

Alchemia



Alchemia Limited (ASX:ACL) Investor Update

February 2013

www.alchemia.com.au

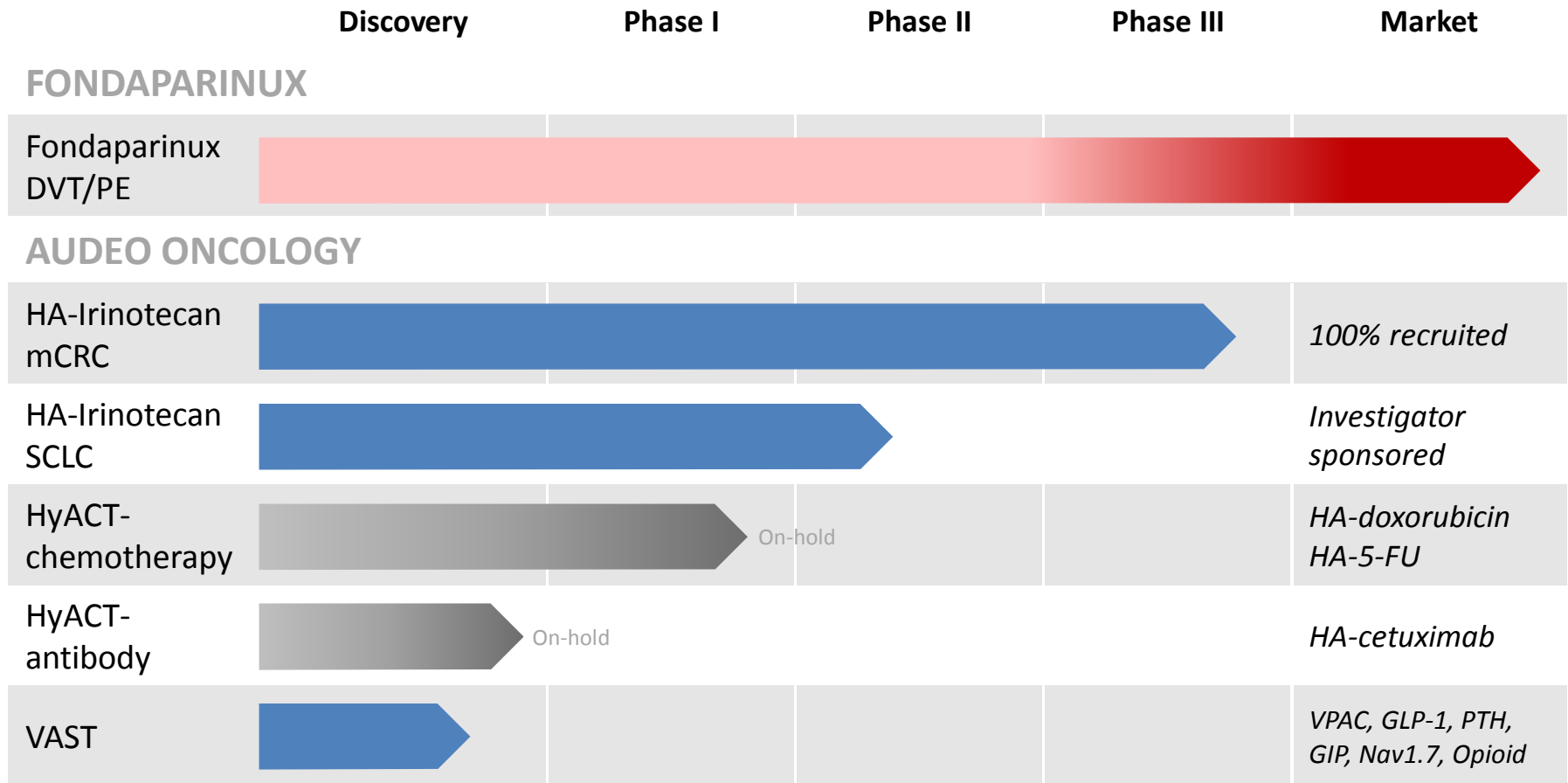
Highlights for financial year to date



- Total revenue of \$9.4 million for the six months ended 31 December 2012
- The recruitment of 415 patients for the pivotal Phase III trial in metastatic colorectal cancer complete
- Receipt of first fondaparinux profit share payments from Dr Reddy's
- Receipt of the R&D tax incentives of \$1.4 million and \$2.0 million for Alchemia Oncology's domestic and overseas spend respectively and \$1.0 million for the domestic spend of Alchemia Limited, all related to the 2012 financial year
- Deferment of the proposed IPO of Audeo Oncology and the demerger of Alchemia Oncology
- Appointment of new CEO
- Cash equivalents of \$6.2 million at 31 December 2012

- Fondaparinux snapshot
 - DRL increasing market share and profits
 - Building market share (22% Q3-12, 25% Q4-12 total market share by volume)
 - Net Profit (\$1.5m Q3-12, \$2.9m Q4-12)
 - Filed in EU 2012; launch expected 2013
- HA-Irinotecan
 - A pivotal Phase III mCRC recruitment closed at 415 patients
 - Phase II for SCLC ongoing
 - Manufacturing scale up underway
 - Commercial studies / business development has been initiated
- Continue to seek financial independence for Audeo

Pipeline



DVT is deep vein thrombosis
PE is pulmonary embolism

mCRC is metastatic colorectal cancer
SCLC is small cell lung cancer

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Generic fondaparinux *Profit Share Improved*

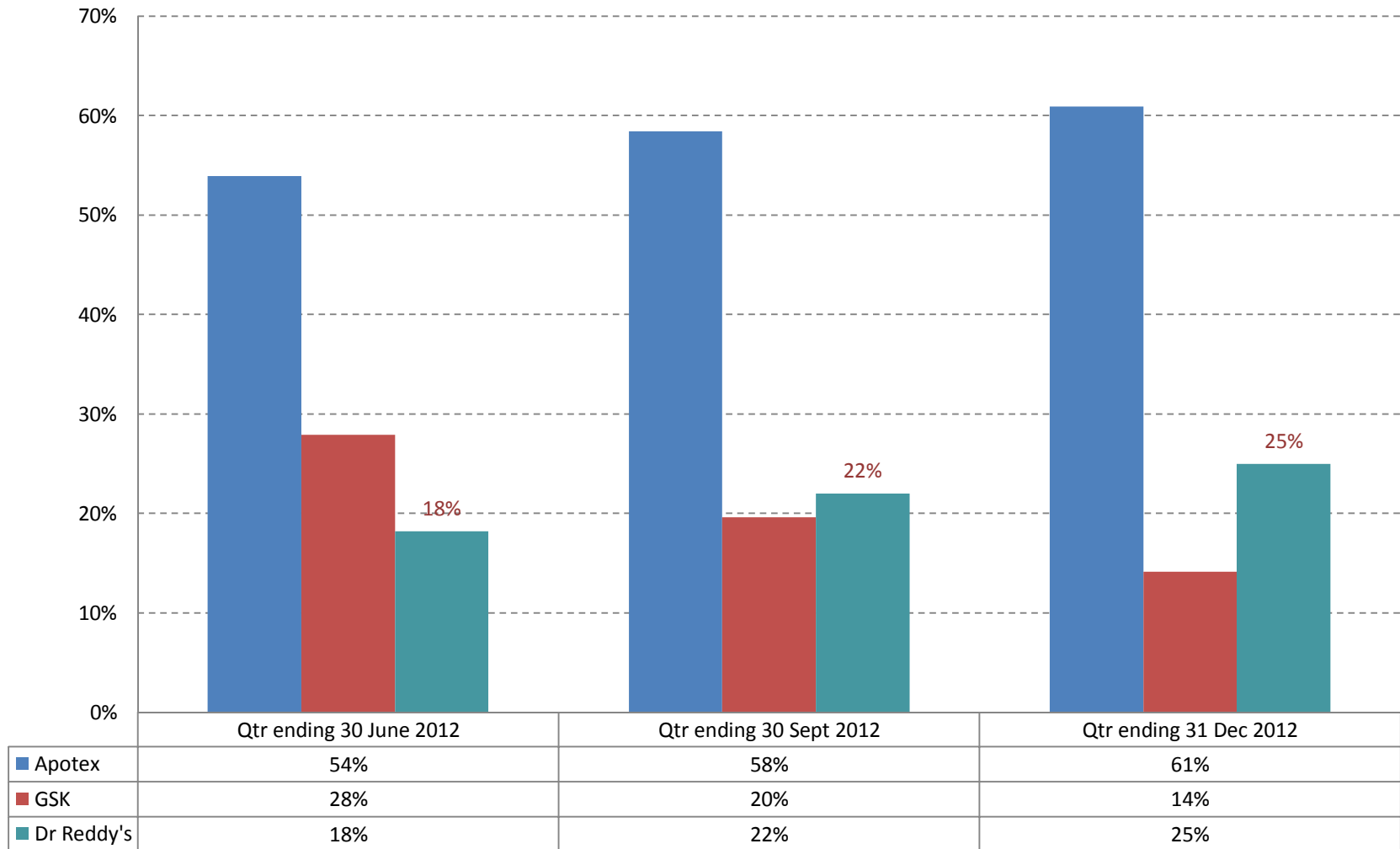
Fondaparinux - Summary



- Market summary
 - GSK loss of share
 - Apotex / DRL gaining share
 - reduction of units (2.5mg; hospital)
 - DRL and Apotex dominating market share
- Dr Reddy's share improving
 - DRL significant increase in retail share
 - DRL limited increase in institutional market share
- Alchemia profit share improved
 - Reduction in API cost
 - Further improvements possible from Sept 2013
- First EU approval expected in 2013



% Market Share by Volume

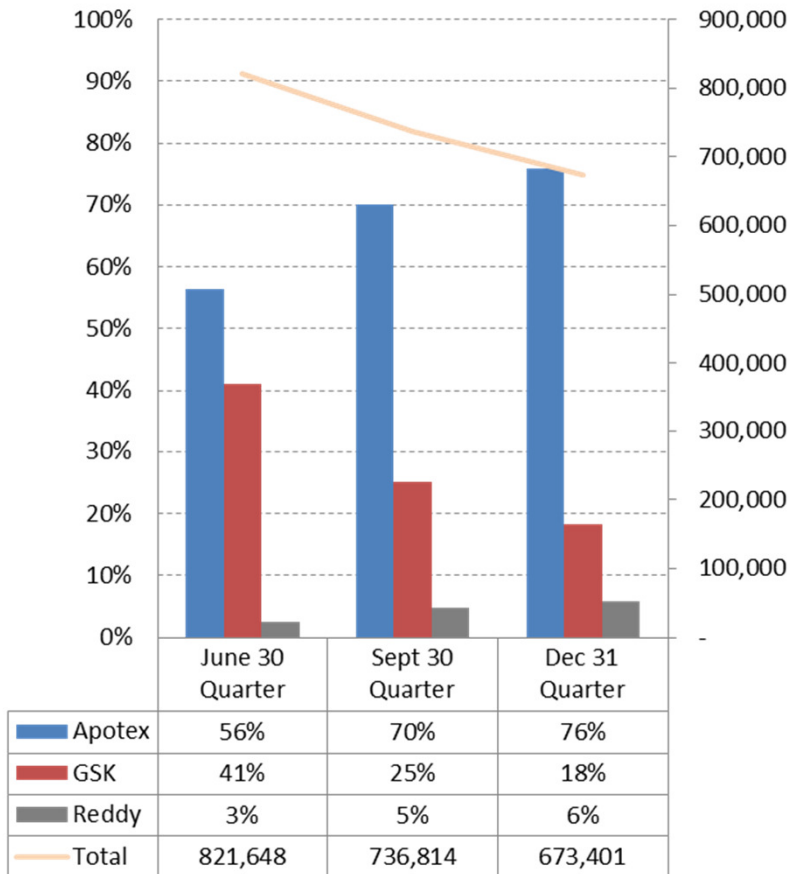


Source: IMS

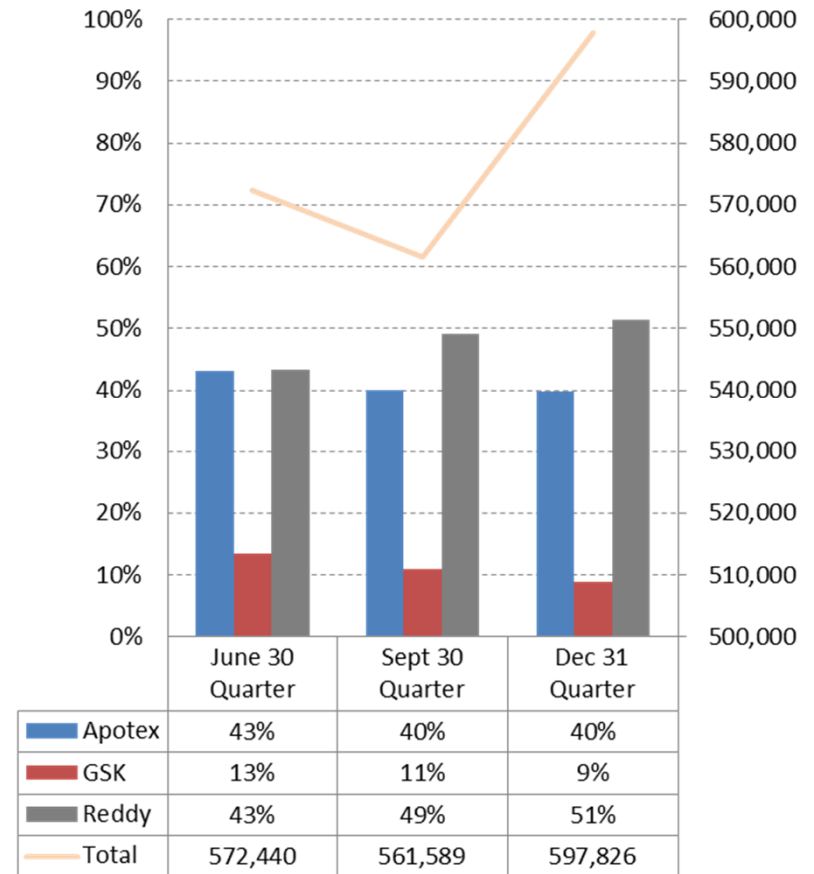
% Market Share (Volume) by Sector



Non-Retail Quarter By Volume



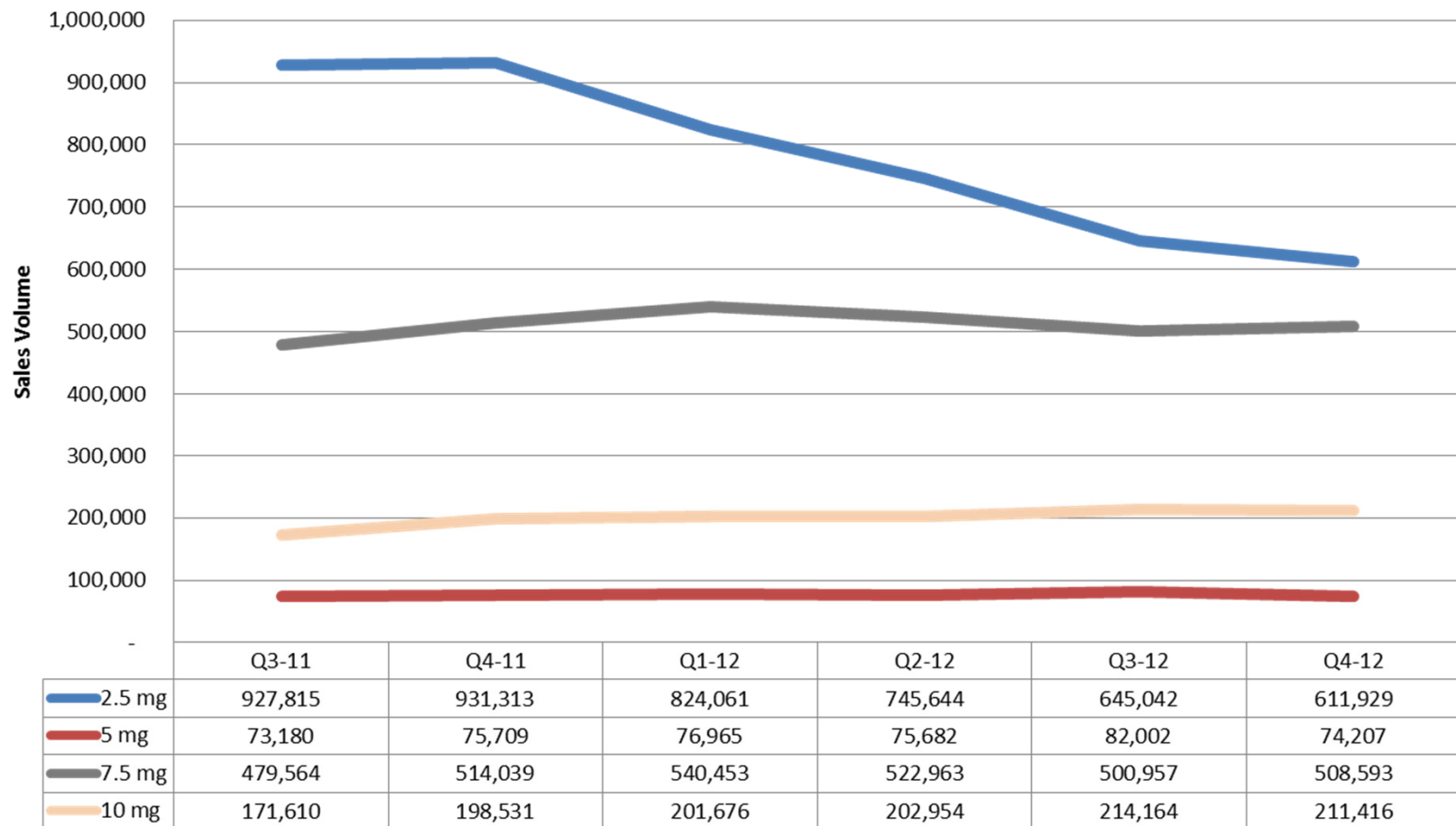
Retail Quarter By Volume



Source: IMS

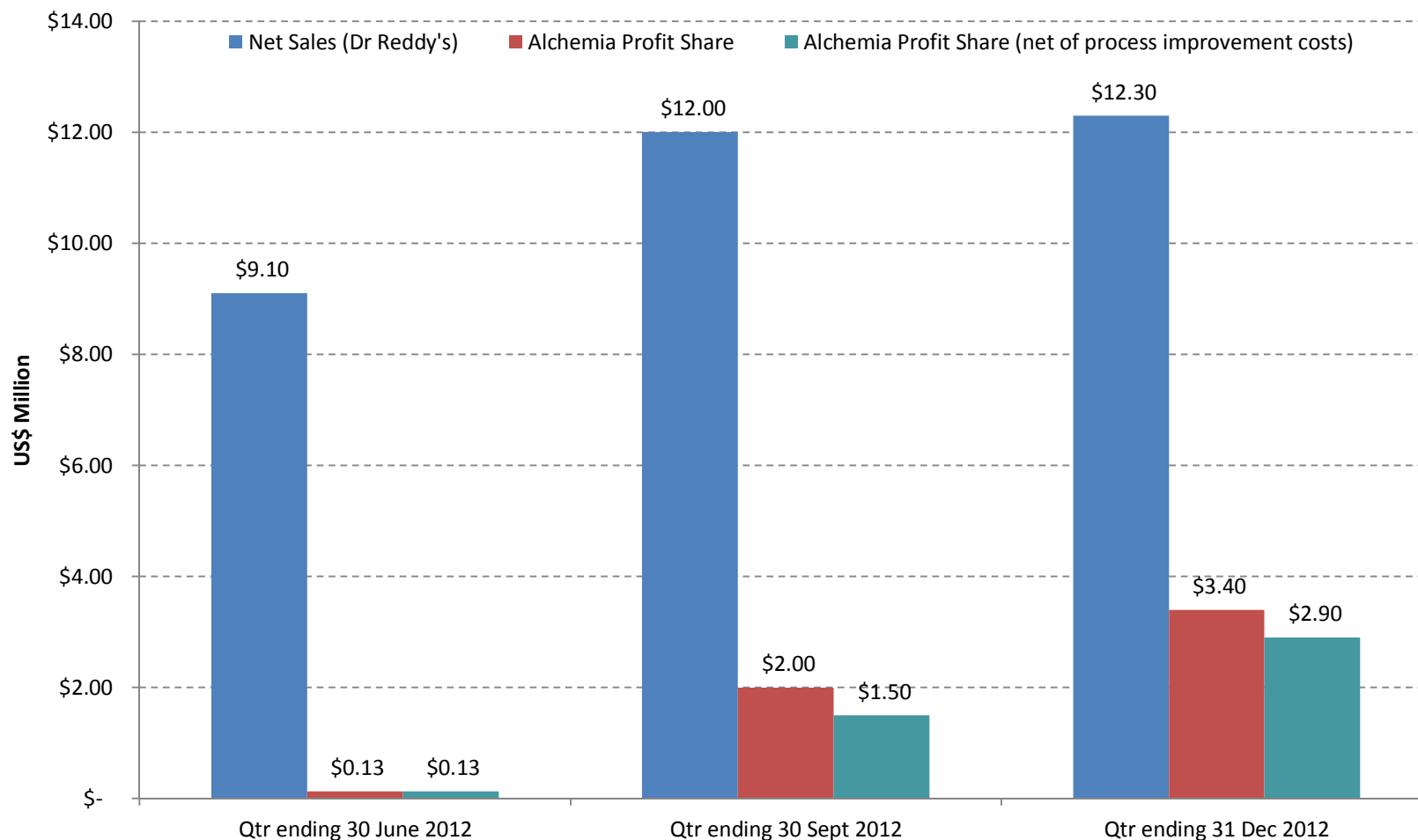
Quarterly Sales Volume by Dosage Form *Alchemia*

Sales volume of 2.5mg, 5.0mg, 7.5mg and 10mg dosage forms of fondaparinux



Source: IMS

2012 Quarterly Performance Comparisons *Alchemia*



Source: IMS

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Audeo Oncology, Inc.

HyACT Platform

HA-Irinotecan

VAST Platform

Audeo is a late-stage, oncology focussed biopharmaceutical company with an integrated pipeline of products stemming from two core technology platforms

- Lead product: HA-Irinotecan is nearing completion of its pivotal Phase III trial in mCRC
 - International, multicentre randomised trial in 76 sites in 7 countries
 - Recruitment of patients completed in February 2013
 - Targeted irinotecan with potential sales of up to \$1.7 billion
 - Product extension in SCLC (Phase II) and other clinical indications planned
- Additional Phase II ready HyACT products
 - HA-doxorubicin and HA-5-fluorouracil
- Preclinical oncology pipeline
 - HyACT antibodies
 - HyACT chemotherapeutics
 - VAST discovery projects

We believe that HyACT has the potential to enhance the efficacy of a range of anti-cancer drugs

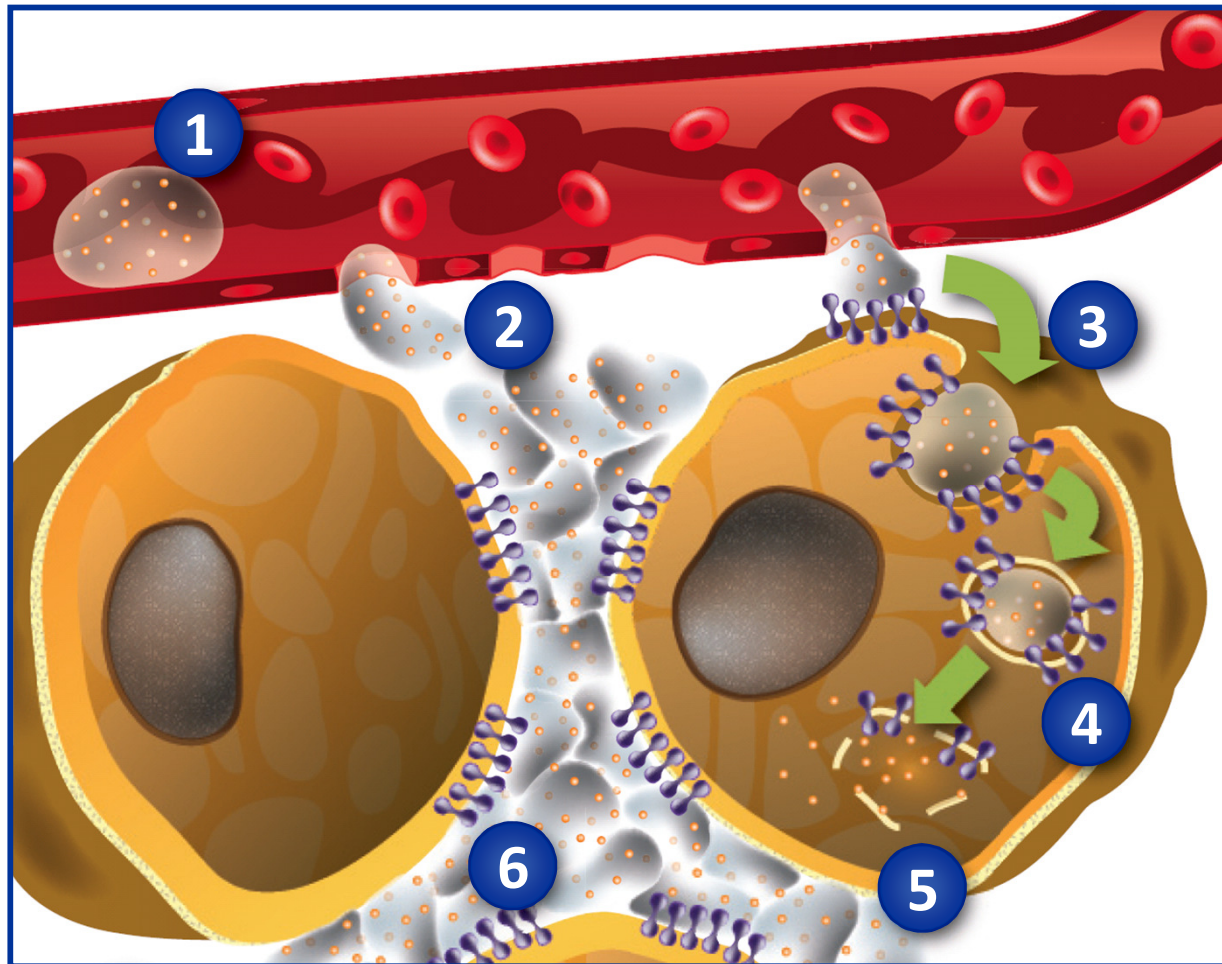
- Proprietary platform uses hyaluronic acid (HA) to target existing drugs to CD44 positive tumours to promote increased drug uptake
- Receptor-based mechanism targets CD44 receptors
- Positive preclinical results with seven HyACT-targeted anti-cancer agents
- Equivalent or superior toxicity profile in Phase I and II clinical evaluation
- No change in plasma pharmacokinetic parameters
- Lead HyACT drug candidate HA-Irinotecan has achieved statistically significant increases in efficacy endpoints in a randomized Phase II trial

HyACT Targets CD44, a Validated Tumour Target

Activated CD44 enables HA binding and internalisation; resulting in more drug entering the tumour cell

- CD44 is a naturally occurring HA receptor, present in many solid tumour cancers
 - CD44 over-expression in tumours associated with:
 - aggressive/metastatic cancers
 - cancer stem cells, which are generally more resistant to chemotherapy
 - CD44 generally not activated in healthy tissue
- Preclinical studies show HA binds to activated CD44 promoting internalisation of HyACT-targeted anti-cancer drug into tumour cells
- Preclinical studies have demonstrated HyACT carries anti-cancer drugs preferentially to cancer cells and increases drug uptake by those cells

HyACT Mechanism of Action



- 1 HyACT-targeted drug delivery vehicle with anti-cancer drug in the bloodstream after infusion
- 2 HyACT-targeted drug accesses the tumour environment through leaky vasculature typical of blood vessels that supply blood to tumours. HyACT-targeted drugs form a drug depot in the extracellular space of the tumour
- 3 HyACT-targeted drug binds to activated CD44 and then is rapidly internalized, resulting in more drug entering the tumour cell
- 4 HyACT-targeted drug is transported into an intracellular vesicle and the hyaluronic acid is degraded
- 5 HyACT-targeted drug is released within the cancer cell, increasing the likelihood of cell death and enhanced tumour response
- 6 The HyACT-targeted drug depot generally persists for at least 24 hours, resulting in repeated cycles of drug internalization and release inside tumour cells

This figure represents our hypothesis regarding the HyACT mechanism of action based on preclinical data and published literature; clinical significance is unknown

- Patients with mCRC, 2nd/3rd line, Irinotecan-naïve
 - 415th patient recruited February 2013
 - 390th patient recruited by 31 January 2013 on time
 - Some centres held open to recruit additional 20 patients to bolster FDA requested substudy, additional improvement to statistical power
- FOLFIRI versus FOLF(HA)-Irinotecan regimen
 - Leucovorin+5FU+Irinotecan vs. leucovorin+5FU+HA-Irinotecan
- Randomized, double-blinded, multi-centre
 - 76 trial sites across 7 countries: Australia and countries in Eastern and Western Europe
 - PSI is managing and coordinating the trial
- Primary endpoint Progression Free Survival (6 weeks or more)
- Primary endpoint analysed after 350 events
 - Statistical review and modelling on available blinded data suggests that on average, patients are continuing treatment for longer than anticipated, before disease progresses. Due to these encouraging results, primary endpoint is likely to be met in early 2014

Colon Cancer - Market Opportunity



- Colorectal cancer = 3rd most common cancer, 10% of all cancer cases
 - 150,000 new cases in the US each year
 - 50,000 deaths each year in US
- Branded Irinotecan (Camptosar, marketed by Pfizer) had sales of over \$950M in 2007
- Recent NCCN Guidelines approved the use and reimbursement of irinotecan in 1st, 2nd and 3rd line mCRC
 - Increasing use of irinotecan-containing regimens in mCRC, especially in combination with targeted therapies (Avastin, Erbitux, Zaltrap)
 - FOLFIRI regime is one of the leading treatments mCRC
 - Single agent Irinotecan recommended for patients who cannot tolerate multiple chemotherapeutic regimens
- Irinotecan use also observed in other cancer indications such as advanced ovarian cancer, glioblastoma multiforme, NSCLC, SCLC

Phase II Trial for the Treatment of SCLC *Alchemia*

- Investigator-sponsored study in Victoria, Australia
 - Success in study has potential to further validate the HyACT platform
- Phase II Study of HA-Irinotecan in SCLC
 - Randomized, approximately 40 patient study
 - HA-Irinotecan + carboplatin vs. Irinotecan + carboplatin
 - Primary endpoints are safety (incidence of grade 3 and 4 toxicity) and tumour cell burden
 - Secondary endpoints include PFS at 6 months, ORR, cumulative dose of Irinotecan, quality of life and OS
 - Original protocol provided for recruitment of first line chemotherapy-naïve SCLC patients
 - Protocol was altered in May 2012 to include second line patients
- Began Phase II enrolment September 2011
 - Seek to obtain clinical data on HA-Irinotecan's activity on cancer stem cells
 - 13 patients currently enrolled

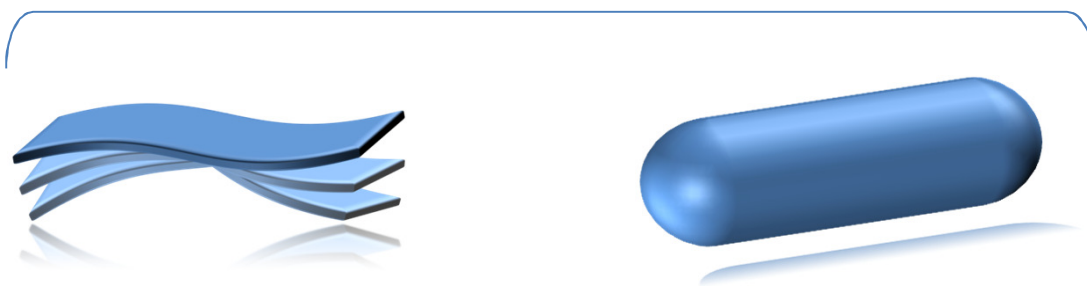
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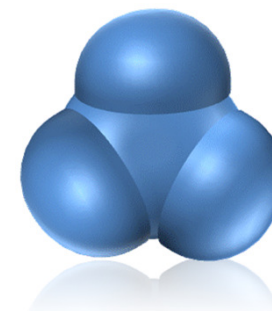
VAST Technology

VAST: Small molecule discovery

Classical pharma small molecule shapes



VAST shapes



- Small molecule drug discovery technology
- An array of diverse compound shapes or “3D keys”, which cover unique chemical territory
- Financially efficient with a focus on productivity through partnerships and grants
 - Partnering with industry and academic partners
 - Grant funding to support internal collaborative drug discovery programs
 - Collaborations with WEHI (oncology), UQ (pain) and MIPS (allosteric modulation)
 - Evaluating with big pharma

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Corporate Overview

Board of Directors

- Melvyn Bridges, Chairman, (ALS Limited, ImpediMed, Tissue Therapies)
- Tracie Ramsdale, PhD, (founder Alchemia)
- Nerolie Withnall (ALS Limited, Computershare, PanAust)
- Up to three additional new directors to be appointed in the short term

Senior Management

- Charles Walker, MBA, CEO ¹
- Tracey Brown, PhD, CSO, VP of Oncology
- Michael West, PhD, Vice President of Intellectual Property and Technology Transfer
- Wim Meutermans, PhD, Vice President of Drug Discovery
- Goslik Schepers, PhD, Vice President of Business Development

1. Charles Walker appointed CEO of Alchemia Limited on 18 February 2013

Plan to Extract Value from Alchemia's Assets



- Maintain focus on HA-Irinotecan, late stage asset close to a key value inflection point
- Ensure that Alchemia maintains a strong position for any partnering/financing activities
 - retain flexibility, but
 - maintain focus of achieving financial independence of Audeo Oncology, Inc.
 - partnering / business development initiative underway
- Audeo Oncology, Inc. :
 - seek financial independence for Audeo
 - seek listing for Audeo on public exchange (e.g. US and/or Australia) (subject to market conditions)
 - retain focus on Alchemia returning funds to shareholders

Upcoming Milestones



- 1st Half – Calendar Year 2013
 - Phase II SCLC trial update
 - DSMB review of Phase III trial
 - IP Update
 - Fondaparinux receipts for Q3 FY13
- 2nd Half – Calendar Year 2013
 - Fondaparinux receipts for Q4 F13
 - Fondaparinux receipts for Q1 F14
 - Phase II trial update
 - R&D tax incentive update
- 2014 onwards
 - Phase III endpoint of trial and results
 - Fondaparinux receipts for Q2 F14
 - Fondaparinux receipts for Q3 F14
 - Phase II trial progress
 - Partnership progress
 - Potential demerger of Audeo Oncology
 - Return of capital from Fondaparinux revenues to Alchemia shareholders
 - Periodic updates

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Appendix

HA-Irinotecan vs irinotecan Phase II for Treatment of mCRC



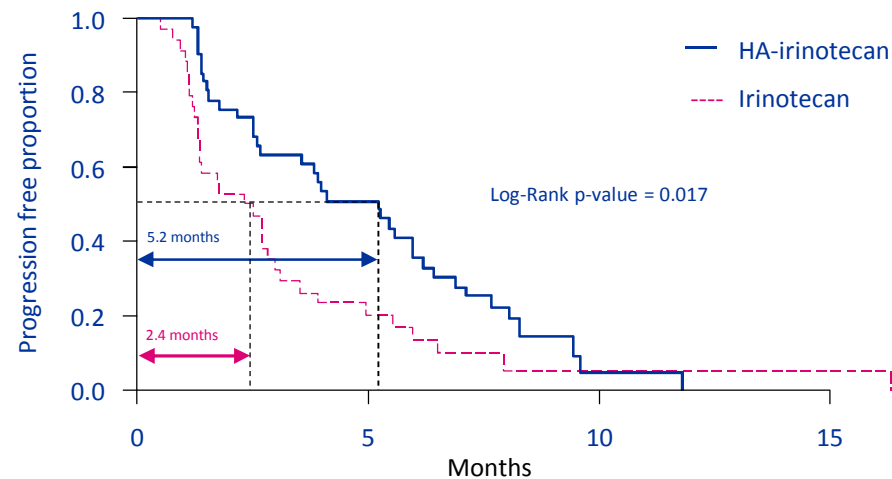
Design Highlights

- Trial included 76 patients in 2nd line metastatic colorectal cancer (mCRC)
- Patients were randomized to receive either Irinotecan alone or HA-Irinotecan
 - Up to 8 cycles of treatment
 - Each cycle containing 350 mg/m² Irinotecan administered every 21 days
- Primary endpoint – Safety (reduced diarrhoea)
- Secondary endpoints – Efficacy (DCR, PFS, TTF, OS)

HA-Irinotecan vs irinotecan Phase II for Treatment of mCRC



Statistically significant increase in progression-free survival (PFS) of 5.2 vs. 2.4 months (p=0.017)



Other Key Results

- Hazard ratio for PFS of 0.46 (p=0.011)
- Increase in disease control rate measured by RECIST (76% vs. 46%, p=0.053)
- Trend towards increased overall survival (10.1 vs. 8 months) (p=0.196)
- Significantly longer time to treatment failure (4.0 months vs. 1.8 months) (p=0.007)
- HA-Irinotecan patients able to be treated for significantly more cycles (six vs. two) (p=0.005)
- Primary endpoint of reduced diarrhea was not achieved
- No significant increase in toxicity was observed