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Prescient Therapeutics Limited (ASX: PTX)

Next Gen CAR-T Platform a Potential Game Changer

22 June 2020

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Prescient Therapeutics Limited (ASX: PTX)

Initiating Coverage

Investment Profile	
Share price ($) as at 19 June 2020	0.057
Issued capital:	
Ordinary shares (M)	394.3
Options (M)	105.2
Fully Diluted (M)	499.5
Market capitalisation ($M)	22.5
12-month Share Price Low/High ($)	0.022/0.15

Board and Management
Steve Engle - Non-Executive Chairman
Steven Yatomi-Clarke - CEO & Managing Director
Dr.James Campbell - Non-Exectuive Director
Dr. Allen Ebens - Non-Executive Director
Melanie Leydin - CFO & Company Secretary

Largest Shareholders	%
Australian Ethical Investment Ltd	8.2
UBS Asset Management	4.8
Credit Suisse Investment Banking and Securities Investment	4.5
Regal Funds Management	4.3
Chris Retzos	3.7
Top 20 Shareholders	**38.6**

Source: IRESS

Share Price

NEXT GEN CAR-T PLATFORM A POTENTIAL GAME CHANGER

Prescient Therapeutics Limited (ASX: PTX) is a clinical stage oncology company with a focus on developing targeted and cellular cancer therapies. Targeted therapies are a focus for anticancer drug development, with the aim of personalising treatment based on a person's genes and proteins to prevent, diagnose and treat the disease. The company has expanded its footprint in the CAR-T market with the acquisition of the exclusive global licence of a next generation CAR-T platform from the University of Pennsylvania.

KEY POINTS

Acquisition of Next Generation CAR-T Platform: PTX has acquired the exclusive global licence to a universal immune receptor (UIR) platform from the University of Pennsylvania (Penn) and a non-exclusive licence to use the Spy Tag/SpyCatcher molecular binding system used by the UIR platform from Oxford University. The company intends to use these licences and technology to build OmniCAR, a next generation cell therapy platform. OmniCAR has the potential to be a game changer for the company with UIRs having the potential to address a number of issues with the current (first generation) CAR-T cell therapies, allowing for more safe and effective treatment of blood cancers and boosting the potential use of CAR-T cell therapy in solid tumours, something that has proved elusive to date. The platform is currently in the pre-clinical stage of development with PTX seeking to undertake a combination of internal and external development. The compensation amount for the licences has not been disclosed, however, the company has stated that the licence agreements are largely back-ended with the upfront payment and initial development costs covered by the companies current cash reserves.

CAR-T Collaboration with Carina Biotech: In November 2019, PTX announced that they had entered into a collaboration with Carina Biotech to develop Carina's CAR-T technologies for the treatment of solid tumours. Originally the parties had agreed to share the IP, however, in early 2020 it was agreed that PTX will be the outright owner of any new IP developed under the collaboration. This puts PTX in a strong patent position with respect to the development of Carina's CAR-T technology. As a result of the new agreement, PTX will be responsible for the carrying costs associated with the collaboration.

PTX 200 Trials in Breast Cancer Produce Encouraging Results: PTX 200 is the most advanced product in the portfolio with a Phase II clinical trial in breast cancer and Phase Ib trials in AML and ovarian cancer currently in progress. In December 2019, the company announced positive results from the Phase IIa clinical trial in HER2 negative breast cancer. The results from 11 women exhibited an overall response rate (ORR) of 91%. 10 of the 11 women were evaluable with two patients having a pathologic complete response and the remaining 8 patients all having partial responses. 9 of the 10 evaluable patients continue to be free of disease progression with progression-free survival averaging 22 months so far, tracking favourably against the 24 month window during which relapse typically occurs. The company will undertake a new trial with a focus on ER+ breast cancer given patients with this disease appear to be the most responsive to PTX 200.

PTX 100 Targeting Ras: PTX 100 is seeking to block a cancer pathway, the Ras pathway. The Ras pathway and Ras mutation is a significant contributor to a number of cancers with more than 30 percent of all human cancers, driven by mutations of the Ras family of genes. To date it has not been possible to develop inhibitors of Ras signalling with existing drug development technologies. Given the significance of the Ras protein, the ability to successfully inhibit the pathway would provide a significant market opportunity. The company is taking a "basket"approach to the trial, assessing the drug candidate on multiple cancers with a view to addressing specific mutations as opposed to the origin of the tumour. The "basket" approach potentially provides a faster way to identify cancer patients who will potentially benefit from the use of the drug candidate.

Investment View: The OmniCAR platform puts PTX at the forefront of CAR-T cell therapy development, providing significant potential value for the company. This is in addition to the value potential from the companies existing product pipeline of targeted cancer therapies. We have not provided a valuation for the company, however have provided information in the below report regarding the value the market has put on oncology products and technology under development to provide an insight as to the potential value of the companies product pipeline. While we view there to be significant upside potential given the companies product portfolio we note that as with all drug development companies there are heightened levels of risk given the nature of the operations.

SWOT ANALYSIS

STRENGTHS

- The acquisition of the licence to the UIR platform and the binding technology puts PTX at the forefront of next generation of CAR-T cell therapy development.
- Compensation for the licence to the UIR platform will be largely back-ended and therefore the company will only be required to pay a small upfront payment, which the company can fund from its current cash reserves. As such, the acquisition will not be dilutive to shareholders.
- The acquisition of the licence to the UIR platform complements the recent collaboration with Carina Biotech for the development of their CAR-T technologies. The collaboration provides a potential platform for the development of OmniCAR.
- Dr. Allen Ebens has joined the PTX board. This is a significant appointment given Dr. Ebens was previously a key executive at Juno Therapeutics, a pioneering company in CAR-T. This appointment provides significant CAR-T therapy development experience to the company and is a significant vote of confidence for the OmniCAR technology.
- PTX is the only ASX-listed company with next generation CAR-T technology providing a unique investment opportunity.
- PTX will now have 100% of the rights to IP that is developed through the collaboration with Carina Biotech putting the company in a strong patent position with respect to the development of Carina's CAR-T technology.

WEAKNESSES

- As with all biotechs, an investment in PTX is speculative given the nature of companies operations.
- The clinical results for PTX 200 have been encouraging, however, there were some toxicity issues from the Phase Ib trials of PTX 200 in AML resulting in the expansion of the AML and ovarian cancer studies. While this is not a negative per se, the expansion of studies results in increased costs and time to complete the trials.

OPPORTUNITIES

- The acquisition of the UIR platform and the Spy Tag/SpyCatcher binding technology provides a significant opportunity in the immunotherapy market to develop the next generation of CAR-T cell therapy. The platform has the potential to address a number of limitations experienced by the current CAR-T cell treatments with one of the biggest opportunities being the potential to progress the use of CAR-T to treat solid tumours.
- The OmniCAR platform has the potential to be an important ingredient for companies developing first generation CAR-T technologies with the company seeking to licence the platform to third-party programs.
- PTX 200 and PTX 100 seek to block/inhibit well known pathways for cancer in AKT and Ras to reduce the resistance and therefore improve the efficacy of chemotherapy treatments. Given the significance of these pathways in numerous cancers, there is a significant potential market if these drug candidates are proven to work.
- The basket approach to the PTX 100 clinical trial has the potential to expedite the clinical progress of the drug candidate, potentially reducing the time for a return on investment.

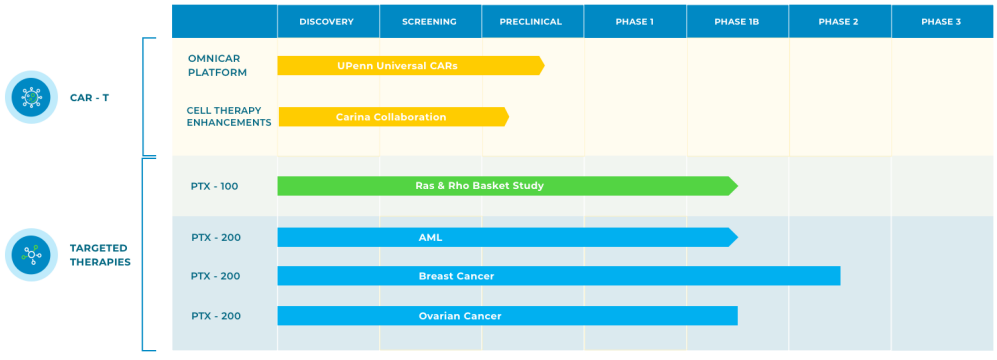
THREATS

- The company has sufficient capital to cover operations and research and development programs at present, however the company is currently not generating material revenue given the nature of its operations and therefore will likely have to raise capital to progress the development of the OmniCAR platform. Capital raisings may be dilutive to existing shareholders.
- There is an increasing level of research and development in the CAR-T field, meaning there is a greater level of competition for commercial agreements with big pharma companies and increasing competition for patient pools for clinical evaluation.

COMPANY OVERVIEW

- PTX is a clinical stage oncology company with a focus on developing targeted and cellular therapies. The company is currently developing PTX 200 and PTX 100 which seek to block the AKT and Ras pathways, respectively, both well known cancer targets. While there are a number of drugs in development for both of these cancer targets, there is yet to be a drug approved that targets either of the pathways.
- By blocking the AKT and Ras pathways the drug candidates seek to reduce the resistance to chemotherapy treatments and therefore improve the response to treatment. Inhibiting these pathways may also have the added benefit of reducing the dosage requirement of chemotherapy making treatment more tolerable for patients.
- The company has three clinical trials in progress for PTX 200 including a Phase II trial in breast cancer and Phase Ib trials in AML and ovarian cancer. In December 2019, the company announced positive results from the Phase IIa clinical trial in HER2 negative breast cancer. The results from 11 women exhibited an Overall Response Rate (ORR) of 91%. 10 of the 11 women were evaluable with two patients having a pathologic complete response and the remaining 8 patients all having partial responses.
- The company commenced a Phase Ib study for PTX 100 in July 2019. The company will be taking a "basket" approach to the trial to assess the safety and efficacy of the drug candidate addressing specific mutations as opposed to the origin of the tumour. This will potentially increase the speed of the development of the drug candidate.
- The company has recently expanded its portfolio to CAR-T cell therapies through a collaboration with Carina Biotech to develop Carina's CAR-T technologies for the treatment of solid cancers and now the acquisition of the exclusive global licence to a modular CAR-T platform from the University of Pennsylvania (Penn) and the non-exclusive licence to the Spy Tag/SpyCatcher binding technology used by the Penn platform, which the company will use to develop the OmniCAR platform.
- The OmniCAR platform is a potential game changer for both the company and for CAR-T cell therapy. The platforms ability to decouple antigen recognition from the T-cell signalling domain and provide multi-antigen targeting with a single cell product means the OmniCAR platform has the potential to improve the safety and efficacy of first generation CAR-T therapies. Current CAR-T technology has shown to be highly effective in blood cancers, however there has been limited success to date with the use of CAR-Ts to treat solid tumours due to the complexity of solid tumours compared to blood cancers. The OmniCAR platform has the potential to overcome these barriers and potentially progress the ability of CAR-T use in solid tumours. This provides a significant market opportunity.

Product Pipeline



Source: PTX

ACQUISITION OF UNIVERSAL IMMUNE RECEPTOR (UIR) PLATFORM

- PTX has announced it has secured an exclusive global licence from the University of Pennsylvania (Penn) for an universal immune receptor (UIR) platform and a non-exclusive licence from Oxford University for the Spy Tag/SpyCatcher molecular binding system employed by the UIR platform.
- The company intends to use the licences to develop OmniCAR, a universal immune receptor platform for next generation cell therapy product development, with a focus on next generation CAR-T.
- The platform is currently in the preclinical stage of development with the company seeking to develop the cell therapies both in-house and externally through collaboration with companies developing first generation CAR-T cell therapies.
- The licence agreement will consist of an upfront payment, milestone payments and royalty payments. The terms of the agreement were not disclosed, however, the company has stated that compensation for the agreement will be largely back-ended, with only a small upfront payment. As such, the company is able to fund the upfront payment for the licences through its existing cash reserves, meaning the agreement is non-dilutive to shareholders. The company has also stated that the initial pre-development of the OmniCAR platform will be covered by its current cash reserves.
- The acquisition of the licence to commercialise and develop the UIR platform puts the company at the forefront of CAR-T cell therapy development, an emerging area of cancer treatment.

FINANCIAL POSITION

- The company generated a loss of $1.7m in 1H'20, a slight increase from the $1.6m loss in 1H'19. Research and development costs were down on the pcp, however, corporate expenses increased. With the company now responsible for all the development costs of Carina Biotech's technology under the collaboration and the development of the OmniCAR platform, we expect research and development expenditure to increase in FY'2021.
- At 31 March 2020, the company had $8.2m in cash reserves. The cash position was boosted in 2019 with a capital raising of $9.1m through a share placement and non-renounceable rights issue. As part of the capital raising the company issued 21.9m options exercisable $0.0625 on or before 31 March 2023. In the event the share price increases above the exercise price there is the potential for the company to raise an additional $1.1m.
- At 31 March, the company had sufficient capital to operate for a further 18 months. Compensation for the recent acquisition of the licences to develop the OmniCAR platform has not been disclosed. The company has stated that the upfront payment is not material is and able to be covered by the company's current cash reserves, however, we would expect that the company will have to raise capital to clinically progress the OmniCAR platform, unless an acquisition or licensing opportunity is realised.

CAPITAL STRUCTURE

- PTX currently has 394.3m shares and 105.2m listed and unlisted options on issue. At 19 June 2020, the company had a market capitalisation of $22.47 million.
- The terms of the licence agreements recently signed for the OmniCAR platform have not been disclosed by the company and therefore we do not know if new shares will be issued to the relevant parties as part of that deal.

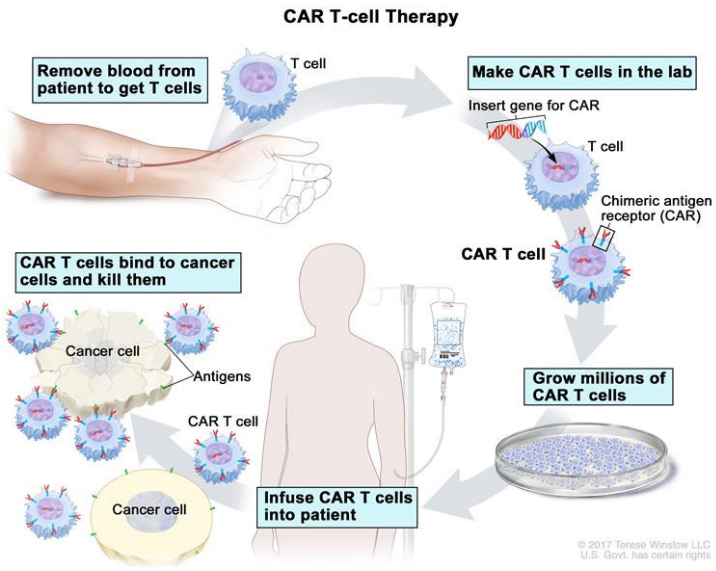
Capital Issued as at 11 June 2020	
Fully Paid Ordinary Shares	394,260,627
Options:	
Options Expiring 31 March 2023 @ $0.0625 (Listed)	95,388,827
Unlisted Options with Varying Exercise Dates and Prices	9,815,000
Fully Diluted	**499,464,454**

OMNICAR PLATFORM

- OmniCAR is a modular CAR-T platform that enables multi-antigen targeting with a single cell product and the ability to control T-cell activity. T-cell activity is able to be controlled because the platform's Chimeric Antigen Receptor (CAR) system decouples antigen recognition from the T-cell signalling domain.
- The OmniCAR platform potentially has applications across many cell therapies, however the company will be focusing on developing next generation CAR-T cell therapy.
- CAR-T cell therapy has provided significant advancements in the treatment of blood cancers with response rates of ~80% in certain lymphomas. The FDA approval of two CAR-T therapies for the treatment of blood cancer in 2017, Kymriah and YesCarta, has seen an increased interest in research and development in the field with a focus on expanding its use to treat solid tumours. However, there has been limited success to date with the use of CAR-Ts to treat solid tumours due to the nature and complexity of solid tumours compared to blood cancers. As discussed below, the OmniCAR platform has the potential to overcome the barriers that currently exist with the use of CAR-T in solid tumours as well as improving the safety and efficacy of CAR-Ts in the treatment of blood cancers.

What is CAR-T Cell therapy?

- CAR-T therapy involves the genetic engineering of a patient's own T-cells. T-cells are immune system cells critical in orchestrating an immune response to the presence of cancerous cells. Essentially CAR-T cell therapy is designed to use a patients immune system to combat cancer.
- To deliver the therapy, blood is drawn from the patient from which the T-cells are separated. A gene is then added that makes the T-cells produce a protein called Chimeric Antigen Receptors (CARs) on their surface. Once the CAR-T-cells multiply in the lab the CAR-T-cells are given to the patient by infusion. The CARs allow T-cells to recognise and kill cancer cells with the specific antigen on their surface. The below graphic provides a visual representation of how CAR-T cell therapy works.



Source: National Cancer Institute (NCI)

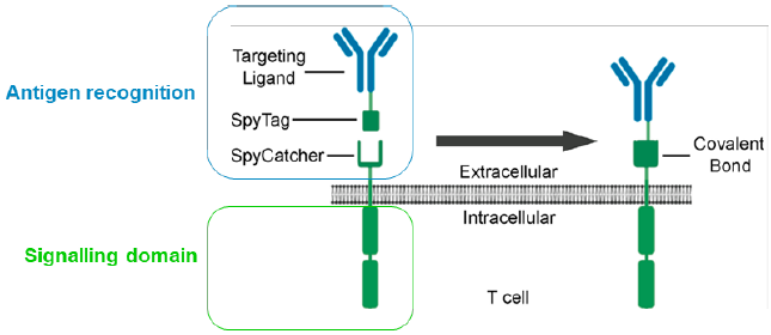
Limitations of First Generation CAR-Ts

- CAR-T cell therapy has seen unprecedented success in some cases with the treatment of blood cancer, however, there are a number of limitations with the current (first generation) therapies. These limitations include:
  - **Time and cost:** CAR-T cell therapies currently cost hundreds of thousands of dollars and it takes time to develop the reengineered T-cells before they can be administered.
  - **Safety/Control:** CAR-T cell therapy can have serious safety implications. To be effective, reengineered T-cells are injected into the body. Once they are injected into the body there is no way of controlling them and this can result in sending a patients immune system into overdrive and result in potentially fatal outcomes or long-term adverse effects.
  - **Lack of Targets:** CAR-T therapy has been effective in blood cancers because of the relatively linear nature of blood cancer, however, solid tumours are much more complex with different cancer types exhibiting different targets and in some cases multiple targets. This has been one of the key barriers to the use of CAR-Ts in solid tumours to date.
  - **Antigen Escape:** A common mechanism of resistance to CAR-T therapy is the loss or down regulation of the target antigen. The CAR-T drives cancer cells to evolve by modulating expression of the target antigen through either loss or diminished expression to a level that is undetectable by the CAR-T-cells. This obviously makes follow up treatment less successful as the cancer cells evade detection. The cancer cells have also shown to switch lineage to avoid detection, meaning the cell morphs to express an alternate antigen.

How Does OmniCAR Work?

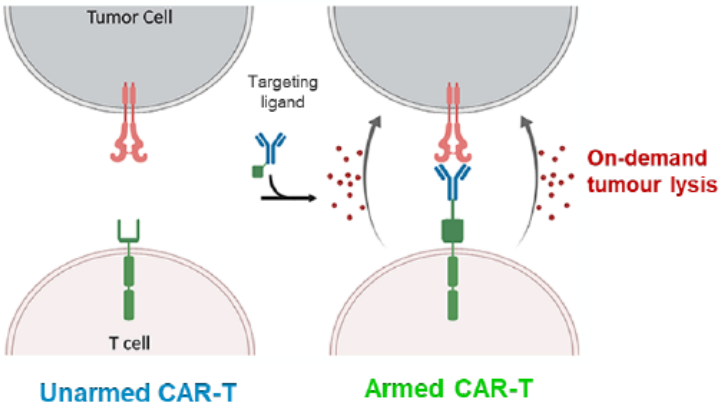
- As mentioned above, OmniCAR is a modular CAR-T platform whereby inactive CAR-T-cells are administered to the patient. The T-cells are activated in a separate administration of the targeting ligand (binder). This provides the clinician control of the T-cells post administration, which is currently not available in first generation CAR-Ts.
- The platform is antigen agnostic and therefore the target can be switched by administering a different targeting ligand.
- The Spy Tag/SpyCatcher binding system, licenced by PTX, is used to deliver the targeting ligand to the cells. The binder is tagged with Spy Tag that covalently binds to the counterpart SpyCatcher on the surface of the engineered cell therapy product.

OmniCAR Platform Mechanism



- The OmniCAR system creates on-demand tumour killing whereby the T-cells remain inactive until the binder is administered. Once armed with the targeting ligand, the CAR-T-cells are capable of binding to and killing the tumour cells.

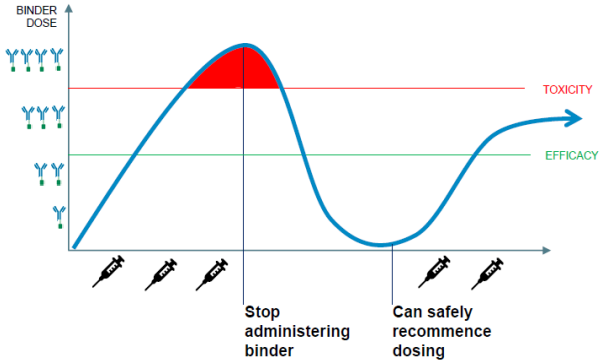
OmniCAR On-Demand Tumour Killing



- Control post administration allows the clinician the ability to limit the amount of targeting ligand administered thereby allowing the clinician to monitor the patients tolerability of the treatment, addressing the safety concerns with current CAR-T therapy.

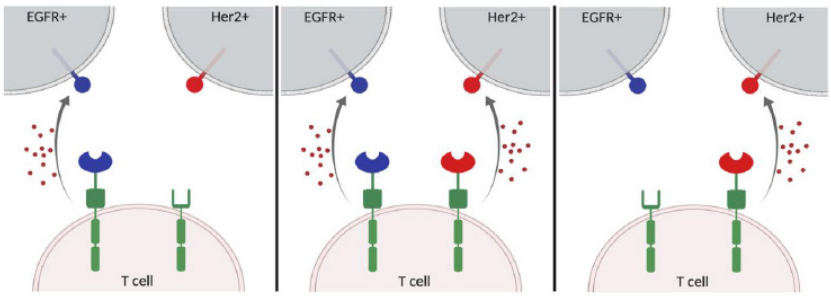
- One of the key features of the OmniCAR platform is the platform allows for the T-cell activity to be switched off by ceasing the administration of the binder or by administering a blocking agent. Therefore, in the event of any safety concerns the treatment can be stopped and reevaluated. The cell activity can subsequently be reactivated to recommence treatment by recommencing the administration of the binder.

Control of T-cell Activity with OmniCAR



- OmniCAR provides the ability to target multiple antigens with a single receptor, single cell product. Given the platform is antigen agnostic, these targets can potentially be administered either sequentially or simultaneously. Preclinical evaluation has proven the ability to target either single or dual antigens through the use of the technology. This addresses the issue of antigen loss and lineage switch which has the potential to improve the current CAR-T treatment of blood cancer as well as address some of the heterogeneity issues experienced with the use of CAR-Ts to treat solid cancers.

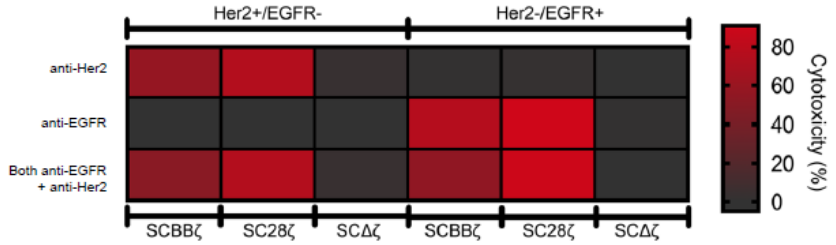
OmniCAR Can Target Single or Dual Antigens



Preclinical Studies

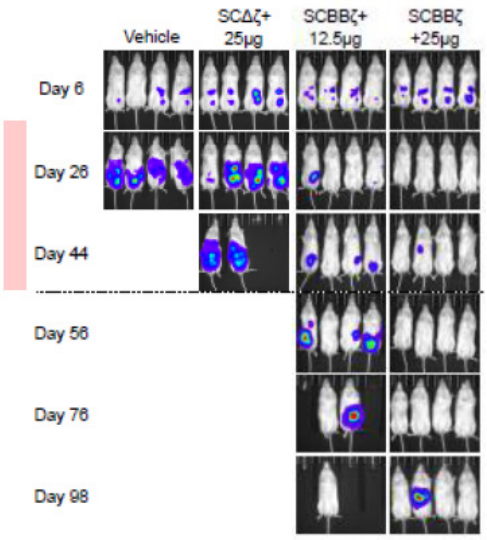
- The platform is in the early stages of development with the platform in the preclinical evaluation stage.
- Cell testing showed that when armed with either single or dual targets, SpyCatcher only targeted cells that expressed those targets. This testing also showed that SpyCatcher can be effective at targeting more than one target.
- While preclinical evaluation has shown "proof of concept" for targeting multiple antigens we note that the safety profile of targeting more than one antigen at any given time will not be fully realised until tested in humans.

SpyCatcher Targeting Single and Dual Oncology Targets



- *In vivo* testing in mice showed that loading more binder resulted in proportional killing of the tumour cells and improved survival rates.

***In Vivo* Testing**



Note: the pink denotes when the mice were dosed. The blue denotes the spread of cancer.
Source: Journal of the American Chemical Society/PTX

Clinical Development

- The company will seek to develop the OmniCAR platform internally as well as externally through collaboration.
- The company will be undertaking regulatory gap analysis to determine the next steps as well as commencing discussions with the appropriate regulatory agencies.
- We expect the company will seek to deliver a proof of concept swiftly through the use of external validation for the technology. The company will likely seek to deliver the proof of concept on known and validated targets in blood cancers before developing the technology for the potential use in solid cancers. The recent collaboration with Carina Biotech provides a convenient pathway for testing on new solid tumour targets.

PTX 200

- PTX 200 is the most clinically advanced drug candidate in the company's portfolio with three clinical trials currently in progress to test the efficacy of PTX 200 in breast cancer, acute myloid leukemia (AML) and ovarian cancer.
- PTX 200 targets tumours that depend on the AKT protein for survival. AKT has been proven to be hyperactivated in numerous cancers, making it an established anticancer target. A number of cancers escape the killing action of chemotherapy drugs by hyper-activating AKT to enable survival. PTX 200 seeks to block the AKT signalling pathway to reduce resistance to chemotherapy treatment.
- PTX 200 provides a different delivery mechanism which is primarily what differentiates it from other AKT inhibitors being developed. Other AKT inhibitors work by mimicking the ATP molecule. PTX 200 works by attaching itself onto the AKT protein, preventing AKT from being activated and thereby allowing the chemotherapy drugs to kill the cancerous cells.
- In the event the results from the clinical trials are positive, the company will be seeking to progress further development of the PTX 200 with big pharmaceutical companies through either a sale or licence agreement.
- In October 2018, the company entered into a strategic collaboration with a private US based drug development company (company not disclosed) to develop new formulations of PH domain and AKT inhibitors. The objective of the collaboration is to develop novel formulations to expand the potential therapeutic applications of PTX 200.

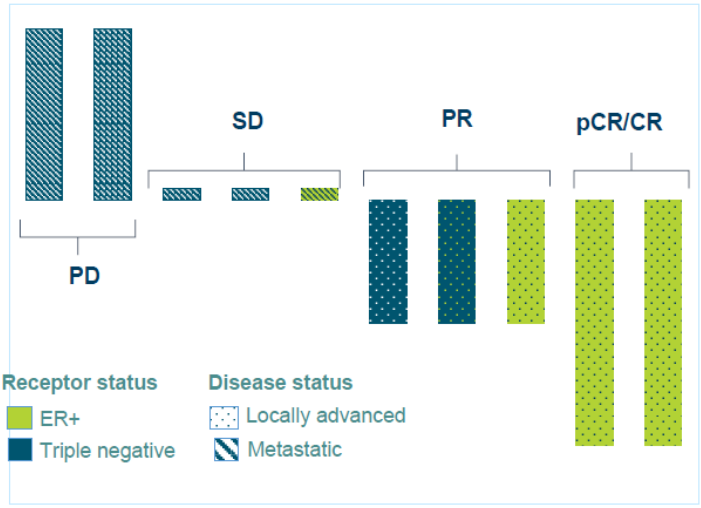
CLINICAL DEVELOPMENT

- There are currently three clinical trials underway for PTX 200 across three different cancers. There are two Phase Ib trials in progress for ovarian cancer and AML and a Phase II trial for breast cancer.

Breast Cancer

- The Phase II trial in HER2 negative breast cancer was initiated after positive results from the Phase Ib trial, which was completed in 1H'CY2018. The Phase Ib trial included 28 patients who received a combination of PTX 200 and the chemotherapy drug Paclitaxel. Of the 28 patients, 10 patients were evaluable of which five patients had locally advanced disease (yet to spread to other parts of the body) and five had metastatic disease (has spread from the primary site to other areas of the body).
- The 10 evaluable patients had an Overall Response Rate (ORR) of 50%, which is above the industry average of 25%. Two patients showed a complete response, three patients showed a partial response, three patients showed a stable response whereby the cancer had not progressed or diminished and two patients showed the cancer had progressed.
- The treatment was particularly successful in the five patients that had the locally advanced disease, with 100% ORR. Two patients showed a complete response and the remaining three patients showed a partial response. Given the expectations for patients with locally advanced breast cancer are an ORR of 25%, these results are particularly encouraging.
- The Phase Ib trial treated patients with triple negative breast cancer (breast cancer that does not have any of the three receptors found on breast cancer cells: estrogen, progesterone and HER2 receptors), and ER+ cancer which has estrogen receptors. Both these types of breast cancer are difficult to treat and as such there is an unmet clinical need.

Response Rates of Breast Cancer to PTX 200 Phase 1 Trial



Note: pCR/CR = Complete Response; PR = Partial Response; SD = Stable Disease; PD = Progressive Disease

Source: PTX

- The Phase II trial will seek to include 26 patients and will be completed in two stages. If at least three complete responses are observed in the first 11 patients, the trial will be expanded to include a further 15 patients. The Phase II trial will focus on locally advanced HER2 negative breast cancer. According to Cancer Australia, 10%-20% of breast cancer diagnosed in Australia each year are locally advanced breast cancer. Five patients from the Phase Ib trial qualified for inclusion in the Phase II trial.
- In December 2019, the company announced positive results from the Phase IIa clinical trial in HER2 negative breast cancer. The results from 11 women with the locally advanced disease exhibited an overall response rate (ORR) of 91%. 10 of the 11 patients were evaluable due to the death of one of the patients. The death was unrelated to PTX 200. Two patients had a pathologic complete response and the remaining 8 patients all experienced partial responses.
- 9 of the 10 evaluable patients continue to be free of disease progression with progression-free survival averaging 22 months so far, tracking favourably against the 24 month window during which relapse typically occurs. The company will undertake a new trial with a focus on ER+ breast cancer given this patients with this disease appear to be the most responsive to PTX 200.
- We note that Roche has progressed it's AKT inhibitor "Ipatasertib" to a Phase III clinical trial where it is being tested in metastatic triple negative breast cancer. The progression of Ipatasertib validates the concept of PTX 200 and AKT as a valid target in breast cancer. We also note that Roche has commenced a Phase Ib study of Ipatasertib in combination with chemotherapy treatment and an immune checkpoint inhibitor. This suggests that there may be potential to investigate the use of PTX 200 with other immunotherapies to enhance the efficacy of treatment.

AML & Ovarian Cancer

- Phase Ib clinical trials are in progress for the use of PTX 200 in AML and ovarian cancer in combination with chemotherapy treatment.
- For the AML trial, PTX 200 will be combined with Cytarabine, a chemotherapy drug used to treat AML. The study includes 13 patients. Two of those patients had a complete response to treatment, however three patients experienced toxicity issues, one of which was determined to be a result of dose limiting. As a result, the company has expanded the trial to explore PTX 200 with a lower dose of Cytarabine. An additional 9 to 12 patients will be recruited for the expansion of the study. A third patient in the program has subsequently shown a complete response.
- The Phase Ib trial for ovarian cancer will treat up to 12 patients. Given the toxicity issues experienced with the AML trials, the study has been expanded to include an additional 18 patients which will use a lower dose of the chemotherapy treatment.

- In December 2019, the company released interim results for the ovarian cancer trial. 80% of the 15 patients treated exhibited disease control with 11 patients exhibiting stable disease and one patient having a partial response. There were seven adverse events across the 15 patients with only one of these events considered related to PTX 200.

PTX 100

- PTX 100 is also seeking to block a significant cancer pathway, the Ras pathway. The Ras pathway and Ras mutation is a significant contributor to a number of cancers. According to the National Cancer Institute (NCI) more than 30 percent of all human cancers, including 95 percent of pancreatic cancers and 45 percent of colorectal cancers, are driven by mutations of the Ras family of genes. Given this, the Ras pathway has been identified as a cancer target that has attracted significant interest, however to date, it has not been possible to develop inhibitors of Ras signalling with existing drug development technologies. Given the significance of Ras protein, the potential market for a Ras inhibitor is substantial.
- Amgen announced encouraging results from Phase I studies of it's Ras inhibitor AMG-510, which has resulted in a surge of interest in the industry. This also highlights the potential interest from big pharma in this area of the market.
- PTX 100 doesn't seek to target Ras directly, but targets the pathway downstream, blocking the cancer growth enzyme known as Geranylgeranyl Transferase-1 (GGT-1), which inactivates Rho, Rac and Ral circuits in cancer cells downstream of Ras. Blocking GGT-1 will hopefully reduce the spread of cancer and lead to a reduction in the resistance to chemotherapy treatment.
- PTX is seeking to follow the development path of Loxo Oncology Inc who were acquired by Eli Lilly and Company for US$8 billion in January 2019. Loxo Oncology developed Larotrectnib, a targeted treatment for cancers with TRK fusions. There was an unmet need in this field even though there is a small patient population with only 2,500-3,000 new cases in the US each year. Loxo Oncology used the basket approach for their clinical trials and it expedited the development with the drug only taking 4 years to gain FDA approval from initiating the Phase I trial.
- Given case studies such as Loxo Oncology, PTX 100 has the potential to represent significant value to the company in the event the drug candidate produces promising results from the clinical trials.

CLINICAL DEVELOPMENT

- The company commenced a Phase Ib clinical trial for PTX 100 across multiple cancers in 2019. The Phase Ib trial will be take a "basket" approach to assess the drug candidate on multiple cancers with a view to addressing specific mutations as opposed to the origin of the tumour. The "basket" approach potentially provides a faster way to identify cancer patients who will potentially benefit from the use of the drug candidate.
- The trials will be lead by Professor H. Miles Prince AM and will be conducted at the Epworth Hospital in Melbourne, Australia. The company has subsequently added Peninsula & Southern Eastern Haematology and Oncology Group (PASO) located in Australia, as a new site to the study to aid recruitment and diversity of cancer types with PASO expected to focus on solid tumours.
- The trial will enrol up to 24 patients with advanced malignancies to evaluate the safety and efficacy of the drug candidate across two different doses. The study will assess PTX 100 with the standard of care chemotherapy treatment across patients with myeloma, T-cell lymphomas, gastric and pancreatic cancers with Ras and RhoA mutations.
- Early stage studies conducted at the Pennsylvania State University and Indiana State University in patients with advanced solid tumours showed that PTX 100 was well tolerated and achieved stable disease in patients.
- In April 2020, the company announced that PTX 100 will proceed to the next dose level following successful completion of the first cohort of patients (three patients) and demonstrating acceptable safety outcomes. Patients treated had varying types of blood cancer. One of the patients in the trial with cutaneous T cell lymphoma experienced symptomatic relief and will continue with PTX 100 treatment.

ONCOLOGY MARKET OPPORTUNITY

- 2019 represented another significant year for the oncology deal making landscape with a total disclosed deal value of US$171 billion. Licensing activity accounted for US$47 billion while M&A activity accounted for US$119 billion, according to BioPharma Dealmakers. 65% of licensing deals were in immunotherapy.
- The below table highlights the US$1 billion plus M&A deals that were done in 2019. Dominating the activity was the BMS acquisition of Celgene for US$74 billion.

Billion Dollar Plus Oncology M&A Deals

Buy Side	Sell Side	Total Projected Deal Value (US$ billions)	Oncology Technology
BMS	Celgene	$74.0	Cell therapy, small molecule
Pfizer	Array Biopharma	$11.4	Precision medicine (MAPK/BRAF)
Eli Lilly	Loxo Oncology	$8.0	Precision medicine (NTRK)
Ethicon	Auris Health	$5.75	Diagnostics (robotics)
Sumitomo Dainippon	Roivant	$3.0	Small molecule (GnRH inhibitor)
Exact Sciences	Genomic Health	$2.8	Diagnostics (genomics)
Merck & Co	ArQule	$2.7	Precision medicine (BTK/AKT/FGFR)
Sanofi	Synthorx	$2.5	Synthetic biology (cytokines)
Merck& Co	Peloton Therapeutics	$2.2	Small molecule (HIF2a)

Source: BioPhama Dealmakers

- There were also a number of billion dollar plus licensing deals in 2019, tabled below. Of the 12 licensing deals, 8 were for immunotherapy technologies. Further to this and supportive for the recent transaction by PTX, the majority of the deals were in the discovery/preclinical phase.

Billion Dollar Plus Oncology M&A Deals

Licensee	Licensor	Total Projected Deal Value (US$ billions)	Mechanism	Clinical Status
AstraZeneca	Daiichi Sankyo	$6.9	Her2 antibody-drug conjugate	Phase III
GSK	Merck KGaA	$4.2	PD-L1-TGFBR fusion protein	Phase II
BeiGene	Amgen	$4.0	Anti-RANK-L antibody, anti CD19 antibody, proteasome inhibitor	Approved
Nanjing CTT	Abpro	$4.0	Bisepecific T cell engagers	Discovery
Gilead	Nurix	$2.3	Protein degradation	Discovery
Genetech	Skyhawk	$2.0	RNA alternative splicing modulators	Discovery
Celgene	Immatics	$1.6	TCR cell therapy	Discovery
Amgen	Hummingbird	$1.2	Antibody drug discovery	Discovery
Jazz	Codiak	$1.1	Exosome therapeutics	Discovery
Takeda	Turnstone	$1.0	Oncolytic virus expressing immunomodulators	Preclinical
Cytovant HK	MediGene	$1.0	TCR cell therapy, antigen loaded DC	Phase II
Jazz	PharmaMar	$1.0	RNZ polymerase II inhibitor	Pre -registration

Source: BioPhama Dealmakers

CAR-T CELL THERAPY MARKET OPPORTUNITY

- CAR-T therapy has become a focus of immunotherapy research and development since the FDA approved the first two CAR-T therapies in 2017 for commercial use in blood cancers in the US - Kymriah and Yescarta.
- In 2018 global sales of Kymriah was US$76m and sales of Yescarta were US$284m. We note this represents the first year of sales post the approval. According to consensus estimates, global sales for both these drugs are expected to increase significantly by 2022, to US$780m for Kymriah and $US1.4b for Yescarta.
- This indicates that a substantial market exists for CAR-T therapies and this has resulted in a number of transactions in the CAR-T space in addition to an increase in the number of clinical trails on CAR-T therapies.

- The market opportunity is two-fold for PTX given the collaboration and 100% IP rights for Carina's CAR-T technologies for solid tumours and the recently acquired OmniCAR platform. Below we provide a table outlining some notable acquisitions of companies with CAR-T assets to highlight the potential market value of CAR-T assets.

Company Acquisitions with CAR-T Assets

Date	Company	Acquired	Deal Value	Technology
August 2017	Celgene	Juno Therapeutics	$9b	JCAR017 (Phase I/II) + 3 x CAR-T and 4 x TCR (Phase I) + 1 x TCR (Phase I/II) + pre-clinical pipeline.
December 2017	Gilead Sciences	Cell Design Laboratories	$587m	Small molecule ON-switch (platform technology) + synNotch dual antigen recognition (platform) + pre-clinical CAR-T pipeline.
January 2018	Gilead Sciences	Kite Pharmaceuticals	$11.9b	KTE-C19 (Phase II complete, ready for market launch) + 1 x TCR and 1 x CAR-T (Phase I) + pre-clinical pipeline.

Source: PTX

- With respect to the OmniCAR platform value potential, there are only a select few companies developing universal immune receptor platforms globally. PTX is the only ASX-listed company to be developing this technology.
- In December 2019, Astellas acquired Xyphos Biosciences for a total of US$665 million with an upfront payment of US$120 million. Xyphos was in the preclinical development of their UIR platform "convertibleCAR". A transaction of this size represents a value that is 40x the current market cap of PTX.

PTX 200 MARKET OPPORTUNITY

- There are currently no commercially available AKT inhibitors, however, given the significance of this cancer target the market for an approved product is expected to be significant.
- Focusing on the HER2 negative breast cancer, the market was US$5.4 billion in 2015, a large majority of which was dedicated to chemotherapy drugs. The market is expected to increase to US$10.6 billion by 2025.
- If the Phase II trials show encouraging results from both a safety and efficacy perspective, we would expect there to be demand from big pharma. We note that Roche have progressed to a Phase III clinical trial with their AKT inhibitor which has a focus on metastatic triple negative breast cancer. With PTX 200 clinical trials focusing on locally advanced HER2 negative breast cancer, PTX 200 may be a nice complement to Roche's AKT inhibitor or an attractive target for a company looking to expand their oncology portfolio.

PTX 100 MARKET OPPORTUNITY

- There is a significant market opportunity for PTX 100 in the event clinical trials produce positive results. The Ras pathway has been termed "undruggable", with many companies failing to be able to inhibit this target. With more than 30 percent of all human cancers, including 95 percent of pancreatic cancers and 45 percent of colorectal cancers, driven by mutations of the Ras family of genes, the market potential for an approved product is substantial.
- We focus on the recent acquisition of Loxo Oncology Inc by Eli Lily for PTX 100, given PTX is seeking to follow the development pathway of Loxo Oncology for their targeted oncology therapy Larotrectnib. Loxo Oncology was acquired for US$8b following the FDA approval of Larotrectnib. The basket approach for the clinical trial allowed for Loxo Oncology to focus on the mutation as opposed to the source of the cancer to determine who would benefit from the treatment. It took only 4 years from the initiation of Phase I clinical trials to FDA approval.
- In the event the clinical trials result in strong response rates to PTX 100 across the multiple cancers, there is the potential for the drug candidate to add significant value to the company with big pharma prepared to outlay significant capital to acquire access to targeted oncology therapies, as highlighted by the Loxo Oncology acquisition.

INVESTMENT VIEW

- PTX provides a unique investment opportunity on the domestic market given the company is the only ASX-listed company with UIR technology. The UIR platform puts PTX at the forefront of CAR-T cell therapy development and given recent activity in the CAR-T space offers significant value potential to the company. We acknowledge that the OmniCAR platform is in the early stages of development and the development of the platform will encounter its own unique challenges.
- The recent collaboration with Carina Biotech for the development of their solid tumour targets provides a convenient pathway for the development of the OmniCAR platform's use in solid tumours.
- The company is also advancing its targeted cancer therapies, PTX 200 and PTX 100. PTX 200 has shown encouraging results in the treatment of locally advance breast cancer. The company will be seeking to secure a partner or a licence deal on the results of the Phase II clinical trial.
- PTX 100 is progressing as desired through the Phase Ib trials with the company proceeding to the next dose levels. In the event the company can continue to generate positive outcomes from the clinical trials for PTX 100 we expect there to be some interest in the drug candidate given the significance of the Ras pathway in cancers and the inability to inhibit this target to date.
- The company will be exposed to both development and financial risks as the company progresses the development of the product pipeline. The company has sufficient cash reserves in the near-term to cover the acquisition of the UIR platform and the initial development, however, we expect the company will have to raise capital to continue to progress the clinical development of the OmniCAR platform, fund the collaboration with Carina Biotech and clinically progress PTX 100.

RISKS

- **Clinical Development Risk:** As with all drug development companies there is the risk that accompanies the clinical development of the product portfolio. The binary nature of drug development means that clinical trials may not provide satisfactory outcomes and therefore may not progress.
- **Competition Risk:** Research and development in oncology therapeutics is continuing to grow given cancer is the second leading cause of death globally. As such the level of competition for in the market place is increasing. This plays a role in the deal making landscape but also results in competition for the patient pool for clinical evaluation.
- **Capital Risk:** The company has cash reserves to maintain the operations and development of its product portfolio for the next 18 months, however, the company will likely have to raise capital to continue to progress the development of the product pipeline. The capital may be raised at a discount to the share price and be dilutive to existing shareholders or the worst case scenario is that the company is unable to raise sufficient capital to progress product development. We view the risk of the worst case scenario as very low given the companies product suite.
- **Regulatory Risk:** A risk of drug development is regulatory risk. Biotech companies are heavily reliant on regulatory bodies to determine whether or not a product can progress through clinical trials and ultimately progress to market.
- **Foreign Exchange Risk:** The company has tried to mitigate foreign exchange risk by moving trials to Australia where possible, however manufacturing of products and development of the OmniCAR platform will likely be based internationally. Therefore, movements in the Australian dollar against relevant currencies will impact the companies operating costs either positively or negatively.

BOARD AND MANAGEMENT

Steve Engle - Non-Executive Chairman: Mr. Engle is CEO of CohBar, a clinical stage biotechnology company focused on the development of mitochondrial based therapeutics, an emerging class of drugs for the treatment of age-related diseases and extending healthy lifespan. Previously, he was CEO of Averigon, an advisory firm to the life science industry. Prior to that, he was Chairman and CEO of XOMA, a developer of antibody therapeutics of multiple diseases, and Chairman and CEO of La Jolla Pharmaceutical Company, which discovered the biology of B cell tolerance, developed the first B cell toleragen for lupus patients, and received an approvable letter from the FDA.

Mr. Engle served as VP of Marketing for Cygnus, a drug delivery company, where he helped gain FDA approval of and launch Nicotrol for smoking cessation. Mr. Engle is a member of the board of AROA, a developer and marketer of regenerative products, and of Author-it Software Corporation, a developer of authoring information solutions for pharmaceutical and biotechnology companies. He is a former director of industry associations, BIO, BayBio and BIOCOM.

Steven Yatomi-Clarke - CEO and Managing Director: Mr. Yatomi-Clarke took over as CEO of Prescient Therapeutics in 2016 and has overseen its progression from start-up phase. Mr. Yatomi-Clarke manages a team in Australia and the US and has been instrumental in strategy development; licensing; initiating and managing clinical trials; fundraising and business development.

Previously, Mr. Yatomi-Clarke had a distinguished career as an investment banker specialising in the life sciences sector, where he was consistently one of the country's most prolific bankers, involved in primary and secondary offerings, corporate advisory and M&A assignments. In particular, he leveraged his combined backgrounds in science and finance to identify undervalued and unlikely opportunities and structure deals for the mutual benefit of companies and investors.

Dr. James Campbell - Non-Executive Director: Dr. Campbell brings to Prescient a solid track record as a scientist and commercial executive. Dr. Campbell has more than 20 years of international biotechnology research, management and leadership experience and has been involved in the creation and/or transformation of multiple successful Australian and international biotechnology companies. He is currently CEO of Patrys Limited, a company developing novel antibody therapeutics for oncology.

Dr. Campbell was previously the Chief Financial Officer and Chief Operating Officer of Chemgenex, which was acquired by Cephalon for $230 million in 2011. His responsibilities ranged from IP management to licensing and business development and as a member of the executive team, he helped steer and transform the company from a $10 million research based entity to a company with completed clinical trials and regulatory dossiers submitted to the FDA and EMA before its $230 million sale. Dr. Campbell also has experience advising private biotechnology companies in the US and New Zealand with capital raisings and partnering negotiations.

Dr. Allen Ebens - Non-Executive Director: Dr. Ebens brings over twenty four years of drug development experience in oncology and hematology, beginning in drug discovery at Exelixis before moving to Genentech where over 11 years he worked from concept to clinic across multiple therapeutic platforms including antibodies, small molecule drugs, antibody-drug conjugates, and T cell recruiting antibodies. Dr. Ebens was recruited from Genentech to establish oncology discovery research at Juno Therapeutics (a CAR-T pioneer), and served as Senior Director, Immune Oncology at NGM Biopharmaceuticals.

Dr. Ebens is currently Chief Scientific Officer of Vera Therapeutics. Dr. Ebens' scientific contributions include numerous peer-reviewed publications of original research, a significant patent portfolio, and the advancement of nine discovery projects from initial concept to clinical development for multiple targets including one marketed therapeutic. He completed his PhD at UCLA and postdoctoral training at UCSF.

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