

# Viralytics

ASCO presentation

Keep CALM and carry on

Pharma &amp; biotech

5 June 2014

**Price** **A\$0.28**
**Market cap** **A\$52m**

A\$1.12/US\$

Net cash (A\$m) end-March 2014 26.5

Shares in issue 184.0m

Free float 55%

Code VLA

Primary exchange ASX

Secondary exchange OTCQX

Updated key efficacy data from the open-label CALM Phase II study in metastatic melanoma, confirmation of Cavatak's benign safety profile and preclinical synergies, in combination with anti-PD-1 immunotherapy, were presented at [ASCO](#). These features, coupled with the potential of further near-term data and wider interest in oncolytic virotherapy, suggest that the prospects for partnering remain promising. Cavatak's safety profile is a significant advantage for a potential combination regimen given the high side effect burden of existing melanoma therapies. The combination approach may form part of the design for a planned US multi-centre Phase II randomised advanced melanoma study due to start late in 2014.

Year end	Revenue (A\$m)	PBT* (A\$m)	EPS* (c)	DPS (c)	P/E (x)	Yield (%)
06/12	0.9	(4.3)	(6.4)	0.0	N/A	N/A
06/13	2.5	(3.7)	(4.5)	0.0	N/A	N/A
06/14e	1.7	(5.6)	(4.7)	0.0	N/A	N/A
06/15e	2.2	(8.2)	(4.5)	0.0	N/A	N/A

Note: \*PBT and EPS are normalised, excluding intangible amortisation, exceptional items and share-based payments.

## Share price performance



%	1m	3m	12m
Abs	(3.4)	(3.4)	4.1
Rel (local)	(3.2)	(3.7)	(6.3)
52-week high/low	A\$0.40	A\$0.23	

## Business description

Viralytics is an ASX-listed biopharmaceutical developing virus applications using a common cold producing virus to target late-stage melanoma and other solid tumour types. The Phase II CALM trial is evaluating intratumoural administration of lead candidate Cavatak in patients with metastatic melanoma.

## Next events

Six-month irPFS CALM data	Q314
Start of randomised Phase II in advanced melanoma	H214
One-year survival data CALM	Q115
Initial STORM data	Q115

## Analysts

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## ASCO: Growing body of CALM data

19/51 (37%) of evaluable patients have now achieved irPFS at six months (the immune-related progression-free survival endpoint of  $\geq 10$  patients was met in September), with 21/33 (63%) alive at one year and a preliminary overall response rate of 26.3% (15/57). No Grade 3 or 4 drug-related adverse events have been seen. Case studies in six patients showed partial/complete reduction of non-injected tumours; activity in both injected and distant tumours evidences a dual mechanism of action (anti-tumour immune response, targeted cancer cell killing).

## Promising preclinical combination data

Preclinical combination data of Cavatak with anti-PD-1 monoclonal antibodies in an in vivo mouse melanoma model showed substantial synergistic anti-tumour effects vs either therapy alone, supporting further clinical investigation of this combination.

## Phase I/II STORM trial could broaden indications

Positive data from the STORM trial could see further Cavatak development in other solid cancers that overexpress ICAM-1. Phase I will evaluate Cavatak alone, while Phase II will study Cavatak combined with standard chemotherapy (docetaxel or carboplatin/paclitaxel) in the most responsive cancer type(s) identified in Phase I.

## Valuation: More data or a deal should boost rNPV

We maintain our A\$141m (A\$0.77/share) risk-adjusted NPV based on a 35% Cavatak success probability in melanoma and modest risk-adjusted revenues from other indications under evaluation in STORM. It includes risk-adjusted upfront and developmental milestones from a yet to be secured deal. Final CALM data, start of the randomised melanoma Phase II and positive STORM data represent valuation upside (increased success probabilities), as would confirmed deal economics.

**Viralytics is a research client of Edison Investment Research Limited**

**Exhibit 1: Financial summary**

	A\$000s	2011	2012	2013	2014e	2015e
30-June		IFRS	IFRS	IFRS	IFRS	IFRS
<b>PROFIT &amp; LOSS</b>						
Revenue		1,406	875	2,493	1,706	2,183
Cost of Sales		0	0	0	0	0
Gross Profit		1,406	875	2,493	1,706	2,183
EBITDA		(2,246)	(4,621)	(3,912)	(5,787)	(8,939)
Operating Profit (before amort. and except.)		(2,302)	(4,659)	(3,934)	(5,817)	(8,977)
Intangible Amortisation		(390)	(390)	(390)	(390)	(390)
Exceptionals		0	0	0	0	0
Other		0	0	0	0	0
Operating Profit		(2,693)	(5,049)	(4,324)	(6,207)	(9,367)
Net Interest		240	317	257	254	737
Profit Before Tax (norm)		(2,063)	(4,342)	(3,678)	(5,563)	(8,240)
Profit Before Tax (FRS 3)		(2,453)	(4,732)	(4,068)	(5,953)	(8,630)
Tax		0	0	0	0	0
Profit After Tax (norm)		(2,063)	(4,342)	(3,678)	(5,563)	(8,240)
Profit After Tax (FRS 3)		(2,453)	(4,732)	(4,068)	(5,953)	(8,630)
Average Number of Shares Outstanding (m)		55.3	67.5	81.5	119.5	184.1
EPS - normalised (c)		(3.7)	(6.4)	(4.5)	(4.7)	(4.5)
EPS - normalised and fully diluted (c)		(3.7)	(6.4)	(4.5)	(4.7)	(4.5)
EPS - (IFRS) (c)		(4.4)	(7.0)	(5.0)	(5.0)	(4.7)
Dividend per share (c)		0.0	0.0	0.0	0.0	0.0
Gross Margin (%)		N/A	N/A	N/A	N/A	N/A
EBITDA Margin (%)		N/A	N/A	N/A	N/A	N/A
Operating Margin (before GW and except.) (%)		N/A	N/A	N/A	N/A	N/A
<b>BALANCE SHEET</b>						
Fixed Assets		3,675	3,267	2,931	2,551	2,163
Intangible Assets		3,607	3,217	2,863	2,473	2,083
Tangible Assets		68	50	68	78	81
Investments		0	0	0	0	0
Current Assets		6,365	7,039	7,281	26,773	18,531
Stocks		365	0	0	0	0
Debtors		995	1,154	2,202	2,202	2,202
Cash		5,005	5,884	5,079	24,570	16,329
Other		0	0	0	0	0
Current Liabilities		(981)	(746)	(1,235)	(1,235)	(1,235)
Creditors		(664)	(746)	(1,235)	(1,235)	(1,235)
Short term borrowings		(317)	0	0	0	0
Long Term Liabilities		0	0	0	0	0
Long term borrowings		0	0	0	0	0
Other long term liabilities		0	0	0	0	0
Net Assets		9,058	9,560	8,978	28,089	19,460
<b>CASH FLOW</b>						
Operating Cash Flow		(3,190)	(3,561)	(3,934)	(5,786)	(8,938)
Net Interest		159	5	0	254	737
Tax		0	0	0	0	0
Capex		(49)	(20)	(40)	(40)	(40)
Acquisitions/disposals		0	0	0	0	0
Financing		2,959	4,455	3,169	25,064	0
Dividends		0	0	0	0	0
Net Cash Flow		(121)	880	(806)	19,491	(8,242)
Opening net debt/(cash)		(4,814)	(4,688)	(5,884)	(5,079)	(24,570)
HP finance leases initiated		0	0	0	0	0
Other		(5)	317	0	0	0
Closing net debt/(cash)		(4,688)	(5,884)	(5,079)	(24,570)	(16,329)

Source: Viralytics accounts, Edison Investment Research

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