

September 2023 Activities Report and Appendix 4C

Key points:

- Cash balance of \$18.7 million with spending in line with budget
- PTX-100 Phase 1b study nearing completion; data to be reported at major hematology conference in December
- CellPryme pre-clinical data continues to surpass current cell therapy approaches
- Collaboration with Thermo Fisher Scientific yields encouraging results
- Business development meetings with international biotech companies continue

MELBOURNE Australia, 31 October 2023: Prescient Therapeutics (ASX: PTX), a clinical stage oncology company developing personalised therapies for cancer, today reported its Appendix 4C quarterly cash flow statement and accompanying Activities Report for the September 2023 quarter.

Financial summary

Prescient ended the quarter with cash reserves of \$18.7 million (\$21.8 million on 30 June 2023) of which \$16 million was held in term deposits with maturities of between six and 12 months. Net operating expenditure during the quarter was \$3.2 million, in line with budget. A total of \$2.4 million was invested in R&D and clinical development activities.

The business is operating with a cash runway of 5.9 quarters based on net cash used during the quarter, however, Prescient expects the actual cash runway to extend beyond this. Payments to related parties of the entity and their associates amounted to \$175,000 and were directly related to non-executive director fees, executive director salary and superannuation.

PTX-100 Phase 1b trial data to be presented in December 2023

The dedicated clinical research team led by principal investigator, Professor H. Miles Prince AM in Melbourne, Australia, continue to report encouraging results from the ongoing Phase 1b trial of PTX-100 in patients with relapsed and refractory T cell lymphomas (TCL).

Prof Prince and his team continue to see encouraging clinical activity in this difficult-to-treat patient population, with four objective responses, including two patients who experienced complete responses (total eradication of their cancer), as previously reported. Moreover, the durability of these responses to date are robust, with seven of ten evaluable patients, including those with stable disease, having durable responses exceeding those typically seen using standard of care treatments, which is typically 3-4



months. Additional TCL patients have been enrolled in the ongoing Phase 1b trial to help inform subsequent clinical development.

The Phase 1b trial is nearing conclusion and Prescient plans to report the Phase 1b data in December. This will coincide with a presentation of Phase 1b data at a prestigious international haematology conference that will be attended by international pharmaceutical and biotech companies and leading oncologists.

Prescient is currently gathering input from leading TCL key opinion leaders ahead of requesting a meeting with the US Food & Drug Administration (FDA), which Prescient will aim to hold in Q1 2024. The FDA meeting will focus on the design of the Phase 2 trial, including the endpoints, and the potential to use the Phase 2 trial as a registrational study. A registration study could lead to a much shorter and faster pathway to approval and commercialisation, in the event of clinical trial success. Although there are many undefined factors, the study could take 2-3 years. If the trial is not permitted to be a registrational study, then conventional Phase 2 study will still be conducted in line with non-accelerated clinical development.

In parallel, Prescient has initiated the manufacturing of additional PTX-100 drug product to support the planned Phase 2 study, with the commensurate regulatory documentation required of a potential registration study. Prescient's chemistry, manufacturing and control (CMC) resources in the US have been strengthened to undertake this crucial work.

The PTX-200 trial in acute myeloid leukemia (AML) is nearing completion and has progressed slower than desired. The changing landscape of AML treatment, with many new available therapies in recent years, has added created challenges for recruitment to this study. Prescient will seek to recruit a final patient to complete a data package and evaluate any avenues for development of PTX-200 with the Principal Investigator, for example combinations with other new AML agents. In the meantime, minimal resources are being spent on the completion of this study.

CellPryme-M proves to be superior to existing cytokines

In August 2023, Dr Christina Scheffler PhD from the Peter MacCallum Cancer Centre presented the latest developments on CellPryme at the ISCT-ANZ Regional Scientific Meeting in Perth. She showed the highly reproducible results of CellPryme-M and CellPryme-A using Her2 targeting CAR-T cells in immunocompetent syngeneic humanised Her2 mice, which are the workhorse *in vivo* model used by Professor Phil Darcy's group.

Dr Scheffler was able to show that pre-treatment with CellPryme-M could improve the *in vivo* function of CAR-T cells expanded in IL2/7. These outcomes were superior to those achieved by CAR-T cells expanded in IL7/15, which is the current industry standard for promoting enrichment of central memory T cells.



Dr Scheffler was able to demonstrate that the most efficacious outcomes were when CellPryme-M and CellPryme-A were used in combination, which confirms previous study results carried out by Prescient the Peter MacCallum Cancer Centre. The reproducibility of these outcomes confirm that CellPryme is robust and performs predictably regardless of the operator.

Prescient would like to congratulate Dr Scheffler for her Early-Stage Professional award for the ISCT-ANZ regional meeting. This award was given to the top ranked abstracts submitted to the meeting. We would also like to thank Dr Jasmine Li for her contributions to prior CellPryme research and development.

OmniCAR: Thermo Fisher Scientific and Prescient collaboration

In September, Thermo Fisher Scientific (Thermo Fisher) and Prescient presented results of the collaboration using non-viral engineering of CAR-T cells for the development of an enclosed, GMP-compliant manufacturing process. In this collaboration, the objective was to introduce the SpyCatcher CAR construct into the *TRAC* locus, which effectively disrupts the gene expression of *TRAC* thereby enhancing T-cell persistence. Gene-editing was achieved through CRISPR/Cas9, with the introduction of CAR construct using a single-stranded DNA template combined with electroporation rather than viral infection of the human T cells.

The process yielded functional OmniCAR-T cells with high viability (>95%) where tumour killing ability was verified *in vitro* using breast cancer cells and Her2 binders. Notably, stem memory and central memory T cells were retained using this process.

These are extremely encouraging results particularly given that functional testing was performed after the cells were cryopreserved and shipped from the Thermo Fisher site in Singapore, to the Peter MacCallum Cancer Centre in Melbourne for evaluation.

It was demonstrated that the entire process is entirely scalable on Thermo Fisher's closed automated systems for GMP manufacturing. This important work is crucial in the development of processes to enable decentralised manufacturing by third-party manufacturers and will likely improve the cost of goods for OmniCAR.

Prescient thanks Thermo Fisher for its commitment of resources and hopes to explore additional avenues of collaboration in the future. The on-demand webinar can be viewed on Cell & Gene Therapy Insights here.

Driving value amidst sector headwinds

The prolonged downturn of the international biotechnology sector, driven by an adverse macro environment, has been widely reported. In this environment, biotech companies must employ strategies to mitigate risk whilst balancing value-adding development activities and fiscal responsibility.



Prescient is pleased to be in a position where its diversified portfolio comprises more mature clinicalstage assets like PTX-100 with a lower risk profile and a shorter potential path to market; and the capital to progress these assets. Simultaneously, sector challenges can also yield opportunities, and Prescient remains vigilant about initiatives that may add value for shareholders.

Additionally, emerging assets with exciting prospects in Prescient's pipeline can be progressed in a fiscally responsible manner.

CellPryme now has a compelling body of evidence to move towards the clinic, and current activities include creating the regulatory packages to enable integration of CellPryme into cell therapy manufacturing and adjuvant treatments. CellPryme-M in particular has a lower hurdle for integration than many other cell therapy technologies. It is being evaluated by several parties under material transfer agreements, to see how CellPryme works with different cell manufacturing protocols. Management's plan is to continue providing CellPryme to potential customers and collaborators for their testing, and eventually move to a licensing model. Prescient has met with many companies who could be potential users of CellPryme and has learned a lot of the diversity of the problems that these parties are seeking to solve and the opportunities to deploy CellPryme. These companies are in different phases of the development of their own products (from early stage through to commercial) and there is a high degree of variability in their resources; technical complexity of their testing requirements and the expected time to evaluate CellPryme.

The OmniCAR platform is an earlier stage asset that carries higher risk and is expensive to move into the clinic. Industry feedback from many companies continues to indicate enthusiasm for this potentially revolutionary approach, but a paucity of resources to adopt it in this risk-averse environment. As previously reported, rather than advance the internal programs (AML, Her2 and GBM) towards the clinic, which would be a considerable strain on resources, Prescient is taking the opportunity to continue to optimise the OmniCAR platform pre-clinically, including improving safety and control features. This adds value to the OmniCAR platform without the considerable investment required to conduct clinical activities. Prescient maintains the belief that modularity can play a role in transforming the next generation of adoptive cell therapies.

Engagement with international biotech sector

Despite sector challenges, it is crucial to maintain engagement with the industry to increase familiarity with Prescient's assets; to demonstrate progress; and to build relationships with third parties. This is especially important in nurturing relationships with potential partners and collaborators, for when the sector environment becomes more favourable and Prescient's data continue to mature. To this end, Prescient continues to present at and engage companies in selected industry conferences, including International Society of Cell & Gene Therapy; BIO International and more recently, the Cell and Gene



Meeting on the Mesa. Prescient will be participating in the upcoming BIO Europe conference, which is a major industry partnering meeting.

Substantial clinical and development progress to continue

The Company is looking forward to the delivery of a number of important clinical and development milestones in coming quarters, namely the conclusion of the PTX-100 Phase 1b study; confirmation with FDA on the design of the Phase 2 study and Phase 2 initiation. The business has a strong cash position, a world-class research, clinical and commercial team and a valuable, diversified pipeline of cancer therapies producing a growing body of supportive data.

All the team at Prescient remains optimistic, motivated and focused on delivering effective new cancer therapies for people with hard-to-treat cancers.

- Ends -

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

About Prescient Therapeutics Limited (Prescient)

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

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, where it is showing encouraging efficacy and safety. The US FDA has granted PTX-100 Orphan Drug Designation for all 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 is currently in a Phase 1b/2 trial in relapsed and refractory AML, where it has resulted in 4 complete remissions so far. PTX-200 previously generated encouraging Phase 2a data in HER2-negative breast cancer and Phase 1b in recurrent or persistent platinum resistant ovarian cancer.

Cell Therapies

CellPryme-M: Prescient's novel, ready-for-the-clinic, CellPryme-M technology enhances adoptive cell therapy performance by shifting T and NK cells towards a central memory phenotype, improving persistence, and increasing the ability to find and penetrate tumours. CellPryme-M is a 24-hour, non-disruptive process during cell manufacturing. Cell therapies that could benefit from additional productivity in manufacturing or increased potency and durability in-vivo, would be good candidates for CellPryme-M.



CellPryme-A: CellPryme-A is an adjuvant therapy designed to be administered to patients alongside cellular immunotherapy to help them overcome a suppressive tumour microenvironment. CellPryme-A significantly decreases suppressive regulatory T cells; increases expansion of CAR-T cells in vivo; increases tumour penetration of CAR-T cells. CellPryme-A improves tumour killing and host survival of CAR-T cell therapies, and these benefits are even greater when used in conjunction with CellPryme-M pre-treated CAR-T cells.

OmniCAR: is a universal immune receptor platform enabling controllable T-cell activity and multi- antigen 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 post- translational 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. OmniCAR is in pre-clinical development.

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.

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

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

For more information please contact:

Company enquiries
Steven Yatomi-Clarke
CEO & Managing Director
Prescient Therapeutics
steven@ptxtherapeutics.com

Investor enquiries Sophie Bradley Reach Markets +61 450 423 331 ir@reachmarkets.com.au

Media enquiries
Andrew Geddes
CityPR
+61 2 9267 4511
ageddes@citvpublicrelations.com.au



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 quarantee 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 forward-looking statements, which reflect the view of Prescient only as of the date of this announcement. Prescient is not under a duty to update any forwardlooking 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: Supplemental COVID-19 Risk Factors

Appendix 4C

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

Name of entity

Prescient Therapeutics Limited			
ABN Quarter ended ("current quarter")			
56 006 569 106	30 September 2023		

.Cor	nsolidated 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	(2,431)	(2,431)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(271)	(271)
	(f) administration and corporate costs	(532)	(532)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	37	37
1.5	Interest and other costs of finance paid	-	-
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	(3,197)	(3,197)

2.	Cash flows from investing activities	
2.1	Payments to acquire or for:	
	(g) entities	-
	(h) businesses	-
	(i) property, plant and equipment	-

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

.Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (3 months) \$A'000
	(j) investments in term deposits with maturities longer than 3 months at acquisition		
	(k) intellectual property	-	-
	(I) 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	18	18
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 (provide details if material)	-	-
3.10	Net cash from / (used in) financing activities	18	18

Con	solidated 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	5,895	5,895
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,197)	(3,197)
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)	18	18
4.5	Effect of movement in exchange rates on cash held	(8)	(8)
4.6	Cash and cash equivalents at end of period	*2,708	*2,708

^{*} In addition to the cash and cash equivalents balance above as at 30 September 2023, the Company holds an additional \$16 million in term deposits with maturity terms ranged between 6 months and 12 months (30 June 2023: \$16 million), classified in the statement of financial position as short-term investments in accordance with AASB.

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	2,708	1,895
5.2	Call deposits	-	*4,000
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)	**2,708	**5,895

^{*}The call deposits included in item 5.2 above, have maturities ranged between 1 month and 3 months at 30 June 2023.

^{**} In addition to the cash and cash equivalents balance above as at 30 September 2023, the Company holds an additional \$16 million in term deposits with maturity terms ranged between 6 months and 12 months (30 June 2023: \$16 million), classified in the statement of financial position as short-term investments in accordance with AASB.

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	175
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.		

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.		

8.	Estimated cash available for future operating activities	\$A'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(3,197)
8.2	Cash and cash equivalents at quarter end (item 4.6)	2,708
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	*2,708
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	*0.8

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: N/A
 - 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?

Yes, refer to 8.5 for details.

^{*} In addition to the cash and cash equivalents balance noted above at 8.4, the Company holds an additional \$16 million in term deposits, classified in the statement of financial position as short-term investments in accordance with AASB, due to the maturity date being greater than 3 months. As a result, the estimated quarters of funding available will be greater than the figure provided in 8.5 due to holding these additional short-term investments. On a pro-forma basis with the \$16 million included, the Company would have estimated quarters of funding available amounting to 5.9.

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?

Yes, refer to 8.5 for details.

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?

Yes, refer to 8.5 for details.

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 October 2023

Authorised by: By the Board

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

Notes

- 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.
- 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.