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Prescient Therapeutics

On the cusp of value creation

Share Price: $0.045

ASX: PTX

Sector: Healthcare

7 March 2024

ASX-listed oncology drug developer Prescient Therapeutics (ASX:PTX) is set for major milestones in the months ahead. The company has several platforms and products in its portfolio, led by PTX-100, which is targeting T-Cell Lymphoma. The company also has two cell therapy platform technologies: CellPryme, which allows enhances adoptive cell therapy performance; and OmniCAR, which allows next-generation cell therapy) products to be developed.

PTX-100 closer to creating value

In our initiation report, we noted that PTX-100 was the most advanced asset the company has. Preliminary Phase 1 data has been encouraging, and was presented at the prestigious ASH meeting in December. This is not just because of the efficacy results and its safety profile, but also given the current lack of treatment options for T-Cell Lymphomas, the dire outlook for those diagnosed with it and clinical data to date, the company's prospects if and when it can take it to market are bright. In fact, even though it has only completed Phase 1, there is potential for this product to gain FDA approval after Phase 2, which PTX plans to initiate before the end of CY24.

CellPryme and OmniCAR development continues

While CellPryme and OmniCAR, are not as developed as PTX-100, these also represent improvements on existing CAR-T technologies and appetising commercial opportunities if and when the company can commercialise them. They are not CAR-T therapies in their own right, but (for reasons which we will come to in this report) can improve CAR-T efficacy when used in combination with them.

Valuation range of 11.6-16.3c per share

We reiterate our valuation PTX as outlined in last November's initiation report, at 11.6c per share base case and 16.3c per share in an optimistic (or bull) case using a Sum of the Parts/DCF methodology.

The key catalysts for the creation of shareholder value in the near-term will be final Phase 1 data and the initiation of Phase 2 data for PTX-100. Please see p.8 for an outline of our valuation rationale and p.9 for the key risks.

Market Cap. (A$ m)	36.2
# shares outstanding (m)	805.3
# shares fully diluted (m)	837.2
Market Cap Ful. Dil. (A$ m)	37.7
Free Float	100%
52-week high/low (C$)	0.30 / 0.053
Avg. 12M daily volume ('1000)	813.5
Website	https://ptxtherapeutics.com

Source: Company, Pitt Street Research

Share price (A$) and avg. daily volume (k, r.h.s.)

Source: Refinitiv Eikon, Pitt Street Research

Valuation metrics	
DCF fair valuation range (A$c)	11.6-16.3
WACC	16.2%
Assumed terminal growth rate	None

Source: Pitt Street Research

Analysts: Stuart Roberts, Nicholas Sundich

Tel: +61 (0)447 247 909

stuart.roberts@pittstreetresearch.com

nick.sundich@pittstreetresearch.com

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Re-Introduction to Prescient Therapeutics and its portfolio of products

Prescient Therapeutics is a biotech company focusing on cancers with unmet needs technologies.

Prescient Therapeutics (ASX: PTX) has a portfolio of assets with outstandinf scientific pedigree, comprising target and cell therapy technologies

PTX-100

PTX-100 is the most advanced asset PTX has, with Phase 1 enrolment completed and preliminary Phase 1 data presented at the world's largest hematology conference, the American Society of Hematology Meeting, in the US in December (Figure 1). A Phase 2 study will potentially be underway by the end of CY24. It is an intravenously administered drug that works by blocking the GGTase I enzyme, a course of action that can cause cancer cells to undergo apoptosis, or die.

PTX picked up this drug in 2014, was granted Orphan Drug Designation by the US FDA in July 2022 for Peripheral T-Cell Lymphoma and for all T-Cell Lymphomas in March 2023. Between 2019 and 2021, a Phase 1 study was undertaken as a dose escalation study in a variety of tumour types. Because a clinical signal was seen in T-Cell Lymphoma, this has been PTX's focus ever since. The data to date is encouraging, with responses observed in patients who had undergone multiple failed prior treatments.

T-Cell Lymphoma is a rare but aggressive cancer with a low survival rate. While only around 5,000-6,000 people a year will be diagnosed with a T-Cell Lymphoma in the US the market opportunity could be in the billions, if Acrotech Biopharma's Folotyn with its $842,585 per patient per year price tag is any guide.

Phase 1b results with PTX-100 were strongly encouraging

Since our initiation report last November, the company released preliminary Phase 1b data and the results were strongly encouraging. Being Phase 1, the study's primary objectives were to demonstrate safety as well as to determine pharmacokinetics (PK) and pharmacodynamics (PD) – which allude to the drug's interaction and effects on the body of the dose receptor. These endpoints were successfully met – there were no drug-related SAEs (Serious Adverse Events). Early-stage efficacy results were also measured and were very encouraging (Figure 1).

Figure 1: Phase 1 data interim results

	Overall Response Rate CR + PR	Clinical Benefit Rate CR + PR + SD>6months
Benchmark[1]	30%	45%
r/r PTCL (n=4)	50% (2/4)	50% (2/4)
r/r CTCL (n=5)	40% (2/5)	80% (4/5)
r/r TCL (n=9)	44% (4/9)	66% (6/9)

Source: Company

Nine of the 25 patients were eligible for assessment. Four patients saw clinical responses, two of which experienced complete eradication of the disease, representing an overall response rate (ORR) of 44%. A further two patients saw Stable Disease (SD) for over 6 months, thus representing a Clinical Benefit Rate (CBR) of 66%. This is very promising for a disease as deadly as T-Cell Lymphoma. Where PTX is headed to next with PTX-100 will be outlined in the next section of the report.

Clever exposure to the emerging cell therapy sector

CAR-T cell therapy is a novel scientific approach that utilises the body's own immune system to fight cancer.

CellPryme and OmniCAR are both CAR-T cell therapy technologies. Before we outline how these work, it is important to outline what CAR-T cell therapy is. CAR-T is a therapeutic approach that utilises the body's own immune system to fight cancer (specifically the T-cells). It works by extracting T-cells from the patient's blood and then genetically engineering them to produce 'Chimeric Antigen Receptors' on their surface which directs a T-cell response to that specific cancer antigen. Subsequently, the patient receives the CAR-T cell therapy in an infusion that can target and destroy cancer cells.

As outlined in greater detail in our initiation report, CAR-T is growing in popularity as a cancer treatment option, because of its effectiveness, but is confronting many challenges that are inhibiting broader adoption, including safety, expensive and cumbersome cell manufacturing, logistics, emerging cell types and targets, and a lack of control of these "living medicines" once they are infused.

Both CellPryme and OmniCAR are complementary platforms that enhance cell therapies, providing investors with a clever exposure to the cell therapy space as this nascent sector continues to emerge and evolve.

CellPryme also represents a major opportunity

CellPryme consists of two complementary CellPryme applications: CellPryme-M (for manufacturing use) and CellPryme-A (for adjuvant use). Adding CellPryme in either (or both) of these settings enhances the cancer killing activity of third-party cell therapies.

CellPryme-M is designed to improve the performance of whatever CAR-T cell therapy employs it by making more 'youthful' cells, that live longer and kill cancer cells for longer. It does so by shifting T and NK cells towards a central memory phenotype, improving persistence, and increasing the ability to find and penetrate tumours.

CellPryme-A is given to the patient alongside cell therapies, and boosts the proliferation of CAR-T cells in the body; overcomes a suppressive tumour microenvironment and increases CAR-T penetration into tumours. Both CellPryme formats are concluding pre-clinical testing and are ready for clinical development. They would be attractive to third parties to incorporate into their own cell therapy development programs, something that could be a further value creation opportunity for the company.

OmniCAR: next-gen, controllable cell therapies

OmniCAR is a pre-clinical platform that is seeking to revolutionise cell therapy by modularising them, thus making them controllable and flexible. It represents a further improvement because it can target multiple antigens and it could not only start an anti-cancer immune response, but stop it and then restart if desired.

OmniCAR is a universal immune receptor platform and a molecular binding system. It was in-licensed by Prescient in 2020 from the University of Pennsylvania and Oxford University. OmniCAR enables controllable T-cell activity and multiantigen targeting with a single cell product and thereby leads to stronger treatment outcomes when used in CAR-T therapy, overcoming the two problems mentioned above, among other benefits. Importantly, PTX's platform is useful not just in CAR-T but in other adoptive cell therapies such as CAR-NK, and so on.

Prescient is progressing pre-clinical development of the OmniCAR platform, seeking to optimise and re-engineer various features. Commercialisation of OmniCAR against any cancer is longer away than PTX-100 – realistically at least 5 years barring any pre-clinical deals that could occur in the next 1-2 years. Nonetheless, there is potential for shareholder value to be created through the achievement of development milestones.

PTX-200

PTX-200 is another intravenous anti-cancer drug that works as a so-called AKT inhibitor that is targeting AML. PTX-200 is an Orphan Drug in AML, having obtained that status in May 2017. However, this drug is non-core for PTX right now, given that nearly a dozen drugs have been approved by the FDA against AML in the last nearly 7 years. Prescient is concluding this study and reviewing its ongoing development.

Catalysts for the creation of shareholder value are coming up

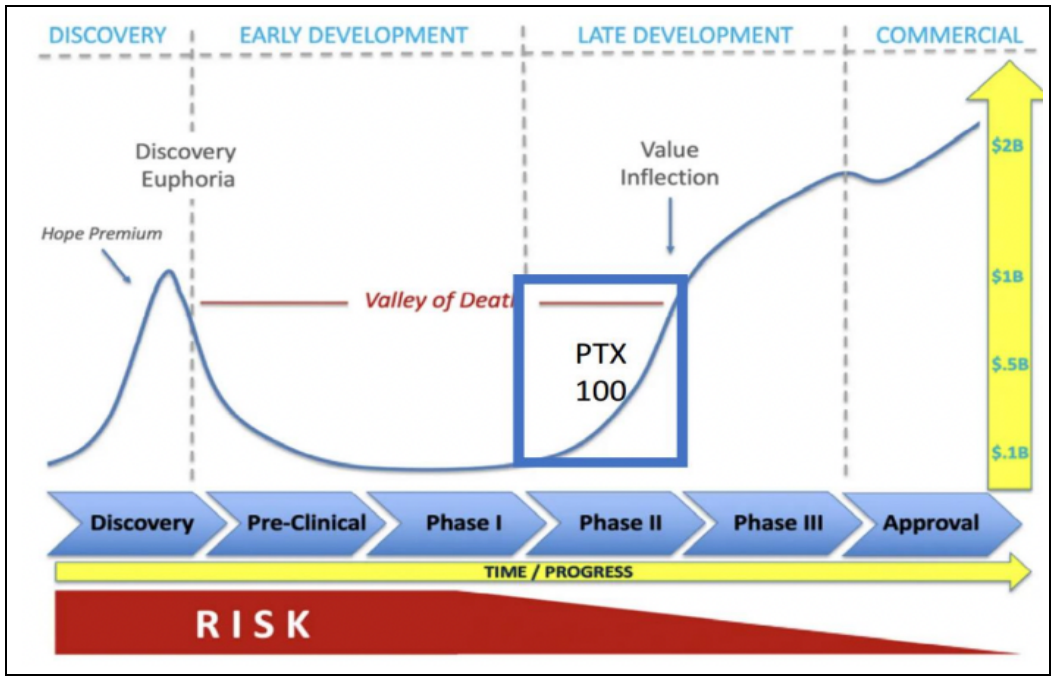
PTX-100 is key

Even though commercialisation of any of PTX's assets is a few years away, there is potential for shareholder value creation in the near-term, especially with PTX-100. PTX is planning a Phase 2 trial to commence before the end of this year. This is possible given the data in Phase 1b passed the necessary thresholds. PTX will meet with the FDA in the June quarter this year to discuss the Phase 2 trial design and the potential for it to be an Accelerated Approval Study. This would mean, subject to successful data, PTX-100 could be submitted for FDA approval if and when it passed this study without the need for a Phase 3 study.

PTX-100 could potentially be commercialised in as little as 3 years from now.

Assuming success, commercialisation could occur in as little as 3-4 years from now, if Phase 2 initiation happened by the end of this calendar year and that it takes another 2 years to complete the study and read out the data. PTX is also expanding the current trial to create a more robust regulatory package. Even if the company had to undertake a Phase 3 study thereafter, successful results in Phase 2 would inevitably lead to a re-rate. In the shorter term, we expect guidance from the FDA as to what clinical data is required, as well as commencement of the Phase 2 trial to be catalysts for the creation of shareholder value. It is rare for ASX companies to pass Phase 2 or reach Phase 3 – if PTX achieved this, there would be no shortage of investors with this company on their radar screens. In fact, it would be big for the entire biotech sector on the ASX (Figure 2).

Figure 2: Biotech Value Map



Source: Company

Orphan drugs have huge potential

Any drug passing through later clinical stages can create value for shareholders, assuming of course it happens successfully. This is particularly true with PTX-100, for two reasons. First, because of the efficacy data at Phase 1b that is remarkable for a disease like TCL. Second, because PTX-100 is an orphan drug – a drug that treats a disease affecting a relatively small number of people in a population[1]. Developers of orphan drugs are able to obtain substantial benefits that non-orphan drug developers get including tax credits, long-term periods of market exclusivity and even waiving of certain fees.

Orphan Drugs can also fetch premium prices (several hundreds of thousands of dollars for example), and this is often reflected in the valuation of companies. One example Horizon Therapeutics – it has Tepezza, the only approved treatment for thyroid eye disease, and was bought by Amgen's in October 2023 for a staggering US$27.8bn. This followed over $3.5bn in sales in the first two full years on the market (2021 and 2022). A figure of US$27.8bn might be too high for PTX at this stage.

Nonetheless, it is not unreasonable to imagine there could be M&A or partnering interest for this drug – the latter could occur even prior to commercialisation. Consider that Neuren Pharmaceuticals (ASX:NEU) tripled in value to ~$2.6bn in CY23 after a partnering deal and commercialisation for its Rett-syndrome treatment during that year. This occurred following its FDA approval, although Dimerix (ASX:DXB) depicts that it is not impossible for deals to be struck prior to approval and even during Phase 3. Such a deal would not only facilitate royalties on sales, but likely provide for payment of certain R&D and commercialisation costs as well as potential upfront payments that could help fund development of OmniCar and CellPryme. Neuren's initial payment, received in July last year, was US$100m.

Other potential developments

PTX is also progressing work with CellPryme and OmniCAR. In particular, the company is nearing completion of pre-clinical development of CellPryme and is preparing regulatory packages for both CellPryme-M and CellPryme-A so that these may enter the clinic in due course. The advantage of these platforms is that they can integrate easily into partner programs without highly disruptive changes to manufacturing processes or protocols mid-stream.

PTX is progressing platform optimisation of OmniCAR to investigate unarmed T-cell activity and improving control features. As a unique and multi-modal platform, this program is involving domain experts across protein and cell engineering and other areas.

[1] The threshold in the US is less than 200,000 people

Our valuation of PTX

We value PTX at 11.6c per share in our base case and 16.3c per share in our bull case.

We reiterate our valuation of PTX from our initiation report. Using a Sum of the Parts rationale (with 2 risk-adjusted DCFs for PTX-100 and CellPryme), we have valued PTX at 11.6c per share in our base case and 16.3c per share in our bull case (Figure 3). Our total valuation of PTX is the sum of the NPV of PTX-100 and CellPryme as well as the company's net cash position (worth 0.7c per share). Our assumptions are summarised in Figure 4.

Figure 3: Our valuation of PTX

Sum of the Parts Valuation	Base Case		Bull case	
Drugs	**A$m**	**A$ps**	**A$m**	**A$ps**
PTX-100	57.65	0.072	81.71	0.101
CellPryme	27.06	0.034	39.91	0.050
rNPV	**84.70**	**0.105**	**121.62**	**0.151**
Cash (close of FY23)	5.89543	0.007	5.89543	0.007
Debt (close of FY23)	-	-	-	-
Equity Value	**90.60**	**0.113**	**127.52**	**0.158**
Current Price		0.045		0.045
Upside		150%		252%

Estimates: Pitt Street Research

Figure 4: Our key DCF assumptions

DCF Assumptions (Base case)	PTX-100	CellPryme
Launch	CY28	CY31
Estimate market size (patient numbers)	5,500	242,100
Growth	2%	1%
Potential market penetration	50%	1%
Realised price (US$)	450,000	450,000
Peak sales (US$m)	2,595	3,528
Peak royalty revenue (US$m)	519	706
Gross milestone revenue (US$m)	75	40
Commercial exclusivity period (years)	10	7
Drug development cost (US$m)	40	58
Partner's share of costs	50.0%	50.0%
Discount rate	16.2%	16.2%
Royalty rate	20.0%	20.0%
Tax rate	21.0%	21.0%
Probability of success	30.00%	15.00%
Risk-adjusted NPV (A$m) - base case	60.52	27.06
rNPV per share (A$) - base case	0.075	0.034

Estimates: Pitt Street Research

Prescient Therapeutics had a market capitalisation on ASX of less than $50m, which is only US$32m. Whatever currency you use, we think the current market capitalisation of Prescient does not begin to take account of the way in which clinical success with PTX-100 in T-Cell Lymphoma can yield a marketed drug in only around three years, where that drug's market opportunity is at least in the hundreds of millions.

Key risks facing PTX

Risks specific to PTX. We see the following major risks for PTX:

- **Timing risk.** There is the risk that the company's products may take longer than expected to move through the clinic.
- **Technical risk.** Some of the technologies that PTX is working with are relatively new and therefore may not therefore be 'bug-free'.
- **Regulatory risk**. There is the risk that regulators may decline to approve PTX products, even if PTX considers the data submitted to be adequate.
- **Commercial risk**. There is the risk that PTX may fail to find commercial partners for its products.
- **Uptake risk**. There is the risk that PTX products are still too expensive in the healthcare markets in which it wants to participate.
- **Funding risk**. There is the risk of future capital raisings proving dilutive to existing shareholders.
- **Key personnel risk**. There is the risk that the company may lose key personnel and be unable to replace them and/or their contribution to the business.

Appendix I – Glossary

Acute Myeloid Leukemia (AML) – A blood cancer characterised by proliferation and accumulation of myeloid blasts in the bone marrow that are blocked at various stages of differentiation. The disease is called acute because patients develop abnormal numbers of these cells very quickly.

Adoptive T-cell therapy – Cancer treatment in which a patient's ownT-cells are engineered to increase their cancer-fighting properties, and then returned to the patient.

Blockbuster – A pharmaceutical drug with more than US$1bn in annual sales.

CellPryme – Prescient's platform technology for creating better quality cellular medicines.

Chimeric antigen receptor T-cells (CAR-T cells) – Chimeric antigen receptor T-cells (also known as CAR-T cells) are T-cells that have been genetically engineered to produce an artificial T-cell receptor for use in immunotherapy.

Complete Response – Elimination of a tumour brought about by a cancer drug.

Clinical Benefit Rate (CBR) - the percentage of advanced cancer patients who achieve complete response

Lymphoma – A cancer of the lymphocytes which the immune system needs to create T and B cells as well as Natural Killer cells. There are two main types of lymphoma, Hodgkin, and Non-Hodgkin, with Hodgkin Lymphoma being characterised by a particular cell type.

OmniCAR – Prescient's platform technology for creating modular cell therapies.

Orphan Drug – A drug that targets a disease affecting less than 200,000 potential patients in the US. Orphan drug designation provides tax benefits as well as market exclusivity in both Europe and the US.

Overall Response Rate (ORR) - The proportion of patients who have a partial or complete response to therapy[2].

Partial Response – A partial reduction in tumour size brought about by a cancer drug.

Pathway – A succession of signals between molecules within a cell to carry out the growth and functions of the cell. Well-known pathways include, but are not limited to MYC, PI3K/AKT, WNT and NOTCH.

pharmacokinetics (PK) and pharmacodynamics (PD)

Progression-Free Survival (PFS) – The length of time a cancer patient undergoing treatment can see no worsening of his or her cancer.

Serious Adverse Effects (SAEs) -

Stable Disease (SD) – Where the disease has not gotten worse, but has not gotten better either.

T Cells – White blood cells that are responsible for killing cells infected by viruses (in the case of 'Cytotoxic T-cells') and inducing B lymphocytes to produce antibodies (in the case of 'Helper T-cells').

T-Cell Lymphoma – A form of Non-Hodgkin Lymphoma impacting only T-cells.

[2] ORR does not include patients that have stable disease but otherwise no response to the therapy.

Appendix II – Analyst Qualifications

Stuart Roberts, lead analyst on this report, has been an equities analyst since 2002.

- Stuart obtained a Master of Applied Finance and Investment from the Securities Institute of Australia in 2002. Previously, from the Securities Institute of Australia, he obtained a Certificate of Financial Markets (1994) and a Graduate Diploma in Finance and Investment (1999).
- Stuart joined Southern Cross Equities as an equities analyst in April 2001. From February 2002 to July 2013, his research speciality at Southern Cross Equities and its acquirer, Bell Potter Securities, was Healthcare and Biotechnology. During this time, he covered a variety of established healthcare companies, such as CSL, Cochlear and Resmed, as well as numerous emerging companies. Stuart was a Healthcare and Biotechnology analyst at Baillieu Holst from October 2013 to January 2015.
- After 15 months over 2015–2016 doing Investor Relations for two ASX-listed cancer drug developers, Stuart founded NDF Research in May 2016 to provide issuer-sponsored equity research on ASX-listed Life Sciences companies.
- In July 2016, with Marc Kennis, Stuart co-founded Pitt Street Research Pty Ltd, which provides issuer-sponsored research on ASX-listed companies across the entire market, including Life Sciences companies.
- Since 2018, Stuart has led Pitt Street Research's Resources Sector franchise, spearheading research on both mining and energy companies.

Nick Sundich, lead analyst on this report, is an equities research analyst at Pitt Street Research.

- Nick obtained a Bachelor of Commerce/Bachelor of Arts from the University of Sydney in 2018. He has also completed the CFA Investment Foundations program.
- He joined Pitt Street Research in January 2022. Previously he worked for over three years as a financial journalist at Stockhead.
- While at university, he worked for a handful of corporate advisory firms.

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