Cancer killing viruses

Oncolytic Virotherapeutics

Viralytics is a company developing a portfolio of oncolytic viruses that have the potential not only to provide a more effective treatment of a range of cancers, but also a substantial improvement in patients quality of life.
### Viralytic’s – Executive Summary

#### Lead Product - CAVATAK™

**Product Aim:**
- A more effective treatment of a range of cancers

**Clinical Development:**
- Phase II USA trial underway
- Phase I trials completed in Australia
- Excellent safety data profile from over 30 subjects

**Product:**
- GMP product manufactured in the USA

**Intellectual Property:**
- Granted patents in USA and Europe

#### Corporate

**Commercialization**
- First acquisition of Virotherapy company by large Pharma for $US1B

**Pivotal Timing:**
- Successful Phase II trial should add significant value to Viralytics

**Listed:**
- One of only 2 listed companies in the world in virotherapeutics

**Financials:** (as at 1 Jun 2012)
- Market Capitalization: US$ 25m
- Cash on hand: US$ 6.5m
- Burn Rate – Historical: US$ 3.5m p.a.
What is Oncolytic Virotherapeutics?

Certain types of viruses have the capacity to selectively attack and destroy cancer cells while leaving normal cells undamaged. Virotherapeutics is a novel field where these viruses are used to treat cancer.

Advantages of Virotherapeutics

- Limited side effects leading to greatly improved quality of life
- Potential to treat a wide variety of cancers
- Synergistic relationship with existing treatment regimes
Oncolytic Virotherapeutics?

Growth of Oncolytic Virotherapeutics

A nexus of drivers
- Strong scientific research
- Quality clinical trial data
- Commercial investment

Virotherapy Publications
Virotherapy Trials

Graph showing the growth of Oncolytic Virotherapeutics with specific data points for publications and trials from 2000 to 2011.
Lead Oncolytic Virus - CAVATAK™

CAVATAK™ - How it works:

- A naturally occurring, genetically unaltered Coxsackievirus A21, targeting the ICAM-1 receptor dominant on metastatic cancer cell

CAVATAK™ binds to tumor cells externally

CAVATAK™ infects tumor cells

CAVATAK™ replicates in and destroys tumor cells

CAVATAK™ released from tumor (cycle repeats)

activates host anti-tumor immune response
CAVATAK™ - a better virus

Unique features of CAVATAK™ allow delivery of more virus to the tumor

- Low level of pre-existing antibodies in the community allowing Intratumoral and Intravenous delivery
- The only targeted virotherapy due to extra-cellular targeting mechanism
- Small size allowing greater dissemination throughout the body than larger viruses
- Prolonged systemic bio-availability
- Rapid oncolytic replication cycle

Representative size of Oncolytic viruses

- Vaccinia virus
- Herpesvirus
- Adenovirus
- Reovirus
- Coxsackievirus A21
  CAVATAK™
CAVATAK™ – Animal Studies

Anti-tumor activity in immune-deficient mice

Presence of tumor shown by colored areas

Tumor eliminated after treatment with CAVATAK™
CAVATAK™ - Phase I Development

Intratumoral trials

- **2 Single Dose Phase I Australian Trials – COMPLETED**
  - Well tolerated: no product related SAEs reported

- **Multi-dose Phase I Australian Trial – COMPLETED**
  - Well tolerated: no product related SAEs reported
  - 56% patients experienced reductions in injected tumor volume or stabilization following 2 injections
  - 2 patients displayed stable disease (RECIST 1.0)
  - 2 of the 3 patients that displayed the greatest tumor response, exhibited significantly elevated levels of serum GM-CSF, which is known to drive the body’s own anti-tumor immune response

Intravenousous trial

- **Phase I Intravenous trial – COMPLETED**
  - Stage IV solid tumors expressing ICAM-1
  - Treatment shown to be well tolerated to date
  - Evidence of secondary viral replication following initial dosing
**CALM study – CAVATAK™ in Late Stage Melanoma**

**Trial Design**

Stage IIIc/IV melanoma subjects  
N=63  

CAVATAK™  
Multiple Intralesional injections up to 10 times  

Dosing up to 18 weeks. Monitor for immune-related Progression Free Survival at 6 months

**Trial Update**

- Approx. 15% of patients have commenced CAVATAK™ treatment  
- Two patients have completed the entire 18 week CAVATAK™ injection schedule  
- Multi-dose administration well tolerated  
- Possible to fully recruit study in 2 years with all clinical sites active  
- Open-label study, data available for viewing during trial progression  
- As clinical data matures, appropriate trial updates released
# Viralytics – the future

## Viralytics - more than Melanoma

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<th>Development</th>
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<tr>
<td>Melanoma (intratumoral)</td>
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<td>Bladder</td>
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<td>Mesothelioma</td>
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| **EVATAK™** | |
|-------------| |
| Ovarian (intraperitoneal) | |
| Prostate (intratumoral) | |
| Gastric (intraperitoneal) | |
Viralytics – the future

Potential to treat Lung cancer

**Normal Lung tissue**
Cells have low level ICAM-1 receptor

**Lung cancer tissue**
Cells express high levels of ICAM-1 making them susceptible to attack from CAVATAK™
Viralytics - the future

Potential to treat Pancreatic cancer

**Normal Pancreatic tissue**
Cells have little to no ICAM-1 receptor

**Pancreatic cancer tissue**
Cells express high levels of ICAM-1 making them susceptible to attack from CAVATAK™
Viralytics Corporate Overview

Who we are

- One of only two publicly traded Virotherapy companies in the world
- **Listed** - on the Australian Stock Exchange *(VLA)* and the OTC market *(VRACY)*
- 20+ patents granted worldwide, 30+ patents pending
- **Head Office** - Sydney
- **Research & Operations** – Newcastle University, Australia
- **Manufacturing** - cGMP manufacture of CAVATAK™ in USA
Board & Executive

Board
Mr Paul Hopper | Chairman - US based director of NASDAQ listed Biotechs with extensive capital markets experience in US and Asia.
Dr Phillip Altman | extensive clinical trial background having established his own clinical research organization.
Mr Peter Molloy | former pharmaceutical exec (Pharmacia), biotech CEO (Biota).
Dr Leonard Post | ex director of BioVex and ex Senior Vice President of R&D at Onyx Pharmaceuticals.

Executive
Mr Bryan Dulhunty | Managing Director, long term capital intensive project specialist.
Professor Darren Shafren | Chief Scientific Officer and Inventor of Technology.
Dr Jeffrey Weisberg | Chief Medical Officer.
The Advisory Board is comprised of international opinion leaders who have extensive experience in the use of viruses as a potential method of treating cancers.

Members of the Advisory Board are:

- **Dr Jeffrey Weisberg** - (Chairman), Clinical Professor of Medicine, Nova Southeastern University College of Osteopathic Medicine, USA
- **Professor Evanthia Galanis, MD** - Professor of Oncology, Mayo Foundation for Medical Education & Research, USA
- **Dr Kevin Harrington** – Reader in Biological Cancer Therapies at Institute of Cancer Research, Consultant Clinical Oncologist, Royal Marsden Hospital, UK
- **Professor Hardev Pandha** - Head of Oncology, University of Surrey, UK
Financials

- Market Capitalization: AU$25m
- Share Price: AU$0.35
- Av. Daily Share Volume: 105,000
- Av. Daily Turnover: AU$150,000
- Cash on Hand: AU$6.5m
- Burn Rate – historical: AU$3.5m p.a.
- Shares on Issue: 75m
- Shareholders: 5,650

A stable company here for the long term

as at 1 Jun 2012
Why invest?

- **Pivotal timing** with the first commercial transactions occurring within virotherapy companies

- **Compelling comparative value** based on successful outcome of current Phase II trial

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<th>Company</th>
<th>Commercial Value/ Deals</th>
<th>Stage of Development</th>
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<td><strong>Amgen/Biovex Inc (USA)</strong></td>
<td>US $1 billion Amgen acquisition of Biovex in 2011</td>
<td>Phase III: Melanoma</td>
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<tr>
<td><strong>Oncolytics Biotech (Canada)</strong></td>
<td>US $300 million Market Capitalization</td>
<td>Phase III: Head &amp; Neck cancer</td>
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<tr>
<td><strong>Jennerex (USA)</strong></td>
<td>€116 million European rights licensing development deal 2010</td>
<td>Phase II: Liver cancer Phase I: Intravenous study</td>
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Contact

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CAVATAK™