

Alchemia



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Alchemia Limited (ASX:ACL)

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- **Corporate Overview**
- HyACT Platform
- HA-Irinotecan
- Non-Oncology Assets
- Summary

One of Australia's Largest Biotechs

- ~US\$175M market cap
- Compelling value proposition: Transformative late-stage oncology asset and approved product generating cash flow

Transformative 2014 Catalyst

- Lead oncology asset, PIII HA-Irinotecan in mCRC
- On track to reach its primary endpoint in 1H CY2014

Oncology HyACT Platform

- Highly differentiated CD44 mediated mechanism
- Broad applications: Across tumor types and across therapeutics

Focus on Commercial Execution

- ~40,000 mCRC US patients treated per year with FOLFIRI/Irinotecan, representing \$1B+ opportunity
- Focused on FDA submission and on preparing for commercialization

Solid Track Record of Innovation

- Fondaparinux, VAST, HyACT oncology platform
- Attracting world-class partners

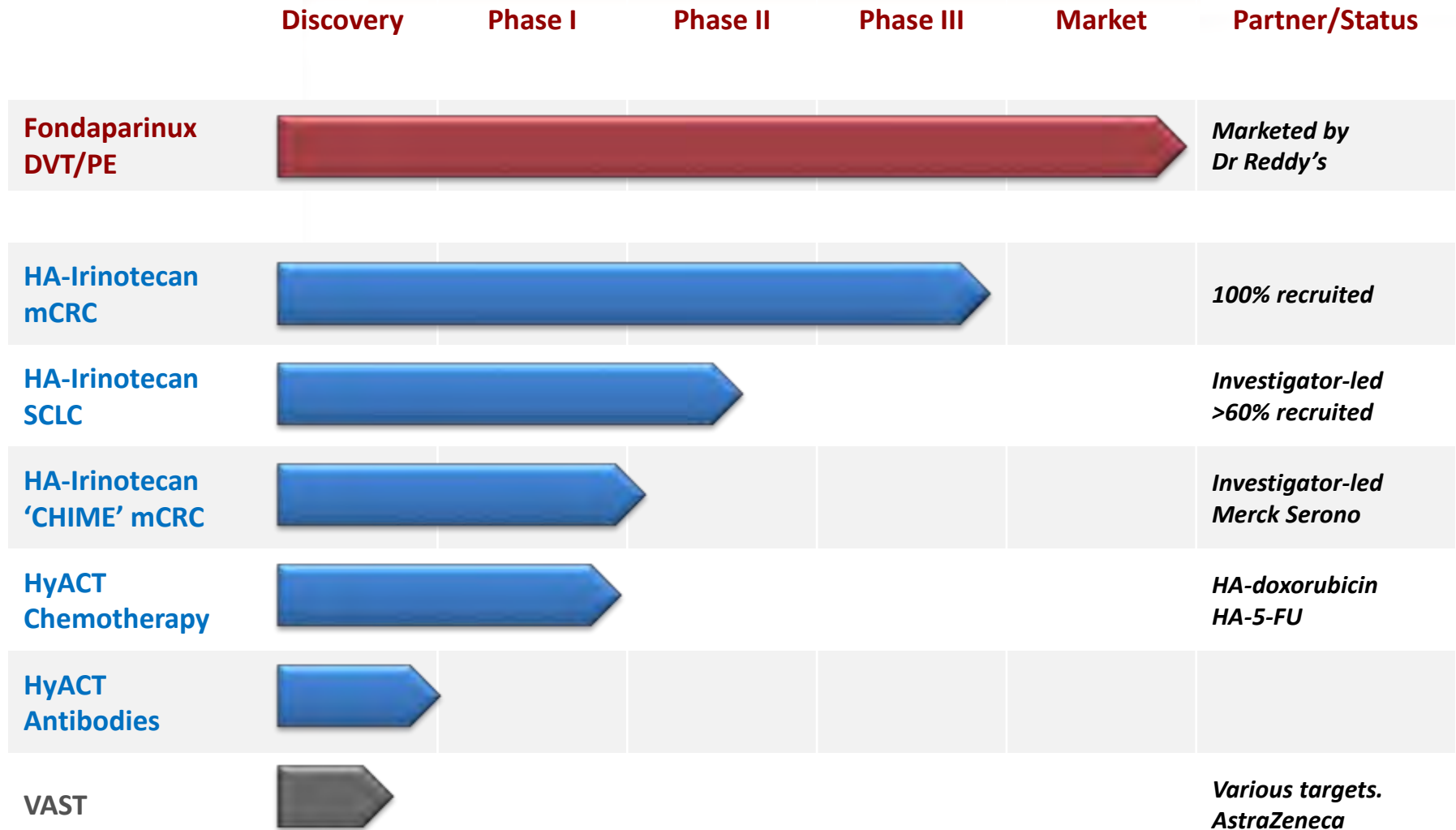
Financial and Capital Structure

- **Market capitalization (Feb 28, 2014)** US\$175M (A\$193M)
- **Current Share price (Feb 28, 2014)** A\$0.595
- **Cash on hand (Dec 31, 2013)** US\$15M (A\$16.4M)
- **No debt**
- **Capital structure**
 - Ordinary shares outstanding 324,410,203
 - Options outstanding 9,349,666
 - Fully diluted 333,759,869

Corporate

- **Recent appointments of Santo Costa (Chairman) and Thomas Liquard (CEO) reinforce ACL focus on US commercial execution with deep experience in:**
 - US oncology/market
 - Commercial execution models
 - 505(b)(2)

Pipeline



DVT is deep vein thrombosis
PE is pulmonary embolism

mCRC is metastatic colorectal cancer
SCLC is small cell lung cancer



Cardiovascular



Oncology



Various Therapies

- Corporate Overview
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Unique Dual Mechanism of Action

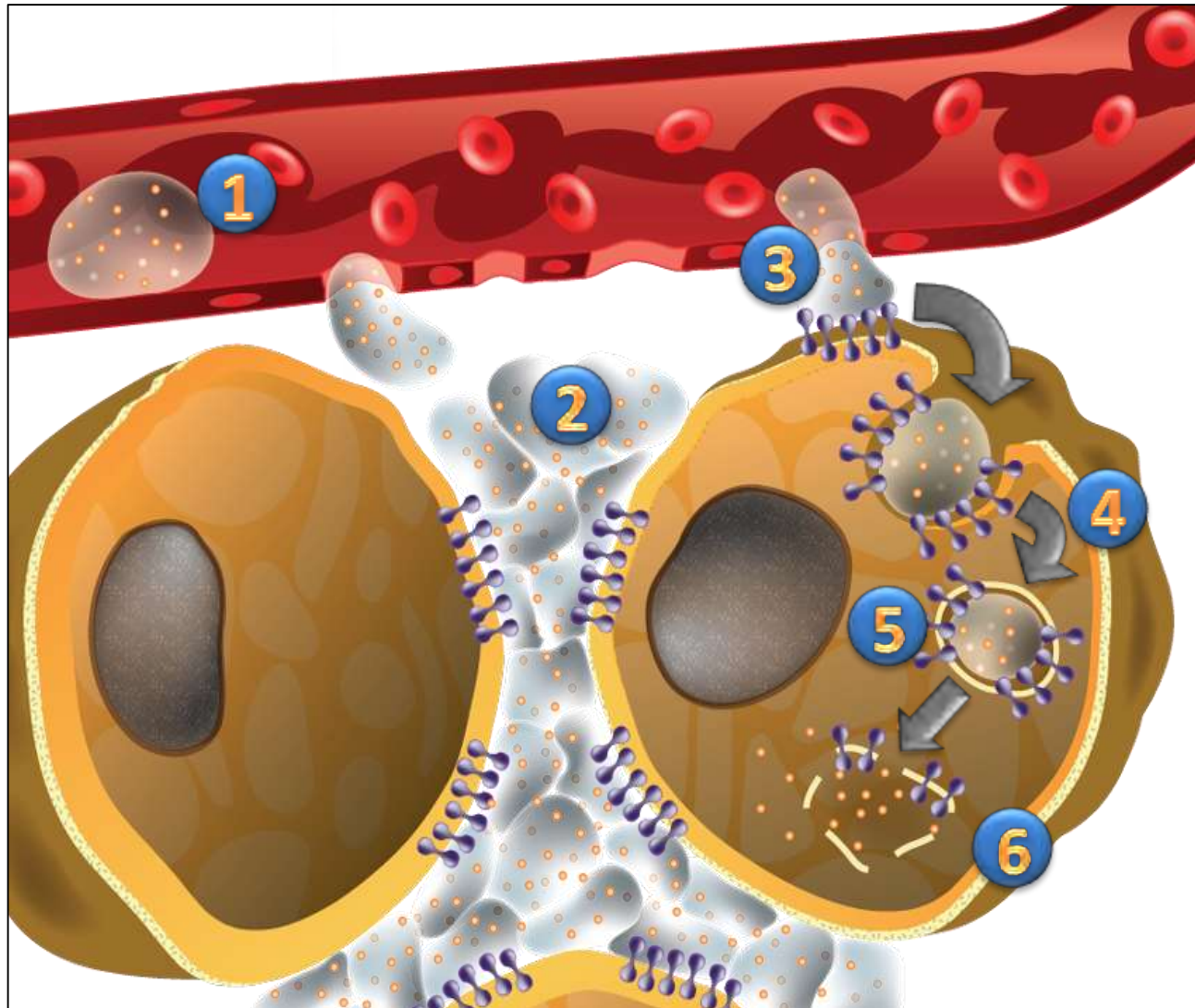
- HyACT targets tumor cells through **unique dual mechanism of action**
 - Drug depot formation around cancer cells increasing the concentration and exposure to drug
 - CD44 Targeting - Hyaluronic acid directly binds to cancer target CD44, triggering internalization of HyACT drug resulting in up to 1000x more anti-cancer drug in tumor cells

Broad Applications

- **Additive** to existing chemotherapeutics without altering their administration or safety
- Platform formulation technology with potential to generate additional assets across broad range of:
 - **Oncology targets** and;
 - **Therapeutics** including chemotherapies and targeted biologics

Transformative

- **505(b)(2) Pathway** - HyACT drugs pose lower risk of development compared with a “new chemical entity,” while still targeting similar pricing
- **Lead HyACT product candidate, HA-Irinotecan, is in a pivotal Phase III clinical trial**



- 1** Entry to tumor environment through leaky vasculature
- 2** HyACT-targeted drug forms 'depot' in tumor microenvironment
- 3** Binds with high avidity to activated CD44
- 4** Binding induced endocytosis
- 5** HyACT-targeted drug held within lysosome
- 6** Breakdown of HyACT and vesicle to release drug internally

CD44 Expression in Solid Tumors

Cancer Type	Normal tissue	% of Tumors with	
Cancer Type	Activated CD44	Activated CD44s	Activated CD44v6
Breast	0	>50%	100%
Colorectal	0	>70%	>80%
Malignant mesothelioma	0	100%	100%
Lung	20% (alveolar macrophages)	91-100%	90%
Prostate	0	78%	>60%
Skin (BCC, SC, melanoma)	100% (keratinocytes)	>70%	>90%
Endometrial	0	>80%	>50%
Pancreatic	0	70-100%	100%

MOA Supporting Rationale

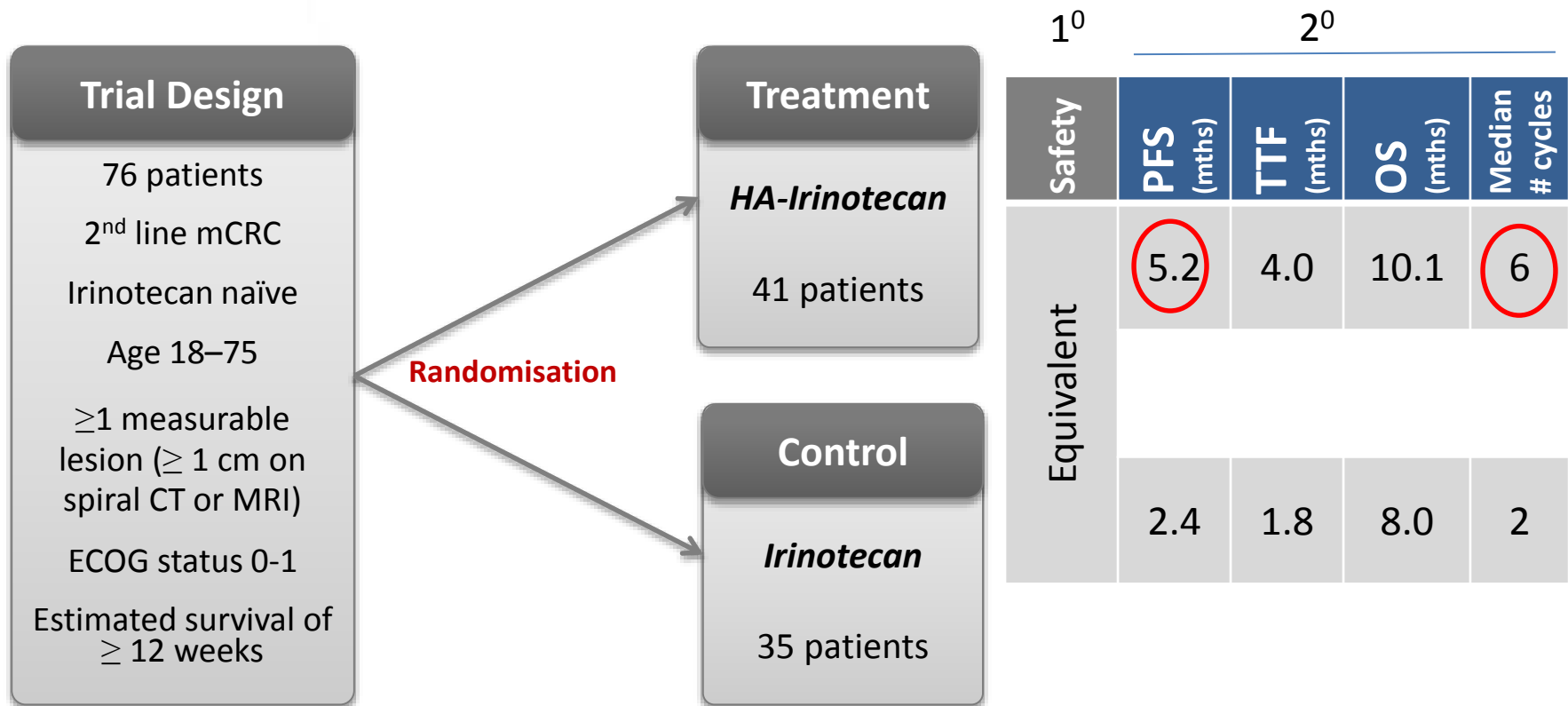
- CD44 is upregulated in solid tumors
- CD44 is the primary receptor for hyaluronic acid
- Binding triggers internalization of HyACT drug resulting in up to 1000x more anti-cancer drug in tumor cells

- Corporate Overview
- HyACT Platform
- **HA-Irinotecan**
 - PII Highlights
 - PIII Program
 - Commercial Value Proposition
 - Potential additional indications
- Non-Oncology Assets
- Summary

Phase II: HA-Irinotecan Metastatic Colorectal Cancer (mCRC)

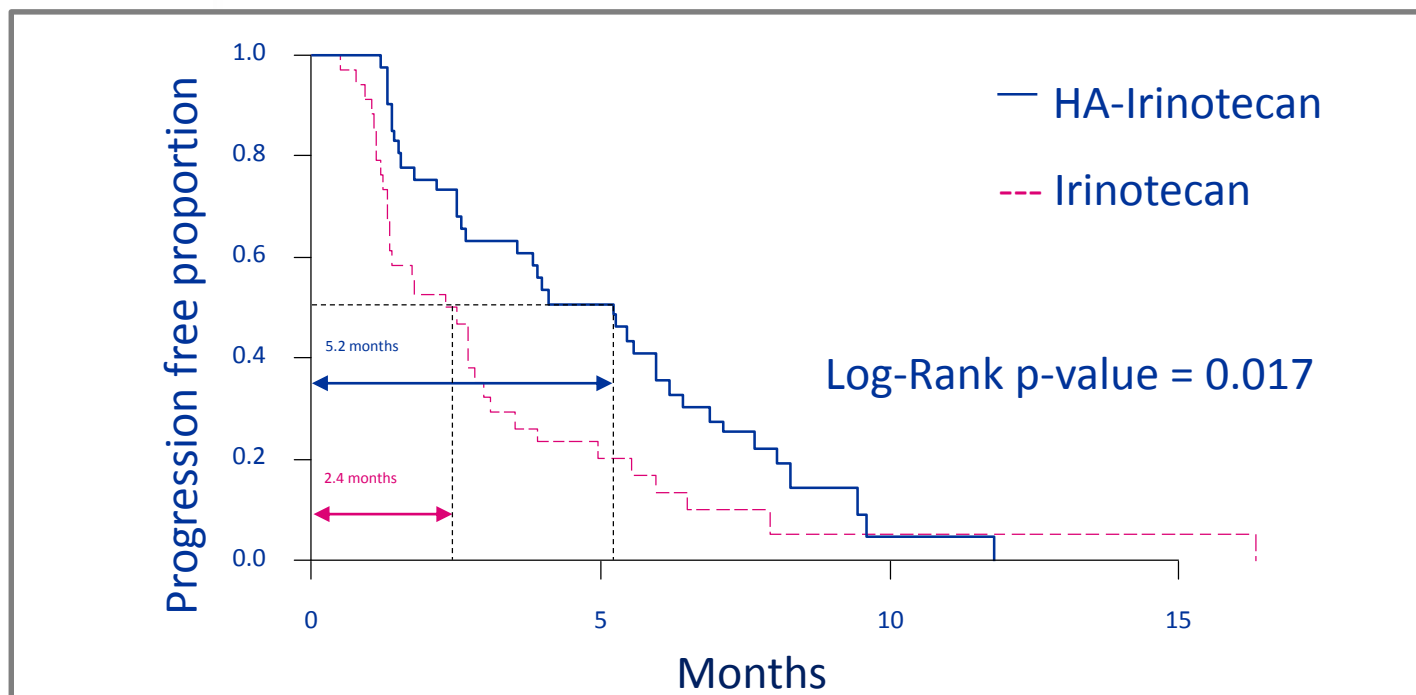
Gibbs et al. Cancer Chemother. Pharmacol. Mar 2010

HA-Irinotecan provided 12 week extension in median PFS with no change in safety, dosing schedule or PK compared with irinotecan alone



Phase II: 12 Weeks Improvement in Median PFS Is Encouraging

Statistically significant increase in median Progression Free Survival (PFS) of 5.2 vs. 2.4 months ($p=0.017$)



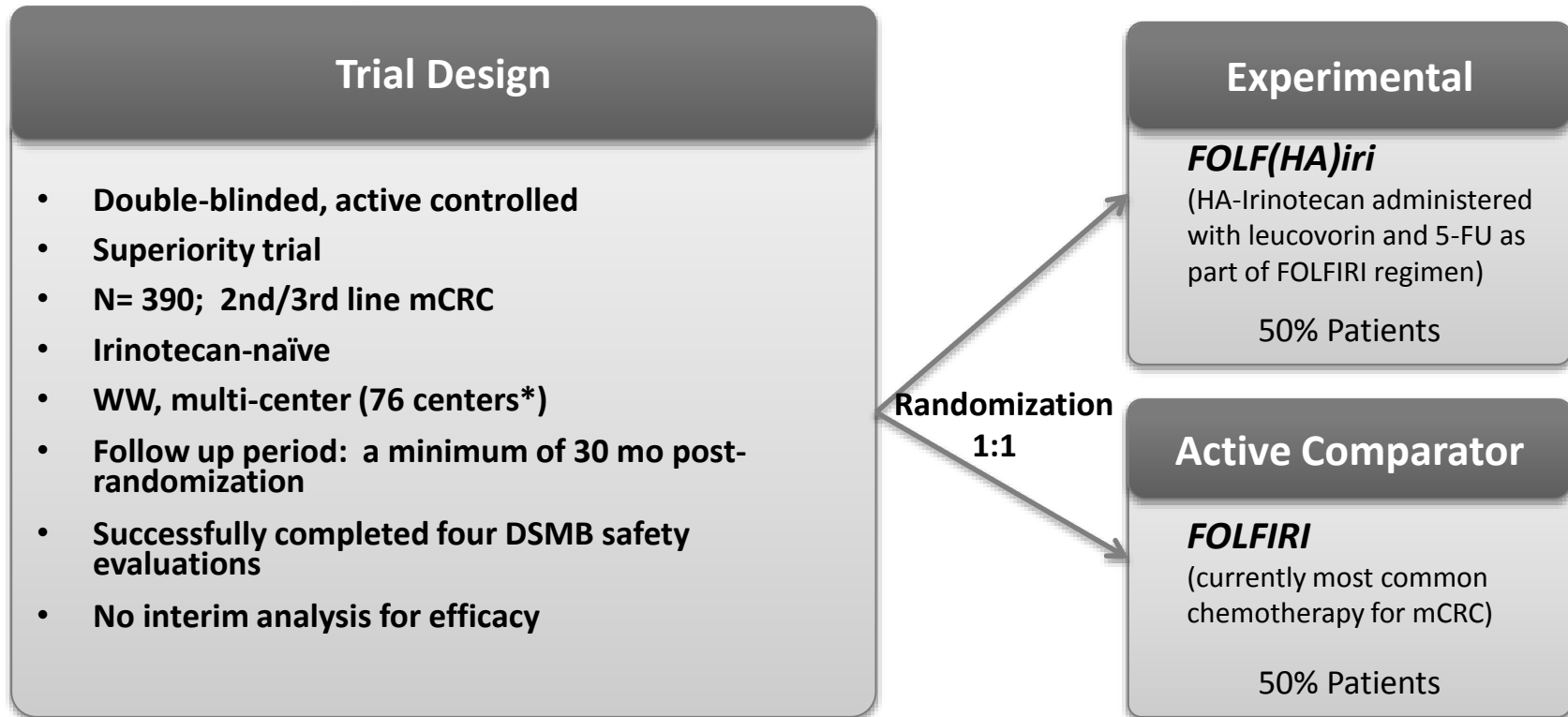
➤ Other Key Results

- Hazard ratio for PFS of 0.56 ($p=0.019$)
- Increase in DCR (76% vs. 46%, $p=0.053$)
- Trend towards increased overall survival (10.1 vs. 8 months) ($p=0.196$)
- Longer Time to Treatment Failure (4.0 months vs. 1.8 months) ($p=0.007$)
- HA-Irinotecan patients treated for significantly more cycles (six vs. two) ($p=0.005$)
- No significant increase in toxicity was observed

Note: DCR = Disease Control Rate

ClinicalTrials.gov Identifier: **NCT01290783**

*Trial is 85% powered to detect ≥ 6 week extension in median PFS ($p=0.05$)
415 patients –over enrolment improves power, primary endpoint expected in
1H CY2014*



* 76 centers in Australia; Eastern EU and Western EU

- **mCRC is one of the most common cancers in the world:**
 - Over 1.2 million new cases diagnosed annually¹
 - Second leading cause of cancer deaths in the US, claiming more than 50,000 lives each year²
- **Target endpoint for the HA-I PIII trial is at least 6 weeks improvement in median PFS**
- **Median PFS improvements from other commercial pharmaceuticals:**
 - Avastin – (2nd line mCRC) median PFS improvement of 10.5 weeks
 - Erbitux – (1st line mCRC) median PFS improvement of 6.5 weeks



2013 total sales of ~\$7B (includes other cancers)*

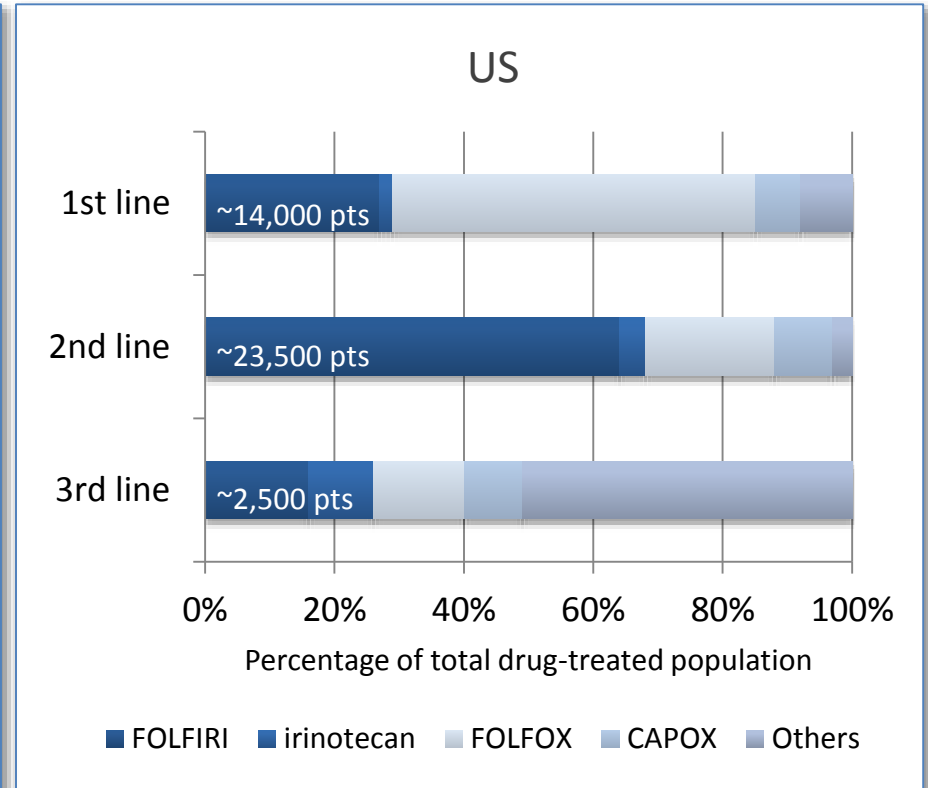
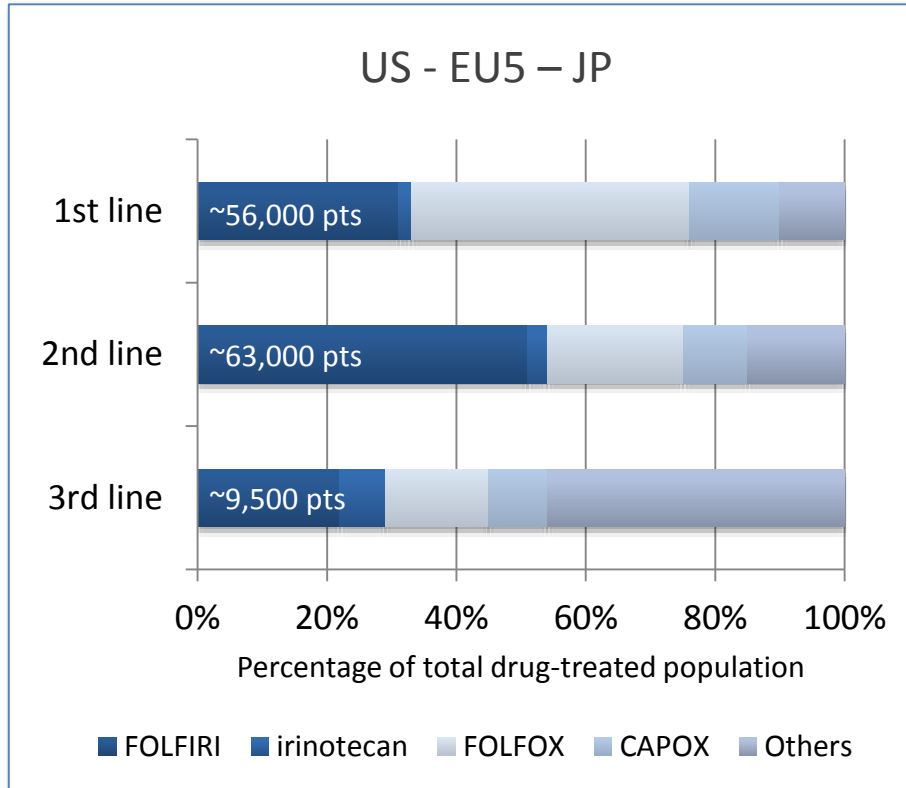


2012 total sales of \$1.15B (includes other cancers)*

*Source: Roche 2013 Annual Report; EMD 2012 Annual Report; (1) WHO, IARC GLOBOCAN, Cancer Incidence and Mortality Worldwide in 2008 at <http://globocan.iarc.fr/>. Accessed February 21, 2014; (2) <http://www.cancer.gov/cancertopics/pdq/prevention/colorectal/HealthProfessional/page3>. Accessed February 21, 2014.

FOLFIRI / Irinotecan Utilization in mCRC Suggests a \$1B+ Opportunity for Alchemia

Chemotherapy use by Line of Therapy



Irinotecan is widely used across all lines in mCRC either as part of the FOLFIRI regimen (irinotecan plus 5-FU and leucovorin), with/without targeted therapies or as a single agent

Patient numbers are FOLFIRI treated patients only

Source: Decision Resources, 2012

○ Small Cell Lung Cancer (SCLC)

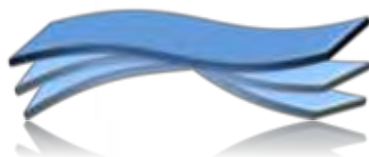
- 27 patients out of targeted 40 patients recruited to investigator-sponsored Phase II trial
 - 2 trial sites in Australia
- Primary endpoints are safety and clinical activity
 - Safety measured by the incidence of grade 3 or 4 toxicity
 - Clinical activity of HA-Irinotecan combined with carboplatin
- Early encouraging signs of clinical activity of HA-Irinotecan combined with carboplatin

○ ‘CHIME’ Trial: Cetuximab + HA-Irinotecan in Metastatic Colorectal Cancer

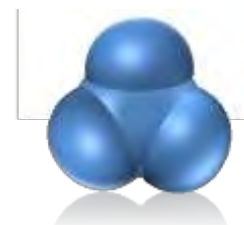
- Joint funded investigator sponsored Phase II trial using HA-Irinotecan in FOLFIRI regimen administered with Merck Serono’s Erbitux
- Primary endpoint is safety, with several efficacy secondary endpoints
- First patient expected in 1H 2014

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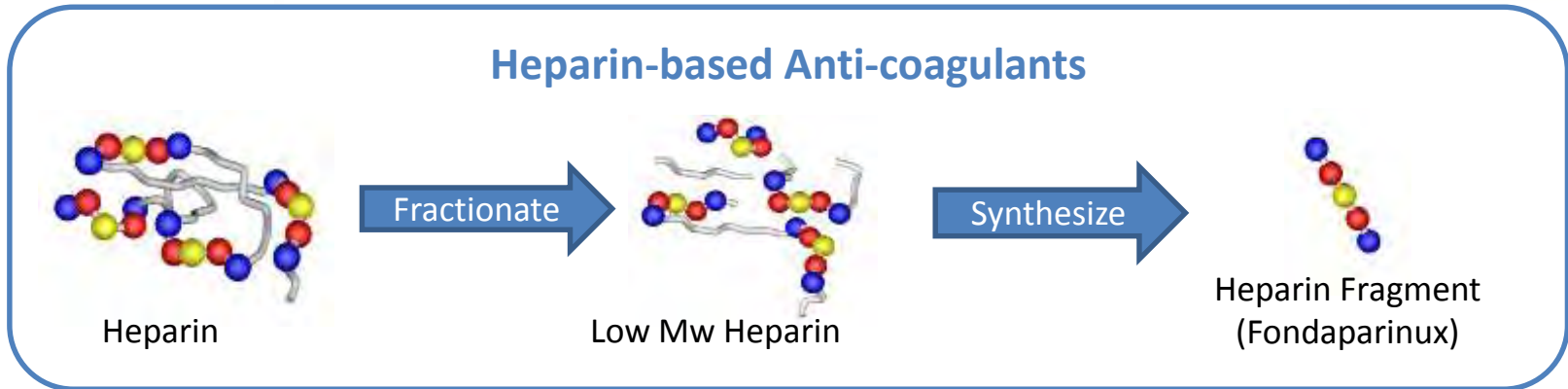
Classical pharma small molecule shapes



VAST shapes

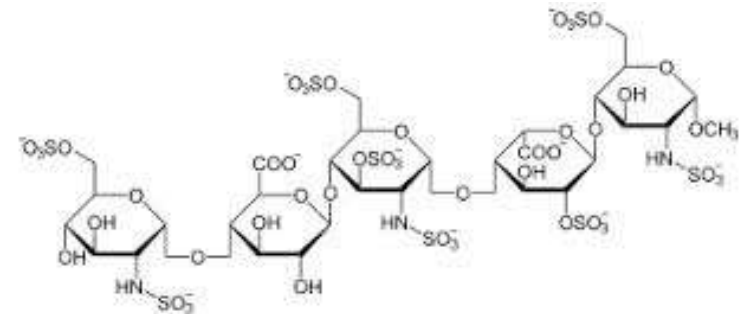


- Drug discovery technology with an array of diverse compound shapes
- Proven platform, enabling the development of a commercial manufacturing process for fondaparinux
- Financially efficient with a focus on productivity through partnerships and grants
- \$240M strategic collaboration with AstraZeneca (April, 2013)
- Grant funding to support internal collaborative drug discovery programs
- Other academic collaborations in oncology, pain and allosteric modulation



Fondaparinux: *Not a typical generic*

- Very difficult to synthesize: 60+ steps
- Even more difficult to scale up to production level
- Patent protection for synthetic route – expiry 2023
- Sole independent generic on the market alongside Arixtra® (GSK, now Aspen) & Apotex Authorised Generic



Financial Results (Q4CY12 – Q4CY13)



Discussion

- Dr Reddy's Market Share
 - ~33% market share of total market (retail + institutional)
 - ~50% market share of retail segment

- ACL Profit share of between US\$2.35M and US\$3.40M to Alchemia per quarter
 - ACL Net profit share deducts ACL contribution of US\$0.50M per quarter toward yield and cost of goods improvement activities,
 - Contribution ends on Dec 31, 2014

- September 30, 2013: Aspen acquired rights to GSK's injectable thrombosis brands, including Arixtra, and its manufacturing facility for \$970M

* Source: IMS

- **Continued competitiveness of Dr Reddy's marketing efforts in the US**

- **Continued improvements in manufacturing costs**
 - Economies of scale and process improvements
 - Expiry in December 2014 of Alchemia's agreement with Dr Reddy's to contribute \$0.5M per quarter for process and production improvements (as announced September 2012)

- **Profit share derived from ROW sales**

- **Pursuing options to best create shareholder value, including assessing the potential monetization of fondaparinux**
 - De-risks asset and provides potential upside for shareholders

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- **Oncology (HyACT assets)**
 - ***PIII HA-I trial in mCRC expected to reach its primary endpoint in 1H CY2014***
 - Potential NDA filing for HA-Irinotecan for mCRC in 4Q2014 – 1Q2015
 - Potential partnership for HA-Irinotecan
 - Potential launch of new HyACT-enhanced chemotherapy clinical trials

- **Fondaparinux**
 - Continued improvements in manufacturing costs
 - New regulatory approvals and launches in new markets by Dr Reddy's

- **VAST**
 - Potential for additional VAST collaborations with pharmaceutical companies

** Note that the contents of this slide does not constitute formal guidance and you are advised to review the disclaimer contained herein*

- **Strong drug development company entering transformative 2014**
 - Strong financial position
 - First product already developed, launched and generating free cash flow, currently funding internal R&D
 - Platform technologies proven to deliver new products
 - Established global Pharma partners

- **Significant near-term catalyst with PIII HA-I trial in mCRC expected to reach its primary endpoint in 1H CY2014**

- **Management team focused on executing on large mCRC commercial opportunity and on further developing the HyACT portfolio**

Alchemia



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➤ **Thomas Liquard – Chief Executive Officer**

- Joined Alchemia in 2013 as COO
- Most recently was Sr Director, Portfolio Development for the Emerging Markets group at Pfizer NY where he spent 7 years in various commercial roles
- Deep experience across the Pharma industry value chain, from clinical development to late stage commercialization, and across multiple therapeutic areas including oncology
- Experienced in business development transactions (licensing, M&A), new product planning, portfolio development and commercialization for both 505(b)(2) and NCE assets

➤ **Tracey Brown, PhD – Chief Scientific Officer, Vice President of Oncology**

- Brings 28 years of relevant research in biochemistry and therapeutic applications of carbohydrates
- She is responsible for the evaluation of lead compounds from both Alchemia's discovery and HyACT programs where her primary role is to take the potential therapeutics into non-clinical development, clinical development as well as executing on the regulatory strategies
- Inventor of HyACT platform and responsible for development of multiple drugs from conception through successful clinical application
- Responsible for overseeing all of Alchemia's oncology discovery, clinical development and regulatory

➤ **Wim Meutermans, PhD – Head of Discovery**

- Joined Alchemia in 2000 and directly responsible for all small molecule drug discovery projects
- 20 years of experience in all non-clinical aspects of drug discovery and one of key inventors of the VAST platform
- Obtained PhD from Katholieke Universiteit Leuven in Belgium

➤ **Imran Ahamed, CPA – Group Financial Controller**

- Appointed Group Financial Controller in February 2013, following one year as Alchemia Oncology's Financial Controller
- Brings 20+ years of accounting and finance experience to Alchemia, having held senior finance positions in investment banking, manufacturing, retail and wholesale sectors in Asia, Southern Africa, the Middle East and Australia

➤ **Santo Costa, JD – Chairman**

- Brings 30 years of extensive international experience serving in senior leadership roles across the life sciences industry
- Previously COO of Quintiles Transnational Corp—responsible for all operating divisions
- Former Sr Vice President, Administration and General Counsel of Glaxo, Inc; Sat on the Company’s Board of Directors and Executive Committee.
- Currently counsel to the law firm Smith, Anderson, Blount, Dorsett, Mitchell & Jernigan in Raleigh, North Carolina and Adjunct professor of clinical research at Campbell University School of Pharmacy.

➤ **Nathan Drona**

- Brings a fifteen year career in international investment banking, most recently as Managing Director of Challiss in New York and Sydney.
- Chairman of Alchemia’s Nominations Committee, a member of Alchemia’s Audit & Risk and Remuneration Committees, and previously served as Alchemia's interim Chairman from July 2013 to March 2014.
- Experienced in corporate finance and has executed more than 25 global banking and M&A engagements in biotech related fields, leading to the award of the “Pharmaceutical Buy-Side M&A Advisor of the Year” by Frost & Sullivan in 2005.

➤ **Tracie Ramsdale, PhD**

- One of original founders of Alchemia and has led development as General Manager and CEO from 1998-2007.
- Holds Master of Pharmacy from Victorian College of Pharmacy and a PhD in Biochemistry from the University of Queensland.
- Currently, adjunct Professor at the School of Chemical and Molecular Biosciences, University of Queensland, a member of the Australian Federal Government's Advisory Council on Intellectual Property and a Fellow of the Australian Academy of Technological Sciences and Engineering.

➤ **Susan Kelley, MD**

- Served on the Board of Directors of ArQule, Inc. since April 2011.
- Previously experience at Bayer Healthcare Pharmaceuticals and Bayer-Schering Pharma in Germany and the United States, serving as Vice President, Global Strategic Drug Development, Cancer; and Vice President, Global Clinical Development and Therapeutic Area Head-Oncology.
- Served as Chief Medical Officer of the Multiple Myeloma Research Foundation/Consortium.

➤ **Tim Hughes**

- Brings 30+ years of experience in investment banking and fund management.
- Most recently served as Investment Counsel at NGS Super and as a commentator on economics and finance for a News Corporation paper.
- Previously spent 13 years as a senior executive at Rothschilds as a board director and executive committee member.