and anticipates having the first patient dosed by the end of the year.

Radiopharm holds an exclusive global license for the pivalate platform technology and also has a collaboration in place with Imperial College of London to develop a therapeutic candidate leveraging the same mechanism of action.

Financial Update

The Appendix 4C Quarterly Cash Flow report is set out below.

Closing cash at the end of the quarter was $1.8 million, decreasing from $11.7 million at the end of the prior quarter.

Cash outflows were unusually high during the period with the net cash used in operating activities during the quarter being $9.9 million. Direct Research & Development expenditure and Staff costs accounting for 95% of the operating expenditure in line with expectations.

Included in the Research & Development payments during the quarter were a number of significant expenses totalling ~$3 million, which will not be repeated going forward, including one off and upfront project payments for:

- Pivalate Phase 2b trial tech transfer and site selection
- PDL-1 nanobody Phase 1 trial in Australia
- HER 2 nanobody Phase 1 trial in USA
- GMP CMC production of 3 different mAbs

In accordance with Listing Rule 4.7C disclosure, 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.

The Board has focussed on prudent management of cash and as a result of careful cost cutting strategy, total expenditure will be reduced by ~30% over the remaining nine months of this financial year.

The company has focused expenditure on projects that will deliver company milestones. To preserve available resources operating overheads have been reduced and discretionary expenditure deferred in line with priorities. Going forward the Company is expecting reduced cash burn compared to the two previous quarters (that include several one-off payments). SG&A costs will continue to remain low, as the team is not planning personnel expansion over the remaining nine months of this financial year.

In support of this cost containment strategy, the Chairman and CEO have taken significant deferment of their remuneration and the Board of Directors have also deferred their fees until further notice. One senior executive role has been made redundant since the end of the quarter and we have closed office space and reduced consultants.

As announced today, on 31 October 2023, the Company is undertaking a Rights Issue to raise $10.0 million and coupled with the expected R&D rebate of over $4 million, this places us in a position to execute on our key programs being:

- Phase 1 Trivahexin (Integrin) for pancreatic cancer;
- Phase 2b Pivalate for brain metastasis,
- Phase 1 PDL-1 nanobody for non small cell lung cancer
- Commence HER2 nanobody Phase 1 in bBreast/ gGastric cancer.

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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 expended between admission and 30 September 2023	Variance	
Offer Costs - IPO[1]	$4,035,282	$3,643,845	$391,437	10%
License fees[1]	$12,760,417	$13,249,949	($489,532)	(4%)
Admin/corporate and general working[2]	$2,835,962	$4,886,535	($2,050,573)	(72%)
Employment[2]	$9,543,591	$11,142,670	($1,599,079)	(17%)
Sponsored research agreements[2]	$3,951,266	$5,127,567	($1,176,301)	(30%)
Milestones[3]	$6,172,980	$0	$6,172,980	100%
Phase 1 clinical trials and manufacturing[2]	$10,700,502	$11,949,434	($1,248 ,932)	(12%)
Total	**$50,000,000**	**$50,000,000**	**$0**	**0%**

[1] Costs remain largely In line with expected use of funds.
[2] Increased expenditure relating to hiring additional employees and engaging in additional corporate and research activities.
[3] Costs incurred are lower compared to funds allocated under the prospectus as a result to the reprioritization of the company's programs.

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.

The Company has now applied all the funds raised in the Initial Public Offering largely in line with the Use of Proceeds set out in its Prospectus.

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.

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

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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 2023

Consolidated 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	(6,381)	(6,381)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(90)	(90)
	(d) leased assets	-	-
	(e) staff costs	(2,880)	(2,880)
	(f) administration and corporate costs	(657)	(657)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	34	34
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	106	106
1.9	**Net cash from / (used in) operating activities**	**(9,868)**	**(9,868)**

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 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	-	-
	(d) investments	-	-
	(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**	**-**	**-**

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**	**-**	**-**

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 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	11,699	11,699
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(9,868)	(9,868)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	-
4.5	Effect of movement in exchange rates on cash held	3	3
4.6	**Cash and cash equivalents at end of period**	**1,834**	**1,834**

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	1,834	11,699
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)**	**1,834**	**11,699**

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	648
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.

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)	(9,868)
8.2	Cash and cash equivalents at quarter end (item 4.6)	1,834
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	1,834
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	0.19

Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.

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:

Cash outflows were unusually high during the period with the net cash used in operating activities during the quarter being $9.9 million. Direct Research & Development expenditure and Staff costs accounting for 95% of the operating expenditure in line with expectations.

Included in the Research & Development payments during the quarter were a number of significant expenses totalling ~$3 million, which will not be repeated going forward including one off and upfront project payments for:

- Pivalate Phase 2b trial tech transfer and site selection
- PDL-1 nanobody Phase 1 trial in Australia
- HER 2 nanobody Phase 1 trial in USA
- GMP CMC production of 3 different mAbs

The Board has focussed on prudent management of cash and as a result of careful cost cutting strategy, total expenditure will be reduced by ~30% over the remaining nine months of this financial year.

The company has focused expenditure on projects that will deliver company milestones. To preserve available resources Operating overheads have been reduced and discretionary expenditure deferred in line with priorities. Going forward the Company is expecting reduced cash burn compared to the two previous quarters (that include several one-off payments). SG&A costs will continue to remain low, as the team is not planning personnel expansion over the remaining nine months of this financial year.

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:

As announced on 31 October 2023, the Company is undertaking a Rights Issue to raise $10 million and coupled with the expected R&D rebate of over $4 million, this places us in a position to execute on our key programs being:

- Phase 1 Trivahexin (Integrin) for pancreatic cancer;
- Phase 2b Pivalate for brain metastasis,
- Phase 1 PDL-1 nanobody for non small cell lung cancer
- Commence HER2 nanobody Phase 1 in Breast/ Gastric cancer.

The Directors believe that the Company can raise sufficient capital based on the success of previous capital raises and the continued development of the Company's projects. In addition, the Company has and will continue to employ cash management strategies such as delaying discretionary operating activities.

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 based on the responses detailed in 8.6.1 and 8.6.2.

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

1 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 October 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.

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