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## **EXECUTIVE SUMMARY**

Prescient Therapeutics Ltd (ASX:PTX) is an ASX-listed biotechnology company focused on novel targeted (precision) cancer therapies, overcoming limitations of previous approaches to problematic pathways

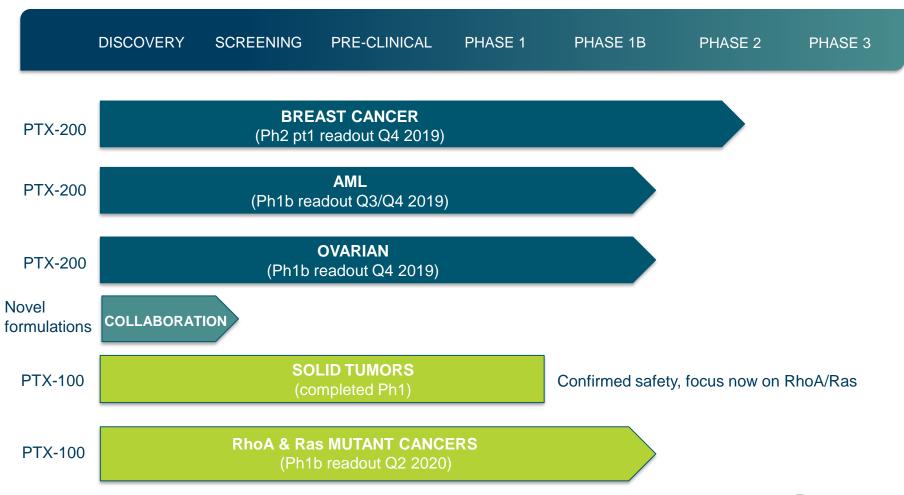
- 4 clinical programs in oncology:
  - » PH domain/Akt inhibitor PTX-200 in 3 trials: Breast Cancer, AML, Ovarian (3 data readouts in 2019)
  - » RhoA inhibitor PTX-100 entering Phase 1b PK/PD clinical trial in Q2 2019
- Leading program PTX-200 in Breast Cancer in Phase 2a reading out Q4 2019
  - Early efficacy signal twice that expected from standard of care
  - » Encouraging durability of responses all pCR/PR patients progression free after 27 months
- Only clinical stage RhoA inhibitor globally targeting fast to market, high value, unmet clinical needs in heme and solid cancers
- Significant acquisition and partnering activity in precision / targeted therapeutics companies, particularly in the clinic.

- Company is raising A\$9.1m:
  - A\$7.0m Two Tranche Placement
  - A\$2.1m Rights Issue
  - 1 free listed option for every 2 shares subscribed.
     Listed options will have a 4 year expiry at a 25% premium to issue price
- Cash balance post raise will fund the Company's current clinical programs for next 18 months and through to multiple value inflection points



# **CLINICAL PIPELINE**

Deep clinical pipeline with 4 data readouts expected in the next 18 months





# **EXPECTED NEWSFLOW & SHARE PRICE CATALYSTS**

- Q2 2019 Commencement of Ph1b PTX-100
- Q3/Q4 2019 Phase 1b PTX-200 results in expanded cohort AML
- Q4 2019 Phase 1b PTX-200 results in ovarian cancer
- Q4 2019 Phase 2 (part1) PTX-200 results in breast cancer
- Q2 2020 Phase 1b PTX-100 results in RhoA/Ras
- Ongoing pipeline development



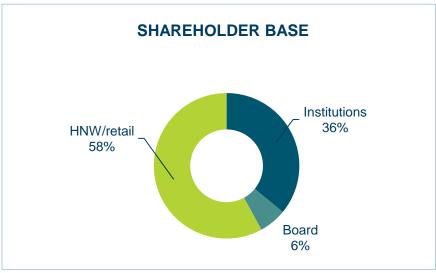
# **CORPORATE SNAPSHOT**

### **KEY METRICS**

ASX Ticker	PTX
Total Issued Capital	211.8 M shares
Options	57.8 M
Share Price <sup>1</sup>	A\$0.058 (US\$0.041)

Market Capitalisation <sup>1</sup>	A\$12.1 M (US\$8.6 M)
Pro Forma Cash Position <sup>2</sup>	A\$10.3 M (US\$7.3 M)
Top 20 Own	52%
6 month turnover <sup>3</sup>	41.0 M shares; A\$3.7 M (US\$2.6 M)





### **RESEARCH COVERAGE**



# **ACHIEVEMENTS SINCE LAST CAPITAL RAISING**

• Since raising \$10m in May 2016, the Company has achieved significant milestones whilst being prudent with its cash balance (still \$3.3m remaining)

May 2016	Now
Breast cancer trial still early	<ul> <li>Ph 1b completed. Achieved encouraging efficacy signal over twice that of standard of care. Ph 2 underway</li> </ul>
No AML trial	Initiated. Ph1b completed with CRs; now new chemo dose
<ul> <li>No prospect of a PTX-100 trial; not even in budget</li> </ul>	<ul> <li>RhoA strategy identified</li> <li>Collaboration with Dana Farber (Harvard University)</li> <li>Unique basket study designed</li> <li>Protocol written; clinician support; trial ready to start - all within budget</li> </ul>
<ul> <li>Manufacturing PTX100 too expensive to even commence (~\$2m)</li> </ul>	New route identified. Manufacturing within existing budget.
	<ul> <li>In addition:</li> <li>New formulation underway</li> <li>Overcame 3x clinical holds and got all programs back on track</li> <li>2x manufacturing runs of PTX-200</li> <li>Building first class team</li> <li>Additional patents</li> <li>Building industry awareness and gaining attention</li> </ul>



## **BOARD OF DIRECTORS**

Experienced; complementary & collaborative



Steven Yatomi-Clarke CEO & Managing Director

- 16 years' experience in healthcare investment banking
- Collaborator on clinical trials conducted in Australia and the US in cancer immunotherapy
- BSc (Hons, Biochemistry & Molecular Biology); BCom (Economics)



Paul Hopper Non-Executive Director

- 25 years experience in international public company markets with a focus on life science and biotechnology
- Former Chairman of Viralytics Ltd (sold o Merck for \$500m). and Executive Chairman of Imugene Ltd.
- Former Director of Somnomed, pSivida, Fibrocell and Founder of Polynoma



Steve Engle Non-Executive Chairman

- Former Chairman and CEO of US-listed XOMA (NASDAQ:XOMA) and La Jolla Pharmaceuticals (NASDAQ: LJPC)
- Currently CEO of Averigon Consulting, an advisory firm to life science industry



James Campbell, PhD Non-Executive Director

- CEO of Patrys Limited (ASX:PAB)
- Previously CFO and COO of Chemgenex Pharmaceuticals (sold to Cephalon)



# FIRST CLASS DEVELOPMENT TEAM WITH PROVEN TRACK RECORD

· Proven success from discovery and clinical development, through to FDA approvals



Said Sebti, PhD Chief Scientific Officer

- · Professor and Chair, Department of Drug Discovery Moffitt Cancer Center
- Co-inventor of PTX-100 & PTX-200
- Named among top 20 Translational Researchers in the world by Nature Publishing Group



**Terry Chew, M.D.**Chief Medical Officer

- Hematologist/oncologist with 20 years experience in biotech & pharma
- 5 New Drug Applications including DaunoXome, Taxotere and DepoCyte



Jim Winkler, PhD VP- Business Development

- VP Drug Discovery & Biology at Array BioPharma
- Key member in Array's partnership deals
- · Director of Oncology Research, GSK



Claudia Gregorio-King, PhD VP - Operations

- Extensive experience in the management of pre-clinical and clinical research and IP
- Regulatory affairs and clinical project management experience with small and large CROs



**Ajay Upadhyay** VP – Clinical Operations

- 24 years in clinical drug development
- · Former Executive Director, Clinical and Outcomes Sciences Medical Affairs at Astellas Pharma
- Former Chief of Staff, US Oncology Business unit at GSK



Mike Preigh, PhD VP - CMC

- Led CMC at Array BioPharma for 10 years
- Successfully brought >20 drug candidates to IND & clinical development
- Previously Pfizer



# PTX-200

# FIRST IN CLASS PH DOMAIN INHIBITOR WITH NOVEL AKT INHIBITION

Breast cancer

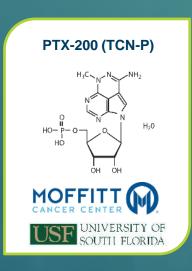
AML

Ovarian cancer



# PTX-200 FIRST IN CLASS PH DOMAIN INHIBITOR LEADING TO NOVEL AKT INHIBITION

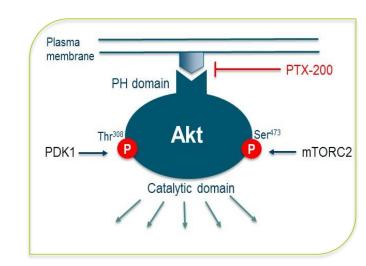
- Akt activation inhibitor that is highly selective for killing tumors with hyperactivated Akt
- Novel mechanism of action
- Inhibits Akt without the toxicity of other attempts
- Anti-proliferative AND pro-apoptotic
- Selectively inhibits regulatory T cells<sup>1</sup>
- Overcomes chemotherapy resistance and causes cancer cells to die
- PTX-200 synergistic with chemotherapy
- Biomarkers: p-Akt, Akt mutation (E17K); high levels of ZNF217

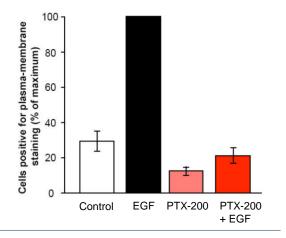




# PTX-200: NOVEL PH DOMAIN INHIBITION TO INACTIVE AKT

- PTX-200 binds to PH domains to inactivate, inter alia, Akt.
  - » Mimics the phosphate of the natural ligand for the PH domain, PIP3
  - By binding to the PH domain, PTX-200 prevents binding to the plasma membrane, thus inhibiting activation of Akt by preventing phosphorylation of both Ser<sup>473</sup> and Thr<sup>308</sup>
- NOT an ATP mimic/direct kinase inhibitor, and therefore avoids off target effects associated with ATP mimic inhibitors.









## **HER2 - BREAST CANCER OVERVIEW**



80% of Breast Cancers are HER2-

BUT THIS IS STILL UNDERSERVED BY NEW DRUGS



#### **MARKET NEED:**

LACK OF PIPELINE AGENTS ADDRESSING

- » RESISTANT ER+ DISEASE
- » NEOADJUVANT THERAPY



- » AKT IS ADVERSE PROGNOSTIC FACTOR
- CORRELATED WITH WORSE DISEASE-FREE SURVIVAL
- DRIVES RESISTANCE TO ENDOCRINE THERAPY



PTX'S NICHE:

NEOADJUVANT

TARGETED THERAPY

FOR HER2- DISEASE

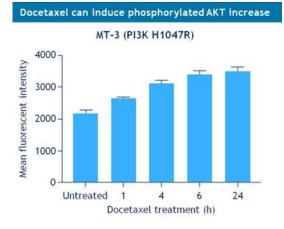


PARTRIDGE AH, RUMBLE RB, CAREY LA, ET AL. AMERICAN SOCIETY OF CLINICAL ONCOLOGY CLINICAL PRACTICE GUIDELINE. JCO 2014 THE PROGNOSTIC VALUE OF PHOSPHORYLATED AKT IN BREAST CANCER: A SYSTEMATIC REVIEW SCIENTIFIC REPORTS | 5:7758, 2015 HYMAN, ET AL; J CLIN ONCOL 2017 JULY 10; 35(20):2251-2259 KIM, ET AL; LANCET ONCOL 2017 AUG 8 PII: S1470-2045(17)30450-3

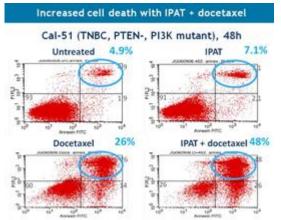


# **ROCHE'S IPATASERTIB: VALIDATING AKT INHIBITION IN BREAST CANCER**

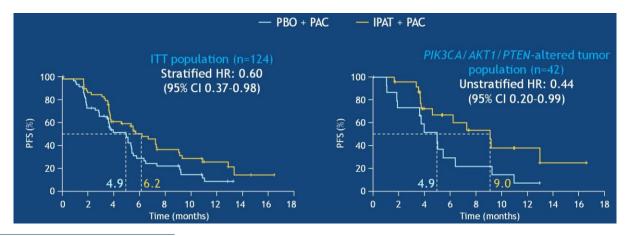
The PI3K/Akt survival pathway is activated in response to chemotherapy



Akt inhibitors enhance the killing of breast cancer cells (~2 fold)



3. ...and Akt inhibition leads to clinical benefit





# WHAT DOES SUCCESS LOOK LIKE FOR THIS DISEASE?

 Studies on all sub-types of locally advanced breast cancer receiving weekly chemo reports a wide range of pCR (8-28%)

- For women with locally advanced **ER+**, **HER2 negative breast cancer**, typical expectations are:
  - » pCR of 16% (11-22%)
  - » ORR of 25%
  - » Treatment with palbociclib + fulvestrant shows ORR of 25%; almost all were partial responses

A meaningful improvement on these response rates would be seen as very encouraging



CANCER: USE AS AN END POINT TO SUPPORT ACCELERATED APPROVAL, OCTOBER 2014.

# PTX-200 BREAST CANCER NOW IN PHASE 2A

 PTX-200 35 mg/m<sup>2</sup> in combination with paclitaxel, followed by AC (doxorubicin & cyclophosphamide) for neoadjuvant therapy





 Stage 1 of Phase 2 trial currently underway in locally advanced breast cancer - Readout Q4 expected 2019



Joseph Sparano, M.D. Principal Investigator



Albert Einstein College of Medicine



Heather Han, M.D.







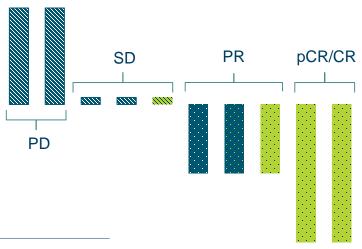


# PHASE 1B EFFICACY RESULTS VERY ENCOURAGING

Metastatic & locally advanced patients			
	ER+	Triple negative	Total
pCR/CR	2	0	2
PR	1	2	3
SD	1	2	3
PD	0	2	2
ORR (	75%	33%	50%

Locally advanced patients				
	ER+	Triple negative	Total	
pCR/CR	2	0	2	
PR	1	2	3	
SD	0	0	0	
PD	0	0	0	
ORR			100%	

# Visual representation of response by breast cancer sub-type



Receptor status

ER+

Triple negative

Disease status

Locally advanced





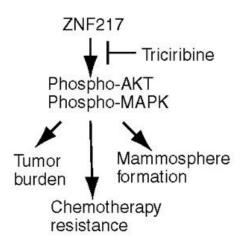
## NO PROGRESSION AFTER 27 MONTHS

- Typically, up to 60% of patients with locally advanced breast cancer will recur by 5 years, the majority of them within the first 2 years.
- All clinical responses seen so far (in locally advanced population counting towards Phase 2 analysis) have demonstrated excellent durability
- All of the patients with a pCR remain free of disease progression to date
- Interestingly, all patients with a PR also remain free of disease progression to date
- Median PFS so far: 27 months
  - Patient with longest PFS so far is 30 months
- Median OS so far: 27 months
  - Patient with longest OS so far is 30 months
- Provides extra evidence of an encouraging efficacy signal in breast cancer
- Whilst Prescient is not formally measuring PFS in this study, pCR is recognised by the FDA as an endpoint to accelerated approval



# BIOMARKER ZNF217 IS PROGNOSTIC OF POOR SURVIVAL AND PREDICTIVE OF RESPONSE TO PTX-200

- ZNF217 overexpressed in 30% of breast and other cancers
- Associated with
  - » Metastasis
  - » Resistance to chemotherapy
  - » Poor survival
- ZNF217 expression is positively correlated with ER expression, and may identify tumors that are sensitive to PTX-200
- PTX-200 was identified after searching among 50,000 drugs on NCI database for drugs that can selectively inhibit ZNF217 overexpressing cells, at a low drug concentration (GI50)
- ZNF217 is predictive of response to PTX-200 in preclinical models
- Clinically, patients with pCRs were positive for high ZNF217
- Seeking to validate in current Phase 2 breast cancer study





## PTX-200 IN AML - EXECUTIVE SUMMARY

- · Akt is highly relevant in AML
- PTX-200 address the "phenotype, not the genotype" in AML mutations
- Like other recent successful strategies in AML, PTX-200 is a targeted therapy complementing a "backbone" of standard chemotherapy
- PTX-200 synergizes with cytarabine in AML cells
- Successful Phase 1 trial in advanced hematologic malignancies (mainly AML) as a monotherapy
  - » 1 CR, 2 PRs in r/r AML; 1 response in refractory CMML
  - » Overall 53% SD in a highly pre-treated population with advanced disease
  - » PTX-200 reduced p-Akt in AML patient blasts
- Granted Orphan Drug Designation by FDA



## PHASE 1B TRIAL UNDERWAY: ACUTE MYELOID LEUKEMIA

- Phase 1 results with PTX-200 (monotherapy) very encouraging
- Now PTX-200 + cytarabine in refractory or relapsed acute leukemia
- Professor Jeff Lancet at Moffitt Cancer Center leading the trial
- Yale Cancer Center and Kansas University Medical Center also participating in trial
  - » 13 patients with cytarabine held constant at 400 mg/m2 as continuous infusion (days 2-6)
  - » 2 CRs
  - » Additional arm with Cytarabine held constant at 200 mg/m2 as continuous infusion (days 2-6)
- Granted Orphan Drug Designation by FDA



Jeffrey E Lancet, M.D.
Principal Investigator

MOFFITT

CANCER CENTER





## PHASE 1B OVARIAN CANCER TRIAL

- Significant need for new products to treat platinum-resistant ovarian cancer
- High pAkt contributes to platinum resistance
- PTX-200 already proven overcome cisplatin resistance and synergize with cisplatin in pre-clinical studies



- Testing PTX-200 in dose escalation in combination plus carboplatin in patients with platinum resistant ovarian cancer
- Phase 1b underway Currently recruiting at H. Lee Moffitt Cancer Center
- Up to 12 patients with an additional 18 in expansion cohort
  - » Expected to complete Q4 2019







# PTX-100

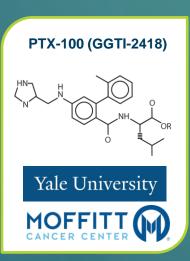
PHASE 1 IN SOLID TUMORS COMPLETED

NOW PURSUING A TRANSFORMATIVE OPPORTUNITY IN RAS & RHO MUTANT CANCERS



# PTX-100 FIRST IN CLASS, FIRST IN MAN GGT-1 INHIBITOR OF RAS PATHWAY

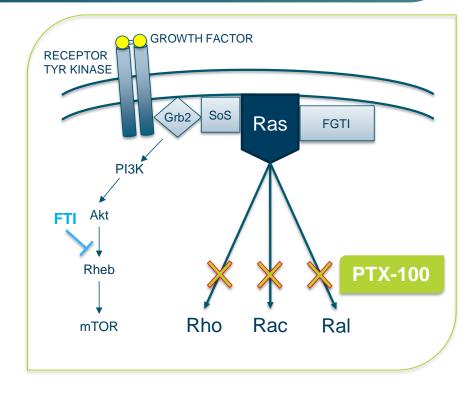
- Inhibitor of the GGT-1 enzyme
- Invented at Yale University and Moffitt Cancer Center
- Single agent activity in mouse models of various cancers
- Combination therapy is also very effective, efficacy in mutant Ras tumors
- Reduces cancer stem cell population in animal models
- p27 a potential companion diagnostic for PTX-100
- Completed Phase 1 trial in advanced solid tumors
  - » well tolerated, large therapeutic index, patients achieved stable disease
- PTX-100 recently discovered to also inhibit a novel cancer causing pathway FBXL2 important in PTEN defective cancers
- Biomarkers: mutant RhoA and mutant Kras; p27Kip; PTEN; RalA/B





## RAS PATHWAY IS AN IMPORTANT BUT ELUSIVE TARGET

- Ras mutated in 30% of all human cancers and 90% in certain cancers
  - » A staggering 3 million new cancers diagnosed worldwide each year with Ras mutations
- Mutant Ras tumors are often unresponsive to current treatments
- Patients with Ras mutant cancers are still significantly underserved due to a lack of suitable targeted therapies
- NCI identified targeting Ras as a high priority with a major initiative to discover therapies for Ras mutant cancers

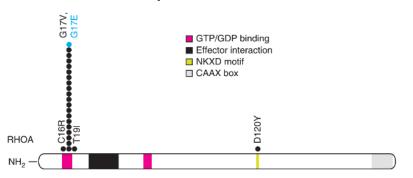


 Targeting Ras directly has proven elusive; PTX-100 disrupts the Ras pathway by inhibiting the activation of Ral, Rac and Rho

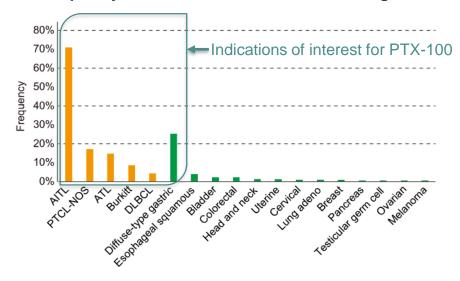


# RHOA MUTATIONS PLAY A PROMINENT ROLE IN TCL PATHOGENESIS

### Schematic of RhoA protein structure, with alterations



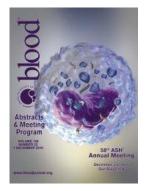
## Frequency of RhoA mutations in human malignancies



- RhoA G17V mutation is a driver of pathogenesis of AITL, PTCL-NOS
- Other RhoA mutations driver a number of other malignancies
- PTX-100 a pan RhoA inhibitor regardless of mutation

nature genetics

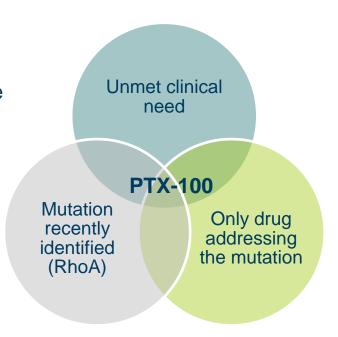






## PTX-100 THE ONLY DRUG TARGETING RHOA

- PTX-100 has a unique position in RhoA mutant malignancies
  - » Only clinical stage RhoA inhibitor globally
- Phase 1 trial in solid tumours completed safety profile established
- Basket PK/PD study expected to begin in Q2 2019; readout Q2 2020;
  - » Myeloma
  - » Lymphoma
  - » Gastric cancer
  - » Pancreatic cancer



- Given unmet need, it is possible only one pivotal trial post successful Phase 1 may be required
  - » "Loxo-style" Basket heme and/or basket solid cancers enriched for RhoA & Ras mutations
  - » Faster path to commercialisation
  - » Small patient population but large potential market value



# **CASE STUDY – LOXO ONCOLOGY (NASDAQ:LOXO)**

- Lead drug Larotrectnib: targeted therapy for cancers with TRK fusions
- An unmet need in **small patient population** (2,500-3,000 cases/year in US)
- Pioneered "one trial to launch" basket study



# CAPITAL RAISING



# **CAPITAL RAISING SUMMARY**

- Prescient is conducting a A\$9.1m capital raising that will fund the Company's clinical programs over the next 18 months:
  - » PTX-100 Basket PK/PD trial
  - » PTX-200 clinical trials
  - » General working capital
- Offer price of A\$0.05 per share represents a 13.4% discount to 5 day VWAP; 23% discount to 30 day VWAP

### Capital raising structure

- A\$7.0m Two Tranche Placement to Sophisticated and Professional investors in Australia and eligible institutional investors in US and Hong Kong
- Fully Underwritten ~A\$2.1m 1 for 5 Entitlement Offer to existing eligible shareholders with registered addresses in Australia and New Zealand at the record date
- Participants will also receive 1 free option for every 2 Placement or Entitlement Offer shares issued
  - Options will be listed on the ASX, with a March 2023 expiry and strike price of A\$0.0625
- Shares issued under the Placement will not be eligible to participate in the Entitlement Offer



# **INDICATIVE TIMETABLE**

Trading halt	Thursday 21 <sup>st</sup> March 2019
Offer announced, lodge Entitlement Offer Prospectus with ASX and company resumes trading	Monday, 25 <sup>th</sup> March 2019
"Ex" date for Entitlement Offer	Thursday, 28 <sup>th</sup> March 2019
Record date for Entitlement Offer	Friday, 29 <sup>th</sup> March 2019
Settlement of New Shares issued under Placement Tranche 1	Friday, 29 <sup>th</sup> March 2019
Allotment of New Shares issued under Placement Tranche 1	Monday, 1 <sup>st</sup> April 2019
Entitlement offer closes	Tuesday, 23 <sup>rd</sup> April 2019
Shareholder meeting to approve Placement Tranche 2	Friday, 26 <sup>th</sup> April 2019
Settlement of New Shares issued under Placement Tranche 2	Thursday, 2 <sup>nd</sup> May 2019
Allotment of New Shares issued under Placement Tranche 2	Friday, 3 <sup>rd</sup> May 2019



# **KEY SPECIFIC RISKS**

Key specific risks include, but are not limited to:

- The nature of drug development is inherently risky, with many drug candidates failing to be successfully developed into marketable products. Prescient's clinical trials may fail to meet their desired endpoints or may have adverse effects for patients which could greatly impact the value of the Company
- the Company's drug candidates, PTX-200 and PTX 100, are still in development and Prescient has not generated any product sales or revenues
- Prescient's clinical trials are costly and time consuming, may be subject to suspension or delay by regulatory authorities, and may ultimately prove unsuccessful. There is also no guarantee that an adequate number of patients can be recruited on time, or at all, for clinical trials
- Prescient may not obtain the regulatory approvals that it requires for sale of its products or the reimbursement approvals required for sales growth, or such approvals may be subject to delay
- As Prescient may need to raise further capital in the future, which may dilute existing Shareholders (including Shareholders that receive Options under this Prospectus). In addition, there can be no guarantee that additional capital can be raised at terms acceptable to Shareholders
- Prescient is dependent on the retention of key personnel and consultants, and the performance of those personnel, as well as the performance of other third-party collaborators
- Prescient may be impacted if its intellectual property is not able to be adequately protected or is subject to challenge by a third party
- there are a number of groups around the world working on technology which could compete with PTX-200 or PTX-100 and their application in oncology, and as such, Prescient may be impacted by competitive or alternative products or technologies
- Prescient is currently entitled to receive an R&D rebate on part of its expenditure in research and development. There is a risk that the Australian Government may make material changes to the rebate scheme, which may adversely impact the funding available to Prescient to fund its operations.





# **CONTACT**

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