OZEQUITIES NEWSLETTER

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FEATURE

Week's Special
VLA: VIRALYTICS PHASE II TRIAL SHOWS SIGNIFICANT PROMISE IN THE TREATMENT OF MELANOMA WITH PARTIAL OR COMPLETE REDUCTION OF TUMOURS IN SOME PATIENTS - *WITH NEGLIGIBLE SIDE EFFECTS*

By Jenny Prabhu and Gerald Stanley

Viralytics Ltd's oncolytic Coxsackievirus (a naturally occurring virus, associated with the development of the common cold) now in Phase II studies offers great hope for patients with metastatic melanoma, even those in stage III or stage IV of the disease. Apart from melanoma, ongoing trials could find possible similar benefits for sufferers from other forms of cancer - and with negligible side effects.

The scourge of melanoma in Australia - Cancer Australia statistics
While melanoma occurs throughout the world, it is most prevalent by far in Australia where it is the 4th most commonly diagnosed cancer after prostate, bowel and breast cancer, accounting for 9.8% of all new cancers.
*In 2010 there were 11,405 new cases of melanoma in Australia - 6,700 new cases in men and 4,705 new cases in women.
In 2014, about 14,240 Australians (8,540 men and 5700 women) are expected to be diagnosed with melanoma of the skin.
The risk of developing melanoma increases with age.
In 2011 there were 1,544 deaths from melanoma, accounting for 3.6% of all cancer deaths.
The five year relative survival from melanoma between to June 2010 was 88.5% for men and 93.6% for women. Relative survival rates for melanoma have increased in recent years in Australia.
*In 2012 melanoma was estimated to account for 22,800 disability adjusted life years in Australia. Of these, 17,200 were years lost due to premature death and 5,600 were years of healthy life lost due to disease, disability or injury.

Treatment - Melanoma Institute Australia statistics
Historically, metastatic melanoma has been considered as one of the most difficult cancers to treat, with a cure remaining elusive.
Currently drug therapies are used in metastatic melanoma (stage IIIC unresectable and stage IV and occasionally in resected stage III melanoma).
Until recently, clinical trials of chemotherapy, immunotherapy and biochemotherapy in metastatic melanoma have failed to significantly improve patient survival. Approximately 15% of patients treated with conventional chemotherapy typically respond to treatment and there are significant side effects associated with this type of treatment.

Drugs so far approved for metastatic melanoma in Australia
As of April 2013 **ipilimumab** (Yervoy) (a CTLA4 antibody, an immunotherapy) and **Interferon** were the only TGA approved drugs for treatment of resected stage III melanoma.

*There can be potentially serious side effects with all currently approved treatments for melanoma.

The best hope so far: T-Vec, acquired by Amgen - Fierce Biotech, March 15 2014
Amgen has reported a new round of late-stage data supporting its cancer-fighting viral vaccine talimogene laherparepvec, better known as T-Vec (a genetically modified herpes virus). In a retrospective analysis of a Phase III melanoma trial investigators found that about two-thirds of the tumours injected with T-Vec shrank 50% or more. And the same effect was seen in about a third of all uninjected tumours in the skin and lymph nodes, providing an indication that the treatment is triggering the desired immune system effect.
Of the 64% of injected tumours which shrank, half registered a complete response, disappearing from view. The company is wrapping up pivotal work now to determine if those tumour responses definitively translate into a longer life for patients, which will determine the fate of this therapy.
While cancer vaccines have had a poor track record in the clinic in recent years, Amgen has tapped T-Vec as one of the big biotech's top prospects. The engineered virus is designed to specifically replicate in cancer cells, expressing the white blood cell growth factor GM-CSF to spur an immune system response. Amgen's then R&D chief Roger Perlmutter--now at Merck ($MRK)--acquired the program about three years ago, buying out BioVex in a $1 billion deal.

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VLA's CAVATAK, in Phase II studies - hope for late stage melanoma patient with minimal side effects
While CAVATAK is only in Phase II studies, and there is a long path ahead, statistics so far have been highly encouraging.
*On June 3, highly respected international scientist Dr Robert Andtbacka, Lead Study Investigator, Huntsman Cancer Institute Utah presented additional positive interim results from the ongoing Phase 2 CALM clinical trial to the Immunotherapy Session of American Society of Clinical Oncology Conference in Chicago:
19 of 51 (37%) of evaluable patients demonstrated immune related progression free survival at six months after the first Cavatak dose.
The preliminary overall response rate was 26% (15/57).
Anti-cancer activity was observed in tumours at injected and non injected sites including lung and other distant tumour metastases.
Multiple CAVATAK administrations were well tolerated by patients
Also, there were very promising preclinical findings for combination of CAVATAK with anti-PD-1 monoclonal antibody, an emerging, potentially major class of cancer immunotherapy.
Viralytics also has the STORM Phase1/12 study under way, studying CAVATAK activity in a variety of tumour types.

*Viralytics has raised $27 million in new funds this year, which will see it through clinical studies to the end of 2016.
(For large scale Phase III trials Viralytics will need to be sponsored by a major pharma).

*Viralytis Scientific Advisory team have internationally respected reputations. Directors and management are committed, highly respected and technically and commercially savvy.

The company has also traded on the US OTCOX Marketplace since August last year.

What the brokers say

Bell Potter analyst John Hester (Bell Potter Securities was lead manager to the placement and rights issue in March that raised $27.1 million) in a comprehensive 27 page report dated February 24 initiated coverage of Viralytics with a "buy" recommendation and a target price of 75c.

The analyst said in his report interim results have shown that "Approximately 35% of patients have shown either a complete or partial response after 6 months of dosing (in the FDA sanctioned Phase II

single arm 54 patient open label CALM clinical trial). *This response rate compare well to the 19% durable response rate recently reported by T-Vec in a Phase III randomised study in a comparable patient base*. (Our italics).
"These results prompted the initiation of a randomised Phase II b trial. Trial results from blinded, randomised studies carry more significance than single arm trials.

The analyst added "There are numerous late stage clinical studies of combination therapies in progress around the world. These have produced modest improvements in survival rates so far".

VIRALYTICS LTD - A SNAPSHOT

Viralytics Ltd had its origins as Medical Innovations Ltd, founded in 1984 and listed on the second board on October 15, 1986, with a psoriasis treatment, Sorafin as its main platform. Medical Innovations became pSiron on August 14 2000 with a portfolio of medical projects, still led by Sorafin.
Then on September 5, 2002, Psiron Ltd announced it had signed a world wide licence agreement with ViroTarg Pty Ltd and its major shareholders the University of Newcastle Research Associates (TUNRA) Ltd and SciCapital Pty Ltd.
The licence agreement covers the ongoing development of ViroTarg's technology relating to the use of oncolytic viruses for the treatment of a range of different cancers. Consideration was a combination of cash and scrip from Psiron of $A5 million and 22.5 million shares based on agreed milestones over the duration of the project. The ViroTarg virotherapy strategy includes the use of an oncolytic Coxsackievirus, a naturally occurring virus, associated with
the development of the common cold.
Psiron funded the continuing research and development of the potential anti-cancer biologicals under the existing researchers, Associate Prof Darren Shafren (inventor), Dr Richard Barry and their team in the School of BioMedical Sciences, the University of Newcastle.
PSiron in 2007 changed its focus to the R&D for therapies delivered using the oncolytic Coxsackievirus associated with the common cold and changed its name to Viralytics. (Cbio floated at $1 per share on February 15 2010 containing technologies including Sorafin).

Viralytics Ltd today
Viralytics is developing Oncolytic Virotherapeutics to treat a broad range of cancers. *The potential offered by Virotherapy is the ability to treat cancer more effectively and with minimal side effects.* Viralytics' most advanced program is the CALM study (CAVATAK in Late stage Melanoma), which is a phase II study directed at investigating the efficacy of CAVATAK in the treatment of Melanoma. An IND application for this study has been approved by the FDA and the trial is now fully enrolled at trial sites in the USA.
Intratumoural and Intravenous Delivery
Viralytics has a portfolio of 5 viruses which it is researching, with it's lead product in development being CAVATAK - the trademarked name of Viralytics' therapeutic formulation of CoxsackievirusA21 – a virus that forms part of the common cold family. CAVATAK has shown in preclinical research that it is able to target and destroy both primary and metastatic cancer cells.
Viralytics' clinical program comprises trials using CAVATAK™ administered either intravenously or directly into the tumour (intratumourally).

CAVATAK is part of the common cold family of viruses.
It is a pharmaceutical product, produced by contract manufacturer SAFC in California. SAFC have a track record in the scale up and manufacture of products in the same field as CAVATAK.
It is naturally occurring, genetically unaltered Coxsackievirus A21. As a cancer therapy CAVATAK™ has the potential to directly target, infect, multiply within and subsequently destroy a wide range of primary and metastasized cancer cells, while leaving healthy cells intact. It works by seeking out and attaching itself to a protein that is highly expressed on cancer cells – (ICAM-1 protein). Once attached to this protein the virus is then able to insert itself into the cancer cell, replicate and literally burst the cancer cell apart. Thousands of progeny then spread and replicate this cycle of destruction. Once the

cancer cells have been destroyed, tumour proteins are released into the blood which activates the body's own immune system, identifying the tumour as foreign which enables the body's own defences to come into play.

VLA's drug development pipeline

In addition to CAVATAK™, Viralytics is also investigating 4 other oncolytic viruses, Coxsackievirus A18,15,13 and ECHOvirus1 (trademarked EVATAK™) as cancer therapeutics. These could be effective as oncolytic therapeutics in their own right or could potentially be used in combination with CAVATAK™.

Other indications are being investigated in phase I trials and pre-clinical studies. Recent pre-clinical research has demonstrated the potential to treat superficial bladder and lung cancer with CAVATAK. The STORM study is assessing the intravenous or systemic delivery of CAVATAK in patients with late stage melanoma, lung, prostate or metastatic bladder cancers.

The Company holds granted patents in all major markets including the USA and Europe.

Progress to date - timeline

Trials of Cavatak have been ongoing since early 2008, including for prostate, breast and brain cancer - with melanoma becoming the main early focus in 2009. *In all trials, no serious drug related side effects have been encountered.*

*In 2010 a Phase 1 late stage melanoma trial of CAVATAK found all patients with late stage melanoma tolerated the treatment and none exhibited any product related serious adverse events.
Injected tumours of 1/3rd of patients reduced in size, injected tumours of a further 22% of patients remained stable. Measurement of other distant tumours showed the overall disease was stabilised in two patients. The trial was a safety trial, and the company was only allowed to inject a single tumour.
All patients had late stage disease and had previously failed or rejected standard therapies.
*In June 2011 Viralytics had received approval from the FDA to use its Investigational New Drug, CAVATAKTM in a phase II trial in the USA, to investigate its effectiveness for the treatment of Late-Stage Melanoma.
*In January 2012 the first Phase II trial for 54 US based patients with intratumoural late stage melanoma began.
Treatment consisted of 10 visits where up to 8 individual tumours were injected with CAVATAK at each visit.
*In July 2012 the first patient commenced the US Phase II CALM extension study. (CAVATAK in Late Stage Melanoma).
To be eligible to join the extension study a patient must have displayed complete or partial tumour reduction or disease stabilisation at six months from the initiation of the CAVATAK treatment.
A positive trial outcome for the Phase II CALM study was immune related progression-free survival at six months for 10/12 of the 54 evaluable patients.
*In November 2013 new CEO Dr Malcolm McColl said in the CALM Phase II trial the milestone of 12 of 35 evaluable patients had reached the six month irPFS target. There was a promising 12 month survival rate in 56% (9 of 16 patients).
There was encouraging activity in non injected, metastatic tumours. Full enrolment of 54 patients was completed in January this year.
There were NO reports of drug related grade 3/4 or serious adverse effects.
*In March 2014 the STORM (Systemic Treatment of Resistant Malignancies) Phase I/II Multi-dose intravenous clinical trial began at three prestigious cancer centres in the UK involving approximately 30 patients with late stage melanoma, prostate, lung or metastatic bladder cancers.
*On June 2 2014 Dr Robert Andtbacka, lead study investigator, Huntsman Cancer Institute, Utah presented at the American Association of Cancer Research Conference.

His presentation focussed on CAVATAK's activity in non injected metastatic tumours in patients participating in the CALM study. Investigators reported partial or complete reduction of non injected tumours in multiple patients who had been on treatment at least 8 weeks. The findings provided promising evidence of oncolytic immunotherapy - when anti cancer activity is observed in tumour cells at the site of injection as well as in tumours at distant body locations.

VIRALYTICS LTD FINANCIALS

Code:	VLA
Last Traded price	27.5cents
Shares Issued	184m.
Market Cap	50.6m

Year ended June 30, Values in $m's

INCOME	**2014 Int**	**2013**	**2012**
Op Revenue	-	-	-
Op Profit (loss)	(3.99)	(4.13)	(4.78)
Net profit (loss)	(3.99)	(4.13)	(4.78)
(Loss)PS (Cents)	(4.6)	(5.1)	(7.1)

BALANCE SHEET	**2014 Int**	**2013**	**2012**
Current Assets	3.45	7.28	7.04
Non Current Assets..	2.72	2.93	3.27
Current Liabilities	1.04	1.23	0.75
Non Current Liabilities	-	-	-
Net Assets & Shareholders' Funds	5.13	8.98	9.56
Intangibles	2.62	2.81	3.20
Net Tangible Assets	2.51	6.17	6.36
Gearing (Net of Cash) %	.nil	.nil	.nil
NTA per share (cents)	2.9	7.1	8.4
Shares Issued (m's)	87.3	87.3	75.4
Options on Issue (m's)	5.0	5.8	4.65

Cash Flows:	**2014 3^{rdQ}**	**2014 Int**	**2013**	**2012**
Cash on hand (at open)	5.08	5.08	5.88	5.00
Operating Activities	(3.82)	(1.78)	(3.93)	(3.55)
Investing	(0.01)	(0.01)	(0.04)	(0.02)
Financing Activities	25.28	-	3.17	4.45
Cash on hand at Year end	**26.53**	**3.29**	**5.08**	**5.88**

1/Completed a $27.1 million capital raising announced on March 13. This will fully fund the company through 2016 including its clinical trial programs.

Directors:

Paul Hopper, Non-Executive Chairman
Mr Hopper has over 20 years experience in the management and funding of biotechnology and healthcare public companies with extensive capital markets experience in equity and debt raisings in Australia, Asia, US and Europe.
Mr Hopper's sector experience has covered a number of therapeutic areas including anti-bacterials, medical devices, antibodies, inflammation and oncology, with a particular emphasis on cancer vaccines. Paul is Head of the Australia Desk and Head of the Life Sciences and Biotechnology practice at the Los Angeles merchant bank Cappello Capital where he is a partner. He also serves as a Director of the American Australian Association and is a member of the Queensland North America Biotechnology Advisory Council.

Mr Hopper has served on the boards of many listed biotechnology and healthcare companies including as Executive Chairman of Bone Medical Limited, Director of pSivida Corp, iSonea, and Advanced Biotherapy Inc. He was the co-founder and Managing Director of Alpha Healthcare Limited. He is based in Los Angeles.

Dr Leonard Post , Non-Executive Director

Dr Post has extensive experience in oncolytic viruses, oncology and virotherapy He was Senior Vice President of R&D at Onyx Pharmaceuticals and was responsible for the co-development (50:50 with Bayer) of Nexavar (sorafenib), from IND through FDA approval for renal cell carcinoma. Dr Post has a strong commercial background which includes founding US-based LEAD Therapeutics in 2007 which was subsequently acquired by BioMarin Pharmaceuticals in 2010. Dr Post currently holds the position of Chief Scientific Officer of BioMarin Pharmaceuticals Inc.

Previously, as VP of Discovery Research at Parke-Davis, he led a multi-national drug discovery organisation of over 800 people, in cancer, infectious diseases, inflammation, cardiovascular and CNS. Prior to that, he held several positions at the Upjohn Company, including Director of Infectious Disease Research. During his industry career spanning more than 25 years, he has led numerous programs that have resulted in multiple clinical candidates across various therapeutic areas.

Dr Post was a Director of and consultant to Biovex Ltd, acquired by Amgen Inc in 2011. He is a Director of two USA-based biotechnology companies and has been a member of a number of Scientific Advisory Boards. Len has a PhD in Biochemistry, University of Wisconsin, Madison.

Dr Phillip Altman, B.Sc (Hons) M.Sc Ph.D, Non-Executive Director

Dr Altman is a well known Australian authority on clinical trials and regulatory affairs with more than 30 years experience in clinical research and regulatory affairs. He is a graduate of Sydney University with an honours degree in Pharmacy, Master of Science and Doctor of Philosophy (pharmacology and pharmaceutical chemistry) degrees. Dr Altman also co-founded and is a Life Member of the largest professional body of pharmaceutical industry scientists involved in clinical research and regulatory affairs (Association of Regulatory and Clinical Scientists to the Australian Pharmaceutical Industry Ltd – ARCS). In addition to working in senior management positions for several multinational companies, including Merrell-Dow, Hoechst, Roussel and GD Searle, Dr Altman established his own company, Pharmaco Pty Ltd, one of the first contract research organizations where he served as a Senior Industry Consultant and he continues to provide consultant support for a range of companies.

Peter Molloy, Non-Executive Director

Mr Molloy is a successful Australian pharmaceutical and biotechnology executive and now an industry consultant and director. In addition to Viralytics, he is a director of Parnell Pharmaceuticals and Synthesis Med Chem USA Inc. Previously, Mr Molloy was the Managing Director and CEO of ASX-listed Biota Holdings Limited (2002-2005), Australia□s premier antiviral drug development company. His previous executive roles in the biotechnology sector included President and CEO of SLIL Biomedical Corp, a Madison Wisconsin based cancer and viral research company; managing director and CEO of Florigene Limited, a Melbourne based biotechnology company focused on genetic modification of plants; and President of Moleculon Inc, a Boston based transdermal drug delivery company.

Mr Molloy has lived and worked in the US for more than 13 years. In addition to this valuable US perspective, he brings considerable big pharmaceutical company experience. He worked as a pharmaceutical marketing executive for 17 years (1979-1996) with his last role as Vice President of Strategic Marketing for Pharmacia. Pharmacia at the time was one of the top 20 global pharmaceutical companies (now part of Pfizer). Over the years Mr Molloy has been involved in the licensing, clinical development and launch of many new pharmaceutical products in Australia. At Pharmacia he was responsible for evaluating new drug candidates and coordinating the launch and marketing strategy for more than 50 pharmaceuticals across 23 countries.

Mr Molloy is a fellow of the Australian Institute of Company Directors and has served on several Australian and US boards, both as managing director and non executive director, including as chairman of two international businesses. He has been a consultant to several Australian and US companies and a guest speaker on licensing and business development at industry meetings including BIO, the Australian Biotech Summit and the Ausbiotech National Conference. He holds a BSc in Microbiology and Biochemistry from the University of Melbourne and an MBA from the University of Adelaide.

Management team:

Dr Malcolm McColl, Chief Executive Officer

Dr. McColl has more than twenty years experience in negotiating at the highest level for international and regional pharmaceutical and biotech companies. He has been involved in over fifty research, development, licensing, mergers and acquisitions and other partnering transactions with a focus on oncology.

Prior to joining Viralytics he was Vice President Business Development at Starpharma and responsible for partnering activities and programs, particularly for pharma applications of Starpharma's Dendrimer technology and he had a lead role in the Docetaxel oncology drug program.

Before joining Starpharma in 2010, he was Director of Business Development, resident in the UK, for global healthcare company, Hospira (formerly Mayne Pharma) and responsible for Europe, The Middle East and Africa. During this period he led negotiations and due diligence for a significant number of licensing and acquisition transactions again with a focus on the field of oncology.

Prior to that he was Hospira's Director of Business Development for the Asia/Pacific region where he completed multiple partnering transactions contributing to strong revenue growth in the region.

He also spent 13 years, working with CSL, culminating in his USA based role as Global Vice President, Business Development for the Animal Health Division where he played a lead role in the entry into the US market and the strategic development and globalisation of the Animal Health business.

Professor Darren Shafren, Chief Science Officer and Inventor of the Technology

Professor Shafren is responsible for research, development and intellectual property management. Dr Shafren is Associate Professor of Virology in the Faculty of Health, University of Newcastle, and works full time on the Virotherapy project. Darren is the inventor of the oncolytic virus technology acquired by Viralytics.

Robert Vickery, Chief Financial Officer

Mr Vickery has over 20 years' experience as a finance professional in industry and professional practice. Most recently he has held senior roles with several biotech and innovation based businesses, including 3 years as CFO and Company Secretary of ASX listed Biosignal Limited. Prior to that he served seven years with the Australian head office of the global Swire Group in a range of treasury, taxation and company secretarial roles. He began his career in professional practice including a period as an Audit Manager with a Sydney based Chartered Accounting firm. Mr Vickery is an Associate of the Institute of Chartered Accountants and an Associate of the Governance Institute of Australia.

Advisory Board:

Dr Jeffrey Weisberg , Chairman, Clinical Professor of Medicine, Nova Southeastern University

Dr Kevin Harrington , Clinical Oncologist, Royal Marsden Hospital, UK

standard cytotoxic agents, such as those used in radiotherapy and/or chemotherapy.

Associate Professor Keith Flaherty, MD **-** Director of the Henri and Belinda Termeer Center for Targeted Therapies, Massachusetts General Hospital Cancer Center, USA

Professor Hardev Pandha is the Head of Oncology at the Postgraduate Medical School, University of Surrey.

Professor Evanthia Galanis, **MD -** Professor of Oncology, Mayo Foundation for Medical Education & Research, USA

Substantial shareholders:

There were no shareholders with more than 2.29% reported in the annual report as of September 11 2013.

*On March 13 CEO Dr Malcolm McColl announced VLA welcomes 12 new specialist healthcare institutional investors as shareholders as part of its now completed $27.1 million capital raising. Institutions with more than 5% include:

*Cormorant Global Healthcare Master Fund with 8.9%

*Abingworth LI.P 6.14%

*****Sabby Healthcare Volatility Master Fund Ltd with 5.8%