

# **September 2021 Activities Report and Appendix 4C**

## **HIGHLIGHTS:**

- Cash balance of \$14.8 million supporting rapid development of multiple cancer programs
- Positive immunogenicity results de-risk OmniCAR ahead of next milestones
- PTX-100Phase 1b trial announced positive safety results with encouraging efficacy signal leading to an expansion study in T cell lymphoma
- Respected global brain cancer expert joins growing Scientific Advisory Board

**MELBOURNE Australia, 28 October 2021** – Prescient Therapeutics Limited (ASX: PTX), today reported its September 2021 quarter results and operating highlights.

The business is in a strong financial position with several anti-cancer programs making timely progress as planned towards multiple value creating milestones.

# Financial update

Prescient ended the quarter with a cash balance of \$14.8 million. Costs for the quarter included investment in ongoing clinical studies of PTX-100 and PTX-200; pre-clinical development of the OmniCAR platform as well as Cell Therapy Enhancements.

Net cash outflows for the quarter were \$1.2 million, with \$0.782 million invested in research and development across Australia and the United States. Payments to related parties and associates (outlined in Section 6.1 of the attached 4C), totaled \$134,000. These payments related to non-executive director fees, salary, superannuation. Prescient maintains a close watch on its cash reserves and operating costs. A strong cash position and prudent financial management provides the foundation for the business to pursue multiple value creating milestones.

## OmniCAR progress: collaboration; manufacturing and immunogenicity testing

During the reporting period, Prescient received positive *in silico* results from immunogenicity testing of OmniCAR's key binding components, SpyTag and SpyCatcher.



Immunogenicity testing evaluates the immune response against a new therapy and the overall safety profile of a new treatment. High levels of immunogenicity can adversely impact CAR-T cell expansion. Results from the tests showed low immunogenicity equal to circulating human antibodies. Prescient is greatly encouraged by these positive results. The results substantially de-risk the platform and open the door to in-house and external collaborations.

# **Cell Therapy Enhancement program**

The Cell Therapy Enhancement (CTE) program under the guidance of a world-leading research team at the Peter MacCallum Cancer Centre in Melbourne, progressed towards a number of important pre-clinical milestones. The nature and outcomes of this work hold significant possibilities for the treatment of cancers by enhancing current generation cell therapy approaches, whilst also being applicabl to next-generation approaches. The CTE work remains undisclosed for competitive reasons, and the Company looks forward to sharing details in due course.

## Targeted therapies continue to make solid clinical progress

Of particular importance during the quarter was the announcement of successful Phase 1b results from the PTX-100 basket trial. PTX-100 exhibited an excellent safety profile, with no serious adverse events related to the drug.

Furthermore, an impressive efficacy signal was observed in two patients with aggressive T cell lymphoma. These patients are typically expected to remain on therapy for 4 months or less, however these patients remained on therapy for 12-17 months. One patient remains on treatment today.

Principal Investigator, Professor Miles H. Prince AM, was greatly encouraged by these responses, given the aggressive nature of their diseases and the failure of up to 7 prior lines of therapy.

PTX-100 will now progress to an expansion cohort study focusing on T cell lymphomas, with a potential for subsequent registration study. Peripheral T cell lymphoma in particular is a cancer of considerable unmet need and represents a potential shorter path to market for PTX-100.

The Phase 1b clinical study of PTX-200 and cytarabine in patients with acute myeloid leukemia is screening patients for a higher dose level of 45 mg/m<sup>2</sup>, although no outcomes were reported during the quarter.



# Scientific Advisory Board welcomes distinguished new member

During the quarter, Professor Donald M. O'Rourke joined Prescient's growing international Scientific Advisory Board. Prof O'Rourke is an acknowledged expert in the treatment of glioblastoma multiforme (GMB), the most aggressive type of brain cancer. Professor O'Rourke is a tenured Professor at the Department of Neurosurgery in the Perlman School of Medicine at the University of Pennsylvania and the Abramson Cancer Centre where he holds the John Templeton Jr MD Chair in Neurosurgery. Prescient is honored to work with Professor O'Rourke and looks forward to working with him to advance the OmniCAR GMB program.

Prescient thanks all shareholders for their support in its effort to bring effective new personalised cancer treatments to clinicians and their patients who need them as soon as possible. The Appendix 4C - Quarterly Cash Flow Report for the quarter is attached.

-Ends -

To stay updated with the latest company news and announcements, <u>please update your</u> <u>details</u> on our investor centre.



#### **About Prescient Therapeutics Limited (Prescient)**

Prescient Therapeutics is a clinical stage oncology company developing personalised medicine approaches to cancer, including targeted and cellular therapies.

#### **Cell Therapies**

OmniCAR: is a universal immune receptor platform enabling controllable T-cell activity and multiantigen targeting with a single cell product. OmniCAR's modular CAR system decouples antigen recognition from the T-cell signalling domain. It is the first universal immune receptor allowing posttranslational covalent loading of binders to T-cells. OmniCAR is based on technology licensed from Penn; the SpyTag/SpyCatcher binding system licensed from Oxford University; and other assets.

The targeting ligand can be administered separately to CAR-T cells, creating on-demand T-cell activity post infusion and enables the CAR-T to be directed to an array of different tumour antigens. OmniCAR provides a method for single-vector, single cell product targeting of multiple antigens simultaneous or sequentially, whilst allowing continual re-arming to generate, regulate and diversify a sustained T-cell response over time.

Prescient is developing OmniCAR programs for next-generation CAR-T therapies for Acute Myeloid Leukemia (AML); Her2+ solid tumours, including breast, ovarian and gastric cancers; and glioblastoma multiforme (GBM).

Cell Therapy Enhancements: Prescient has several other initiatives underway to develop new cell therapy approaches.

#### **Targeted Therapies**

PTX-100 is a first in class compound with the ability to block an important cancer growth enzyme known as geranylgeranyl transferase-1 (GGT-1). It disrupts oncogenic Ras pathways by inhibiting the activation of Rho, Rac and Ral circuits in cancer cells, leading to apoptosis (death) of cancer cells. PTX-100 is believed to be the only GGT-1 inhibitor in the world in clinical development. PTX-100 demonstrated safety and early clinical activity in a previous Phase 1 study and recent PK/PD basket study of hematological and solid malignancies. PTX-100 is now in a Phase 1b expansion cohort study in T cell lymphomas.

PTX-200 is a novel PH domain inhibitor that inhibits an important tumour survival pathway known as Akt, which plays a key role in the development of many cancers, including breast and ovarian cancer, as well as leukemia. Unlike other drug candidates that target Akt inhibition, PTX-200 has a novel mechanism of action that specifically inhibits Akt without non-specific kinase inhibition effects. This highly promising compound has previously generated encouraging Phase 2a data in HER2-negative breast cancer and Phase 1b in recurrent or persistent platinum resistant ovarian cancer, with a Phase 1b/2 trial currently underway in relapsed and refractory AML.

The Board of Prescient Therapeutics Limited has approved the release of this announcement.

Find out more at www.ptxtherapeutics.com or connect with us via Twitter @PTX AUS and LinkedIn.

Steven Yatomi-Clarke CEO & Managing Director **Prescient Therapeutics** 

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#### **Disclaimer and Safe Harbor Statement**

Certain statements made in this document are forward-looking statements within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. These forward-looking statements are not historical facts but rather are based on the current expectations of Prescient Therapeutics Limited ("Prescient" or the "Company"), their estimates, assumptions, and projections about the industry in which Prescient operates. Material referred to in this document that use the words 'estimate', 'project', 'intend', 'expect', 'plan', 'believe', 'guidance', and similar expressions are intended to identify forward-looking statements and should be considered an at-risk statement. These forward-looking statements are not a guarantee of future performance and involve known and unknown risks and uncertainties, some of which are beyond the control of Prescient or which are difficult to predict, which could cause the actual results, performance, or achievements of Prescient to be materially different from those which may be expressed or implied by these statements. These statements are based on our management's current expectations and are subject to a number of uncertainties and risks that could change the results described in the forward-looking statements. Risks and uncertainties include, but are not limited to, general industry conditions and competition, general economic factors, global pandemics and related disruptions, the impact of pharmaceutical industry development and health care legislation in the United States and internationally, and challenges inherent in new product development. In particular, there are substantial risks in drug development including risks that studies fail to achieve an acceptable level of safety and/or efficacy. Investors should be aware that there are no assurances that results will not differ from those projected and Prescient cautions shareholders and prospective shareholders not to place undue reliance on these forwardlooking statements, which reflect the view of Prescient only as of the date of this announcement. Prescient is not under a duty to update any forward-looking statement as a result of new information, future events or otherwise, except as required by law or by any appropriate regulatory authority.

Certain statements contained in this document, including, without limitation, statements containing the words "believes," "plans," "expects," "anticipates," and words of similar import, constitute "forward-looking statements." Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause the actual results, performance or achievements of Prescient to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Such factors include, among others, the following: the risk that our clinical trials will be delayed and not completed on a timely basis; the risk that the results from the clinical trials are not as favourable as we anticipate; the risk that our clinical trials will be more costly than anticipated; and the risk that applicable regulatory authorities may ask for additional data, information or studies to be completed or provided prior to their approval of our products. Given these uncertainties, undue reliance should not be placed on such forward-looking statements. The Company disclaims any obligation to update any such factors or to publicly announce the results of any revisions to any of the forward-looking statements contained herein to reflect future events or developments except as required by law.

This document may not contain all the details and information necessary for you to make a decision or evaluation. Neither this document nor any of its contents may be used for any other purpose without the prior written consent of the Company.

**Supplemental COVID-19 Risk Factors** 

Please see our website : <u>Supplemental COVID-19 Risk Factors</u>

# **Appendix 4C**

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

#### Name of entity

**ABN** 

**Prescient Therapeutics Limited** 

Quarter ended ("current quarter")

56 006 569 106

30 September 2021

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	(782)	(782)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(216)	(216)
	(f) administration and corporate costs	(470)	(470)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	3	3
1.5	Interest and other costs of finance paid	(3)	(3)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	-
1.8	Other (provide details if material)	-	-
1.9	Net cash from / (used in) operating activities	(1,468)	(1,468)

	Cas	sh flows from investing activities	
2.1	Pay	ments to acquire or for:	
	(a)	entities	-
	(b)	businesses	-
	(c)	property, plant and equipment	-
	(d)	investments	-
	(e)	intellectual property	-
	(f)	other non-current assets	-

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (3 months) \$A'000
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)	210	210
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)	(3)
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 (provide details if material)	-	-
3.10	Net cash from / (used in) financing activities	207	207

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	16,097	16,097
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,468)	(1,468)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-

Consolidated 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)	207	207
4.5	Effect of movement in exchange rates on cash held	43	43
4.6	Cash and cash equivalents at end of period	14,879	14,879

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	4,879	6,097
5.2	Call deposits	10,000	10,000
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)	14,879	16,097

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	134
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
Noto: i	fony amounts are aboun in items 6.1 or 6.2 your quarterly activity report must include	lo a description of and an

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.

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
Loan facilities	-	-
Credit standby arrangements	-	-
Other (please specify)	-	-
Total financing facilities	-	-
Unused financing facilities available at qu	arter end	-
Include in the box below a description of each facility above, including the lender, intere 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.		tional financing
	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.  Loan facilities  Credit standby arrangements  Other (please specify)  Total financing facilities  Unused financing facilities available at qualiculate in the box below a description of each rate, maturity date and whether it is secured facilities have been entered into or are proposed.	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.  Loan facilities  Credit standby arrangements  Other (please specify)  Total financing facilities  -  Unused financing facilities available at quarter end  Include in the box below a description of each facility above, including rate, maturity date and whether it is secured or unsecured. If any addifacilities have been entered into or are proposed to be entered into af

8.	Estim	nated cash available for future operating activities	\$A'000	
8.1	Net cash from / (used in) operating activities (item 1.9)		(1,468)	
8.2	Cash a	and cash equivalents at quarter end (item 4.6)	14,879	
8.3	Unuse	ed finance facilities available at quarter end (item 7.5)	-	
8.4	Total a	available funding (item 8.2 + item 8.3)	14,879	
8.5	Estimation 8	ated quarters of funding available (item 8.4 divided by 8.1)	10	
		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?			
	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?			
	8.6.3	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?		
	Note: w	here item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above	e 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: 28 October 2021

Authorised by: 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.