



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 pa¹
- 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

Corporate Snapshot

Shares on Issue

Ordinary		52.8m
Performance Shares		10.0m
Options (various)		19.2m

Market Capitalisation

Share price (1 Mar '17)		\$0.19
Market Capitalisation		\$11.0m
Net Cash (31 Dec '16)		\$3.0m

Major Shareholders

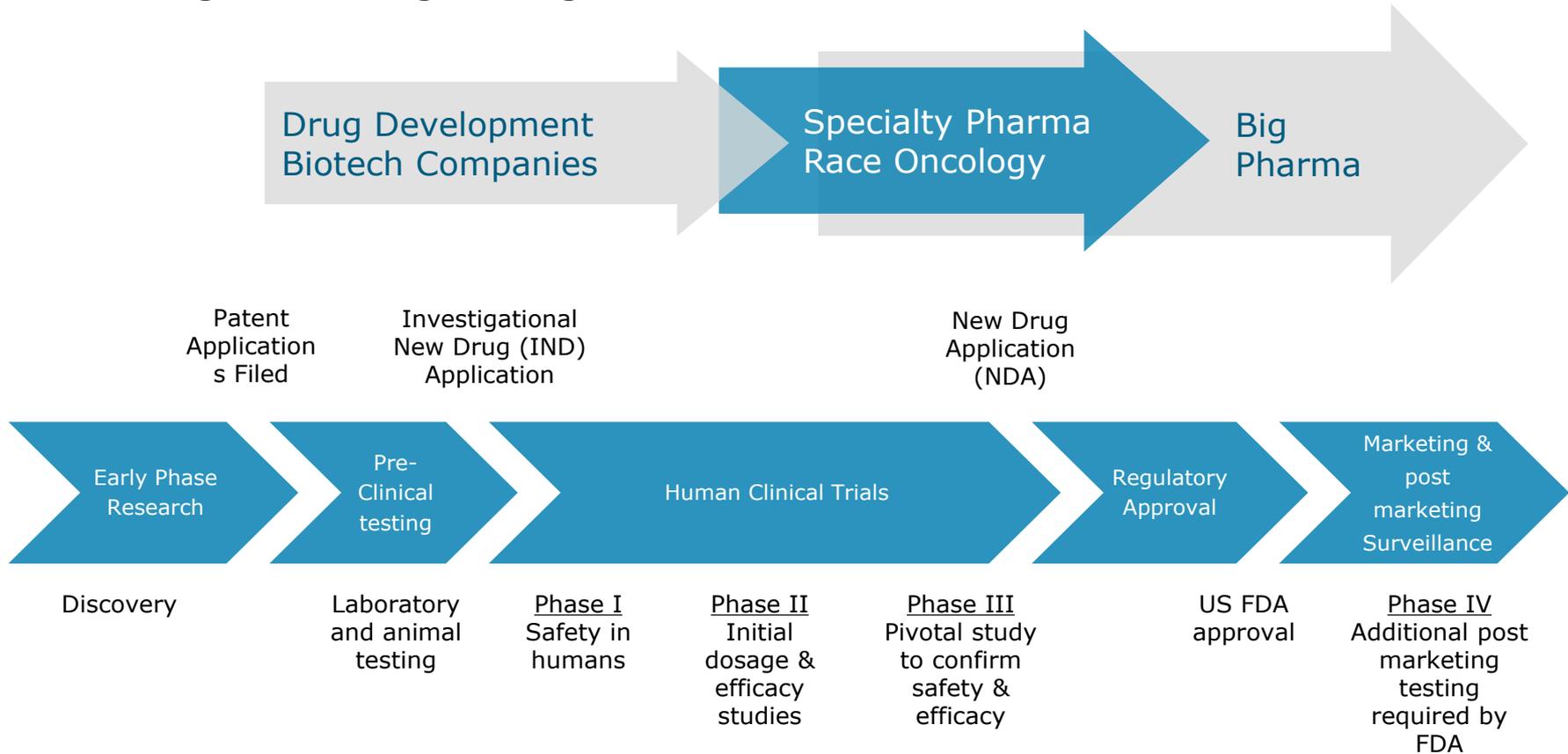
Update Pharma. Inc.	15.0m	28.4%
Peter Molloy (CEO)	4.0m	7.6%
Top 20 Shareholders	33.0m	62.5%

¹ IMS Health Study: "Global Market for Cancer Treatments Grows to \$107 Billion in 2015"



Race Business Model

Pursuing Late Stage Drug Assets



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

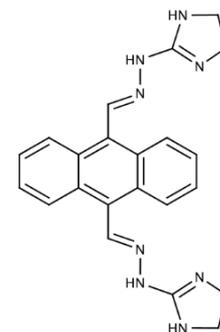
Dual value
creation pathways:

(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
small molecule
drug with real
advantages

Bisantrene History

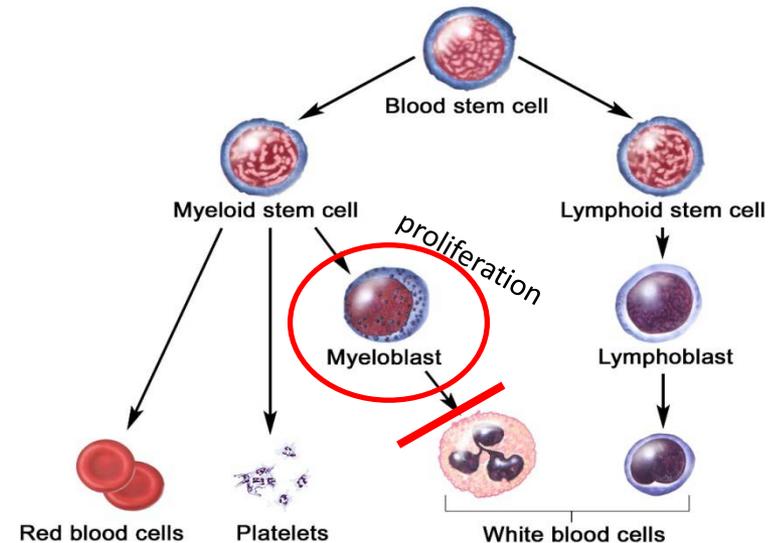
- Developed by US pharma company Lederle in the 1980s
 - Tested in >40 phase II clinical studies by Lederle and US NCI (National Cancer Institute)
 - Est. US\$100-200m spent on Bisantrene development (based on 2017 costs for the same studies)
 - Impressive activity in relapsed/refractory Acute Myeloid 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

Rescued late stage
drug asset
+ Proven activity
+ Recent patent
filings

AML (Acute Myeloid Leukemia)

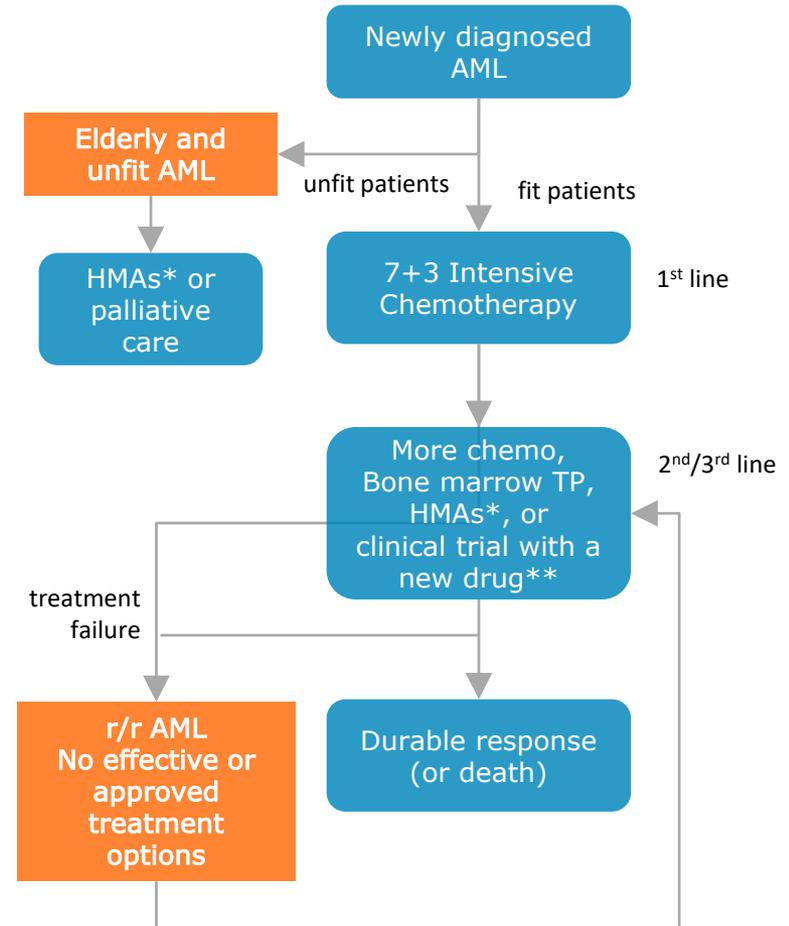
- Progenitor white blood cells (myeloblasts) fail to differentiate into functional white blood cells
 - Myeloblasts proliferate and build up in bone marrow and blood
 - Shortage of crucial white blood cells
- Rapidly progressive
 - 74% die <5 years, mainly due to infections or treatment related mortality
- Orphan disease
 - Around 20,000 new patients a year in the US
 - Disease mainly of the elderly: incidence growing as population ages

AML is a blood cancer caused by proliferation of myeloblasts and a shortage of white blood cells



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:
azacitidine 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

Study	Phase	Number of AML Patients	Complete Response*
Study 1, 1987	II	40	50%
Study 2, 1989	II	10	40%
Study 3, 1989	II	15	47%
Study 4, 1993	II	7	72%
Study 5, 1994	II	13	38%
Total/Average		85	48%

*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

505(b)(2)
accelerated
approval pathway

US Pivotal Clinical Trial

- 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

Bisantrene could
be approved in
the US after a
single pivotal trial

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

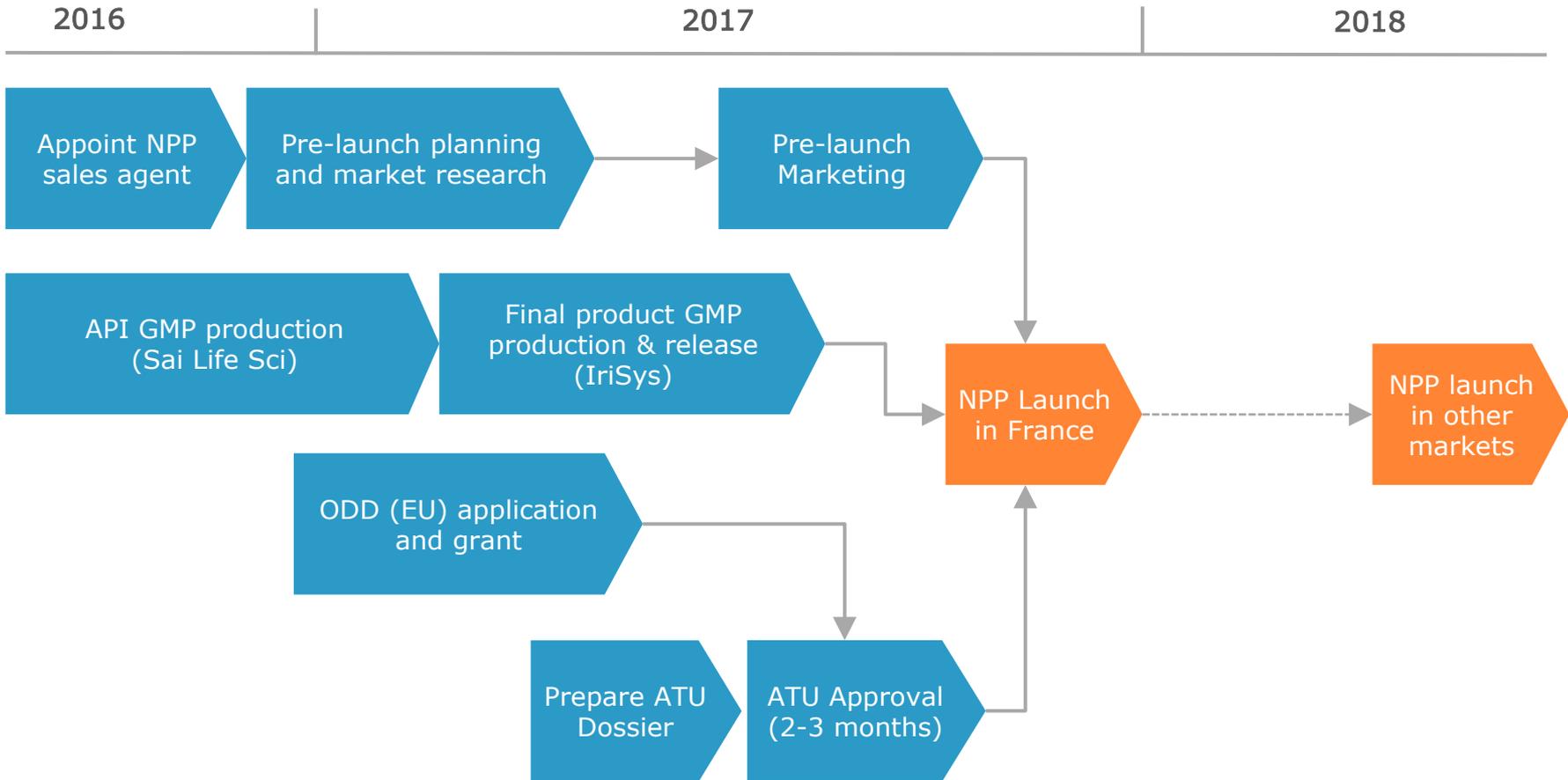
Bisantrene has
filed patents and
additional
protection under
the US ODD

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 be 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

Early sales opportunity
delivers profitable sales
and commercial proof
of concept

NPP Pathway in France



Race value-added since listing

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

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 Bisantrone to NPP markets outside Europe (Asia)

Major value
inflection points in
short term

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 Bisantrone 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 Bisantrone 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



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