Specialty Pharmaceutical Business
Focused on Fast-to-Market Opportunities

ASX: RAC
Investor Presentation
March 2017
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Race Oncology Overview

- **Business Model - Specialty Pharma**
  - Rescuing, rediscovering or repurposing overlooked drugs that can deliver early commercial milestones
  - ASX Listing July 2016 (ASX: RAC), raised $4.3m at $0.20

- **Market Focus – Oncology**
  - Cancer drug market is worth >US$100 billion pa\(^1\)

- **Initial Drug Asset - Bisantrene**
  - Chemotherapy drug tested in >40 phase II clinical studies before it was lost in a series of pharmaceutical mergers in the 1990s
  - Race owns recent patent filings on Bisantrene
  - Orphan Drug in US - 7 years market exclusivity
  - First sales expected before end of 2017

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### Corporate Snapshot

<table>
<thead>
<tr>
<th>Shares on Issue</th>
<th>52.8m</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ordinary</td>
<td></td>
</tr>
<tr>
<td>Performance Shares</td>
<td>10.0m</td>
</tr>
<tr>
<td>Options (various)</td>
<td>19.2m</td>
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</tbody>
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<table>
<thead>
<tr>
<th>Market Capitalisation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Share price (1 Mar ‘17)</td>
</tr>
<tr>
<td>Market Capitalisation</td>
</tr>
<tr>
<td>Net Cash (31 Dec ‘16)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Major Shareholders</th>
</tr>
</thead>
<tbody>
<tr>
<td>Update Pharma. Inc.</td>
</tr>
<tr>
<td>Peter Molloy (CEO)</td>
</tr>
<tr>
<td>Top 20 Shareholders</td>
</tr>
</tbody>
</table>

\(^1\) IMS Health Study: “Global Market for Cancer Treatments Grows to $107 Billion in 2015”
Race Business Model

Pursuing Late Stage Drug Assets

Drug Development Biotech Companies → Specialty Pharma Race Oncology → Big Pharma

- Patent Application(s) Filed
- Investigational New Drug (IND) Application
- New Drug Application (NDA)
- Early Phase Research
- Pre-Clinical testing
- Laboratory and animal testing
- Phase I Safety in humans
- Phase II Initial dosage & efficacy studies
- Phase III Pivotal study to confirm safety & efficacy
- Human Clinical Trials
- Regulatory Approval
- US FDA approval
- Phase IV Additional post marketing testing required by FDA
- Marketing & post marketing Surveillance

The Drug Development Value Chain
Initial Drug Asset: Bisantrene

Near Term – European Named Patient Program (NPP)
- A NPP provides patients with access to life-saving drugs that are not yet approved
- In certain EU countries, the drug can be sold under the NPP to hospitals and patients
- Race expects sales of Bisantrene to start before end of 2017

Longer Term – General marketing approval in the US
- Bisantrene qualifies for 505(b)(2) pathway to approval
- 505(b)(2) allows Race to accelerate the regulatory process by using the large database of historical preclinical and clinical data to support its marketing application for Bisantrene
- Bisantrene may only require a single pivotal clinical (registration) study to gain approval

Dual value creation pathways:
(1) NPP Sales
(2) FDA Approval
Bisantrene Overview

Related to the anthracyclines
- Most frequently prescribed cancer drugs, 1st line treatment for many cancers
- But anthracyclines cause cardiac toxicity, limiting their usefulness
- Also, cancers can become resistant to anthracyclines

Bisantrene advantage
- Greatly reduced cardiac toxicity
- Effective in heavily anthracycline pre-treated patients

Potential uses
- Cancer patients who have reached their cardio-toxic limit with anthracyclines or whose cancer is resistant to anthracyclines
- Shown to be active against Acute Myeloid Leukaemia (AML), breast cancer, lymphoma & ovarian cancer
Bisantrene History

- Developed by US pharma company Lederle in the 1980s
  - Tested in >40 phase II clinical studies by Lederle and US NCI (National Cancer Institute)
  - Est. US$100-200m spent on Bisantrene development (based on 2017 costs for the same studies)
  - Impressive activity in relapsed/refractory Acute Myeloid Leukaemia (AML)
  - Approved, but not marketed, in France in 1990 for treating AML
  - Lost in big pharma mergers in 1990s: Lederle → Wyeth → Pfizer

- Bisantrene re-discovered and rescued in 2013-2016
  - New patents filed (valid to 2034 if granted)
  - Orphan Drug Designation (confers 7 years exclusivity in US)
  - Race Oncology formed to complete development of Bisantrene and bring this valuable drug to market
AML (Acute Myeloid Leukemia)

- Progenitor white blood cells (myeloblasts) fail to differentiate into functional white blood cells
  - Myeloblasts proliferate and build up in bone marrow and blood
  - Shortage of crucial white blood cells

- Rapidly progressive
  - 74% die <5 years, mainly due to infections or treatment related mortality

- Orphan disease
  - Around 20,000 new patients a year in the US
  - Disease mainly of the elderly: incidence growing as population ages
**r/r AML: Unmet Medical Need**

1st line treatment is Intensive Chemotherapy (IC)
- 7 days of treatment with cytarabine + 3 days with an anthracycline
- Known as ‘7+3’ chemotherapy
- Treatment has not improved in 30 years
- There is no approved 2nd line treatment, but several approaches used in practice

Once patients fail 1st and 2nd line they are relapsed/refractory (r/r) AML
- No effective or approved treatment; palliative care often the only option

Bisantrene will be aimed at r/r AML
- Potentially elderly and unfit as well

*Hypomethylating agents: azacytidine or decitabine

** Targeted drugs aimed at cytogenetic sub-populations
Bisantrene in r/r AML

- Average 48% remission rates in five AML studies (1987-1994)
  - Patients were mostly heavily pretreated with up to 8 cycles of chemotherapy and were relapsed or refractory

- Approved in France in 1990 for treating AML
  - Specifically for r/r AML and AML where anthracyclines were contraindicated

- Race now seeking FDA approval for r/r AML

<table>
<thead>
<tr>
<th>Study</th>
<th>Phase</th>
<th>Number of AML Patients</th>
<th>Complete Response*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study 1, 1987</td>
<td>II</td>
<td>40</td>
<td>50%</td>
</tr>
<tr>
<td>Study 2, 1989</td>
<td>II</td>
<td>10</td>
<td>40%</td>
</tr>
<tr>
<td>Study 3, 1989</td>
<td>II</td>
<td>15</td>
<td>47%</td>
</tr>
<tr>
<td>Study 4, 1993</td>
<td>II</td>
<td>7</td>
<td>72%</td>
</tr>
<tr>
<td>Study 5, 1994</td>
<td>II</td>
<td>13</td>
<td>38%</td>
</tr>
<tr>
<td>Total/Average</td>
<td></td>
<td>85</td>
<td>48%</td>
</tr>
</tbody>
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*Generally defined as no myeloblasts detected in the blood and less than 5% in bone marrow
US Approval Pathway: 505(b)(2)

- Pre-IND meeting with FDA 14 Feb 2017
  - Bisantrene qualifies for 505(b)(2) expedited approval pathway
  - Significantly risk-mitigating for Race

505(b)(2)
- Expedited development pathway
- Can be used where the sponsor uses an identical drug to a previously investigated or approved drug
- Allows Race to use historical clinical and preclinical data on Bisantrene and not have to repeat these studies
FDA confirmed r/r AML is target indication in US

Protocol for pivotal (registration) study now being developed
- Target is r/r AML
- IND to be filed in 2017
- Likely a multi-site study: US, France and Australia

Bisantrene is a late stage clinical asset that could be approved after a single study
Commercial Protection

- Race owns two filed patents on Bisantrene
  - "Compositions to Improve the Therapeutic Benefit of Bisantrene and Analogs and Derivatives Thereof”
  - "Combinatorial Methods to Improve the Therapeutic Benefit of Bisantrene and Analogs and Derivatives Thereof”

Both patents are in national phase (pending) in:
- US, EU, Australia, Canada, China, Korea, New Zealand
- Patents (if granted) expire 2034
- Race owns both patents 100% (no royalty payable to others)

In addition, Bisantrene has been granted an ‘Orphan Drug Designation’ (ODD) in the US
- Confers 7 years of market exclusivity in US from date of FDA approval
- Effectively a ‘mini-patent’ in its own right
- European ODD filing has been submitted
European Named Patient Sales

- Race expects first sales of Bisantrene in 2017
  - Under a Named Patient Program (NPP) in Europe

- Named patient sales are legal in France, Italy, Turkey
  - France will the first NPP market for Bisantrene

- NPP sales of unapproved drugs allowed where:
  - Patients have no other treatment recourse (e.g. r/r AML)
  - Patients are nominated by a doctor
  - The indication is an orphan disease and a EU orphan drug designation (ODD) has been granted to the drug
  - NPP is essentially “compassionate use” but the drug can be sold to the hospital (in some cases is paid for by the patient)

- Value of NPP
  - Revenues and profitable cash flow for Race in the medium term
  - Commercial proof-of-principle for Bisantrene and valuable clinical usage by oncologists
NPP Pathway in France

2016
- Appoint NPP sales agent
- API GMP production (Sai Life Sci)

2017
- Pre-launch planning and market research
- Final product GMP production & release (IriSys)
- ODD (EU) application and grant
- Prepare ATU Dossier
- ATU Approval (2-3 months)

2018
- Pre-launch Marketing
- NPP Launch in France
- ATU Approval (2-3 months)

NPP launch in France

NPP launch in other markets
## Race value-added since listing

<table>
<thead>
<tr>
<th>Key goal</th>
<th>At listing: Jul 2016</th>
<th>+9 months (Mar 2017)</th>
</tr>
</thead>
<tbody>
<tr>
<td>API Manufacturing</td>
<td>No API available</td>
<td>GMP manufacturing of API completed with enough drug for NPP and clinical trials</td>
</tr>
<tr>
<td></td>
<td>Manufacturers still to be identified</td>
<td></td>
</tr>
<tr>
<td>Finished product manufacturing</td>
<td>Manufacturers still to be identified</td>
<td>IriSys appointed, manufacturing of finished product underway</td>
</tr>
<tr>
<td>Scientific Advisory Board</td>
<td>No key opinion leaders (KOLs) on board</td>
<td>3 top US KOLs recruited (Memorial Sloan Kettering, Johns Hopkins, Fred Hutchinson)</td>
</tr>
<tr>
<td>505(b)(2) development pathway</td>
<td>Not confirmed by FDA</td>
<td>Successful pre-IND meeting 505(b)(2) confirmed with FDA</td>
</tr>
<tr>
<td></td>
<td>No FDA interaction yet</td>
<td></td>
</tr>
<tr>
<td>NPP marketing strategy</td>
<td>No EU NPP sales agent identified</td>
<td>CarthaGenetics appointed Launch plans ready</td>
</tr>
<tr>
<td>Clinical strategy</td>
<td>Phase II bridging study before pivotal</td>
<td>May be able to skip bridging study saving 18mths and $3m</td>
</tr>
<tr>
<td>EU Orphan Drug Designation</td>
<td>No ODD status in Europe</td>
<td>ODD application filed, awaiting EMA approval</td>
</tr>
</tbody>
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Milestones 2017-2018

2017
- Complete manufacturing of finished product ready for named patient sales and start of pivotal clinical study
- Secure EU Orphan Drug Designation in Europe
- Apply for NPP authorisation in France and generate first sales
- File IND in US, prepare for pivotal study

2018
- Start pivotal study in r/r AML: US, France, Australia
- Build NPP sales in France
- Launch NPP in other EU countries
- License Bisantrene to NPP markets outside Europe (Asia)
Management

**CEO: Peter Molloy**
- Experienced biotech CEO with success on ASX (Biota)
- 17 years big pharma marketing: Int’l Marketing VP, Pharmacia Man Director, Pharmacia
- Launched 23 products, 40 licensing deals, delivered 10x growth

**CSO: John Rothman PhD**
- Co-inventor on Bisantrene patents
- Director/Sr Dir at Roche; Exec VP for Science & Operations, Advaxis
- Multiple drug approvals at Roche; outstanding pharmaceutical scientist

**Chairman: Bill Garner MD MPH**
- US physician and entrepreneur
- Founder of several firms: Update Pharma, Urigen, Invion, Del Mar Pharmaceuticals,
- Co-inventor on Bisantrene patents

**SVP Bus Dev: Gordon Beck**
- Experienced pharma executive
- Roche: Global Business Team leader (oncology, ID, CVS, CNS)
- BMS: Director, Cardiovascular Marketing and Business Development
Investment Summary

- Specialty pharma company with low risk business model
- Low base operating cost and expedited path to market
- World-class team with deep oncology and commercial experience
- Bisantrene: late-stage clinical asset that could be approved in the US after a single pivotal trial
- Sales expected to start in 2017 under NPP in Europe

Near term value inflexion points
- NPP: EU orphan drug designation, NPP authorisation, complete manufacturing, first sales
- FDA: File IND, prepare for pivotal clinical trial
ASX code: RAC

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