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ASX Limited  
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## **PTX Shareholder Newsletter**

**9 November 2015, Melbourne, Australia:** Prescient Therapeutics Limited (ASX: PTX), a clinical stage oncology company, provides the following market update via a shareholder newsletter.

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

PTX is a clinical stage oncology company developing novel compounds that show great promise as potential new therapies to treat a range of cancers that have become resistant to front line chemotherapy.

Lead drug candidate PTX-200 inhibits an important tumor survival pathway known as AKT, which plays a key role in the development of many cancers, including breast and ovarian cancer, as well as leukaemia. This highly promising compound is now the focus of two current clinical trials. The first is a Phase 1b/2 study examining PTX-200 in breast cancer patients at the prestigious Montefiore Cancer Center in New York. A Phase 1b/2 trial of the compound in combination with current standard of care is also underway in patients with recurrent or persistent platinum resistant ovarian cancer at Florida's H. Lee Moffitt Cancer Center. These trials are funded in part by grants from the U.S. National Cancer Institute. In addition, PTX is planning a Phase 1b/2 trial evaluating PTX-200 as a new therapy for acute myeloid leukemia.

PTX's second novel drug candidate, PTX-100, is a first in class compound with the ability to block an important cancer growth enzyme known as geranylgeranyl transferase (GGT). It also blocks the Ral and Rho circuits in cancer cells which act as key oncogenic survival pathways, leading to apoptosis (death) of cancer cells. PTX-100 was well tolerated and achieved stable disease in a Phase 1 trial in advanced solid tumors.

PTX has licensed access to its Co-X-Gene™ platform technology to French biotechnology company Transgene for use in two immunotherapeutic products.

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PTX (Prescient Therapeutics) is a clinical stage company developing new treatments for a range of cancers that have become resistant to chemotherapy.

**INVESTOR NEWSLETTER**  
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ASX Code	PTX
Total Issued Capital	57.2 m Shares
Options	\$4.3 m (ex A\$0.10; exp 12 Oct 2017)
Share Price (at 29/10/2015)	\$0.058
Market Capitalisation (at 29/10/2015)	A\$3 m
Cash Position (at 30/6/2015)	A\$1.0 m
Top 20 Shareholders Own	33%
6 Month Turnover (at 20/10/2015)	21.4 m shares

## FROM THE EXECUTIVE DIRECTOR

Dear Shareholders,

We are poised to begin extracting some of the potential value from our lead programs.

In order to progress development of our lead oncology drug PTX-200 as expeditiously as possible, we have launched a Share Purchase Plan (SPP) to raise up to \$1.03 million.

These funds will be used to drive development and we strongly encourage existing shareholders to take part in this opportunity which has great potential to deliver investor value as we hit key clinical milestones over the next 12 months.

Existing investors will be entitled to subscribe for up to \$15,000 in new fully paid ordinary shares without incurring brokerage or other transaction costs. The issue price will be determined at the issue date, based on a 20% discount to the volume weighted average price (VWAP) of PTX shares traded on the ASX during the five days immediately prior.

Shareholders should note, this SPP will be fully underwritten by Patersons Securities to \$1.03 million.

In another important development, we have recently accepted the resignation of our Managing Director Dr Rob Crombie, who is leaving the company for personal reasons.

We thank him for his contribution over the past 18 months and are now engaged in a global search for a new Managing Director who will steer our company through its next important phase of development.

I will oversee operations until this appointment is finalised, in collaboration with our Chairman and a high calibre Board of Directors.

I impress upon you that we are not an early stage, pre-clinical company. Prescient is in an enviable position, with multiple programs now examining the efficacy of our drug candidates on a range of cancer targets, including breast and ovarian cancers.

Already we have taken great strides forward toward realising the commercial value of PTX-200, as well as our second cancer drug candidate, PTX-100.

In the last year we have taken control of Investigational New Drug applications with the US FDA covering both of these novel products.

These important regulatory milestones are enabling us to pursue development in the high value US market.

Investors can be assured that the fundamentals of our company are strong, and extremely promising.

Both our drug candidates hold great promise as new treatments for cancer and could improve patient survival times.

Two major trials are underway in breast and ovarian cancers. We also have a third trial in Acute Myeloid Leukaemia (AML) expected to commence in early 2016.

Our trials are being steered by world-renowned cancer experts who have great confidence in the drugs we are developing.

Shareholder value will be created as we hit and achieve milestones in each of these programs. But we require your support now to progress these programs as expeditiously as possible.

Your support is important.

### TO SUMMARISE:

- We have two novel and highly promising cancer drug assets
- Both drugs result from research at some of the world's most prestigious institutions (Yale University and the Moffitt Cancer Center in Florida (third largest cancer centre in the US))
- Trials in progress are being conducted under two separate US IND (Investigational New Drug) applications. Basically, this is a green light from the US FDA to progress trials in the US and is a key regulatory pathway
- In a major vote of confidence, two of our trials (PTX-200 in breast cancer and ovarian cancer patients) have been partially funded by US authorities (National Cancer Institute and Department of Defense)
- We have world class cancer experts driving our programs (Professor Said Sebti and



**ABOVE: Paul Hopper, Executive Director**

Professor Joseph Sparano. Please see later in this newsletter for further detail from both).

**Edison Investment researchers recently valued our company at A\$36 million, or A\$0.66 per share. Analysts noted several pending inflection points that would unlock value in the near term.**

**These key milestones include the launch of a new and promising clinical trial expected to start in the first half of next year.**

This trial will be held in patients with Acute Myeloid Leukaemia, a blood cancer which represents an area of great unmet medical need.

In addition, we expect the release of interim data in mid next year from the ongoing US trial of PTX-200 in breast cancer patients.

Positive interim data will be eagerly received by investors and the wider biotech community. A positive result brings potential for a favourable impact on the existing share price.

Finally, thank you for your ongoing support. There is potential for solid upside in the short to medium term.

We believe we are on the cusp of great opportunity and this SPP will provide us with the working capital to begin unlocking real value.

I look forward to your support,  
Sincerely,

**Paul Hopper**  
**Executive Director**





## MILESTONES TO WATCH

	2014	2015	1H2016	2H2016
<b>BREAST CANCER</b>	TRENSFER BREAST CANCER IND		✓	
	COMPLETE PHASE 1B			
	INITIATE 1B			
<b>OVARIAN CANCER</b>	INITIATE PHASE 1B	✓		
	TRANSFER OVARIAN CANCER IND			
	DOSE ESCALATION AND INTERIM ANALYSIS			
<b>ACUTE MYELOID LEUKEMIA</b>	COMPLETE PHASE 1B			
	IND ALLOWED BY US FDA			
	INITIATE PHASE 1B			
<b>OTHER</b>	DOSE ESCALATION AND INTERIM ANALYSIS			
	COMPLETE PHASE 1B			
	ONGOING BD INITIATIVES			

INTERVIEW WITH  
PROFESSOR  
JOE SPARANO

Professor of Medicine & Obstetrics, Gynaecology, and Women's Health at the Albert Einstein College of Medicine NY



Above: Professor Joe Sparano



Albert Einstein College of Medicine NY



New York based medical oncologist and clinical researcher Professor Joe Sparano brings a global reputation in oncology to Prescient's Scientific Advisory Board. Currently a Professor of Medicine and Women's Health at the Albert Einstein College of Medicine in New York, he is also the Associate Chairman for clinical research in the Department of Oncology at the prestigious Montefiore Medical Center. His work and research is globally regarded, with his reputation particularly built on developing novel therapeutic approaches for breast cancer, lymphoma and HIV-associated cancers. He has been involved in the development of numerous Phase I, 2, and 3 NCI sponsored, investigator-initiated and industry sponsored trials and has steered development and validation of prognostic and predictive biomarkers for "personalised medicine".

Professor Sparano also serves as Chair of the Eastern Cooperative Oncology Group Breast Cancer Committee, Vice-Chair of the NCI Breast Cancer Correlative Science Committee, and is a member of the NCI Breast Cancer Steering Committee.

Here he discusses Prescient's ongoing breast cancer trial, the need for new therapies and the commercial opportunity presented.

## Q: WHAT MAKES PTX-200 SO PROMISING?

A: PTX-200 kills tumours that depend on the cancer-causing protein AKT for survival. In context, many human cancers escape the killing action of chemotherapeutic drugs by hyper activating AKT to enable cell survival.

In addition, PTX-200 sensitises tumour cells for chemotherapy treatment so patients are more likely to respond to existing therapies and not develop chemotherapy resistance.

Our drug PTX-200 does not work like other AKT inhibitors. Other AKT inhibitors work by mimicking a molecule known as ATP. Ours has a different mechanism of action which means there is a reduced risk of toxicity.

## Q: CAN YOU EXPLAIN IN VERY SIMPLE TERMS HOW IT WORKS, PARTICULARLY FOR THOSE INVESTORS WHO MAY NOT HAVE A SCIENTIFIC BACKGROUND?

A: PTX-200 works by attaching itself onto the cancer-causing protein AKT. This prevents AKT from becoming "activated". When AKT is not activated, chemotherapy drugs can do the job they are supposed to do – kill cancerous cells.

## Q: YOU ARE STEERING A MAJOR STUDY OF PTX-200 ON PATIENTS AT THE ALBERT EINSTEIN COLLEGE OF MEDICINE. HOW IS THIS TRIAL PROGRESSING?

We have already treated 15 patients with metastatic breast cancer, although there are a few patients that have presented with lung cancer and oesophageal cancer that we have also treated with the same drug regimen. The next step is to complete the Phase 2 dose and to progress the trial into the next stage – an expansion phase in women with metastatic breast cancer.

## DOES PTX-200 HOLD HOPE FOR OTHER CANCERS?

A: Yes, the pathway that we are targeting, the AKT pathway is a 'master switch' that is activated in many different cancers, not only the cancers that we are currently tackling including breast, AML and ovarian but also others including glioblastoma, thyroid, lung, gastric, pancreatic, prostate, renal, lymphoma, multiple myeloma, and melanoma. We are thus in the enviable position of being able to target a number of cancers with PTX-200, making it a platform play.

## Q: WHAT IS THE ENDGAME FROM A CLINICAL POINT OF VIEW – IE – WHAT DO YOU THINK PTX-200 MIGHT BE ABLE TO ACHIEVE FOR CANCER PATIENTS?

A: In the short-term it is hoped that we can provide a treatment regime for late-stage patients that have failed all other therapies. However, as we show the safety profile of our drug we will endeavour to treat earlier stage patients where we may be able to have more profound effects and rather than being a combination product, we could act as a stand alone therapy.

## Q: IF THE CURRENT BREAST CANCER TRIAL RETURNS POSITIVE RESULTS, WHAT ARE THE NEXT STEPS?

A: Our aim would be to progress the trials in partnership with large pharmaceutical companies whose products we are able to improve. They become natural partners in advancing these products to market.



## CONGRATULATIONS TO OUR CHIEF SCIENTIFIC OFFICER, PROFESSOR SAID SEBTI



Above: Professor Said Sebti

## Chair of the Department of Drug Discovery at the Moffitt Cancer Center – the third largest cancer centre in the US

Any company can only be as good as those propelling it forward – and Prescient is extremely fortunate to have drawn world class scientists to its leadership team.

It is therefore with great pride that we acknowledge our Chief Scientific Officer Professor Said Sebti, who was recently named one of the top 20 global translational researchers by the esteemed scientific journal, Nature Biotechnology. Professor Sebti was also recently elected as a member of the National Academy of Inventors.

Shareholders can be heartened a scientist of this calibre, and with intimate knowledge of our drugs, is steering development of our lead assets.

Professor Sebti is currently the Manual and Adelina Garcia Professor and Chair of the

Department of Drug Discovery at Moffitt, which is the third largest cancer centre in the US.

He is a co-inventor of both our lead cancer drugs (PTX-100 and PTX-200) and has an outstanding track record in cancer drug development, with his extensive research particularly focused on understanding why defective circuits in a tumour contribute to the onset of cancer and then, finding new drugs capable of disrupting these tumour lifelines.

He was included on the prestigious Nature Biotechnology list by patent analytics firm IP Checkups, which investigates the work of scientists around the world.

Inclusion on the tightly-held Nature list comes only after careful examination of work over the previous five years and a scientist's 'H index' – a score based on the impact of published work.



Moffitt Cancer Center & Research Institute, established in 1986 in Tampa, Florida

## ACUTE MYELOID LEUKAEMIA

We are in the final planning stages for a major Phase 1b/2 trial of our lead drug candidate **PTX-200** in patients with **Acute Myeloid Leukaemia (AML)**, which is a type of cancer affecting the blood and bone marrow.

This trial is on track to begin in the first half of next year and is being closely watched by both clinicians and specialist biotech investment funds in the United States, who are keenly aware of the great near term opportunity our drug may provide to AML patients.

Put simply, there are very few treatment options for patients with this disease, which is most apparent in adults over 60.

As populations age around the world, the incidence of this disease is rising (there are 13,000 new cases diagnosed in the US each year) but the outlook for patients remains grim – with only 25% of patients surviving five years from diagnosis.

We are hoping to change this scenario and improve patient survival outcomes. All information to date suggests our drug PTX-200 may provide a breakthrough opportunity.

This next trial will examine PTX-200 in combination with standard chemotherapy cytarabine.

Patients selected for the trial will have refractory or relapsed disease – that is, the disease has not gone into remission after first line therapy. This is extremely common in AML and happens in up to 20% of cases.

Even for those patients who do go into remission, relapse is extremely common and there are few further treatment options.

Our drug is showing potential to treat patients with refractory AML or those who have relapsed. A Phase 1 study produced highly encouraging results, **with 17 of 32 trial patients showing stable disease after just one cycle of treatment. A further three patients achieved >50% reduction in the number of bone marrow blasts**, which are abnormal immature white blood cells inside the bone marrow.

Prescient has already selected its trial site for this next stage study and has finalised trial protocols. We will enrol 18 patients at the Lee Moffitt Cancer Center in Florida, under the guidance

of highly regarded oncologist Dr Jeffrey Lancet. He currently holds position as Professor of Oncologic Sciences at the Moffitt Cancer Center and University of South Florida and is the Section Chief of Leukaemia in the Department of Malignant Hematology at the Moffitt Cancer Center.

Recruitment is expected to take six to nine months. An IND application is currently being prepared, which will give us a green light from the Food and Drug Administration to conduct this study in the high value US market.

Investors should note, we expect substantial value to be created as we reach and hit key milestones in this AML program.

These milestones will include trial initiation, dose escalation and interim data analysis as well as study completion. Each step on the commercialisation path is important – not just the end result.

We look forward to announcing the launch of this study next year and then, reporting positive progress along the way.