Morgans IN ALLIANCE WITH CIMB

# Alchemia

ACL AU / ACL.AX

COMPANY NOTE

| Market Cap | Avg Daily Turnover | Free Float |
|---|---|---|
| US$169.3m | US$0.18m | 80.0% |
| A$181.7m | A$0.19m | 324.0 m shares |

| | |
|---|---|
| Current | A$0.56 |
| Target | A$0.88 |
| Prev. Target | A$0.88 |
| Up/Downside | 57.4% |

STOCK RATING: ADD / HOLD / REDUCE

**Morgans Analyst(s)**

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# Moment of truth approaches

*ACL plans to report top line results for its pivotal Phase III trial in metastatic colorectal cancer this quarter. We are confident of a successful read out and we have run some sensitivities on the impact on our price target. In this note we review a number of the existing treatments and other compounds in development and reflect on the clinical trial so far.*

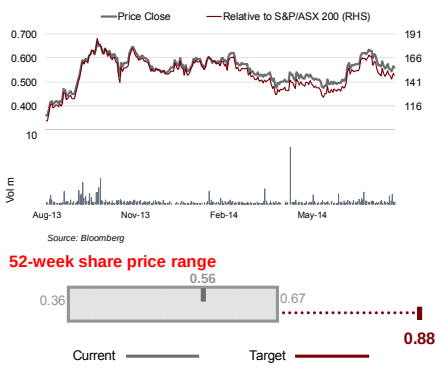
We have made no changes to our forecasts ahead of the Phase III read out. As a result our price target and DCF valuation currently sit at A$0.88. Our model is most sensitive to changes in the probability of success (currently at 70%), with a 5% change increasing /decreasing our valuation by A$0.04/(A$0.04). If the Phase III trial is successful we would move our probability calculation to 90% and subsequently the price target to A$1.04. ACL is in a solid cash position with A$11.1m in cash at 30 June 2014.

## Phase III read out this quarter

ACL is due to report in September top line data for its 415 patients phase III clinical trial in metastatic colorectal cancer (mCRC). The primary endpoint of the trial is at least 6 weeks improvement in median progression free survival (PFS). If the trial results are positive (as we expect) then the time lines to approval would include a regulatory submission in 1HCY15, additional data from the trial, as well as data from the CHIME trial (see report for more detail) with a product launch expected in 1HFY16. We have assumed a licensing deal is entered into in FY15. Depending on the timing of a licensing transaction, we do not rule out the need for additional capital.

## What you should do

Clearly this is a binary event for ACL, with the risk being a poor clinical trial outcome and the share price falling below our fondaparinux valuation of A$0.31ps. If a client's risk appetite is appropriate, ACL is solid risk/reward play.



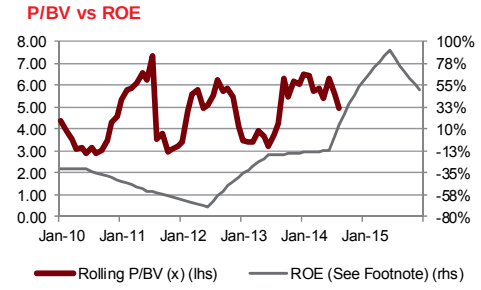

## Financial Summary

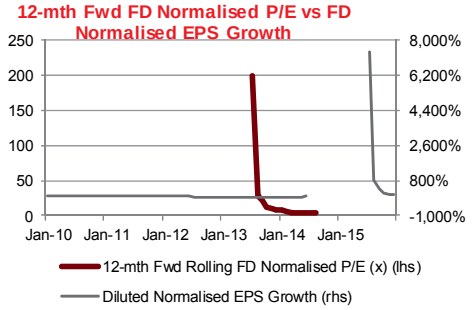
| | Jun-12A | Jun-13A | Jun-14F | Jun-15F | Jun-16F |
|---|---|---|---|---|---|
| Revenue (A$m) | 0.34 | 24.08 | 13.62 | 57.42 | 42.68 |
| Operating EBITDA (A$m) | -14.14 | -3.67 | -3.12 | 48.22 | 33.21 |
| Net Profit (A$m) | -15.08 | -4.79 | -3.74 | 47.36 | 23.84 |
| Normalised EPS (A$) | -0.05 | -0.01 | -0.01 | 0.15 | 0.07 |
| Normalised EPS Growth | (21.6%) | (73.1%) | (22.0%) | NA | (49.7%) |
| FD Normalised P/E (x) | NA | NA | NA | 3.83 | 7.61 |
| DPS (A$) | - | - | - | - | - |
| Dividend Yield | 0% | 0% | 0% | 0% | 0% |
| EV/EBITDA (x) | NA | NA | NA | 2.72 | 3.06 |
| P/FCFE (x) | NA | NA | NA | NA | NA |
| Net Gearing | (57.8%) | (40.1%) | (52.8%) | (66.1%) | (79.9%) |
| P/BV (x) | 6.35 | 5.60 | 6.33 | 2.39 | 1.82 |
| ROE | (70.0%) | (16.9%) | (12.2%) | 90.5% | 27.1% |
| % Change In Normalised EPS Estimates | | | 0% | 0% | 0% |
| Normalised EPS/consensus EPS (x) | | | 1.05 | 1.06 | 0.43 |

SOURCE: MORGANS, COMPANY REPORTS

## Share price info

| Share px perf. (%) | 1M | 3M | 12M |
|---|---|---|---|
| Relative | -10.4 | 4.8 | 45.8 |
| Absolute | -9.7 | 5.7 | 53.4 |
| **Major shareholders** | | | **% held** |
| Alan Gray | | | 19.9 |




## Profit & Loss

| (A$m) | Jun-12A | Jun-13A | Jun-14F | Jun-15F | Jun-16F |
|---|---|---|---|---|---|
| **Total Net Revenues** | **0.34** | **24.08** | **13.62** | **57.42** | **42.68** |
| **Gross Profit** | **0.34** | **24.08** | **13.62** | **57.42** | **42.68** |
| **Operating EBITDA** | **-14.14** | **-3.67** | **-3.12** | **48.22** | **33.21** |
| Depreciation And Amortisation | -1.73 | -1.60 | -1.44 | -1.45 | -1.45 |
| **Operating EBIT** | **-15.87** | **-5.28** | **-4.55** | **46.76** | **31.75** |
| Financial Income/(Expense) | 0.39 | 0.22 | 0.82 | 0.61 | 2.01 |
| Pretax Income/(Loss) from Assoc. | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Non-Operating Income/(Expense) | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| **Profit Before Tax (pre-EI)** | **-15.48** | **-5.06** | **-3.74** | **47.37** | **33.76** |
| Exceptional Items | | | | | |
| **Pre-tax Profit** | **-15.48** | **-5.06** | **-3.74** | **47.37** | **33.76** |
| Taxation | 0.40 | 0.27 | 0.00 | -0.01 | -9.93 |
| Exceptional Income - post-tax | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| **Profit After Tax** | **-15.08** | **-4.79** | **-3.74** | **47.36** | **23.84** |
| Minority Interests | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Preferred Dividends | | | | | |
| FX Gain/(Loss) - post tax | | | | | |
| Other Adjustments - post-tax | | | | | |
| Preference Dividends (Australia) | | | | | |
| **Net Profit** | **-15.08** | **-4.79** | **-3.74** | **47.36** | **23.84** |
| Normalised Net Profit | -15.08 | -4.79 | -3.74 | 47.36 | 23.84 |
| **Fully Diluted Normalised Profit** | **-15.08** | **-4.79** | **-3.74** | **47.36** | **23.84** |

## Cash Flow

| (A$m) | Jun-12A | Jun-13A | Jun-14F | Jun-15F | Jun-16F |
|---|---|---|---|---|---|
| EBITDA | -14.14 | -3.67 | -3.12 | 48.22 | 33.21 |
| Cash Flow from Invt. & Assoc. | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Change In Working Capital | 1.55 | -12.65 | 4.73 | -13.61 | 4.39 |
| (Incr)/Decr in Total Provisions | | | | | |
| Other Non-Cash (Income)/Expense | | | | | |
| Other Operating Cashflow | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Net Interest (Paid)/Received | 0.39 | 0.22 | 0.82 | 0.61 | 2.01 |
| Tax Paid | 0.40 | 0.27 | 0.00 | -0.01 | -9.93 |
| **Cashflow From Operations** | **-11.80** | **-15.84** | **2.43** | **35.20** | **29.68** |
| Capex | -0.07 | -0.09 | -0.28 | -0.11 | -0.13 |
| Disposals Of FAs/subsidiaries | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Acq. Of Subsidiaries/investments | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Other Investing Cashflow | 0.37 | -6.23 | 0.00 | 0.00 | 0.00 |
| **Cash Flow From Investing** | **0.30** | **-6.33** | **-0.28** | **-0.11** | **-0.13** |
| Debt Raised/(repaid) | -8.60 | 9.68 | -2.15 | -35.09 | -29.55 |
| Proceeds From Issue Of Shares | 20.09 | 12.48 | 0.00 | 0.00 | 0.00 |
| Shares Repurchased | | | | | |
| Dividends Paid | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Preferred Dividends | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Other Financing Cashflow | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| **Cash Flow From Financing** | **11.49** | **22.16** | **-2.15** | **-35.09** | **-29.55** |
| Total Cash Generated | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| **Free Cashflow To Equity** | **-20.09** | **-12.48** | **0.00** | **0.00** | **0.00** |
| **Free Cashflow To Firm** | **-11.88** | **-22.38** | **1.34** | **34.49** | **27.54** |

BY THE NUMBERS

SOURCE: MORGANS, COMPANY REPORTS

# BY THE NUMBERS

## Balance Sheet

| (A$m) | Jun-12A | Jun-13A | Jun-14F | Jun-15F | Jun-16F |
|---|---|---|---|---|---|
| Total Cash And Equivalents | 14.02 | 12.98 | 15.13 | 50.22 | 79.78 |
| Total Debtors | 0.08 | 12.38 | 3.36 | 14.16 | 10.52 |
| Inventories | 0.00 | 0.00 | 0.68 | 2.87 | 2.13 |
| Total Other Current Assets | 1.57 | 0.68 | 0.68 | 0.68 | 0.68 |
| **Total Current Assets** | **15.67** | **26.04** | **19.85** | **67.93** | **93.11** |
| Fixed Assets | 0.39 | 0.43 | 0.59 | 0.57 | 0.58 |
| Total Investments | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Intangible Assets | 16.06 | 14.73 | 13.41 | 12.08 | 10.76 |
| Total Other Non-Current Assets | 0.25 | 0.30 | 0.30 | 0.30 | 0.30 |
| **Total Non-current Assets** | **16.70** | **15.45** | **14.29** | **12.95** | **11.63** |
| Short-term Debt | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Current Portion of Long-Term Debt | | | | | |
| Total Creditors | 3.32 | 4.99 | 1.38 | 0.76 | 0.78 |
| Other Current Liabilities | 1.69 | 0.88 | 0.89 | 0.89 | 0.89 |
| **Total Current Liabilities** | **5.01** | **5.87** | **2.26** | **1.64** | **1.66** |
| Total Long-term Debt | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Hybrid Debt - Debt Component | | | | | |
| Total Other Non-Current Liabilities | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| **Total Non-current Liabilities** | **0.00** | **0.00** | **0.00** | **0.00** | **0.00** |
| Total Provisions | 3.10 | 3.24 | 3.24 | 3.24 | 3.24 |
| **Total Liabilities** | **8.11** | **9.11** | **5.50** | **4.88** | **4.90** |
| Shareholders' Equity | 24.27 | 32.38 | 28.64 | 76.00 | 99.84 |
| Minority Interests | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| **Total Equity** | **24.27** | **32.38** | **28.64** | **76.00** | **99.84** |

## Key Ratios

| | Jun-12A | Jun-13A | Jun-14F | Jun-15F | Jun-16F |
|---|---|---|---|---|---|
| Revenue Growth | (59%) | 6962% | (43%) | 322% | (26%) |
| Operating EBITDA Growth | 12.2% | (74.0%) | (15.2%) | NA | (31.1%) |
| Operating EBITDA Margin | (4145%) | (15%) | (23%) | 84% | 78% |
| Net Cash Per Share (A$) | 0.05 | 0.04 | 0.05 | 0.16 | 0.25 |
| BVPS (A$) | 0.09 | 0.10 | 0.09 | 0.23 | 0.31 |
| Gross Interest Cover | -100,442 | -33,407 | -28,836 | 296,028 | 201,018 |
| Effective Tax Rate | 0.0% | 0.0% | 0.0% | 0.0% | 29.4% |
| Net Dividend Payout Ratio | NA | NA | NA | NA | NA |
| Accounts Receivables Days | 42.4 | 94.4 | 210.9 | 55.7 | 105.8 |
| Inventory Days | N/A | N/A | N/A | N/A | N/A |
| Accounts Payables Days | N/A | N/A | N/A | N/A | N/A |
| ROIC (%) | (120%) | (40%) | (20%) | 279% | 78% |
| ROCE (%) | (71.8%) | (17.9%) | (12.2%) | 90.5% | 38.4% |

SOURCE: MORGANS, COMPANY REPORTS

# Recap on the program

## 1. Colorectal cancer treatment overview

### 1.1 Fourth most common cancer

Colorectal cancer (CRC) is a cancer that develops in the colon or rectum. Current prognosis for the disease is poor, with a five-year survival rate of less than 60%, dropping as low as 5%, depending on detection and type of cancer. Globally more than one million cases occur each year, resulting in over 700,000 deaths. CRC is the fourth most common cause of cancer death. The rate of CRC diagnosis has increased, especially in Asia, attributed to uptake of a "Western lifestyle": poor diet and reduced exercise at old age.

### 1.2 Treatment options and approved drugs

The main categories of treatment for cancers are: surgery (remove it), chemotherapy (poison it), radiotherapy (irradiate it) or biologic therapies (interrupt it). In the case of CRC if the cancer progresses to metastatic colorectal cancer the clinician will usually choose a chemotherapy combination. The FDA has approved nine non-surgery treatments for CRC, which can be split in two categories: chemotherapies (Figure 1) and targeted therapies (Figure 2). Fluorouracil combined with Irinotecan (known as FOLFIRI) is used as first line treatment in Europe and second line treatment in Australia and US.

**Figure 1: Chemotherapies (in order of FDA approval)**

| |
|---|
| Fluorouracil – blocks DNA replication |
| Irinotecan (Pfizer) – a topoisomerase-1 inhibitor |
| Oxaliplatin (Sanofi) – plantinum-based therapy blocking DNA synthesis |
| Capecitabine (Roche) – a prodrug metabolised to fluorouracil |

SOURCES: MORGANS, COMPANY REPORTS

**Figure 2: Targeted therapies**

| |
|---|
| Avastin - Bevacizumab (Roche) – humanized VEGF-A inhibitor |
| Vectobix - Panitumab (Amgen) – fully humanized EGFR inhibitor |
| Erbitux - Cetuximab (Eli Lilly) – partially humanized EGFR inhibitor |
| Zaltrap - Aflibercept (Regeneron) – Recombinant fusion protein for VEGF inhibition |
| Stivarga - Regorafenib (Bayer) – multi-kinase inhibitor targeting angiogenic, stromal and oncogenic RTKs |

SOURCES: MORGANS, COMPANY REPORTS

### 1.3 New treatments under development

ACL has developed a treatment for mCRC by combining irinotecan with hyaluronic acid, which increases the amount of irinotecan that is targeted to the tumour, allowing for a greater dose of the irinotecan with reduced toxicity. Excluding ACL's product, there are five notable novel treatments in development for CRC, refer Figure 3. ACL's clinical data to date supports further clinical development, refer Figure 4. Results from the phase II trial were strong, with a 12 week extension in median progression free survival (PFS) and no change in safety or dosing schedule compared to irinotecan alone.

**Figure 3: Novel treatments**

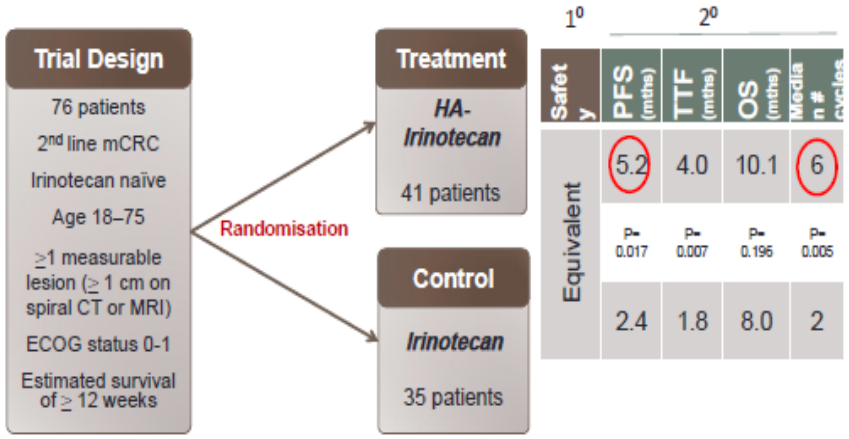
| Novel treatments in development for CRC | Phase of development |
|---|---|
| MGN1703 (Mologen AG) – immunotherapy designed as a TLR9 agonist | 2 |
| Imprime PGG (Biothera) – immunotherapy binding CR3 to target tumour cells | 3 |
| Xilonix (XBiotech) – humanized IL-1α inhibitor | 3 |
| BAY 43-9006 (Bayer) – multi-kinase inhibitor, including VEGFR, PDGFR and Raf kinases | 2 |
| TAS 102 (Taiho Oncology) – combination of a DNA synthesis inhibitor (FTD) and a compound to prevent FTD degradation, | phase 3 (primary endpoint met 12/5/14 |

SOURCES: MORGANS, COMPANY REPORTS

**Figure 4: Phase II Data supports further clinical development**

*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*




SOURCES: Prof Gibbs et al. Cancer Chemother, Pharmacol, March 2010

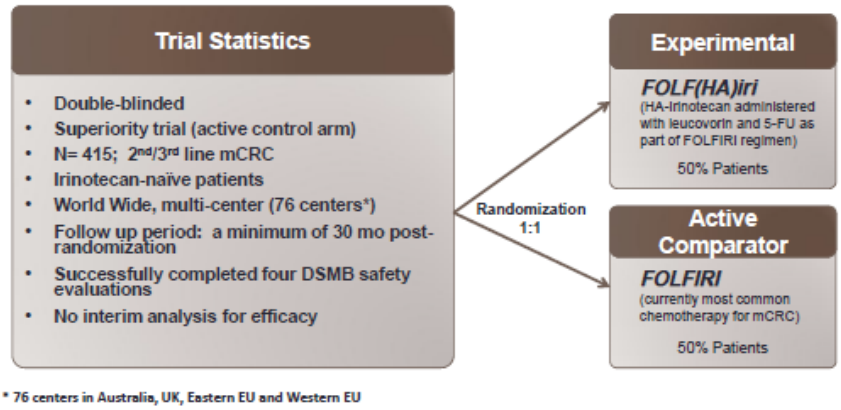
## 1.4 ACL's Phase III trial about to read out

ACL's Phase III enrolment was completed in February 2013, with a total of 415 patients across 76 centres in Australia, UK, and Europe. Top-line data is expected in September 2014. The trial is comparing the standard CRC chemotherapy treatment FOLFIRI (fluorouracil combined with irinotecan) to FOLF(HA)iri, which uses HA-irinotecan instead, refer Figure 5. The primary endpoint of the study is PFS of six weeks or more.

**Figure 5: Phase III trial design**

ClinicalTrials.gov Identifier: NCT01290783

*Trial completed enrolment of 415 patients in February 2013*
*Top-line data (primary endpoint) expected in September 2014*

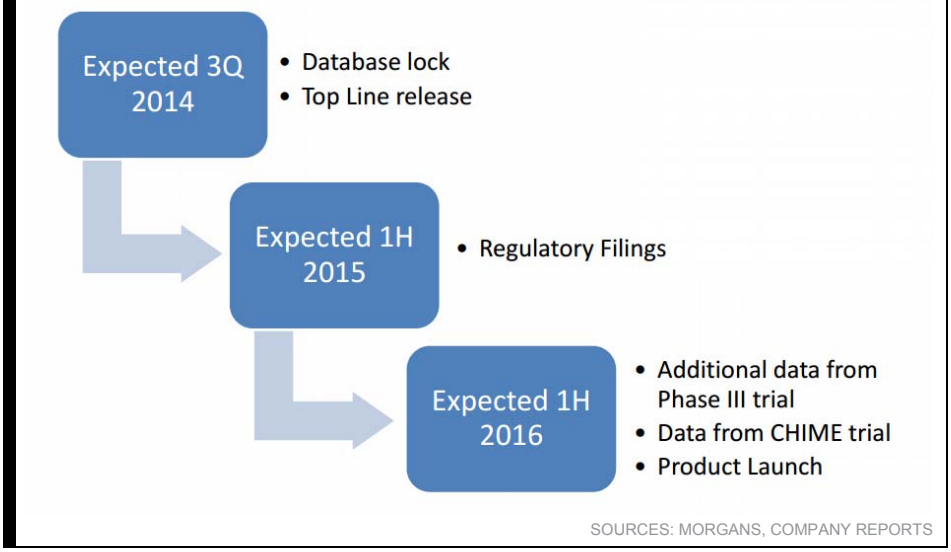



* 76 centers in Australia, UK, Eastern EU and Western EU

SOURCES: MORGANS, COMPANY REPORTS

## 1.5 Outline of timeline to approval

**Figure 6: Timeline to approval**




## 1.6 Clinical considerations

Assuming success in phase III trial and regulatory filing, HA-irinotecan would be positioned as a strong choice compared to standard irinotecan as a first, second or third line treatment for CRC given its benefits of reduced toxicity and improved PFS. However, success in uptake of the treatment would also depend on drug cost as well as the market and marketing. An important consideration is whether HA-irinotecan, a chemotherapy, will be used by clinicians in combination with targeted therapies. To address this, a secondary study (CHIME trial), in phase II, is examining the efficacy of FOLF(HA)iri combined with cetuximab, a common targeted therapy for CRC. Management has undertaken clinician surveys and believe that a 2 month difference in PFS would change practice by 50% uptake.

## 1.7 Other programs underway

ACL has a number of other clinical programs underway including two investigator sponsored trials. A Phase II small cell lung cancer trial of 40 patients and a Phase II trial using HA-Irinotecan in the FOLFIRI regimen administered with Erbitux (known as the CHIME trial).

# 2. VALUATION & SENSITIVITIES

## 2.1 If successful valuation upgrade

We have made no changes to our forecasts ahead of the Phase III read out. As a result our price target and DCF valuation currently sit at A$0.88. Our model is most sensitive to changes in the probability of success (currently at 70%), with a 5% change increasing /decreasing our valuation by A$0.04/(A$0.04). If the Phase III trial is successful we would move our probability calculation to 90% and subsequently the price target to A$1.04.

Cash position is sound at A$11.1m as at 30 June 2014.

# 3. Risks

Clearly this is a binary event for ACL, with the risk being a poor clinical trial outcome and the share price falling below our fondaparinux valuation of A$0.31ps. If a client's risk appetite is appropriate, ACL is solid risk/reward play.

| | |
|---|---|
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| CALOUNDRA | (07) 5491 5422 |
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| | (02) 9615 4500 |
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| CAMBERWELL | (03) 9813 2945 |
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