

## ASX Announcement

### Race AGM presentations and strategic update

- Race unveils strategic update and “Three Pillar” strategy, designed to deliver outsized commercial returns for shareholders
- Copies of Chairman’s address and presentation for today’s Annual General Meeting of shareholders attached
- A longer form video presentation will be released to shareholders during the week commencing 7 December 2020

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**30 November 2020** – Race Oncology Limited (**Race** or the **Company**) (ASX: RAC) is pleased to attach a copy of the Chairman’s address being delivered by Dr John Cullity at today’s Annual General Meeting of shareholders. Following the address is a strategic update presentation, which will be delivered by Phil Lynch, CEO and Managing Director, together with Dr Daniel Tillett, CSO and Executive Director.

CEO/Managing Director, Phil Lynch commented, “2019-2020 has been a pivotal period for Race. New data on Bisantrene’s potential as both a highly targeted precision oncology drug and as a better chemotherapeutic approach led the Board to examine and refine our strategy. We are pleased to share our new Three Pillar strategy, which positions Bisantrene as a much higher value and multi-faceted transactional opportunity and is designed to deliver better therapeutic alternatives for patients across a range of cancer types.”

Investors wishing to attend today’s Annual General Meeting can find access details in the Notice of Meeting as lodged with the ASX on 28 October 2020.

A longer form video presentation will be released to shareholders during the week commencing 7 December 2020.

## Chairman's address, 2020 AGM

This past financial year has been exceptional, if not spectacular, with respect to clinical progress, human resource build-out, fortification of our balance sheet and construction of strategy.

At last year's AGM, we announced the 5-path strategy to maximize Bisantrene. The team has diligently executed against that strategy and made genuine progress in advancing the clinical and commercial prospects for our core asset.

Race achieved a substantial milestone when in June this year we reported that expectations had been far exceeded by Bisantrene clinical data. A 40% patient response rate was observed in the 10-person, single cycle, single agent, Acute Myeloid Leukaemia (or AML) trial conducted by Clinical Professor Arnon Nagler at Chaim Sheba Medical Center in Tel Aviv, Israel. Moreover, the trial showed that Bisantrene was well tolerated, with no unexpected toxicities. These data demonstrated the utility of Bisantrene in a modern AML context and build further upon our drug's extensive historical data set.

As well as looking back, today we plan to talk about events that have occurred this financial year and to provide you with guidance as to where we're heading. For instance, last week we were pleased to report important pre-clinical data which had been produced in collaboration with University of Newcastle's Hunter Medical Research Institute. These pre-clinical data support and underscore the decision to take Bisantrene into breast cancer clinical trials. Phil and Daniel will cover this more in their strategic update.

We have a strong, capable Board and Management team, in addition to key alliances and vendor partnerships that effectively provide the Company with needed expertise and capacity to execute upon strategy.

We were joined last year by Dr Daniel Tillett, as both an Investor and Director, then later as our Chief Scientific Officer. Daniel has made a significant contribution to this year's results, particularly in helping to reshape our strategic plan. Dr Bill Garner who helped found Race stepped down from the Chair role and later our Board. To Bill, our sincere thanks for his contributions and leadership. Chris Ntoumenopoulos, also a founding Director, stepped down after years of valued service and also receives our thanks.

Our former CEO Peter Molloy left the business in mid-2020 following which Daniel and I shared executive responsibilities. At that time, we appointed Phil Lynch to the Board and, observing his proven leadership skills, invited him to take on the Chief Executive role and lead in partnership with Daniel – a strategy that has worked well. The Chair of our Clinical Advisory Board, Professor Borje Andersson joined the Board of Directors in January this year and later assumed executive responsibilities as Chief Medical Officer. Thank you Borje.

At last year's AGM, we shared with you a cash balance of \$1.7m – as of September 30 this year, our balance was \$5.66m. We continue to run a lean, efficient business, taking on

costs and resources judiciously, and commit to maintaining that approach as we execute against strategic objectives.

Let me share my excitement about the new strategic plan. Bisantrene has an established legacy of safety and efficacy in AML and that remains core to our strategy. However, in a July scientific publication, our drug was shown to be a potent inhibitor of Fat Mass and obesity associated (FTO) protein, which has recently come to light for the central role it plays in the proliferation of a wide range of cancers. This association was made via a remarkable preclinical study led by investigators at the City of Hope Hospital in Los Angeles, supported by a US National Institutes of Health (NIH) grant and published in the high impact journal, *Cancer Cell*. This exceptional research shone a light on the potential transformation of Bisantrene from being an “old chemotherapeutic” to a **targeted therapeutic agent** with broad application across oncology – both solid and so-called liquid tumours. FTO effectively repositions Bisantrene, and in so doing recalibrates the transactional landscape – again as reflected in today’s strategy.

We have considerable work ahead to unlock the FTO opportunity, but we have the team and strategies to do so. Race Oncology is dedicated to constructing outsized value for Bisantrene and its shareholders, so with new strategy comes both the drive and focus to identify value maximising partnerships and alliances. We’ll be setting to that all the more this year.

So again, it’s been a significant year of progress. Yet I’m confident that we have the plans and programs identified to build upon it. Together with the Board, allow me to express our appreciation for the support of shareholders and our anticipation as we progress on this exciting journey.

Dr. John Cullity

Chairman

-ENDS-

### **About Race Oncology (ASX: RAC)**

Race Oncology is an ASX listed precision oncology company with a Phase II/III cancer drug called Bisantrene.

Bisantrene is a potent inhibitor of the Fat mass and obesity associated (FTO) protein. Over-expression of FTO has been shown to be the genetic driver of a diverse range of cancers. Race is exploring the use of Bisantrene as a new therapy for melanoma and clear cell renal cell carcinoma, which are both frequent FTO over-expressing cancers. The Company also has compelling clinical data for the use of Bisantrene as a



chemotherapeutic agent with reduced cardiotoxicity in Acute Myeloid Leukaemia (AML), breast and ovarian cancers and is investigating its use in these areas.

Race is pursuing outsized commercial returns for shareholders via its 'Three Pillar' strategy for the clinical development of Bisantrene. See more at [www.raceoncology.com](http://www.raceoncology.com).

**Release authorised by:**

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RACE  
ONCOLOGY

ANNUAL GENERAL MEETING  
PRESENTATION, 30 NOVEMBER 2020



# INTRODUCING THE NEW RACE



# PRECISION ONCOLOGY

# 2019-2020 A PIVOTAL PERIOD FOR BISANTRENE

**July 2019**

First patient treated in Phase II Bisantrene trial

**Nov 2019**

5 Path Strategy released for Bisantrene

**May 2020**

Race starts preclinical breast cancer study for Bisantrene

**June 2020**

Bisantrene highlighted as potent inhibitor of FTO in *Cancer Cell*

**Sept 2020**

CCSA appointed clinical + FDA regulatory strategic advisors

**Nov 2020**

Bisantrene data published in the European Journal of Haematology

**Nov 2020**

Breast cancer clinical trial program initiated

**Aug 2019**

Race Announces 3rd US patent for Bisantrene

**March 2020**

Phase II Bisantrene trial recruitment completed

**June 2020**

Impressive 40% response in Phase II AML trial

**July 2020**

Race secures 4th US patent for Bisantrene

**Nov 2020**

Bisantrene data to be presented at ASH 2020

**Nov 2020**

Impressive pre-clinical Bisantrene breast cancer results

# STRATEGIC UPDATE

## ACTIVITIES THAT LED US HERE

### Informed by

Regulatory assessment



M&A evaluation



Board evaluation



### Key decision

Race positioning Bisantrene as a **precision oncology agent**, with differentiated chemotherapeutic potential

### Which means

Evolved strategy to pursue **outsized rewards** for Race Oncology and its shareholders





# THREE HEROES

1 The drug

2 The team

3 The three pillars strategy



# 1. THE DRUG. BISANTRENE

Bisantrene is an anti-cancer agent developed in the 1980s by Lederle Pharmaceuticals

It was tested in >40 human trials; showed excellent activity in AML (acute myeloid leukemia), breast and ovarian cancer and was approved in France for AML.

Since acquiring Bisantrene, Race has



Successfully  
manufactured  
the GMP drug



Built a strong patent  
position



Received US Orphan  
Drug designation  
(7 years exclusivity)



Secured Rare  
Paediatric Disease  
designation and  
Priority Review  
Voucher designation

- Completed a single agent R/R AML trial in Israel with a 40% response rate – July 2020
- Released pre-clinical breast cancer data providing evidence to advance into human clinical trials as a potentially safer breast cancer treatment option

## 2. THE TEAM. SEASONED BOARD AND EXECUTIVE, KEY OPINION LEADERS

### BOARD



*Dr John Cullity,  
Non-Executive Chairman*



*Mr Phil Lynch,  
CEO and Managing Director*



*Dr Daniel Tillett,  
CSO and Executive Director*



*Prof Borje Andersson, MD  
CMO and Executive Director*

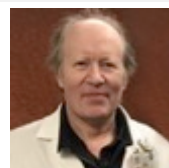
### MANAGEMENT



*Mr Phil Lynch,  
CEO and Managing Director*



*Dr Daniel Tillett, PhD  
CSO and Executive Director*



*Prof Borje Andersson, MD  
CMO and Executive Director*

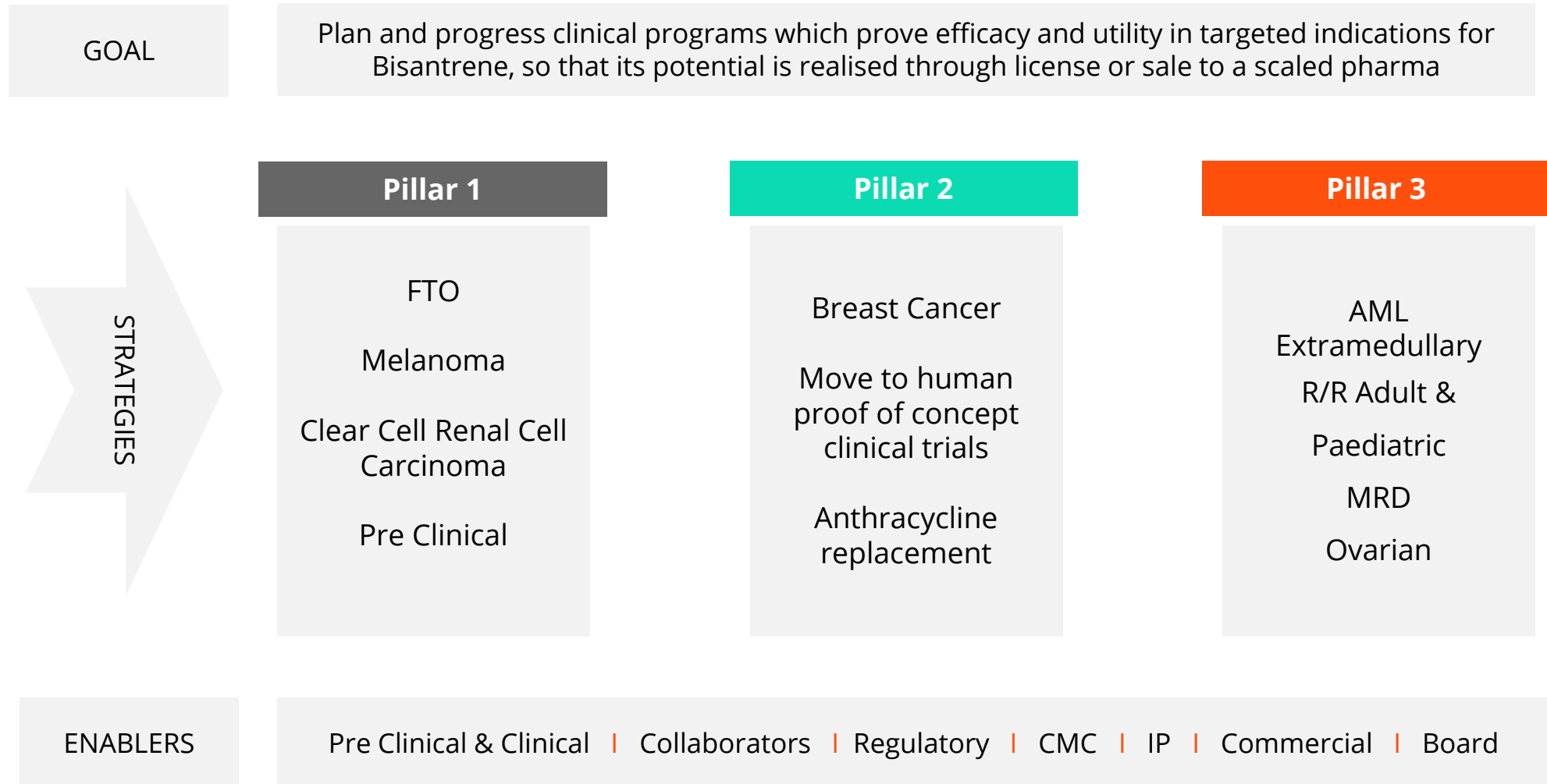


*Dr Marinella Messina, PhD  
Clinical Program Director*

## 2. THE TEAM. EXTENDED RACE TEAM

Business Advisors & Consultants		Clinical Advisors		Industry Partners and Scientific Collaborators	
Accountants	Onyx Corporate Pty Ltd	Clinical Advisory Board	Prof. Borje Andersson, MD, PhD, MD Andersson Cancer Centre, USA	Clinical Manufacturing Drug Product	IrySys LLC
Contracts Lawyer	Elevate Legal			Clinical Manufacturing Drug Substance	GVK Bio
IP Manager	Roberts Foster LLP			Clinical Manufacturing Packaging	PCI Pharma
Patent Lawyers	Ditthavong & Steiner P.C.	Clinical Advisory Board	Jaap-Jan Boelens, MD, PhD, Memorial Sloane Kettering, Cancer Centre, USA	Clinical Research Organisation	George Clinical
Patent Lawyers	Griffith Hack			Clinical Research Organisation	Proxima Clinical Research Inc
R&D Tax Lawyers	MJ Associates	Clinical Advisory Board	Didier Blaise, MD, Institut Paoli Calmettes, Haematology Dept., France	Clinical Research Organisation	Datapharm Australia Pty Ltd
Investor and Public Relations	IR Department			Clinical Research Organisation	Novatrials Ltd
Clinical Manufacturing Manager	DelBioPharma LLC	Scientific Advisors		Clinical Research Organisation	Agilex BioLabs Pty Ltd
Regulatory Affairs	CCS Associates	Collaborator	Nikki Verrills, PhD, University of Newcastle & Hunter Medical Research Institute	Clinical Research Organisation	Cyprotex Discovery Limited
Quality Assurance	Dianna Goldman Consulting Inc.	Collaborator	Jerome Wielens, PhD, University of Melbourne		
Calvary Mater Newcastle Hospital	Hunter Medical Research Institute				

# 3. THE THREE PILLAR STRATEGY



# PILLAR 1

## FTO

### Rationale

City of Hope identifies Bisantrene as highly potential FTO targeted agent at low dose

### Next Steps

Pre clinical evaluation in Melanoma and Clear Cell Renal Cell Carcinoma

Seek to run clinical trials to confirm FTO is a clinically valuable target

### Ambition

Show Bisantrene a clinically potent inhibitor of FTO in a range of cancers

## NEW FOCUS

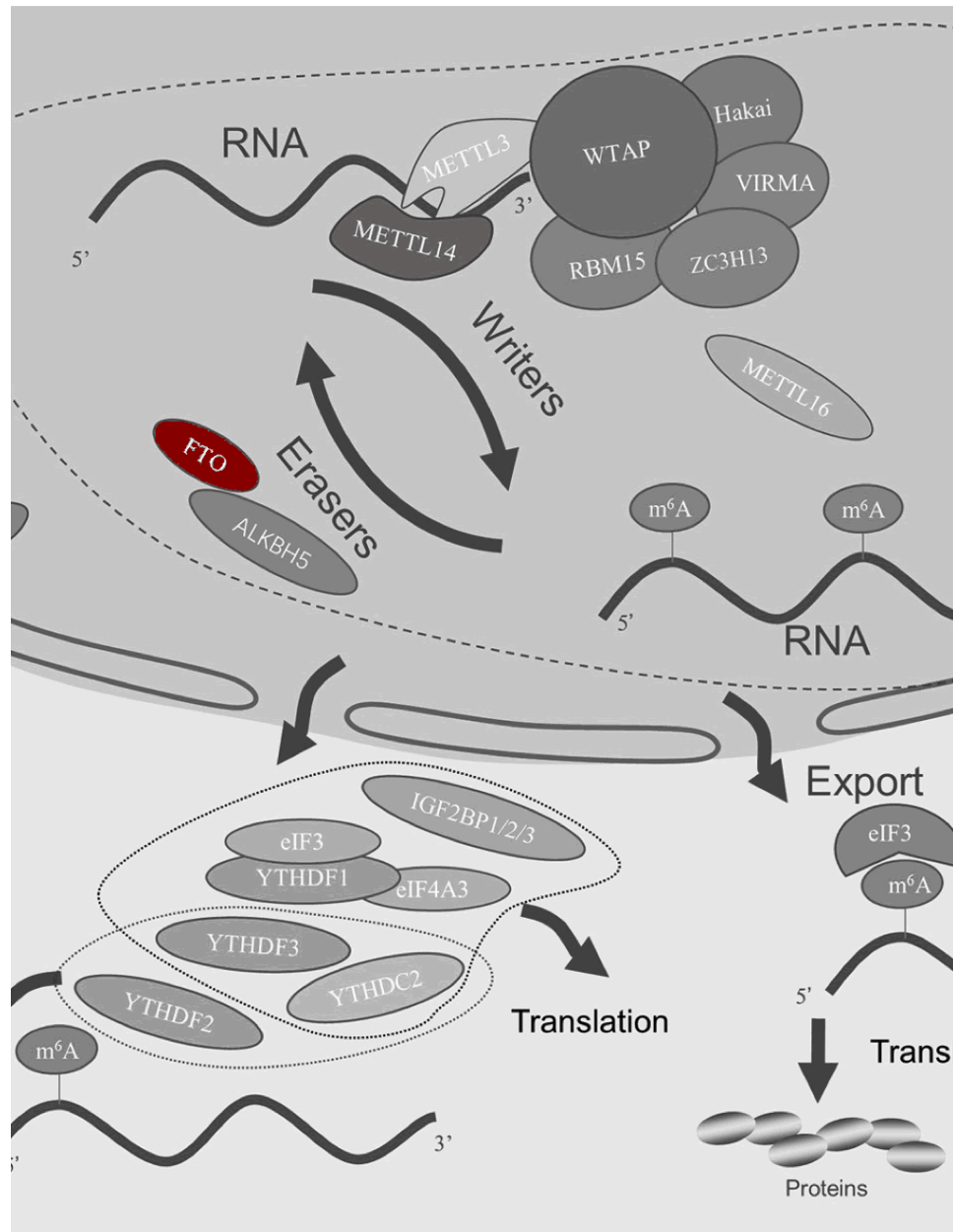
### Pillar 1

FTO

Melanoma

Clear Cell Renal  
Cell Carcinoma

Pre Clinical



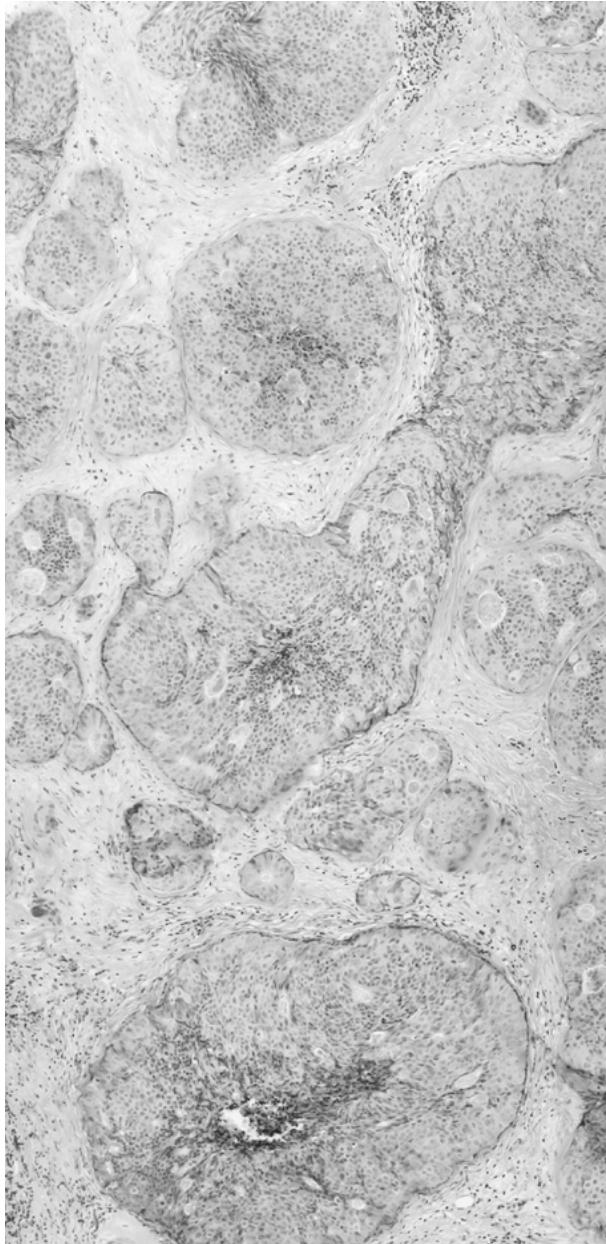
# FTO

## CENTRAL ROLE IN CANCER

- Scientific discoveries over the last decade have identified dysregulation (loss of control) of RNA methylation as a key driver of cancer development<sup>1</sup>
- Changes in m<sup>6</sup>A RNA methylation control the expression of key genes in cancer development and growth<sup>2</sup>
- Fat mass- and obesity-associated Protein (FTO) is an m<sup>6</sup>A RNA demethylase<sup>1</sup>
- Increases in the expression of FTO protein drive cancer development and metastasis
- Reduction of FTO activity kills or slows the growth of a wide range of cancers including leukaemia, breast, lung, ovarian, gastric, brain, melanoma, pancreatic, etc – **hard to find a cancer where FTO is not an important factor**
- **One of the hottest areas of cancer research**

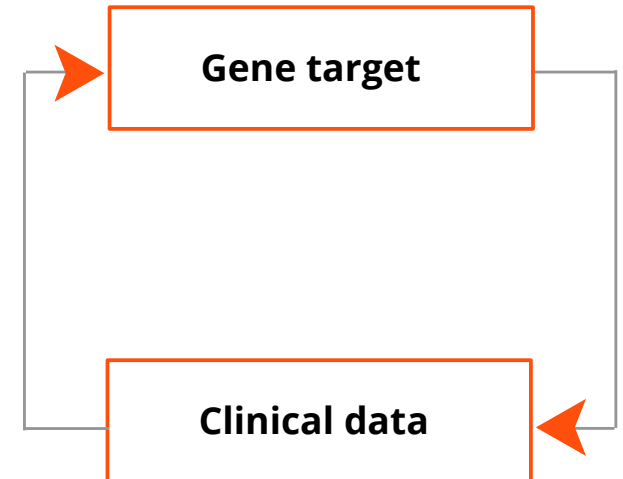
1. Deng, X., Su, R., Stanford, S., & Chen, J. (2018). Critical Enzymatic Functions of FTO in Obesity and Cancer. *Frontiers in Endocrinology*, 9, 724–7

2. Huang, H., Weng, H., & Chen, J. (2020). m<sup>6</sup>A Modification in Coding and Non-coding RNAs: Roles and Therapeutic Implications in Cancer. *Cancer Cell*, 37(3), 270–28

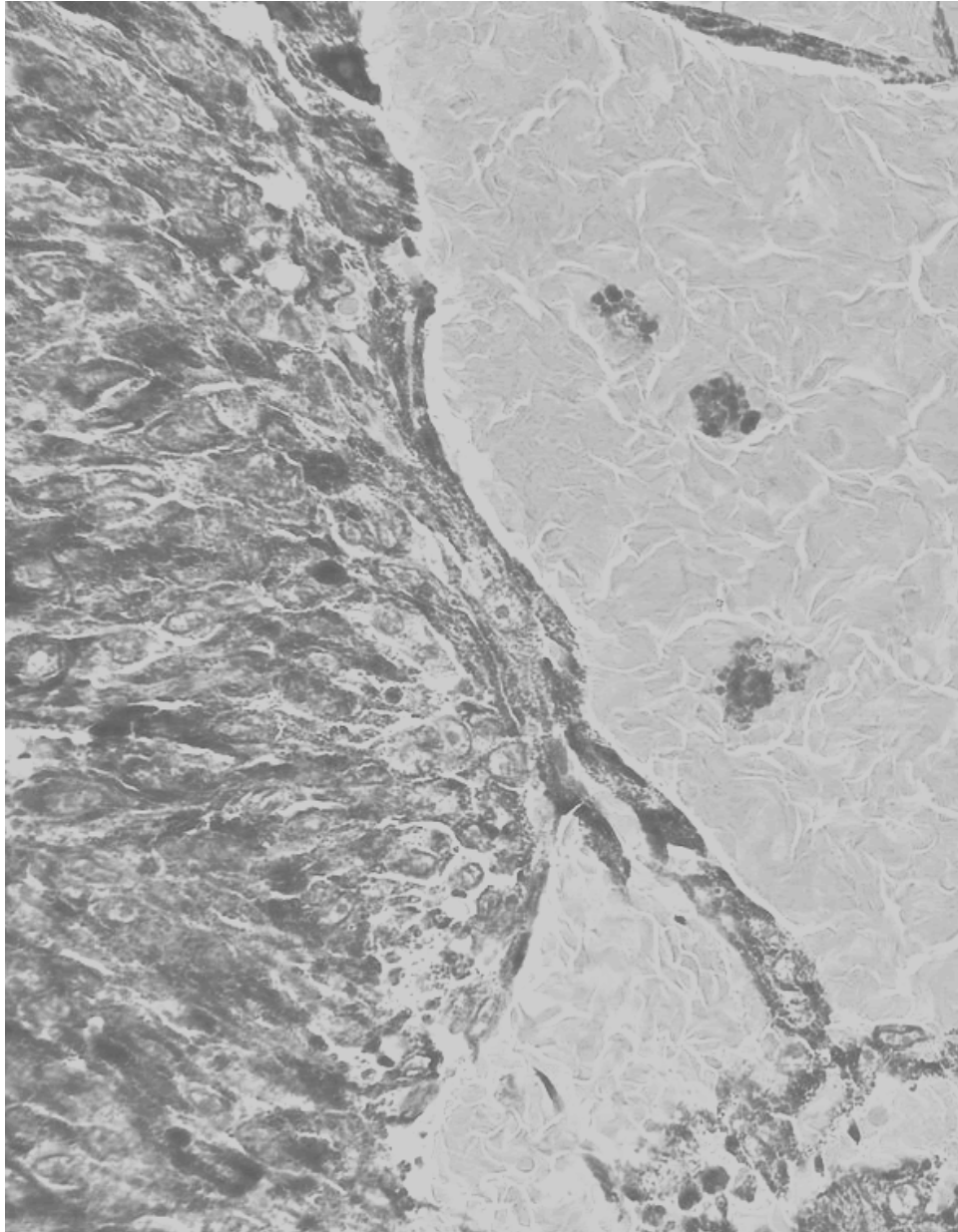


## THE TARGETED AGENT CHALLENGE

- To run a clinical trial using a cancer gene target (i.e. FTO) you need clinical data showing that the cancer target is predictive of a clinical response.
- **Problem.** Need clinical data to run a targeted agent trial, but you can only gather clinical data by running a clinical trial
  - 'Chicken and the egg'
- **What is the solution?**
  - Find a cancer type where your target is overexpressed in a higher percentage of patients (50-90%) AND where you have preclinical or clinical data that your drug works
  - Run a non-targeted clinical trial in this cancer type
  - Use the data from this trial to design and run target "basket" trial (all cancers)







# MELANOMA OPPORTUNITY

- One of the most dangerous cancers: 7000 deaths (USA), 1500 (Aust)<sup>1</sup>
- Major improvements in treatment (BRAF/MEK inhibitors, immune checkpoint), but the 5-year survival rate for advanced melanoma is still as low as ~25%<sup>1</sup>
- **Major problem** - *treatment resistance*
- **FTO**
  - FTO was found to be overexpressed in ~50% of all metastatic melanomas<sup>2</sup>
  - FTO overexpression causes treatment resistance to PD-1 (immune checkpoint) inhibitors<sup>2</sup>
  - **Down-regulation of FTO has been shown to overcome PD-1 resistance<sup>2</sup>**

1. [www.cancer.net/cancer-types/melanoma/statistics](http://www.cancer.net/cancer-types/melanoma/statistics)

2. Yang, S., Wei, J., Cui, Y.-H., Park, G., Shah, P., Deng, Y., et al. (2019). m6A mRNA demethylase FTO regulates melanoma tumorigenicity and response to anti-PD-1 blockade. *Nature Communications*, 10(1), 1131–14.

# CLEAR CELL RENAL CELL CARCINOMA

- 10<sup>th</sup> most common cancer; often only diagnosed after metastasis<sup>1</sup>
- **New treatments.** TKI, checkpoint inhibitors<sup>1</sup>
- 5-year survival rate still very low (~12%)<sup>1</sup>
- 90% of ccRCC are caused by mutations in the von Hippel-Lindau (VHL) tumour suppressor gene<sup>2</sup>
- **FTO**
  - FTO was found to be synthetically lethal in cells with inactive VHL<sup>3</sup>
  - **Inhibition of FTO was found to kill VHL(-) ccRCC cancers<sup>3</sup>**



# FTO

## NEXT STEPS



### Melanoma and clear cell renal cell carcinoma have the right properties to overcome the targeted agent “chicken and the egg” problem

- FTO target: 50% melanoma; 90% ccRCC
- Past clinical evidence of bisantrene working in these cancers (Phase I/II)<sup>1,2</sup>
- Good modern pre-clinical data
- Two different mechanism of action (reduces clinical risk)



### Preclinical

- Studies to be performed in melanoma and ccRCC models to show Bisantrene has efficacy in these cancers
- **13 patents submitted on the use of bisantrene in these cancers**



### Goal

- Initiate proof-of concept Phase I/II clinical trials in one or both cancers
- Generate clinical data to support a target driven “basket” trial



1. Hoff, Von, D. D., Myers, J. W., Kuhn, J., Sandbach, J. F., Pocelinko, R., Clark, G., & Coltman, C. A. (1981). Phase I clinical investigation of 9,10-anthracenedicarboxaldehyde bis[(4,5-dihydro-1 H-imidazol-2-yl)hydrazone] dihydrochloride (CL216,942). *Cancer Research*, 41(8), 3118–3121.

2. Alberts, D. S., Mackel, C., Pocelinko, R., & Salmon, S. E. (1982). Phase I Clinical Investigation of 9,10-Anthracenedicarboxaldehyde Bis[(4,5-dihydro-1 H-imidazol-2-yl)hydrazone] Dihydrochloride with Correlative in Vitro Human Tumor Clonogenic Assay. *Cancer Research*, 42(3), 1170–1175.

# PILLAR 2

## BREAST CANCER

### Rationale

- Large indication and clear patient need
- Safety and efficacy for Bisantrene from historical trials

### Next Steps

- Positive pre clinical data to be assessed by Advisory Board
- Translate to proof of concept Phase I/II trial
- Initiated George Clinical program assessment

### Ambition

- Position Bisantrene as alternative chemotherapeutic with a low cardiotoxic profile
- Potential FTO implications via low dose therapy

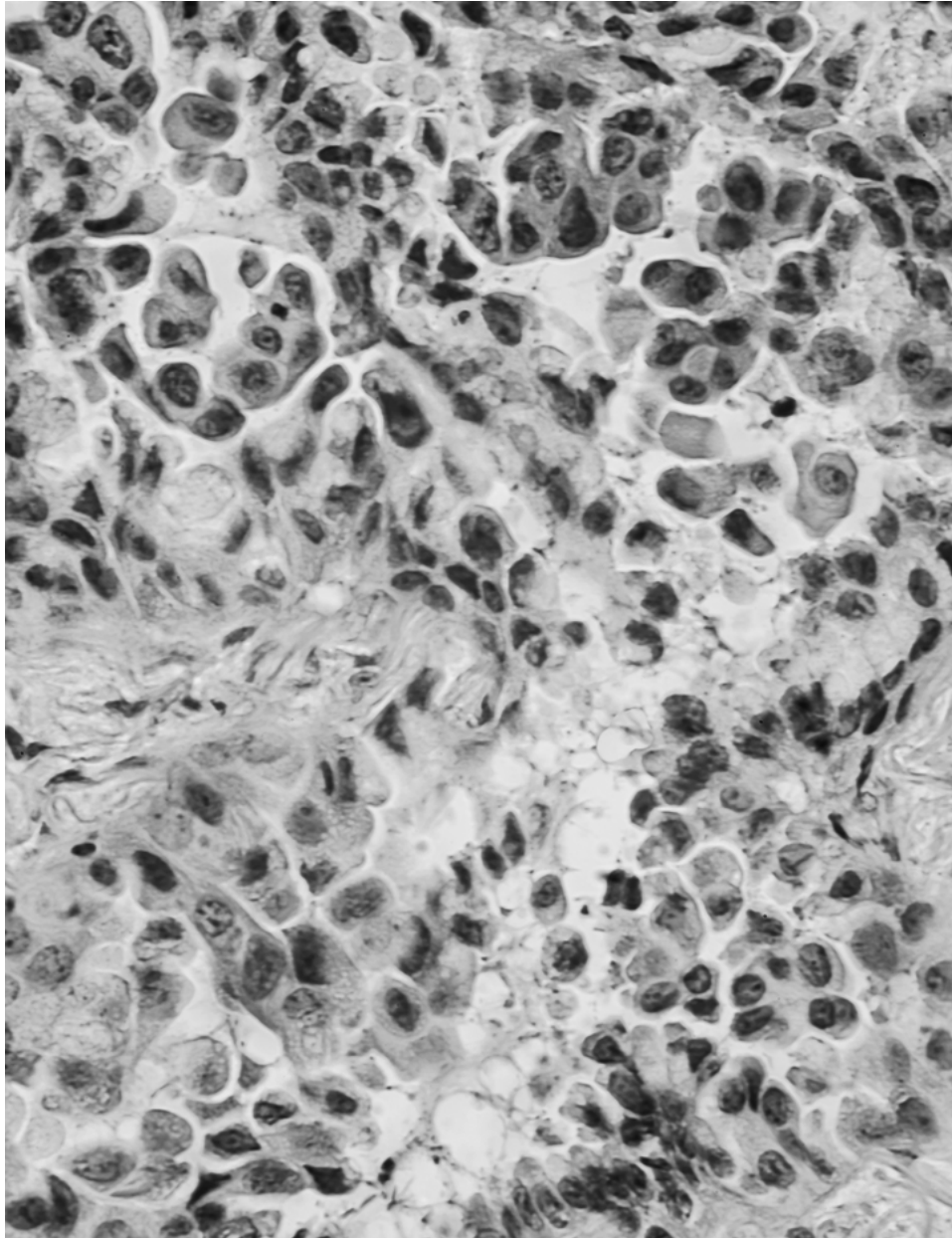
## PROGRESSING

### Pillar 2

Breast cancer

Move to proof of concept human clinical trials

Anthracycline replacement



# BREAST CANCER

## RECENT PRECLINICAL RESULTS<sup>1</sup>

- Bisantrene as a single drug shows similar efficacy to doxorubicin and epirubicin in a range of different breast cancer types
- Bisantrene shown in both historical clinical and recent preclinical studies to kill breast cancer cells resistant to doxorubicin
- Cyclophosphamide shown to act very similarly when used in combination with either Bisantrene, doxorubicin or epirubicin
- Results provide the necessary preclinical evidence to advance Bisantrene into human breast cancer clinical trials as a potentially safer treatment

1. ASX Release: 24 November 2020

# BREAST CANCER

## COMBINATION TRIAL



### Phase I/II proof-of-concept (POC) trial in breast cancer

Use drug combinations where preclinical data show an additive effect with Bisantrone



### Use optimal drug dosing, administration and combinations

Historical breast cancer trials used sub-optimal dosing and administration of Bisantrone (but still showed good activity!)



### Goals

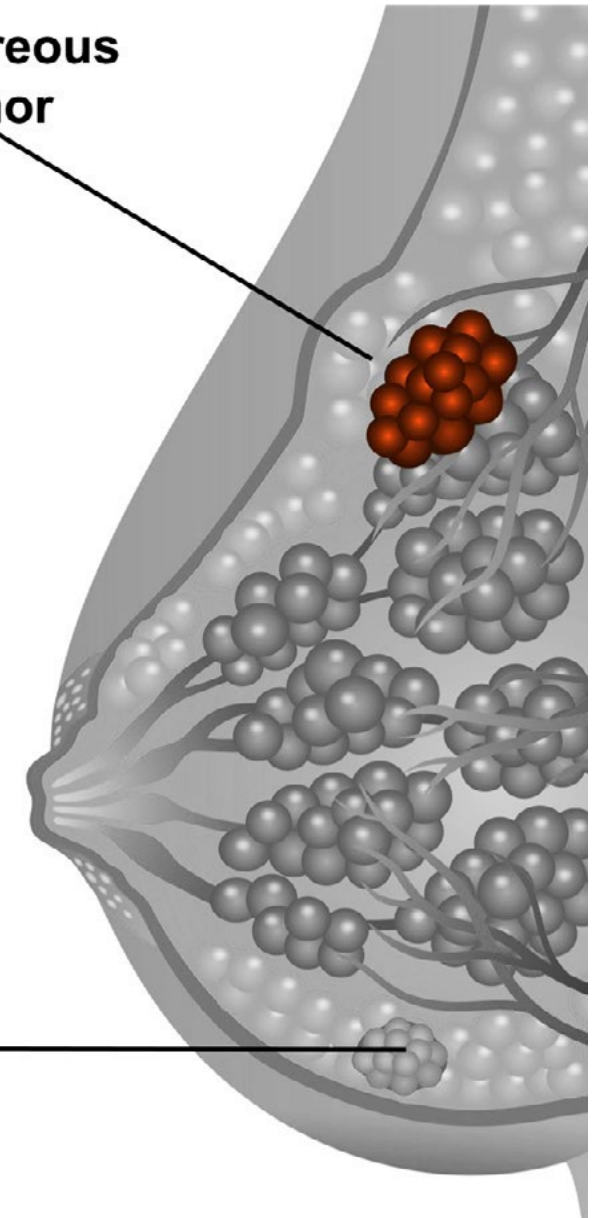
Access much larger cancer market than AML (> 2 million cases per year)

Show equivalent efficacy to existing treatments, but with fewer serious side effects (less damage to the heart)

Displace the current anthracyclines used in breast cancer treatment

Carcinoma  
Tumor

Benign  
Lump



# PILLAR 3

## EXTRAMEDULLARY AML

### Rationale

Unmet patient need

Bisantrene EMD history and recent Israel trial observations

Potential FDA approval via 505(b)(2) and ladder to PRV

### Next Steps

Full feasibility assessment

### Ambition

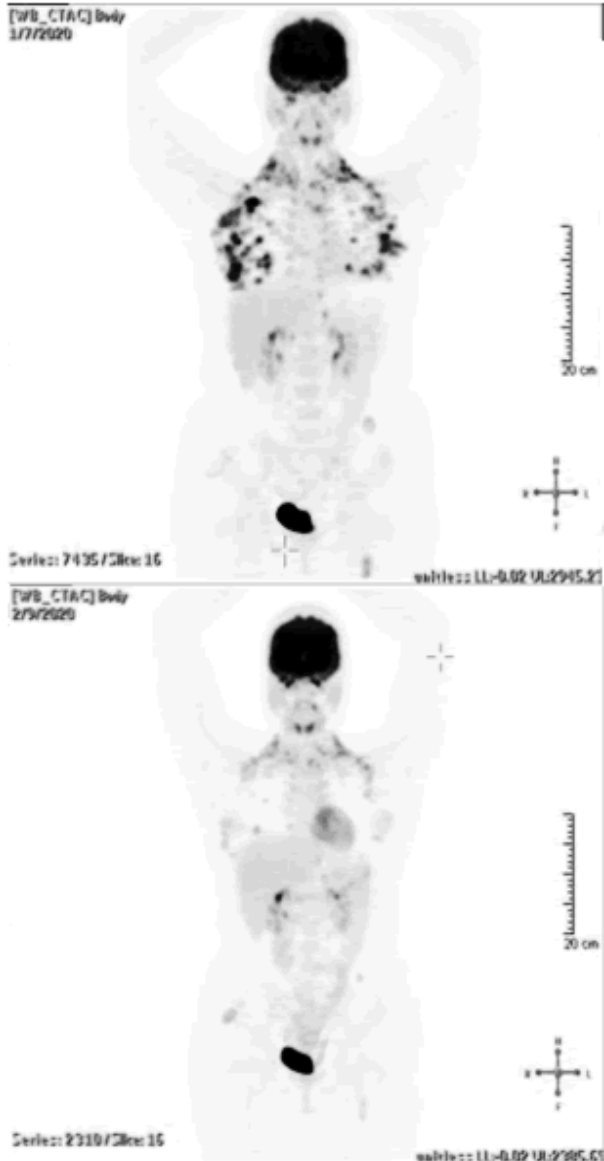
Multi-site, international pivotal clinical trial to prove efficacy

Extend to paediatric sub-type to qualify for PRV award

## ASSESSING

### Pillar 3

AML  
Extramedullary  
R/R Adult &  
Paediatric  
MRD  
Ovarian



## EXTRAMEDULLARY AML

- **Why extramedullary (EM) AML?**
  - **Recent Israel results** - 4/4 responders had EM AML
  - **Unmet clinical need** - no clinical trials and EM AML patients excluded
  - EM AML patients have a worse outcome than non-EM AML patients
  - PET has shown EM AML is much more common than previously thought (~20%)<sup>1</sup>
  - Small number of patients needed for pivotal trial (50-75)
  - Potential for expansion into paediatric AML; pathway to PRV
  - FDA 505(b)(2) pathway to approval
- **Next Stage - *full feasibility study*** (currently underway)

<sup>1</sup>Stölzel, F., Lüer, T., Löck, S., Parmentier, S., Kuithan, F., Kramer, M., et al. (2020). The prevalence of extramedullary acute myeloid leukemia detected by 18FDG-PET/CT: final results from the prospective PETAML trial. *Haematologica*, 105(6), 1552–1558. <http://doi.org/10.3324/haematol.2019.223032>



# PILLAR 3

## R/R AML DRUG COMBINATION

### Rationale

Adult combination to address R/R in AML

Paediatric patient need and PRV opportunity

### Next Steps

Feasibility study: assessing drug, trial options & regulatory

### Ambition

Combination has superior efficacy for R/R AML patients

Paediatric study unlocks PRV value options

## ASSESSING

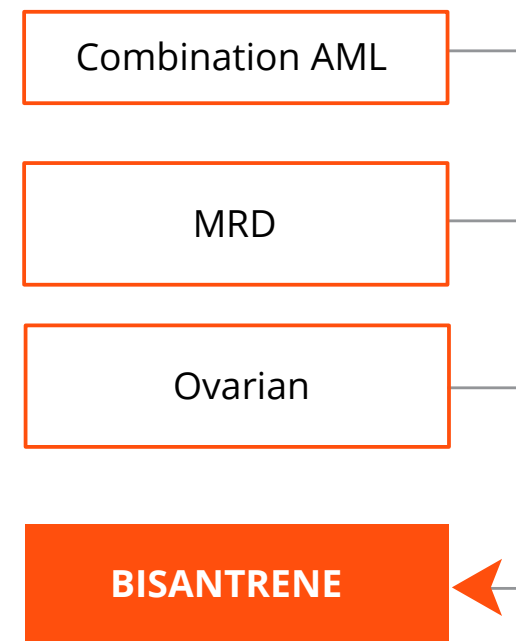
### Pillar 3

AML  
Extramedullary  
R/R Adult &  
Paediatric  
MRD  
Ovarian



## FEASIBILITY STUDIES

- **Combination R/R AML**
  - Combine Bisantrene with two nucleoside analogues for R/R AML salvage in adult & paediatric
  - CCSA review identified potential regulatory issues with trial design so need for full review
  - **Next Stage** - *full feasibility study* (underway)
- **MRD**
  - **Next stage** – *internal feasibility study* (2021)
- **Ovarian**
  - **Next stage** – *internal feasibility study* (2021)



# KEY EVENTS

PILLAR	PROGRAM OBJECTIVE	2021	2022
Pillar 1	Target FTO tumours to drive cancer regression via RNA methylation pathway	Pre-clinical <i>(in vitro)</i>	POC clinical trial(s)
FTO			
Pillar 2	Less cardiotoxic chemotherapeutic effective as replacement therapy	POC Clinical Trial Start (AUS)	Clinical trial <i>cont</i>
Breast			
Pillar 3	R/R Salvage treatment in unique paediatric population to pursue PRV	FDA PRE & IND to start Clinical Trial (US)	Clinical trial <i>cont.</i>
AML	EMD - Niche population as FDA approvable indication with PRV potential	Clinical Trial Start (AUS) / FDA PRE & IND	Expand Clinical Trial - multi-site US



## NEAR TERM

### ACTIVITIES: 1H CY 2021

- FTO pre-clinical programs
- Breast cancer clinical trial design – 13 weeks
- Feasibility studies to guide choice and utility on:
  - Adult R/R AML
  - Paediatric R/R AML and PRV
  - Extramedullary AML and PRV

# CORPORATE OVERVIEW

# CORPORATE SNAPSHOT

ISSUED CAPITAL	
Shares	128.2m
Options	28.2m
Shareholders (27 November 20)	2,674
MARKET CAPITALISATION	
Share price (27 November 20)	\$2.15
Market value (27 November 20)	\$275.6m
Cash (30 Sept 20)	\$5.66m
Enterprise value	\$270m
SIGNIFICANT SHAREHOLDERS	
Bill Garner	11%
Daniel Tillett (Director & CSO)	8%
Merchant Opportunities Fund	8%



# TRANSACTIONAL VALUE OBSERVATIONS



## Insights<sup>1</sup>

- Value differs little between early and late stage buy outs
- Efficacy data is largest value differentiator
- **Precision oncology driving superior value** in oncology – 80% value associated with top 15% of tumour types which include melanoma and breast cancer



## Plans

- Phase 2 assets – primary market research and health economics
- Transaction comparable and sum of parts analysis
- Engagement with market analysts – ASX and global
- Develop asset based intrinsic valuation models
- Connection through industry and investor channels
- Supported by team with strong transactional experience

1. Torreya - Oncology Company Value Drivers - April 2020

# CONCLUDING COMMENTS



**STRATEGY** – capitalises on FTO insights while protecting legacy chemotherapy credentials



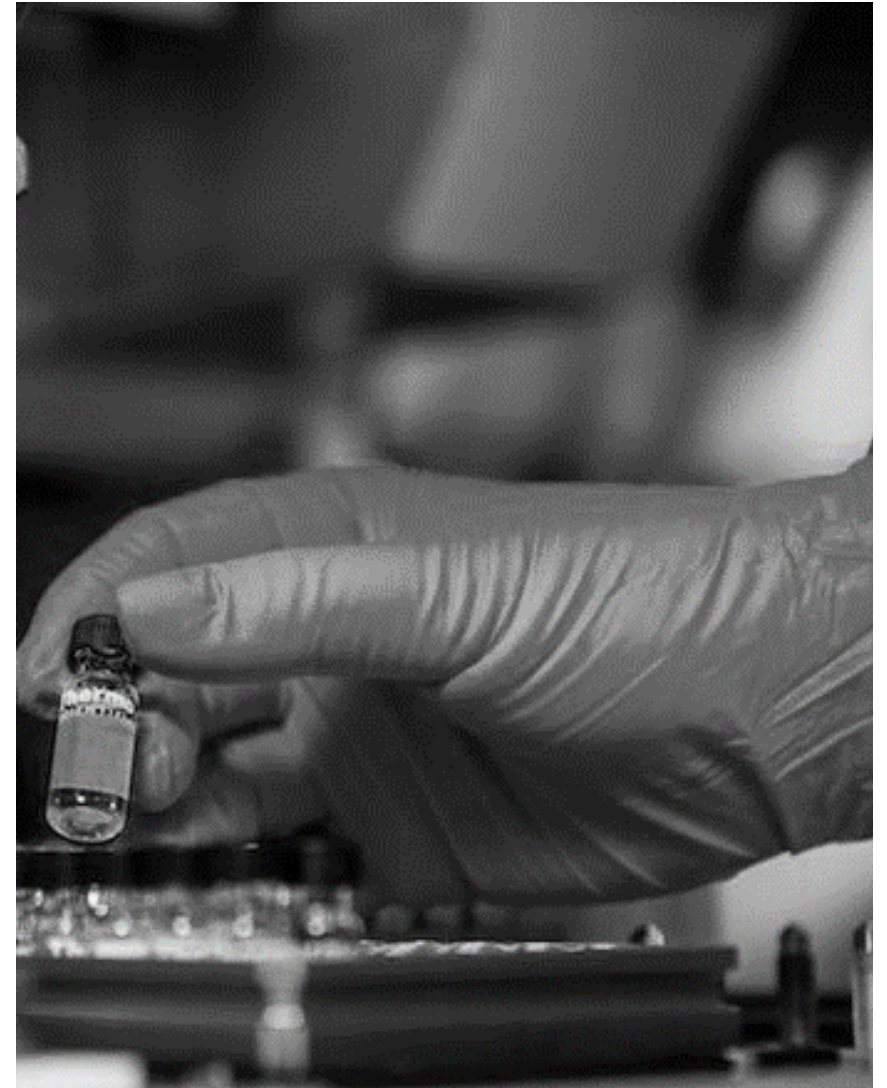
**RISK REWARD** – multi leg strategy reduces executional risk and maximises potential for outsized returns



**TEAM** – is focused on shareholder return, via sale / license to pharma partner



**CLINICAL PROGRESS** – will be gated and advanced appropriately







RACE  
ONCOLOGY

[raceoncology.com](http://raceoncology.com)

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