BELL POTTER

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Speculative
Refer to key risks on page 4 and general bio technology warning on page 6. Speculative securities may not be suitable for retail clients

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Viralytics (VLA)

Merck Collaboration Validates Strategy

Recommendation
Buy (unchanged)
Price
$0.68
Valuation
$0.96 (unchanged)
Risk
Speculative

GICS Sector

Pharmaceuticals & Biotechnology

Expected Return	
Capital growth	**41%**
Dividend yield	**0.0%**
Total expected return	**41%**
Company Data & Ratios	
Enterprise value	**$101m**
Market cap	**$125m**
Issued capital	**184.4m**
Free float	**100%**
Avg. daily val. (52wk)	**$154,000**
12 month price range	**$0.28 - $0.93**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	0.63	0.71	0.30
Absolute (%)	7.94	-4.23	130.51
Rel market (%)	6.89	3.99	135.76

Merck and VLA to contribute drug in STORM

The treatment landscape for many of the more common cancers continues to expand thanks to the success of the combination of checkpoint inhibitors drugs such as Merck's anti – PD1 therapy Keytruda with new drugs such as CAVATAK. Friday's announcement that Merck and Viralytics are to collaborate in a combination study of CAVATAK and Keytruda while not surprising, is a significant validation of Viralytics' clinical trial program and its strategy to initiate the STORM study.

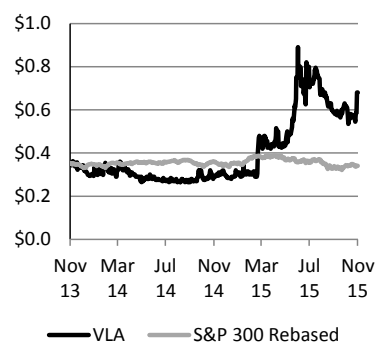
In addition to the obvious efficacy CAVATAK has now displayed in clinical trials, the one property CAVATAK possess which makes it highly suitable for combination with Keytruda is its suitability for intravenous administration. The STORM study was designed to evaluate the efficacy of CAVATAK under this mode of administration – initially as a monotherapy where investigators were looking for signals of efficacy, then in the second stage, possibly in combination with either a chemotherapy or a checkpoint inhibitor therapy.

At this time Viralytics has disclosed only very limited data from the early patients in the STORM study. As Merck has now decided to contribute its drug pembrolizumab (Keytruda) to the second stage of the study, it is not unreasonable to conclude that subsequent results from STORM have continued to provide encouraging results. The theory is that CAVATAK up regulates immune system activity in patients that have been heavily pre-treated with surgery and various regimes of chemotherapy. Upregulation of the immune system prior to the administration of Keytruda may result in improved efficacy of the combination relative to either drug as a monotherapy.

The initiation of this clinical trial collaboration is not expected to effect the progress of the CAPRA study – also involving a combination of CAVATAK and Keytruda in late stage Melanoma.

Maintain Buy rating and Price Target – No changes to earnings or price target following this announcement. We continue to believe VLA is significantly undervalued.

Absolute Price



SOURCE: IRESS

Earnings Forecast

June Year End	FY15	FY16e	FY17e	FY18e
Revenues	2.5	3.0	50.0	60.0
EBITDA $m	-4.4	-5.5	41.5	50.5
NPAT (underlying) $m	-4.3	-5.4	41.1	50.1
NPAT (reported) $m	-4.3	-5.4	41.1	50.1
EPS underlying (cps)	-2.3	-2.9	22.3	27.2
EPS growth %	-50%	26%	-861%	22%
PER (x)	-29.2	-23.2	3.0	2.5
FCF yield (%)	-4%	-4%	33%	42%
EV/EBITDA (x)	-23.0	-18.4	2.4	2.0
Dividend (cps)	-	-	-	-
Franking	0%	0%	0%	0%
Yield %	0.0%	0.0%	0.0%	0.0%
ROE %	-17.2%	-27.8%	67.9%	45.3%

SOURCE: BELL POTTER SECURITIES ESTIMATES

Background to STORM

STORM Phase I/II Trial (Systemic Treatment of Resistant Malignancies)

The following is an extract from our initiation report on VLA from March 2014.

This trial is investigating the efficacy of CAVATAK either with or without a chemotherapy agent across a variety of solid tumours including non small cell lung, colorectal, breast and prostate. The trial is being run in the UK and commenced in early 2014.

The study is being conducted at three leading cancer centres in the UK. The lead study investigators are prominent oncologists Professor Hardev Pandha (The University of Surrey), Professor Kevin Harrington (The Institute of Cancer Research and The Royal Marsden, London) and Professor Alan Melcher (St James's University Hospital, Leeds).

Earlier Phase I trials using single intravenous escalating doses in just 10 patients showed good tolerability and some encouraging preliminary data on tumour targeting, particularly in melanoma patients. Patients in this suffered from late stage melanoma, colorectal, breast or prostate cancers.

Viralytics researchers have previously shown successful tumour targeting and cancer cell destruction following intravenous delivery of CAVATAK to mice bearing human melanoma and breast cancer tumours.

CAVATAK has a defined extracellular targeting mechanism in binding to cancer cell surface ICAM-1. In contrast, other oncolytic viruses such as T-Vec and Reolysin rely on intracellular mechanisms for selective tumour cell targeting, which may result in lower efficacy in tumour cell targeting. Furthermore, a majority of cancer patients have pre-existing antibodies to both T-Vec and Reolysin questioning successful intravenous virus delivery. Pre-existing antibody levels to CAVATAK are much lower, in the order of about 15-20% of the patient populations, offering this as a potential advantage to systemic viral delivery.

Figure 1 - Summary of PhaseI clinical trials

	Type	Disease stage	Indication	Patients
VLA-01	Single dose intratumoural	Stage IV	Melanoma	2
VLA-02	Single dose intratumoural	Stage IV	Melanoma	3
VLA-03	Multi dose escalational intratumoural	Stage IV	Melanoma	9
VLA-04	Single dose intravenous	Stage IV	Melanoma, Colorectal, Breast, Prostate	10
VLA-05	Multidose intratumoural	Stage IV	Head and Neck	4

SOURCE: COMPANY DATA

The trial will consist of 2 sequential parts: the first part (VLA009A) is a study of intravenous CVA21 as a single agent for the treatment of 4 different advanced solid tumours; the second part (VLA009B) is a study of intravenous CVA21 in combination with cytotoxic therapy appropriate for the solid tumour selected in the first part.

Both parts will be open-label, multi-centre, ascending dose escalation (3+3 design) dose-finding and signal-seeking studies. In the final cohort for VLA009A, there must be a minimum of three subjects in each of the four solid tumours (NSCLC, prostate, bladder and melanoma) who have biopsy of an accessible lesion and complete one cycle of treatment before enrolment is completed.

VLA-009A: This part is expected to enrol from 18 to 27 subjects.

VLA009B: This part is expected to enrol from 9 to 18 subjects.

Merck Collaboration

The FDA approved Keytruda for the treatment of non small cell lung carcinoma (NSCLC) in October 2015. Lung cancer is the leading cause of cancer death in the United States, with an estimated 221,200 new diagnoses and 158,040 deaths in 2015, according to the National Cancer Institute. NSCLC is the most common type of lung cancer. Keytruda is also approved for late stage melanoma.

The second part of the STORM study has now been redesigned to assess the intravenous delivery of CAVATAK in combination with Keytruda in advanced non small cell ling cancer or Metastatic Bladder cancer. The final expansion cohort of 80 patients across both indications is new. The aim of the study is to establish a recommended dose regime for the combination and to evaluate efficacy. Patient biopsies will be assessed for change in tumour microenvironment.

Pending results from the STORM study, the parties may extend the collaboration to include a potential phase III clinical trial for one or more indications.

In our view the most significant risk in the STORM trial was whether sufficient quantity of the drug (i.e. therapeutic dose) would reach the tumour. We await further data in this regard and this should be available within weeks. Viralytics will be presenting a poster at an upcoming immunotherapy conference.

COMMERCIAL TERMS NOT DISCLOSED

The key for investors is to understand what rights and obligations VLA has negotiated as part of the collaboration. VLA has in excess of $20m in cash and a well established trial program underway with support from a high quality shareholder register. CEO Malcolm McColl has therefore completed this agreement from a position of strength.

Also interesting that rather than initiate a whole new study, Merck agreed to collaborate on an existing study – which it does not control. Rather, Viralytics remains the sponsor of the STORM study.

If the clinical trial in the two indications is successful it is likely the two drugs would be approved as a combination with either party benefiting from additional drug sales. i.e. The absence of any cash up front or discussion of a license agreement in this announcement leads us to believe that VLA intends to build out the data dossier before partnering. As the data dossier builds and continues to show promising results, a partnering deal at this point may well undervalue the asset.

It remains to be seen how this collaboration develops in relation to the funding of an approval study. Nevertheless should the collaboration study prove successful we expect that Viralytics will have an abundance of options for further development of CAVATAK, all of which should result in further value creation for shareholders.

Viralytics Limited

The company has one candidate in the clinic being CAVATAK (CVA21).

CAVATAK is an oncolytic (cancer cell destroying) virus with a dual mode of action. The virus replicates inside the cancer cell eventually causing the cell to lyses (or rupture). The lytic process releases tumour cell debris that may illicit a response by the patient's immune system against the tumour, providing a secondary but important immunotherapeutic effect. Such an immune response may be enhanced by the systemic circulation of tumour cell components complexed with foreign CAVATAK proteins or simply the presence of actively replicating virus within the tumour cell.

The preclinical studies show that CVA21 binds to the intracellular adhesion molecule (ICAM-1) receptor which is over expressed in many human cancer cells. Normal viral defences limit the spread of the virus in non-cancerous cells, hence CAVATAK is highly targeted towards any cancer cell which expresses the ICAM-1 receptor. CAVATAK does not have a material effect on normal cell activity as evidenced by its relatively benign side effect profile observed in current clinical program.

By virtue of its size and non-enveloped viral shell, CAVATAK is suitable for administration via direct injection into the tumour (intratumoural injection) or by intravenous (IV) administration. In particular suitability for IV administration differentiates CAVATAK from Amgen's T-Vec, making CAVATAK also suitable for treatment of other solid cancers types that are not accessible to treatment via direct injection. This topic is the subject of the STORM study.

CAVATAK is a proprietary formulation of the genetically unmodified human Coxsackievirus A21 (CVA21). CVA21 is a naturally occurring virus that is associated with common head cold. Its oncolytic properties were discovered by the scientific team led by Chief Science Officer – Professor Darren Shafren at the company's research facilities in Newcastle, Australia. The initial preclinical studies were conducted on *in vitro* cultures of human cancer cells and then later in *in vivo* testing on grafted human cancers in mice.

Valuation is determined using a discounted cash flow model.

RISK AREAS

New technology may emerge. There are many clinical trials underway around the globe in the treatment of melanoma. There is the potential that one or more of these trials may yield outcomes that render CAVATAK and other drugs for the treatment of metastatic melanoma obsolete.

CAVATAK is untested in a large randomised trial. The interim results from CAVATAK are encouraging and supportive of further testing. It is not uncommon for cancer drugs to fail in large, randomised Phase III trials. Successful results in small Phase II trials are not a precursor to success in larger Phase III trials.

The long term side effect profile of CAVATAK is unknown. There is no long term data on the side effect profile of CAVATAK, hence we do not know if it will have any long term side effects that are yet to emerge.

Viralytics has one drug in the clinic. If CAVATAK does not show efficacy in future clinical trials or fails to come to market, it is likely the company would be of less value.

Viralytics
as at 9 November 2015

Recommendation	Buy, Speculative
Price	$0.68
Valuation	$0.96

Table 1 - Financial summary

Profit & Loss (A$m)					
Year Ending June	**FY14**	**FY15**	**FY16e**	**FY17e**	**FY18e**
Transaction income	-	-	-	50.0	60.0
R&D Incentive payments	2.5	2.5	3.0	-	-
Total revenues	2.5	2.5	3.0	50.0	60.0
Total revenues	2.5	2.5	3.0	50.0	60.0
Clinical trials	**2.7**	**3.4**	**5.0**	**5.0**	**6.0**
Other expenses	***5.3***	***3.5***	***3.5***	***3.5***	***3.5***
EBITDA	***-5.5***	***-4.4***	***-5.5***	***41.5***	***50.5***
Depreciation -	0.0	0.0	0.0	0.0	0.0
Amortisation	0.4	0.4	0.4	0.4	0.4
EBIT	-5.9	-4.8	-5.9	41.1	50.1
Net interest	0.3	0.5	0.5	-	-
Pre tax profit	-5.6	-4.3	-5.4	41.1	50.1
Tax expense	-	-	-	-	-
NPAT- normalised	-5.6	-4.3	-5.4	41.1	50.1
Net abnormal items	-	-	-	-	-
Reported NPAT	-5.6	-4.3	-5.4	41.1	50.1

Cashflow (A$m)					
Gross cashflow	-5.7	-5.0	-5.5	41.5	52.2
Net interest	0.3	0.5	0.5	0.0	0.0
Tax paid	0.0	0.0	0.0	0.0	0.0
Operating cash flow	-5.4	-4.5	-5.0	41.5	52.2
Maintenance capex	0.0	-0.1	0.0	0.0	0.0
Free cash flow	-5.4	-4.6	-5.0	41.5	52.2
Business acquistions	0.0	0.0	0.0	0.0	0.0
Proceeds from issuance	25.1	0.0	0.0	0.0	0.0
Movement in borrowings	0.0	0.0	0.0	0.0	0.0
Dividends paid	0.0	0.0	0.0	0.0	0.0
Issuance cost	0.0	0.0	0.0	0.0	0.0
Change in cash held	19.7	(4.5)	(5.0)	41.5	52.2
Cash at beginning of period	5.1	24.4	21.6	16.6	58.1
Cash at year end	24.4	21.6	16.6	58.1	110.3

Balance Sheet (A$m)					
Cash	24.3	21.6	16.6	58.1	110.3
Receivables	2.8	2.9	2.9	2.9	0.5
Inventory	-	-	-	-	-
Property, Plant and Equipment	0.1	0.1	0.1	0.1	0.1
Intangible assets	2.4	2.0	1.6	1.2	0.8
Other	0.1	0.1	0.1	0.1	0.1
Total assets	29.7	26.6	21.2	62.3	111.7
Trade payables	0.8	1.7	1.7	1.7	1.0
Provision for income tax	-	-	-	-	-
Debt - interest bearing debt	0.0	0.0	0.0	0.0	0.0
Total Liabilities	0.8	1.7	1.7	1.7	1.0
Net Assets	28.9	24.9	19.5	60.6	110.7
Share capital	87.0	87.6	87.6	87.6	87.6
Convertible notes	0.6	-	-	-	-
Retained earnings	(61.9)	(66.2)	(71.6)	(30.5)	19.6
Reserves	3.1	3.5	3.5	3.5	3.5
Shareholders Equity	28.8	24.9	19.5	60.6	110.7

Last sale 08/11/2015	0.68
Recommendation	Buy (Spec)
Issued Capital	184.5
Market Cap	125.4

Profitability Ratios					
Year Ending June	**FY14**	**FY15**	**FY16e**	**FY17e**	**FY18e**
EBITDA margin	0.0%	0.0%	0.0%	0.0%	0.0%
EBIT margin	0.0%	0.0%	0.0%	0.0%	0.0%
EBIT growth	0.0%	0.0%	0.0%	0.0%	0.0%

Valuation Ratios (A$m)					
Reported EPS (cps)	-4.7	-2.3	-2.9	22.3	27.2
Normalised EPS (cps)	-4.7	-2.3	-2.9	22.3	27.2
EPS growth (%)	-7%	-50%	26%	-861%	22%
PE(x)	**-14.5**	**-29.2**	**-23.2**	**3.0**	**2.5**
EV/EBITDA (x)	-18.5	-23.0	-18.4	2.4	2.0
EV/EBIT (x)	-17.2	-21.1	-17.2	2.5	2.0
NTA (cps)	14.4	12.4	9.7	32.2	59.7
P/NTA (x)	4.7	5.5	7.0	2.1	1.1
Book Value (cps)	15.7	13.5	10.6	32.9	60.1
Price/Book (x)	4.3	5.0	6.4	2.1	1.1
DPS (cps)	-	-	-	-	-
Payout ratio %	0%	0%	0%	0%	0%
Dividend Yield %	0.0%	0.0%	0.0%	0.0%	0.0%
Franking %	0%	0%	0%	0%	0%
FCF yield %	-4%	-4%	-4%	33%	42%

Performance Ratios					
ROA	-18.8%	-16.1%	-25.5%	66.0%	44.8%
ROE	-19.4%	-17.2%	-27.8%	67.9%	45.3%
ROIC	-20.4%	-19.3%	-30.3%	67.9%	45.3%
Net debt/Equity	0%	0%	0%	0%	0%
Net debt/Assets	0%	0%	0%	0%	0%
Gearing	net cash	net cash	net cash	net cash	net cash
Net debt/EBITDA (x)	n/a	n/a	n/a	n/a	n/a
Interest cover (x)	n/a	n/a	n/a	n/a	n/a

SOURCE: BELL POTTER SECURITIES ESTIMATES

Recommendation structure

Buy: Expect >15% total return on a 12 month view. For stocks regarded as 'Speculative' a return of >30% is expected.

Hold: Expect total return between -5% and 15% on a 12 month view

Sell: Expect <-5% total return on a 12 month view

Speculative Investments are either start-up enterprises with nil or only prospective operations or recently commenced operations with only forecast cash flows, or companies that have commenced operations or have been in operation for some time but have only forecast cash flows and/or a stressed balance sheet.

Such investments may carry an exceptionally high level of capital risk and volatility of returns.

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