

## March 2023 Activities Report and Appendix 4C

### Key points:

- Encouraging clinical results from PTX-100 trial in T Cell Lymphoma patients
- FDA grants Orphan Drug Designation to PTX-100 for all T cell lymphomas
- Strong cash balance of \$19.9 million
- A total of \$4.8 million from exercise of PTXOC options both during and after the reporting period
- Commercial expertise bolstered with global pricing and access specialist
- Ongoing development of next generation OmniCAR platform
- CellPryme being evaluated by potential partners

**MELBOURNE Australia, 28 April 2023** – Prescient Therapeutics (ASX: PTX), a clinical stage oncology company developing personalised therapies for cancer, today reported its March 2023 quarter results and operating highlights.

Prescient continues to make solid progress on all fronts. The very strong results from the company's clinical programs underline its position as an emerging global leader in the next generation of personalised cancer therapies.

### Financial update

The Company ended the March 2023 quarter with a cash balance of \$19.9 million. Immediately following the reporting period an additional \$3.7 million was banked from the exercise of PTXOC options. This took the total amount of funds received from the exercise of options to \$4.8 million, with over 97% of options exercised. The Company thanks its shareholders for their support. This provides the business with the financial security to continue to execute and deliver on its clinical and business development programs.

Costs for the quarter included manufacturing and clinical trial support costs for PTX-100 and PTX-200 as well as the ongoing development of the OmniCAR platform.

Cash outflows for the quarter were \$2.2 million, of which \$1.5 million was ongoing research and development.



Payments during the quarter to related parties of the entity and their associates amounted to \$284,000 and were directly related to non-executive director fees, executive director salary and superannuation.

Prescient continues to progress its valuable portfolio of cancer therapies in a planned and disciplined manner whilst managing finances responsibly.

### **PTX-100 encouraging clinical progress**

First-in-class targeted therapy, PTX-100, continues to demonstrate encouraging activity as the program builds clinical and regulatory momentum.

The highlight of the March 2023 quarter was continued encouraging clinical results from the ongoing Phase 1b of PTX-100 trial led by world-renowned cancer specialist and Principal Investigator, Professor H. Miles Prince AM in Melbourne, Australia. The trial of PTX-100 involves patients with relapsed and refractory T cell lymphomas (TCLs), a very hard to treat cancer representing unmet clinical need.

In a clinical trial update provided during the quarter, Prescient reported an excellent safety profile, with very few serious adverse events. Prescient also reported a robust response rate from evaluable patients so far, including two patients who experienced a total eradication of their cancer. Additionally, 7 of 10 evaluable patients had durations of response exceeding standard of care. Such good results are not generally expected with this disease or in an early Phase 1b trial aimed at confirming safety.

Prescient and the investigators are encouraged by these highly promising outcomes. While the expanded cohort of patients with TCL has met its minimum enrolment, the study will be extended to create a more robust data package for interactions with regulatory bodies.

Also in March, PTX-100 received Orphan Drug Designation from the US FDA for the treatment of all TCLs. This designation granted by the FDA is broader than requested by Prescient and underscores the importance of developing more effective therapies for this patient population.

The Prescient team is now working to schedule a Phase 2 trial in the same patient population and will seek Accelerated Approval with the US FDA in an orphan indication. If this is granted, Accelerated Approval could pave the way for the Phase 2 trial to be the study enabling expedited regulatory approval of PTX-100. If Accelerated Approval is not granted, the Phase 2 trial will proceed as per conventional drug development pathways. An additional manufacturing campaign of PTX-100 has commenced to support the Phase 2 study.



Prescient looks forward to reporting on further progress of this highly promising and important program in the coming months.

The Phase 1b trial of PTX-200 and cytarabine in relapsed and refractory AML is actively recruiting, following intermittent institutional disruptions beyond Prescient's control. The trial has yielded four patients with complete remissions and another with a partial remission so far. After decades without innovation, the landscape for AML treatments has changed drastically in recent years, with new therapies being used in different combinations with existing therapies. Following completion of this study, Prescient will determine, in consultation with the Principal Investigator, Professor Jeff Lancet, what next steps will look like, including use of cytarabine.

### **Commercial expertise bolstered**

Prescient is pleased to announce that it has appointed global pricing expert Mr Ed Schoonveld as advisor for global commercial, pricing and access. Mr Schoonveld will assist Prescient in guiding its commercial strategy for PTX-100 in particular as the program matures to incorporate considerations pertaining to commercial opportunities for various indications, competitive landscapes, label claims, patient access for various lines of therapy and potential pricing considerations.

Mr Schoonveld is a global authority on pricing and health economics having authored the definitive reference book on global pricing and market access that has been used widely in the pharmaceutical industry for over a decade. Mr Schoonveld has advised leading global pharmaceutical companies including Wyeth, Eli Lilly and BMS on market access strategies, global pricing policies, clinical trial designs and internal organisational and process challenges.

Adding a professional of Mr Schoonveld's calibre and experience to the Prescient team comes at a very important time for the Company as a crucial inflexion point for PTX-100 draws closer, and the Company must now make strategic decisions normally reserved for pharmaceutical companies and commercial stage biotechs.

Whilst the nature of biotechnology drug development necessarily focusses on scientific and clinical aspects, Prescient must now sharpen its focus on other strategic inputs, including commercial considerations, pricing and patient access. This is crucial in planning for success, and Mr Schoonveld's experience and insights in guiding other drugs to commercial success will be very valuable indeed.



### Ongoing progress of next generation OmniCAR platform

While much of the focus this quarter has been on PTX-100, ongoing development on the OmniCAR platform continued during the quarter, particularly in the AML and Her2 programs. OmniCAR is a next-generation, universal Chimeric Antigen Receptor (CAR) platform that is controllable, with “plug and play” capabilities to enable a wider range of cancers to be targeted. These features seek to give clinicians greater control and targeting of a wider range of cancer tumours compared to the CAR-T treatments currently in use and under development.

OmniCAR is at the forefront of cell therapy innovation and is built on decades of clinical testing and evidence by many of the world’s leading medical researchers. There is strong interest among cancer specialists seeking ways to overcome the obvious limits of current CAR-T therapies and the urgent need for effective new treatments.

During the quarter, OmniCAR continued its progress towards first in human trials. The variables in a controllable, modular CAR-T system are substantial, including pharmacokinetics of the binder, and the optimum dosing schedules and relative and absolute amounts of OmniCAR-T cells, binders, and pre-arming. Prescient is rigourously and systematically investigating these variables.

The macroeconomic headwinds facing biotechnology worldwide have hit cell therapy developers particularly hard. Investors have demonstrated a diminished risk appetite and aversion to the expensive clinical studies that cell therapies require. There is also a lack of enthusiasm for undifferentiated and overlapping programs, and whilst OmniCAR clearly stands out from its peers in this regard, it is not immune to the broader sector sentiment. Similarly, cell therapy companies in US and Europe continue to trim their own development pipelines and continue to lay off a considerable proportion of their workforces.

From a business development perspective, this has naturally created a challenge to the adoption of OmniCAR by potential partners that were otherwise eager to evaluate OmniCAR to create next generation pipeline assets. Pleasingly, as the development of OmniCAR continues to unfold, it nevertheless continues to generate increasing interest as a solution for overcoming key limitations of existing cell therapies – namely post-infusion control, antigen multivalence and redirection, and the ability enhance the various types of immune cells being investigated as cell therapies.



Prescient is in the fortunate position to have a robust cash balance and believes that it is prudent to conserve these reserves, whilst the market remains uncertain as to when negative sector sentiment may turn. Advancing this novel platform into a first in human clinical trial will be extremely expensive to conduct and will expend the Company's cash reserves quickly, especially alongside a Phase 2 PTX-100 trial. Instead, Prescient is taking the opportunity to further optimize the OmniCAR platform pre-clinically, incorporating feedback from potential partners and the latest and most robust developments in cell therapy, including gene editing.

Advancing OmniCAR in this responsible manner will position the platform favourably for when the broader cell therapy sector regains momentum. This strikes a sustainable balance between fiscal responsibility, whilst adding real value to the exciting OmniCAR platform.

### **CellPryme ready to enhance current and future cell therapy treatments**

While current generation and emerging cell therapies have shown great progress, their wider use is limited by several well-documented issues, including limitations with durability and efficacy. Prescient's CellPryme platform was created to directly address these limitations.

In the short time since its unveiling, CellPryme's data has made a strong impression with many cell therapy developers. The cost-effective nature of CellPryme, and its ability to be incorporated into third party programs relatively easily, has attracted interest even in this cautious environment.

Prescient is pleased to report that CellPryme is currently being evaluated by several external parties to enhance their own cell therapy programs. Such evaluations may lead to commercial arrangements for CellPryme.

Prescient has an active business development program and will continue to present to several high profile industry conferences in coming months with the goal of raising awareness among the global cell therapy industry, research institutions and potential commercial partners.

During the reporting period, an international trademark was granted for CellPryme, which combines with Prescient's patent applications to protect and add value to CellPryme. As a product on the cusp of commercialisation and with brand potential, this trademark is very valuable for CellPryme.



## Solid progress set to continue

With a deep pipeline of valuable next generation cancer therapies backed by a growing body of positive clinical evidence and a healthy cash balance, Prescient is well positioned to become a global leader in the next generation targeted and cellular therapies.

The company remains focused on making the most of its valuable assets, collaborations and partnerships for shareholders, medical professionals and their patients with hard-to-treat cancers.

– Ends –

To stay updated with the latest company news and announcements, [please update your details](#) 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.

### 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

**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.

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).

**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.

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

Find out more at [www.ptxtherapeutics.com](http://www.ptxtherapeutics.com) or connect with us via Twitter [@PTX\\_AUS](https://twitter.com/PTX_AUS) and [LinkedIn](https://www.linkedin.com/company/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, securing adequate funding for Prescient and its operations, 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 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 and/or scientific studies will be delayed and not completed on a timely basis; the risk that the results from the clinical trials and/or scientific studies are not as favourable as we anticipate; do not work at all, or have unacceptable safety issues; the risk that our clinical trials and/or scientific studies will be more costly than anticipated; the risk that Prescient may not secure adequate funding to pursue its business plans; the risk that Prescient's business plans may change due to commercial, scientific or other reasons; 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**

56 006 569 106

**Quarter ended ("current quarter")**

31 March 2023

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (9 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(1,462)	(3,868)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs	(381)	(884)
(f) administration and corporate costs	(397)	(1,306)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	135	214
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	1,691
1.8 Other (provide details if material)	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(2,105)</b>	<b>(4,153)</b>
<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire or for:		
(g) entities	-	-
(h) businesses	-	-
(i) property, plant and equipment	-	-
(j) investments	-	-

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (9 months) \$A'000
(k) intellectual property	-	-
(l) 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)	-	-
<b>2.6 Net cash from / (used in) investing activities</b>	<b>-</b>	<b>-</b>
<b>3. Cash flows from financing activities</b>		
3.1 Proceeds from issues of equity securities (excluding convertible debt securities)	-	11,296
3.2 Proceeds from issue of convertible debt securities	-	-
3.3 Proceeds from exercise of options	1,129	1,250
3.4 Transaction costs related to issues of equity securities or convertible debt securities	-	(685)
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)	-	-
<b>3.10 Net cash from / (used in) financing activities</b>	<b>1,129</b>	<b>11,861</b>
<b>4. Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1 Cash and cash equivalents at beginning of period	20,952	12,264
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(2,105)	(4,153)

Appendix 4C  
Quarterly cash flow report for entities subject to Listing Rule 4.7B

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (9 months) \$A'000</b>
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)	1,129	11,861
4.5	Effect of movement in exchange rates on cash held	(5)	(1)
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>19,971</b>	<b>19,971</b>

<b>5.</b>	<b>Reconciliation of cash and cash equivalents</b> at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	<b>Current quarter \$A'000</b>	<b>Previous quarter \$A'000</b>
5.1	Bank balances	7,971	6,952
5.2	Call deposits	12,000	14,000
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>19,971</b>	<b>20,952</b>

<b>6.</b>	<b>Payments to related parties of the entity and their associates</b>	<b>Current quarter \$A'000</b>
6.1	Aggregate amount of payments to related parties and their associates included in item 1	284
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. <b>Financing facilities</b> <i>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.</i>	<b>Total facility amount at quarter end \$A'000</b>	<b>Amount drawn at quarter end \$A'000</b>
7.1 Loan facilities	-	-
7.2 Credit standby arrangements	-	-
7.3 Other (please specify)	-	-
7.4 <b>Total financing facilities</b>	-	-
7.5 <b>Unused financing facilities available at quarter end</b>		-
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. <b>Estimated cash available for future operating activities</b>	<b>\$A'000</b>
8.1 Net cash from / (used in) operating activities (item 1.9)	(2,105)
8.2 Cash and cash equivalents at quarter end (item 4.6)	19,971
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	19,971
8.5 <b>Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	<b>9.49</b>
<i>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.</i>	
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?	
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 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?	
<i>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.</i>	

## 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: 28 April 2023

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".
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.