Healthcare - Biotechnology

Viralytics Limited
(ASX: VLA)

Overview Report

Equity | Australia
November 19, 2008

VIRIATHUS®

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Company Description:

Viralytics is pioneering revolutionary new cancer therapies using oncolytic viruses to seek out and destroy cancer cells. Researchers have found that certain viruses have the capacity to preferentially target, infect and destroy cancer cells relative to normal healthy cells. The Company's lead product CAVATAK™ is a form of the Coxsackievirus A21 (CVA21). In human clinical trials, this naturally occurring virus has shown indications of efficacy at low doses, demonstrated rapid action, and has been well tolerated. The preliminary human data supports indications of anti-cancer activity of CAVATAK™ previously displayed in animal models. If CAVATAK™ continues to prove safe and effective in clinical trials, its low toxicity in combination with approved cancer therapies may make it a first choice product in cancer treatment.

The Company completed one small Phase 1 CAVATAK™ trial in late-stage melanoma patients in 2006 and currently has two Phase I CAVATAK™ clinical trials underway. The first of these current studies is a dose escalation trial in late-stage melanoma patients, administering CAVATAK™ intratumorally. Preliminary data from this trial indicates intratumoral administration of CAVATAK™ induced reductions in the size of some injected tumors. The second is a dose escalation trial in late-stage melanoma, prostate and breast cancer patients, administering CAVATAK™ intravenously. Based on results to-date, the Company believes advancing its CAVATAK™ clinical program to Phase II trials is warranted.

Informational Report Highlights:

- **CAVATAK™ advantages versus conventional cancer therapies**

Evidence suggests that CAVATAK™ may offer greater efficacy with fewer side-effects than existing cancer treatments. CAVATAK™ preferentially targets/infects cancerous cells and may remain in the body, continuing to replicate, until all targeted cancer cells are destroyed. The self-proliferating characteristic of CAVATAK™ may eliminate the need for extensive re-dosing. In addition, CAVATAK™ may demonstrate synergistic effects when used in combination with chemotherapy and other anti-cancer drugs.

- **International recognition of Viralytics technology**

Research by the Company's Chief Scientific Officer Darren Shafren and his colleagues regarding the potent oncolytic effects of CAVATAK™ has been published in *Clinical Cancer Research*, *Journal of Virology*, *International Journal of Cancer*, *British Journal of Hematology*, *Journal of Oncology* and other leading, peer reviewed journals.

In addition to current trials, Viralytics is expanding the range of cancers for potential clinical evaluation to include multiple myeloma, ovarian, brain, colorectal/gastric and head/neck cancers. CAVATAK™ has been awarded orphan drug status by the FDA for the treatment of late-stage melanoma.

Financial Data:

Price: 0.043
Market Capitalization (mln): .....AU$13.5
Shares Out standing (mln): 281.2
Float (mln): 215.4
Avg. Volume (90 day, approx.): 149,447
52 Week Range: $0.038-0.12
Exchange: .....Australian ASX

Recent Milestones:

- European and U.S. patents secured on core CAVATAK™ technology.
- Notice of Allowance by U.S patent office on core technology for a second product, EVATAK™.
- Phase I dose escalation intratumoral trials in melanoma and dose escalation intravenous trials in melanoma, breast and prostate cancer underway.
- Began discussions with the FDA regarding toxicity results, laying the groundwork for FDA-approved Phase II trials.
- Contracted with specialist U.S. manufacturer for scale-up of CAVATAK™ production.

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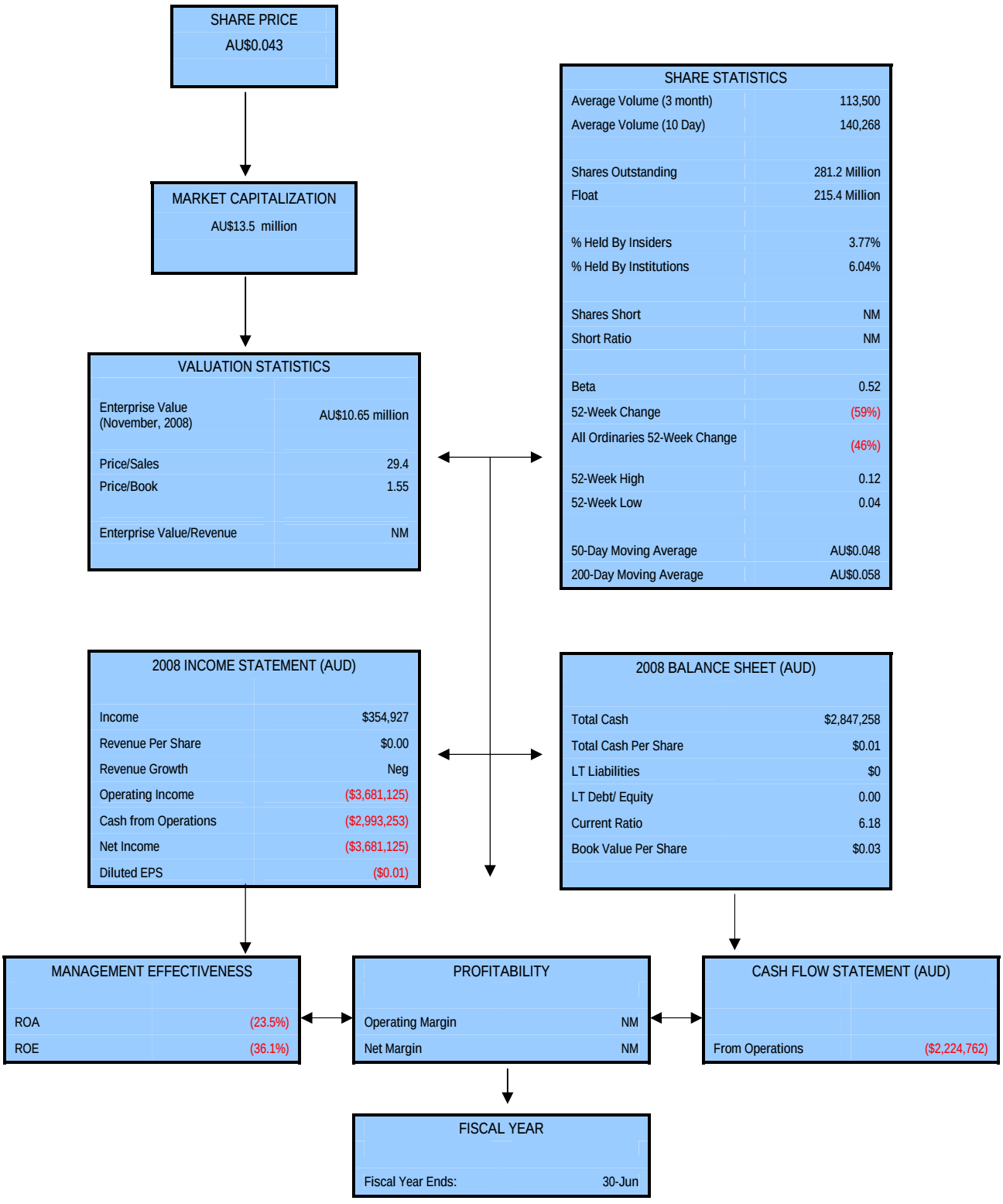
Balance Sheet (AUD)	Jun 08
Cash	2,847,258
Working capital	2,497,928
Current Ratio	6.2x
Long-Term Obligations	0
LT Debt to Equity Ratio	0%

P&L Data:(000)	Jun 05	Jun 06	Jun 07	Jun 08
Revenues	703	70	523	355
Expenses	(8,028)	(8,061)	(4,493)	(4,036)
Operating Loss	(8.061)	(8,028)	(4,196)	(3,681)
Net Loss	(7,999)	(9,272)	(4,196)	(3.681)
EPS	(0.05)	(0.06)	(0.02)	(0.01)

Margin: (%)	Jun 05	Jun 06	Jun 07	Jun 08
Gross Margin	61.6	NM	3.1	NM
Operating Margin	NM	NM	NM	NM
Net Margin	NM	NM	NM	NM

Financial Metrics



Healthcare - Biotechnology

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(ASX: VLA)

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Information Overview

Viralytics Ltd (ASX: VLA) is an Australian biotech company developing cutting-edge viral therapies for the treatment of various cancers. The Company has secured U.S. and European patents covering the technology for its lead product CAVATAK™ and has been granted a Notice of Allowance from the U.S. patent office covering the technology for a second product, EVATAK™. These patents cover a range of viruses which have demonstrated the capacity to specifically target, infect and destroy cancer cells. The Company's products are based on oncolytic virotherapy, a technology being researched worldwide which could potentially revolutionize cancer treatment. In pre-clinical studies and early clinical trials, CAVATAK™ has demonstrated rapid action, shown indications of efficacy at low to moderate doses and has been well-tolerated by patients.

CAVATAK™ is the natural form of Coxsackievirus A21 (CVA21), one of the viruses that cause the common cold. CVA21 is a naturally occurring virus which has shown significant cancer-fighting effects in animal models. CAVATAK™ owes its cancer-infecting characteristics to the cancer cell receptor molecules to which it attaches. The two CAVATAK™ binding receptors – ICAM-1 (Intercellular Adhesion Molecule-1) and DAF (Decay Accelerating Factor) - are over-expressed on the surface of many types of cancer cells.

At present, the Company is involved in Phase I clinical trials of CAVATAK™ as a potential treatment for melanoma, breast cancer and prostate cancer. Viralytics research team is also expanding the range of cancers addressed by its technology to include multiple myeloma, ovarian, glioma (brain cancer), colorectal/gastric and head/neck cancers. If CAVATAK™ continues to prove safe and efficacious in further clinical testing, the product's low toxicity in combination with approved cancer therapies such as biotherapeutics, radiation and chemotherapy may help accelerate its time to market and make CAVATAK™ a product of first choice in cancer treatment.

Viralytics has significantly advanced its clinical program in 2008 and taken the necessary steps to ensure international recognition of its product development efforts through publications in peer reviewed journals. Recent achievements include:

- Advancing the total number of patients dosed with CAVATAK™ in pilot and Phase I clinical trials to 14 patients to-date, providing valuable clinical data;
- Completing dosing of the second of three groups of patients in the Phase I intratumoral trial of CAVATAK™ in late- stage melanoma patients. Patients being recruited for the third group will receive a CAVATAK™ dose 100 times higher than the first group;
- Recently presented preliminary data from this trial at an Australian Cancer conference highlighting that (i) intratumoural injection of CAVATAK™ induced reductions in the volume of some injected tumors and (ii) serum bio-marker activity suggested the possible development of host-immune responses against CAVATAK™ infected melanoma cells.
- Commencing dosing of the second group of patients in the Phase I intravenous trial of CAVATAK™ in late-stage melanoma, prostate

and breast cancer patients. This second group of patients is receiving multiple intravenous infusions of CAVATAK™;

- Obtaining core patents in the U.S. and Europe that secure its intellectual property;
- Adding two independent U.S.-based non-executive directors to the Board of Directors who can assist the Company in securing international product licensing deals. A Chief Operating Officer has been hired to lead manufacturing scale-up and non-clinical projects and a Business Development Representative has been recruited to pursue international partnering;
- Commissioning a U.S. specialist manufacturer to commence design and scale-up of CAVATAK™ production at the manufacturer's GMP-compliant facility and supply product for future clinical requirements;
- Meeting with the FDA to review the Company's toxicology results and lay the groundwork for FDA-approved Phase II clinical trials and a future FDA submission.

Through its relationship with the University of Newcastle, Viralytics gains access to a research facility and infrastructure that would cost millions of dollars to replicate.

The Company's Chief Scientific Officer, Darren Shafren, leads Viralytics' research team at the University of Newcastle. Dr. Shafren is Associate Professor of Virology in the Faculty of Health, University of Newcastle, and has over 20 years experience in basic and molecular virology. He is also the founding inventor of the oncolytic virus technology which Viralytics has acquired. Viralytics has three full-time staff and 12 contract researchers at the university. Through the Company's research relationship with the University of Newcastle, Viralytics gains access to a leading edge research facility and related infrastructure which would cost millions of dollars to reproduce. The facility provides resources for virus manufacturing, clinical trial bio-marker testing and basic oncolytic virus research.

The Company's focus on controlling costs has enabled Viralytics to advance its lead product and clinical programs at costs that are a fraction of competitors' expenditures. During FY 2008, Viralytics progressed two Phase I clinical trials of CAVATAK™ while simultaneously reducing cash outflows and total expenses. The Company's cash outflows fell to AU$3.0 million in FY 2008 from AU$3.3 million in the previous year and total expenses dropped to AU$4.0 million from AU$4.5 million. Many of Viralytics' competitors are spending far larger sums to achieve comparable progress. For example, Oncolytics Biotech (NASDAQ:ONCY) is burning through cash at the rate of C$1.6 million per month in support of its Phase I and Phase II trials, and reported expenses totaling C$16.8 million in 2007. Cell Genesys (NASDAQ:CEGE) spent US$54.6 million on research and development in the six months ended June 30, 2008. Medigene (MDGGn.DE) estimates its cash burn rate in support of clinical programs at 2.5 million EURO (approximately US$3.25 million) per month. The ability to accomplish more while spending less differentiates Viralytics from many competitors in this space and enhances value for the Company's shareholders.

The Company has formed an international collaboration with Professor Abhijit Guha of the Labatt Brain Tumour Research Center in Toronto, Canada, regarding applications for CAVATAK™ in treating brain cancer. Professor Guha is a leading expert on brain cancer and the President of the Society for Neuro-Oncology in the U.S.

History of Oncolytic Virotherapy

The notion of using viruses to fight cancer has existed for decades. In the 1940s and 1950s, researchers performed studies in animal models to assess viruses as a treatment for tumors. In 1956, one of the first human clinical trials of an oncolytic virus was conducted on patients with advanced cervical cancer. Although the results of this study were promising, research was not advanced because there was no technology available at the time for purifying the virus and safely delivering the viral treatment. In 1991, interest in oncolytic viruses was re-ignited following publication of results in *Science* magazine of a Georgetown University study using the Herpes Simplex virus to treat brain cancer.

Oncolytic Viruses Defined

Oncolytic viruses are viruses that infect and replicate in cancer cells while leaving most normal cells undamaged. Like all viruses, oncolytic viruses penetrate a host cell and "trick" it into replicating more of the virus until the host cell's membrane ruptures and the cell is destroyed.

Naturally occurring viruses have been identified that innately prefer targeting and replicating in cancer cells.

Engineered versus Non-engineered Viruses

Researchers are working with both engineered and non-engineered oncolytic viruses in their fight against multiple types of cancer. Non-engineered viruses are naturally occurring viruses that have been found to innately prefer targeting and replicating in cancer cells. The Coxsackievirus is an example of a non-engineered virus; others include the Newcastle Disease virus, Measles virus, Parvovirus, Seneca Valley virus and Reovirus. Viruses that do not preferentially attack cancer cells must be genetically modified to selectively target and replicate within such cells. Examples of engineered viruses include the Adenovirus, the Herpes Simplex virus, Influenza and the Vaccinia virus.

Mechanism of Action

Infecting the tumor cell, the oncolytic virus compromises the cell's natural defense mechanisms and gives the virus time to thrive and replicate. The virus continues to reproduce in a cell until the cell membrane ruptures. Freed from the host cell, newly created viruses spread to neighboring cancer cells and continue the cycle. Oncolytic viruses preferentially replicate in cancer cells. Once all of the cancer cells are destroyed, the virus is generally no longer able to replicate and is cleared from the body.

Therapeutic Benefits

Clinical studies suggest that oncolytic virotherapy may offer significant therapeutic advantages when compared to traditional cancer treatments. These benefits include:

Chemotherapy destroys one healthy cell for every six cancer cells. Oncolytic viruses can destroy only one normal cell for every 100,000 cancer cells.

- ***High therapeutic index:*** Compared with traditional therapies, oncolytic viruses offer a much higher therapeutic index, i.e. greater efficacy with fewer side-effects. Some oncolytic viruses have been found to have therapeutic indexes as high as 100,000-to-one. That means only one normal cell is destroyed for every 100,000 cancer cells destroyed. This is in marked contrast to chemotherapy, which commonly produces a therapeutic index of six-to-one, meaning one normal cell is destroyed for every six cancer cells.
- ***Better anti-tumor efficacy***: Chemotherapy and cancer drugs are cleared from the body within a brief period of time and require repeated dosing to be effective. Viruses can remain in the body and continue to replicate until all cancer cells are destroyed. This self-

proliferating characteristic of viruses may mitigate the need for extensive re-dosing.

- ***Synergies with existing cancer therapies***: Some oncolytic viruses have demonstrated significant synergistic effects when used in combination with chemotherapy and radiation. Combination therapies could potentially lead to accelerated time to market and more effective treatments.

Current Industry Research

Most clinical studies currently underway focus on intratumoral or intravenous delivery of oncolytic viruses. While intravenous delivery holds the promise of systematic treatment and destroying cancers that have metastasized, a challenge faced by researchers is maintaining therapeutic levels in the presence of the body's immune system response. The immune system creates antibodies to destroy viruses. Intravenously delivered oncolytic viruses must overcome pre-existing antibodies to have a therapeutic effect. To address this challenge, researchers are studying ways to moderate the immune system response and/or are focusing on viruses for which most patients have few existing antibodies.

Viralytics Virotherapy

Viralytics' technology is based on two naturally occurring families of viruses associated with the common cold – Coxsackieviruses and Echoviruses. Chief Science Officer Darren Shafren was the first to identify the anti-cancer therapeutic effect of these viruses. In eight years of pre-clinical studies, Coxsackieviruses and Echoviruses have demonstrated potent anti-cancer effects over a range of cancers. Viralytics has published its results in peer reviewed journals and initiated clinical trials of its lead product in late-stage melanoma, breast and prostate cancer patients.

CAVATAK™ (CVA21) uses ICAM-1 and/or DAF receptor molecules to attach to cancer cells. These receptors are highly over-expressed in many cancer types.

CAVATAK™ (Coxsackievirus A21:CVA21)

CAVATAK™ is Viralytics' trade name for Coxsackievirus A21 (CVA21) a naturally occurring human virus first isolated over 50 years ago. CVA21 infections are often symptomless but may sometimes resemble the common cold. CVA21 infects cells by attaching to the outside of the cell to specific receptors on the cell's surface. CVA21 uses the receptors ICAM-1 and/or DAF to infect cells.

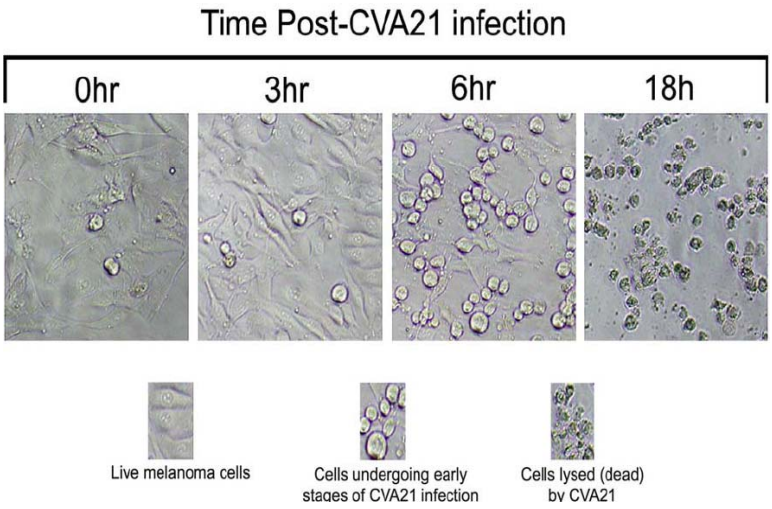
ICAM-1 expression on normal tissues cells is limited. As a result, the oncolytic action of viruses using ICAM-1 is quite specific. ICAM-1 has been found to be present in increased amounts in melanoma, breast, prostate, head/neck, colon cancer and multiple myeloma cells.

Laboratory and animal studies have demonstrated that:

- Laboratory cultures of human melanoma, multiple myeloma, prostate, brain, and breast cancer cells have high levels of ICAM-1 and DAF and were highly susceptible to rapid destruction by CVA21;
- In live laboratory mice lacking a normal immune system, the tumor burden of the above cancerous cells was rapidly reduced following a single injection of CVA21;
- In live laboratory mice, tumors distant from the site of the virus injection also showed effects of destruction by the virus.

Small doses of CVA21 caused the cancer cells to begin breaking apart in just 6-10 hours.

Small doses of CVA21 caused the cancer cells to begin breaking apart in just 6-10 hours and release thousands of newly formed virus particles. The rapid speed at which CVA21 destroys cancer cells and replicates is important since this enables small doses to have a potent anti-cancer effect.



Pre-clinical and early Phase I human trial results have encouraged Viralytics to further develop CAVATAK™ as a cancer treatment. The Company commenced its first Phase I trial in 2005 involving patients with metastatic melanoma, injecting a single dose of CVA21 directly into the tumor. This trial was completed in 2006. Subsequenly this has expanded into 2 further trials, an intratumoral treatment at increasing dosages and a intravenous treatment of prostate cancer, breast cancer and melanoma.

Coxsackievirus A21-DAFv (CVA21-DAFv)

CAVATAK™ requires both ICAM-1 and DAF receptors to bind to the surface of cancer cells. In 2004, Viralytics researchers generated a variant of CVA21 able to bind to cancer cells using only the DAF receptor. This discovery was published in the November 2004 issue of the *Journal of Virology*.

Like CAVATAK™, CVA21-DAFv is a naturally occurring virus. DAF is a protein that cancer cells produce. It has been well studied in cancer research and found to be over-expressed in many cancer types to the point where researchers think it may be an ideal target for antibody approaches to cancer treatment. Viralytics believes CVA21-DAFv may target a different range of human cancers than CVA21, which requires ICAM-1 interactions.

EVATAK™ (Echovirus type 1:EV1)

"Echo" is an abbreviation of "Enteric cytopathic human orphan." The term orphan was applied to this virus because it was not linked to a human disease when it was discovered.

The Echovirus being studied by Viralytics is Echovirus type 1. Patients infected with EV1 generally display no symptoms although some may present with a mild respiratory infection. Studies have shown that EV1 binds to the Integrin Alpha-2 Beta-1, which is found in large quantities on the surface of ovarian and prostate cancer cells.

In 2005, Professor Shafren and his colleagues published results of studies using EV1 to infect ovarian cancer cells and tumors growing in mouse models. Their results were published in *International Journal of Cancer*. These studies demonstrated that rapid destruction of ovarian cancer cells could be achieved using small doses of EV1. Total destruction of ovarian cancer cells was achieved in just nine days. Viralytics believes EV1 may potentially offer an effective, safe treatment for ovarian cancer.

In May 2008, Company researchers also published results in *The Prostate* highlighting the oncolytic activity of EV1 in mouse models of human prostate cancer as well.

Viralytics has protected its intellectual property with patents and patent applications that give the Company exclusive rights to commercially exploit its technology over the 20 year patent life. In addition, Viralytics has trademarked its CVA21 and EV1 products as CAVATAK™ and EVATAK™, respectively. These trademarks uniquely identify and differentiate its technology.

Development Strategy

The Company's Phase I clinical trials are designed to prove safety and efficacy of CAVATAK™ as a mono-therapy**.** Once safety of the basic product is established, Viralytics may pursue trials of CAVATAK™ in combination with chemotherapy and other existing cancer treatments.

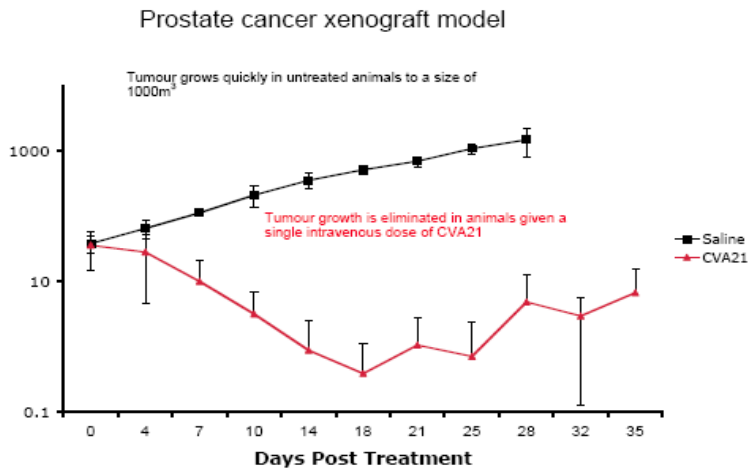
Establishing CAVATAK™ synergies with existing cancer therapies may enhance time to market and licensing partnership opportunities.

Studies show that viruses used in combination with existing cancer treatments may act synergistically, reducing cancerous tumors more effectively than either treatment used alone. Establishing synergistic effects for CAVATAK™ may allow the Company to accelerate its product's time to market and pursue licensing partnerships. Two Phase I trials of CAVATAK™ are underway at two separate hospitals and the Company is laying the groundwork for Phase II trials.

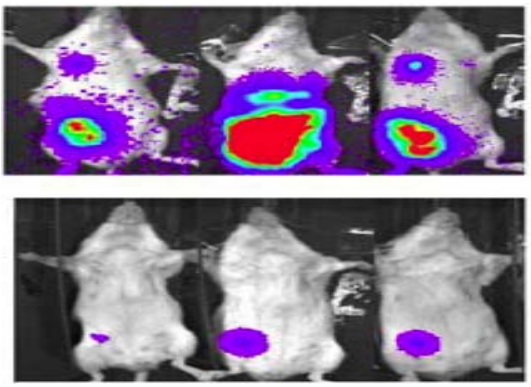
Published Research

In the January 2004 edition of *Clinical Cancer Research*, Professor Shafren and his colleagues discussed the potent anti-cancer activity demonstrated by CVA21 in human melanoma models in mice. Results showed human tumors grown in mice were eliminated by a single low dose of CVA21.

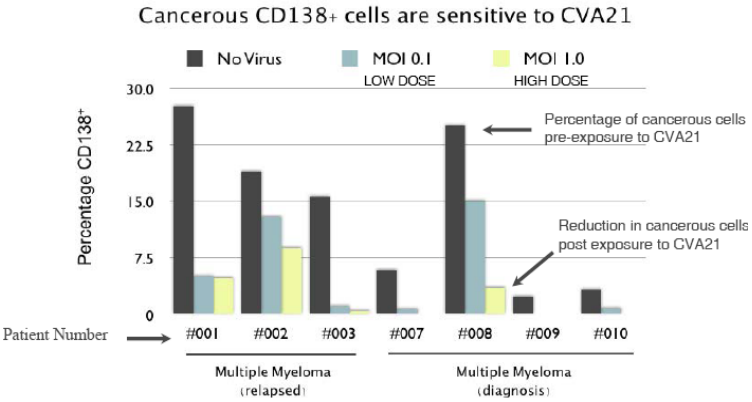
In November 2006, Viralytics researchers presented results of a study assessing the effects of CVA21 on human prostate cancer tumors grown in mouse models. Researchers presented these results at the European Study Group on the Molecular Biology of Picornaviruses in Finland. The data indicated (shown below) that a single intravenous dose of CVA21 quickly reduced tumor size. In contrast, normal saline treated animals experienced rapid tumor growth.



In March 2007, Company researchers presented findings of studies using CVA21 to treat human breast cancers grown in mouse models. Their findings were presented at the 4th International Conference on Oncolytic Viruses as Cancer Therapeutics in Scottsdale, AZ, USA. The data evidenced potent oncolytic effects of CVA21 on human breast cancer in mouse models, including metastatic spread, the most serious form of cancer. In these studies, a single intravenous dose was administered. The graphic below compares tumor reduction in CVA21 treated mice with normal saline treated mice.



The following month (April 2007), Company researchers published study results in the *British Journal of Hematology* demonstrating the powerful oncolytic effect of CVA21 in human multiple myeloma cell lines and bone marrow samples taken from multiple myeloma patients. The graph below highlights the sensitivity of multiple myeloma cells to destruction by CVA21, even at very low virus doses.



Phase I trials of CAVATAK™ as an intratumoral treatment for melanoma and as an intravenous treatment of melanoma, breast and prostate cancers are underway.

In February 2008, Company researchers published results in *Breast Cancer Research and Treatment* demonstrating the dramatic oncolytic activity of CVA21 against *in vitro* cell cultures and *in vivo* tumours of human breast cancer grown in mice. Furthermore, in May 2008, Company researchers published results in *The Prostate* highlighting the oncolytic activity of CVA21 in a mouse model of human prostate cancer.

Phase I Clinical Trials Underway

Viralytics has administered CAVATAK™ to 14 patients to date in its clinical programs and has two Phase I human trials currently underway.having completed its first Phase 1 clinical trial in 2006;

Phase I Trial: Dose Escalation Melanoma Intratumoral Trial

The purpose of this trial is to assess CAVATAK™ performance without its dilution to other areas of the body. In this study, CAVATAK™ is being injected directly into the tumor. Surface tumors are readily accessible in late-stage melanoma, allowing researchers to easily monitor the injection site and tumor changes.

This study progressively increases dosage with each new group of patients. The doses of CAVATAK™ are expressed in $TCID_{50}$ (50% Tissue Culture Infectious Dose), which is a term virologists use to measure how much virus is delivered. Dosing in the study began at two doses of 10^7 $TCID_{50}$ and rises 100-fold to two doses of 10^9 $TCID_{50}$. Patients have stage IV melanoma, an aggressive stage of the disease that has not responded to other treatments.

Viralytics has completed dosing the first two groups of patients at low and moderate doses, respectively. Each group consisted of three patients. After treating the first six patients, researchers have:

- Reached an intratumoral dose of two doses of 10^8 $TCID_{50}$
- Observed no drug-related serious side-effects
- Observed reductions in the volume of some injected tumors
- Observed serum bio-marker activity suggesting the possible development of host-immune responses against CAVATAK™ infected melanoma cells
- Noted that the treatment was well tolerated by all patients
- Obtained approval to treat the final group of patients at the trial's maximum dosage level.

Phase I Trial: Dose Escalation Prostate Cancer, Breast Cancer and Melanoma Intravenous Trial

When a cancer metastasizes, cells from the original tumor spread to other parts of the body and begin growing as new tumors in lymph nodes, vital organs and other remote locations. Viralytics believes intravenous delivery of CAVATAK™ will enable the virus to travel through the body and destroy remote tumors in addition to the primary tumor.

Viralytics believes Phase II trials are warranted. These may involve CAVATAK™ as a combination therapy with biologics, chemotherapy or radiation.

The Company's Phase I intravenous trial progressively increases the dosage levels and number of doses to patients with late-stage cancers and monitors their tolerance to CAVATAK™. A secondary goal is to assess tumor response and other investigative measures in prostate and breast cancer and melanoma. The trial involves dosing 26 patients. The first patient was injected with virus in March 2008 and the first group of two patients has completed the study. The first patient in the second group has also been treated. After treating these patients, Viralytics researchers have:

- Administered two intravenous doses of 10^6 $TCID_{50}$
- Observed no drug-related serious adverse effects
- Noted that the treatment was well tolerated in all patients.

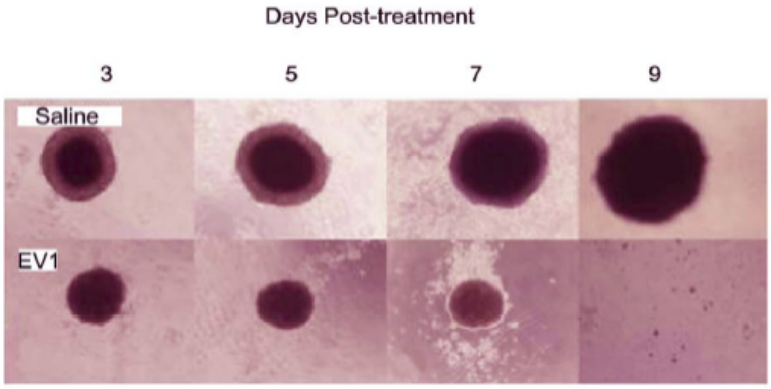
Through these trials, the Company is able to, not only study the direct action of the virus on human tumor cells, but also measure various biomarker activities that can be used to assess the biological action of CAVATAK™ in humans. While the Company is not yet ready to publish final data from these trials, the evidence suggests that human administration of CAVATAK™ is well tolerated. In addition, preliminary data on CAVATAK™ biological activity is supportive of pre-clinical findings. Based on these finding, Viralytics believes Phase II clinical trials are warranted, possibly using CAVATAK™ in combination with chemotherapy, biologics or radiotherapy.

EVATAK™ (Echovirus-1 or EV1)

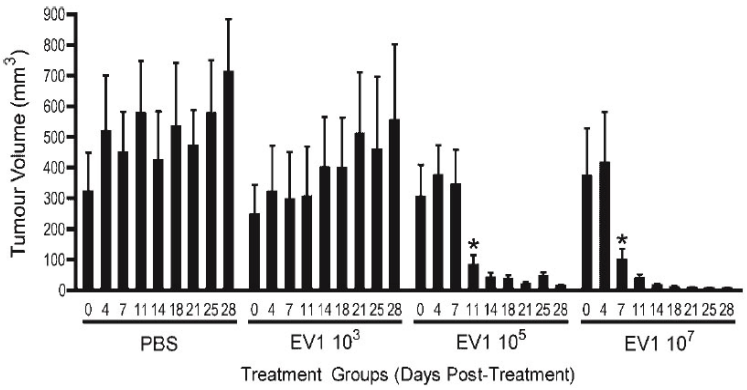
While Viralytics primary focus is advancing CAVATAK™ through clinical development, the Company is also establishing pre-clinical data in support of its next product, EVATAK™. This product targets cancer cells with a different receptor molecule than CAVATAK™ and may offer a treatment for different cancer types. Pre-clinical studies evaluating the oncolytic effect of EVATAK™ on ovarian and prostate cancers are adding depth and value to the Company's product pipeline.

EV1 studies published in the 2007 edition of *International Journal of Cancer* indicate potent oncolytic activity in an ovarian cancer mouse model. Two tumors were grown on each mouse and the primary tumor was injected with EV1 while the second tumor was left untouched. The study found that

both the primary tumor and second tumor stopped growing. This effect was long-lasting. The Company believes these findings offer evidence of EV1's capacity to travel through the blood and attack both primary and remote tumors.



In May 2008, Company researchers published results (displayed below) in *The Prostate* highlighting the oncolytic activity of EV1 in mouse models of human prostate cancer.



Viralytics has hired a GMP-compliant manufacturer specializing in viruses to produce CAVATAK™ for ongoing clinical trials.

Phase II Trial Preparations:
To prepare for Phase II trials, the Company has secured the services of a GMP-compliant manufacturer based in the U.S. and specializing in the manufacture of viruses. By contracting with this manufacturer for larger-scale production, Viralytics ensures that a sufficient supply of CAVATAK™ is available for Phase II clinical trials. This also reduces development risk by optimizing and scaling up CAVATAK™ production early in the clinical trial process.

Viralytics is involved in ongoing discussions with the FDA regarding CAVATAK™. The U.S. is the world's largest pharmaceutical market and has some of the most stringent regulatory requirements for drug approval. The Company recognizes that meeting FDA regulatory requirements is critical to its efforts to access all major international markets and has requested FDA review and comment on its planned toxicology program. These discussions will guide the Company's research efforts and assist in the design of FDA-approved Phase II clinical trials. Viralytics has also recruited a leading Australian-based clinical toxicologist and an eminent U.S.-based pharmaceutical toxicologist to assist in the development of its overall toxicology strategy.

Viralytics' strategy of seeking FDA feedback is a textbook approach to enhancing shareholder value.

Viralytics strategy of seeking FDA input at this time is a textbook approach for maximizing long-term shareholder value and contrasts significantly with the practices of many smaller Australian biotech companies, which concentrate exclusively on Australian regulatory standards. This single market approach often slows progress towards commercialization since companies must start the clinical trial process over from scratch to secure FDA approval and U.S. sales. The value a biotech company creates for its shareholders is largely determined by time to market for new products and the product's patent life. By bringing its products to market more quickly, Viralytics will enhance returns for its shareholders.

In addition to U.S. and European patents, Viralytics has been awarded orphan drug status for CAVATAK™ for treatment of patients with late-stage melanoma. Orphan drug status could potentially accelerate the FDA review process, provide U.S. tax benefits and provides CAVATAK™ with seven years market exclusivity.

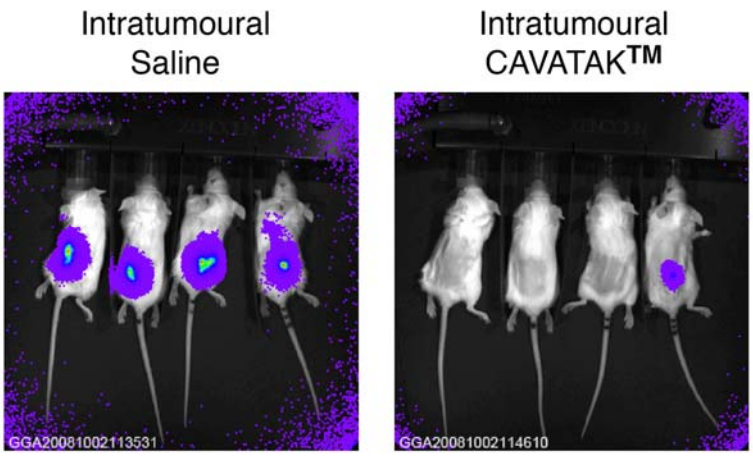
International Collaboration

In April 2007, the Company formed a collaborative arrangement with Professor Abhijit Guha of the Labatt Brain Tumour Research Center in Toronto, Canada. The purpose of the collaboration is to explore applications for oncolytic viruses in the treatment of primary brain cancers.

Dr. Guha is Professor of Neurosurgery at the University of Toronto and practices at the Toronto Western Hospital, which is part of the University Health Network in Toronto. He is Co-Director and Senior Scientist at the Arthur and Sonia Labatt Brain Tumour Research Center at the Hospital for Sick Children in Toronto and President of the Society for Neuro-Oncology in the U.S. This multi-disciplinary organization is dedicated to promoting advances in neuro-oncology through research and education.

Dr. Guha is one of the world's leading experts on glioma, an aggressive form of brain cancer. Malignant gliomas, the most common tumors of the central nervous system, often respond poorly to surgery, radiation and chemotherapy. The disease is generally fatal, usually within 1-2 years of the onset of symptoms. The National Cancer Institute estimates 21,810 new cases of brain cancer will be diagnosed in the U.S. this year.

Preliminary studies have confirmed: (i) the oncolytic activity of CAVATAK™ in laboratory cultures of human glioblastomas (GBM), (ii) the presence of high levels of the CAVATAK™ binding molecule (ICAM-1) in biopsy samples of human GBM, and (iii) destruction of human GBM tumours grown in mice by CAVATAK™ (see below).



Other Investments

Viralytics owns 3.1% of the outstanding capital of CBio Limited, a public, non-traded company developing CPN10 as a potential treatment for inflammatory diseases. Viralytics values this investment at AU$1.2 million, or approximately $1.00 per share.

In addition, Viralytics owns approximately 45% of InJet Digital Aerosols Ltd. (IDAL), a public, non-listed company whose patent portfolio has been licensed to Canon Inc. to commercialize its technology. IDAL's patents cover a technology for delivering medicines to patients via inhalation using a proprietary InJet delivery mechanism. Under the terms of the Canon agreement, IDAL will receive 10% worldwide royalties on all pharmaceutical royalties and 0.5% royalties on the sale price of InJet devices.

Both IDAL and Canon are encouraged by the technology's progress and they are optimistic concerning its prospects for commercial success. The InJet device could potentially enhance the effectiveness of drugs and overcome many of the difficulties associated with current drug delivery methods. In 2007, IDAL undertook a AU$500,000 fund-raising from new shareholders at 15 cents per share. IDAL has approximately 450 million shares issued. Due to the requirements of Australian accounting standards, Viralytics carries the value of its IDAL investment at zero on its balance sheet.

In early FY 2008, Viralytics held a 22.1% equity interest in Analytica Ltd, a listed company developing safety medical devices. During the year, the Company sold all of its Analytica shares. The net proceeds of the sale totaled AU$897,600 and included a AU$201,276 net profit on share sales.

Management & Board of Directors

In October 2008, Viralytics announced a restructuring of its Board of Directors and Management team, effective from the close of the Company's November 18th annual meeting. The restructured team is described below**:**

Paul Hopper
Independent Chairman (Non-Executive)

Paul Hopper

Mr. Hopper is based in Los Angeles, CA and has over 20 years experience in the management and funding of biotechnology and healthcare public companies. He has been involved in over $200 million in equity and debt financings in Australia, Asia, the U.S. and Europe.

His sector experience includes anti-bacterials, medical devices, antibodies, inflammation and oncology, with a particular emphasis on cancer vaccines. He is the director of a private U.S. biotech company expected to commence U.S. Phase III clinical trials for a melanoma cancer vaccine in early 2010. Mr. Hopper is also a director of Boston-based pSivida Corp (NASDAQ:PSDV), a drug delivery technology company, and Somnomed Limited (ASX:OM), a global manufacturer and marketer of dental devices for sleep disorders. Mr. Hopper is Managing Director at the Los Angeles merchant bank, Cappello Group. He has served as Chairman or Director of many listed biotech and healthcare companies, including Bone Medical Limited, Advanced Biotherapy, Inc., Australian Cancer Technology Limited and Medaire Ltd. He was the co-founder and Managing Director of Alpha Healthcare Limited.

Peter Molloy
Independent Director (Non-Executive)

Peter Molloy

Mr. Molloy joined the Viralytics board in September 2008. He is a successful Australian pharmaceutical and biotechnology industry executive who is now a U.S.-based industry consultant. Based in La Jolla, CA, Mr. Molloy most recently served as the Managing Director and CEO of Biota Holdings Limited (2002-2005), Australia's premier anti-viral drug development company. Under his leadership, this company grew from $25 million to $250 million in market value. Biota Holdings was recognized as Australia's top industry performer in the November 2005 issue of PWC's *BioForum* magazine.

He previously served as 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 company focused on the genetic modifications of plants, and as President of Moleculon Inc, a Boston-based transdermal drug delivery company. Mr. Molloy spent 17 years as a marketing executive for Pharmacia, including his last role as Vice President of Strategic Marketing. At Pharmacia, he evaluated new drug candidates and was responsible for the launch and marketing strategy of more than 50 new drugs across 23 countries. Mr. Molloy holds an undergraduate degree in Microbiology and Biochemistry from the University of Melbourne and an MBA from the University of Adelaide.

Bryan Dulhunty
Managing Director & CEO

Bryan Dulhunty

Mr. Dulhunty is a Chartered Accountant with over 25 years of experience in CEO, CFO and other executive roles for international and high-growth listed companies. In 2001, he founded CoSA Pty Ltd, a company specializing in financial assurance and management services for the

biotechnology sector. Mr. Dulhunty has served as a director for a number of public and private biotechnology companies.

Dr. Phillip Altman
Executive Director – Clinical Affairs

Dr. Phillip Altman

Dr. Altman is a well-known Australian authority on clinical trials and regulatory affairs with more than 30 years experience. He has held senior management positions with several multinational companies, including Merrell-Dow, Hoechst, Roussel and GD Searle. Dr. Altman founded his own company, Pharmaco Pty. Ltd., one of Australia's first contract research organizations, and served as Senior Industry Consultant. He has been involved in over 100 clinical trials (Phase I through Phase IV) and has been personally responsible for the marketing approval of numerous new drugs and dosage forms since beginning his career in the pharmaceutical industry in 1974.

Dr. Altman is a graduate of Sydney University with an Honors degree in Pharmacy, Master of Science and Doctor of Philosophy (pharmacology and pharmaceutical chemistry) degrees. He co-founded and is a life member of ARCS (Association of Regulatory and Clinical Scientists to the Australian Pharmaceutical Industry).

Darren Shafren
Chief Scientific Officer

Darren Shafren

Professor Shafren is Associate Professor of Virology in the Faculty of Health, University of Newcastle, Australia and has over 20 years experience in basic and molecular virology. Dr. Shafren is the founding inventor of the oncolytic virus technology which Viralytics acquired in 2006.

Stephen Goodall
Chief Operating Officer

Stephen Goodall

Mr. Goodall has specialised in biotechnology product development for over 25 years, including process and product development, facilities design and construction and international registration of medical products. He has been a senior executive and director of both public and unlisted biotechnology companies. He is based at the Company's Newcastle facilities and is responsible for day-to-day operations, GMP virus manufacture and FDA regulatory discussions.

Gavin Clark
Business Development Representative

Gavin Clark

Mr. Clark, based in the U.K., has a prolific background in international partnering, including licensing, collaborations and mergers and acquisitions. Most recently, he co-founded Dublin-based Procela Partners. Since 2002, he has provided business advice to numerous biotech companies, including Acumen Pharmaceuticals, Pintex, Pliva dd and PowderMed. Mr. Clark previously served as Director of Global Licensing – Infectious Diseases at Glaxo Wellcome and as VP Business Development at Tibote until its acquisition by Johnson & Johnson.

Sarah Prince
Company Secretary

Sarah Prince

Ms Prince is a solicitor for Company Matters Pty. Ltd. and also serves as Company Secretary for National Leisure & Gaming Limited and Palau Pacific Exploration Pty. Ltd.

Scientific Advisory Board

Professor Chris Burrell
Professor Burrell heads the Infectious Disease Laboratory at the Institute for Medical and Veterinary Science (MVS).

Professor Eric Gowans PhD
Professor Gowans is Senior Principal Research Fellow at the Macfarlane Burnet Institute in Melbourne.

Professor Ian Campbell PhD
Professor Campbell is group leader of the VBRC Cancer Genetics Laboratory at the Peter MacCullum Cancer Center in Melbourne.

Market Overview

U.S. costs for initial cancer care were $6.7 billion in 2002 and are climbing steadily.

$6.7 billion U.S. cancer treatment market

Each year, more than 12.5 million new cases of cancer are diagnosed worldwide. In the U.S. more than 1.4 million new cancer cases are diagnosed annually. Breast cancer and prostate cancer are the most common cancers diagnosed in the U.S., with each accounting for approximately 25% of new cases each year. Current treatments for cancer, which include drugs, chemotherapy, radiation and surgery, are expensive and contributing to rising healthcare costs. As a percent of GDP, U.S. healthcare costs are forecast to climb from 16% in 2008 to 20% by 2016. A study published in the June 2008 online edition of *Journal of the National Cancer Institute* revealed that U.S. cancer care costs hit $6.7 billion in 2002 and are continuing to climb. Rising costs are the result of an aging U.S. population, more Americans being diagnosed with cancer, higher prescription drug costs and the fact that more patients are receiving radiation and chemotherapy.

Over the course of the study, which collected data on over 300,000 cancer patients, the average cost for treating lung cancer rose $7,139 to $39,891. Prostate cancer treatment costs increased $5,345 to $41,134. The cost of treating breast cancer jumped $4,189 to $20,964.

Doctors and patients are being forced to consider costs in making cancer treatment decisions. New affordable therapies are urgently needed.

These costs didn't include many new, more expensive drugs in use. Sales of many cancer drugs exceed US$1.0 billion annually. Doctors and patients are being forced to consider costs in making treatment decisions. There is an urgent need for affordable cancer therapies that are safe, efficacious, and extend patient survival rates while ensuring a good quality of life.

Viralytics is developing oncolytic viruses for the treatment of melanoma, prostate cancer, breast cancer, multiple myeloma, ovarian cancer and glioma (brain cancer). When compared to traditional cancer treatments, oncolytic viruses offer the following possible advantages:

- Enhanced efficacy – increased patient survival rates using the oncolytic virus at low doses with reduces toxicity compared to existing toxic anticancer treatments;
- Improved quality of life for patients due to the less toxic nature of the therapy;
- Shorter hospital stays due to improved safety and tolerability;
- Reduced hospital costs which lowers direct and indirect medical costs;
- Synergistic – Oncolytic viruses can be used as a mono-therapy or in combination with existing therapies.

Melanoma

Approximately one million new cases of skin cancer are diagnosed in the U.S. each year. Melanoma is a particularly aggressive form of skin cancer which is unfortunately increasing in incidence. It occurs in the same skin cells that give rise to moles. Melanoma is not only the most aggressive skin cancer but also the most aggressive of any type of cancer. Due to higher ultraviolet light exposure rates, melanoma rates are four times higher in Australia and New Zealand than in Europe and North America.

Research from the U.S. National Cancer Institute estimates 62,480 new cases of melanoma will be diagnosed in the U.S. in 2008 and 8,420 melanoma-related deaths will occur. One in 55 Americans will be diagnosed with melanoma during their lifetime. When detected early, melanoma can be treated successfully by surgically removing the infected

skin. Unfortunately, once melanoma has spread beyond the original site, it becomes very difficult to treat. As a result, the need is critical for new, improved melanoma treatments.

Breast cancer
Breast cancer is one of the common forms of cancer in women. National Cancer Institute statistics indicate that 182,460 American women will be diagnosed with breast cancer in 2008 and that 40,480 women will die from the disease. One in eight U.S. women will be diagnosed with breast cancer during their lifetime. It is also the most prevalent cancer among women worldwide, with more than one million cases diagnosed annually.

Studies indicate that nearly 16% of American males will be diagnosed with prostate cancer during their lifetime.

Prostate cancer
Prostate cancer is a very common cancer in males. The National Cancer Institute estimates that 186,320 new cases of prostate cancer will be diagnosed in the U.S. this year and 28,660 men will die from the disease. Statistics indicate that nearly 16% of American men will be diagnosed with prostate cancer during their lifetime. If caught early, prostate cancer is highly treatable. Five-year survival rates for American men treated for prostate cancer exceed 90%.

Head and neck cancer
Cancers of the head and neck, which include cancers of the buccal cavity, head and neck subset, larynx, pharynx, thyroid, salivary glands and nose/nasal passages, account for about 6% of all malignancies in the U.S. Approximately 45,000 new cases of head and neck cancer are diagnosed each year. If caught early, the prognosis is excellent. However, about half of all cases of head and neck cancer are not identified until the disease is at an advanced stage.

Ovarian cancer
Ovarian cancer is a particularly difficult cancer to treat as it has often spread to areas of the abdominal cavity by the time it is diagnosed. Statistics indicate that 67% of ovarian cancers are not diagnosed until the cancer has already spread. The National Cancer Institute estimates 21,650 new cases of ovarian cancer will be diagnosed in the U.S. in 2008 and that 15,520 women will die from the disease. Fortunately, ovarian cancer is relatively rare. Statistics indicate one in 72 American women will be diagnosed with ovarian cancer during their lifetime.

Multiple myeloma
Multiple myeloma is a type of blood cancer. At present, there is no cure for this disease. According to the National Cancer Institute, 19,920 new cases of multiple myeloma will be diagnosed in the U.S. this year, and 10,690 Americans will die from this disease. Multiple myeloma accounts for approximately 1.0% of all cancers diagnosed annually.

Brain cancer
Approximately one in 165 Americans will be diagnosed with brain cancer during their lifetime. This condition is difficult to treat; five-year survival rates for brain cancer patients are low at only 34%. The National Cancer Institute predicts 21,810 new cases of brain cancer will be diagnosed in the U.S. in 2008 and 13,070 Americans will die from the disease.

Competition

Oncolytic viruses are more effective, less toxic, require less starting material and require fewer doses than chemotherapy, radiation or monoclonal antibody therapy.

Oncolytic Virotherapy Advantages
Oncolytic viruses have significant advantages over other cancer therapies being utilized or tested today. Many viruses have exquisite selectivity and only infect and kill certain types of cells. In addition, a single systemic dose of oncolytic virus will infect all tumor masses, known and unknown, as well as cancer cells circulating in the bloodstream. Viruses amplify the dose inside the tumor mass. All of these characteristics suggest oncolytic viruses are more effective, less toxic, require reduced input dosage and require fewer repeat doses than chemotherapy, radiation or monoclonal antibody therapy.

Industry Competitors
Many of the companies developing oncolytic viruses are privately-held biotechs funded by venture capitalists and in an early development stage. While the large pharmaceutical companies possess the resources to commercialize oncolytic viruses, most have opted to wait for clinical evidence that the technology is viable for commercial applications.

Viralytics' competitors include Oncolytics Biotech (NASDAQ:ONCV), privately-held Jennerex Biotherapeutics, privately-owned Wellstat Biologics, Cell Genesys (NASDAQ:CEGE), privately-owned Neotropix, privately-held BioVex and German-based Medigene (MDGGn.DE). Crusade Laboratories in the United Kingdom is also developing oncolytic viruses for the treatment of brain cancer. In addition, the Mayo Clinic is working with the vaccine strain of the measles virus and commencing Phase I trials in glioma and ovarian cancer.

The original pioneer in this field, Onyx Pharmaceuticals, developed an engineered version of the Adenovirus called Onyx 015 and partnered with Warner Lambert, which later merged with Pfizer. Pfizer and Onyx abandoned this program in 2001. In 2005, the Onyx 015 program was sold to Shanghai Sunway Biotech, a Chinese company. Sunway has successfully commercialized an oncolytic virus for the treatment of head and neck cancer in China.

CAVATAK™ triggers cancer cell death in 6-10 hours; engineered viruses require 24-48 hours. Since pre-existing antibody levels are low, CAVATAK™ may display enhanced oncolytic activity in ~80% of the potential patient population.

Technology Comparison
The companies researching oncolytic viruses are evaluating a variety of virus types which they believe may address a range of different cancers. At this stage in the development of the market for oncolytic viruses, it is important to note that the success of any participant's clinical program benefits every participant. Favorable media coverage heightens the visibility of the overall market and serves as a validation of the value of these technologies.

In general, the companies developing oncolytic viruses break down into two groups, consisting of those focused on naturally occurring viruses (Viralytics, Oncolytics Biotech, Wellstat Biologics and Neotropix) and those studying genetically engineered viruses (Cell Genesys, Crusade, BioVex and Medigene). Naturally occurring viruses being evaluated include the Newcastle Disease virus, Reovirus, Measles virus, Seneca Valley virus and Coxsackievirus. Viralytics' lead product CAVATAK™ is the natural Coxsackievirus A21. Genetically engineered viruses being assessed in pre-clinical studies and clinical trials include Adenoviruses and the Herpes Simplex virus.

Viralytics believes CAVATAK™ possesses several characteristics that make it particularly valuable as a cancer-fighting virus. First, CAVATAK™

has demonstrated the capacity to trigger cancer cell death in just 6-10 hours. Adenoviruses work much more slowly, requiring as many as 24-48 hours to achieve the same effect. The rapid action of CAVATAK™ should result in increased tumor destruction and quicker release of newly produced virus into the blood stream.

Second, much of the world's population has already been exposed to Adenoviruses, Measles virus, Reovirus, Vaccinia virus and the Herpes Simplex virus through vaccination or natural exposure. As a result, the level of serum antibodies, or the population's immunity to these viruses, is high. High antibody levels limit the usefulness of these viruses. In contrast, relatively few people have been exposed to CAVATAK™; Viralytics believes pre-existing antibodies may be present in only ~20% of the population. Low natural immunity levels suggest that CAVATAK™ may display enhanced oncolytic activity in ~80% of the potential patient population.

Third, the size of the virus is a potential efficacy factor since large viruses delivered intravenously have a tendency to get trapped in certain parts of the body, reducing the amount of virus free to circulate through the bloodstream. Small viruses have a greater likelihood of reaching different organs where remote tumors are located. At 25 nanometers in diameter, CAVATAK™ is much smaller than the 80 nanometer Adenovirus.

Most oncolytic viruses attach to any cell. CAVATAK™ preferentially bonds to cancer cells, improving the odds that more viral load is delivered

Finally, many oncolytic viruses fail to discriminate as to where they bond; while the virus may preferentially replicate in cancer cells, it attaches both to cancer cells and normal cells. Viralytics' viruses bond preferentially to the surface of cancerous cells. This greater specificity implies a higher probability of delivering large quantities of virus to the cancer cells and more potent oncolytic activity.

Oncolytics Biotech, Inc.

Canadian-based Oncolytics Biotech is developing cancer treatments based on the human Reovirus, which has shown the capacity to selectively replicate in Ras-activated cancer cells. An activated Ras pathway is found in approximately two-thirds of cancers and may be involved in most metastatic diseases. The company has completed seven human clinical trials with its lead product Reolysin® and has more trials underway in the U.S. and the U.K. In September 2008, Oncolytics Biotech began enrolling patients for a Phase II clinical trial of Reolysin® as a combination therapy for patients with advanced head and neck cancers. The trial, which is a 14-patient, single-arm, open-label, dose-targeted trial of Reolysin® given intravenously in combination with paclitaxel and carboplatin, will take place at the Cancer Therapy and Research Center at the University of Texas Health Science Center in San Antonio.

Cell Genesys

Cell Genesys is pursuing two clinical stage product platforms – cancer immunotherapies and oncolytic virus therapies. The company's lead oncolytic virus product CG0070 is an investigational product for the treatment of recurrent bladder cancer. CG0070 is made from Adenoviruses which have been engineered to replicate in and destroy target cancer cells and secrete GM-CSF, a potent immune cytokine that may stimulate a systematic anti-tumor immune response. Cell Genesys is developing CG0070 in partnership with Novartis AG. In May 2008, the company announced encouraging interim data from its Phase I clinical trial in recurrent bladder cancer. Of 16 patients who completed dosing at the two lowest of three doses being evaluated, ten showed measurable anti-tumor activity.

Jennerex Biotherapeutics
San Francisco-based Jennerex is developing oncolytic vaccines based on the Poxvirus strain, used to vaccinate millions of people worldwide against smallpox. The company's lead product JX-594 is being studied in Phase II trials for primary liver cancer. JX-594 was genetically engineered to enhance its safety/ cancer selectivity and expression of GM-CSF. During three Phase I trials, the product demonstrated the capacity to safely destroy tumors in patients with diverse cancer types. In October 2008, the company completed treatment for the first patient cohort in Phase I clinical trials of JX-594 delivered by intravenous injection. No significant toxicities were reported and treatment was well tolerated. Patients in the trial have advanced metastatic solid tumors refractory to standard therapy. The trial, involving 12-15 patients, is being conducted initially at clinical sites in the U.S. and will subsequently open at sites in Canada.

Neotropix
Pennsylvania-based Neotropix is developing oncolytic viruses for the treatment of solid tumors. The company's lead product, NTX-010 is a naturally occurring virus which is highly selective for certain tumor cell types expressing a biomarker that indicates the cancer has neuro-endocrine properties. In October 2008, the company began enrolling neuro-endocrine cancer patients for an expanded clinical trial of NTX-010. After reviewing safety data from the current Phase I dose escalation study, Neotropix decided to expand the study across a range of related cancers, including carcinoid cancers. The company anticipates making efficacy results from the expansion phase of the study available in 2009. In addition to the phase expansion, NTX-010 has been given Orphan Drug status for neuro-endocrine cancer. At present, few treatment options are available for these patients.

BioVex
In June 2008, privately-held BioVex released positive results from its Phase II clinical trial of lead product OncoVEX-$^{GM-CSF}$ for melanoma. The company is also involved in Phase I/II clinical trials of its lead product for head and neck and pancreatic cancer. In the melanoma study, 50 patients with inoperable late-stage melanoma were enrolled and received OncoVEX injections every two weeks for a year. Among 43 patients currently evaluable, tumors injected with OncoVEX routinely responded, often with local complete responses or palliative benefit. Six patients showed complete clinical responses and another six patients achieved a partial response. Other patients have shown clinical benefit, including prolonged periods of stable disease as well as post treatment response after being withdrawn from the study. The FDA has approved BioVex's Phase III clinical trial design for evaluating OncoVEX in previously treated patients with metastatic melanoma. The Phase III study will begin in early 2009, with a projected biologics licensing application filing in late 2010.

MediGene
German biotech MediGene is developing oncolytic viruses based on the Herpes Simplex virus (HSV), genetically modified for the selective destruction of tumor cells. MediGene is conducting two Phase I/II clinical trials and plans to spin its HSV program off as an independent company. MediGene's lead HSV technology drug candidate NV 1020 is being evaluated in clinical trials with patients suffering from advanced colorectal cancer. After concluding the Phase I part of the trial, MediGene continued at the maximum dosage level in a clinical Phase II. In October 2008, Medigene published positive results from its Phase II trial.

Wellstat Biologics

Headquartered in Gaithersburg, Maryland, privately-owned Wellstat Biologics is developing oncolytic viruses for the treatment of cancer, especially via systemic administration. Wellstat's lead agent PV701, a form of the Newcastle Disease virus, is in clinical testing using intravenous administration. A second oncolytic virus PV327 is expected to move into clinical development in the near future.

Milestones

U.S. and European patents covering CAVATAK™ technologies were awarded in 2008.

In the past 12 months, Viralytics has improved the protection of its intellectual property, advanced its research and clinical trials, secured new funding and restructured and expanded its Management team and Board of Directors.

Intellectual Property

Viralytics strengthened its intellectual property position by acquiring intellectual assets previously held through an exclusive license. The Company was also awarded U.S. patents covering its Coxsackieviruses (CVA 13,15,18 and 21), including CAVATAK™, for all ICAM-positive cancers in April and was granted a European patent in October covering all Coxsackieviruses, for all ICAM-positive cancers. In addition patents have previously been granted in other countries such as Australia.

Furthermore the Company received a Notice of Allowance by the U.S patent office covering all Echoviruses used for the treatment of all cancers bearing expression of the integrin $\alpha_2\beta_1$, including the core EVATAK™ (EV1) technology. Patents covering the Echovirus intellectual property have previously been granted in Singapore and South Africa.

Viralytics is researching treatments for melanoma, multiple myeloma, prostate, breast, ovarian, brain, colorectal/gastric, and head & neck cancers.

Research and Development

The Company has expanded the range of cancers that its panel of oncolytic viruses may treat. Viralytics has generated strong animal model data in prostate/breast cancers and melanoma and has expanded its focus to include multiple myeloma, ovarian, brain, colorectal/gastric and head and neck cancers.

In addition, the Company continues to publish its findings in leading international peer reviewed journals. The most recent publication discussed the potent oncolytic effects of CVA21 and EV1 in human prostate cancer and appeared in *The Prostate* in May 2008.

Clinical Trials

The Company successfully completed its first human pilot and Phase I study and has two new Phase I clinical trials currently underway at two Australian hospitals.

The first is a Phase I dose escalation trial involving intratumoral administration of CAVATAK™ to three groups of late-stage melanoma patients. The low and medium dose groups have completed dosing and the high dose group is being recruited. The third group will receive a dose 100 times higher than the first group. Preliminary data from this trial recently presented at an Australian Cancer conference highlighted that (i) intratumoural injection of CAVATAK™ induced reductions in the volume of some injected tumors and (ii) serum bio-marker activity suggested the possible development of host-immune responses against CAVATAK™ infected melanoma cells.

The second clinical trial is a Phase I dose escalation trial involving intravenous administration of CAVATAK™ to patients with late-stage melanoma, breast and prostate cancer. The first group of two patients has completed the study and treatment of the second group is underway.

An independent Data Safety Committee reviews safety data for each group of patients. To date, there have been no significant product-related safety

concerns and approvals to proceed with higher dosing levels have been obtained at every stage of the process.

Viralytics completed a AU$3.1 million funding and reduced operating cash outflows and net losses in FY 2008.

Financing
Viralytics completed an AU$3.1 million capital raise in December 2007, consisting of a share purchase plan to existing shareholders and a share placement. The Company also raised AU$898,000 in FY 2008 through the sale of non-core assets. At June 30, 2008, Viralytics had cash of AU$2.85 million, up from AU$1.9 million in the previous fiscal year-end.

The Company reduced operational cash outflows to $3.0 million in FY 2008 from $3.3 million in FY 2007 and $5.3 million in FY 2006. Operating losses were reduced to $3.7 million this year from $4.2 million last year and $9.3 million two years ago. Expenditures relating to research, patents and clinical trials accounted for 87% of all expenditures. Net assets fell to $8.7 million in FY 2008 from $11.7 million in FY 2007 because of the net loss and writedown in the carrying value of the Company's CBio investment.

Board Restructuring
In October 2008, Viralytics announced structural changes to enhance its Board of Directors and allow the Company's executives to more fully devote their time to operating goals. These changes go into effect after the close of Viralytics annual meeting on November 18th.

Paul Hopper joins the board as its independent non-executive Chairman. With Mr. Hopper's addition, the board now has two U.S.-based independent non-executive directors, whose presence may help the Company secure international licensing deals with major pharmaceutical companies and attract new investment.

Bryan Dulhunty, the Company's current Executive Chairman and CEO becomes Viralytics' Managing Director and CEO. Current Chief Scientific Officer and Executive Director Professor Darren Shafren will step down as executive director to focus fully on the CSO role.

Investment Risks

Viralytics is likely several years away from generating product revenues.

Development-stage products not approved for commercial sale
The Company's oncolytic viruses are in research and development. Viralytics has not generated any product sales and is likely years away from product revenues. The Company's products will require significant additional research and development, including extensive pre-clinical and clinical testing and regulatory approval prior to commercial use. There are many reasons why initially promising products fail to be successfully commercialized. Clinical trials may be suspended for safety or efficacy reasons. Even if research and development efforts are successful, there is no guarantee that products will obtain regulatory approval or be manufactured in commercial quantities at reasonable costs.

Clinical trials are very expensive and time-consuming. Viralytics may seek a pharma industry partner for Phase II/III trials and an FDA filing.

Intellectual Property
The intellectual property rights on which Viralytics relies to protect the technology underlying its research and future products may not be adequate, which could enable third parties to use the Company's technology or very similar technology and thereby reduce Viralytics' ability to compete in the market. The Company's success will depend on its ability to obtain, protect and enforce patents on its technology and to protect its trade secrets. There is no guarantee that any patents Viralytics owns or licenses will afford meaningful protection for its technology and the products. Others may challenge the Company's patents or the patents of the Company's licensors. As a result, these patents could be narrowed, invalidated or rendered unenforceable. In addition, current and future patent applications on which Viralytics depends may not result in the issuance of patents in Australia, the U.S. or foreign countries.

Cost of clinical trials
Clinical trials are very costly and time-consuming, especially for larger Phase III clinical trials. The results of pre-clinical or early- stage clinical trials are not necessarily predictive of safety or efficacy, and later-stage clinical trials may fail to show desired safety and efficacy. The Company, the FDA or other regulatory authorities may suspend or terminate clinical trials at any time. There is no guarantee that adequate numbers of patients can be recruited for clinical trials. Other unforeseen developments could prevent or delay completion of clinical trials or increase the Company's costs.

Funding risk
Viralytics will likely need significant additional capital to fund its ongoing product and technology development programs. The Company may seek to obtain funding by issuing additional shares, borrowing money or entering into collaborative agreements. Issuing equity dilutes the interests of existing shareholders while debt financing sometimes contains restrictive covenants.

Dependence on third-party collaborators
To complete development and commercialize its products, the Company may pursue collaborative arrangements with pharmaceutical and biotech companies, academic institutions or other partners. Third party collaborators may be asked to assist with funding or performing clinical trials, manufacturing, regulatory approvals or product marketing. If the Company can't find a partner, Viralytics would be required to develop and commercialize its products at its own expense. Self-funding may limit the number of product candidates and strain the Company's internal resources.

Operating losses and negative cash flow

The Company expects to incur operating losses for the next several years due to the cost of its development programs, clinical trials, manufacturing activities and to a lesser extent, general and administrative expenses. There is no guarantee that the Company can successfully develop, manufacture and commercialize any products, or achieve positive cash flow or profitability.

Summary

Viralytics has a product in clinical trials, an international collaboration, a deep new product pipeline and improving prospects for international licensing agreements.

Viralytics is developing leading-edge therapies using oncolytic viruses to safely and effectively treat melanoma, breast, prostate and other cancers. The Company's lead product CAVATAK™ has demonstrated potent oncolytic effects in animal models and has shown indications that it is safe, effective at low doses and well tolerated by patients in Phase I clinical trials. The first of the two clinical trials currently underway involves direct injection of CAVATAK™ into melanoma tumors. The study is designed to progressively increase dosing across three groups of patients. The first two groups of patients have completed dosing and the third group is being recruited. The second clinical trial is an intravenous administration of CAVATAK™ to patients with late-stage melanoma, breast and prostate cancer. Intravenous delivery may allow CAVATAK™ to travel through the body to attack both primary and remote tumors. This trial also progressively increases dosing, monitoring patients for their tolerance to CAVATAK™. The second group has commenced multiple intravenous dosing.

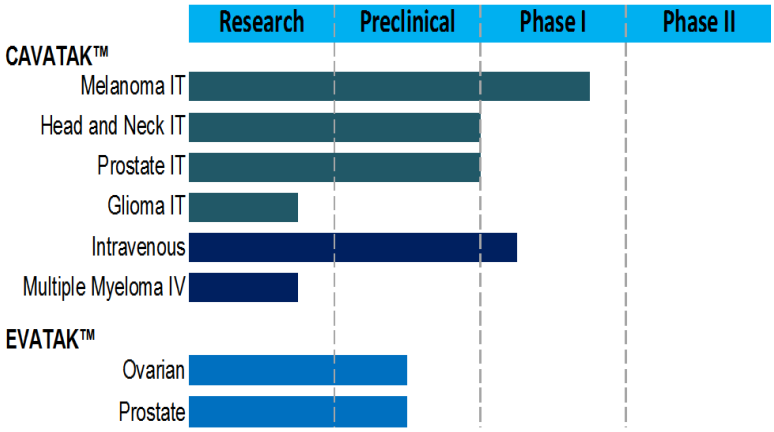
Cancer treatment is a multi-billion dollar worldwide market. The disease is the second highest cause of death after cardiovascular disease worldwide and the incidence of cancer is increasing despite advances in early diagnosis, chemotherapy and surgery. More than 12.5 million new cancer cases are diagnosed worldwide each year and initial treatment costs in the U.S. alone exceed $6.7 billion. There is an urgent need for new cancer therapies that are safe, effective and ensure a good quality of life for patients.

CAVATAK™ provides a breakthrough technology for cancer treatment. Viralytics has identified benign viruses that preferentially target cancer cells over normal tissue. The Company's targeted therapy may offer a powerful technique for fighting cancer, particularly in late-stage disease where tumors have begun to metastasize. The Company's naturally occurring viruses demonstrate indications of anti-cancer activity without toxic chemotherapy or invasive surgery, thereby improving quality of life for patients.

During 2008, Viralytics advanced its clinical program through two Phase I trials and expanded the range of cancers addressed by its technology to include multiple myeloma, ovarian, brain, colorectal/gastric and head and neck cancers. The Company has secured U.S. and European patents protecting its technology, has additional patent applications pending, and was awarded FDA orphan drug status for CAVATAK™ as a treatment for late-stage melanoma. Orphan drug status may result in expedited FDA review, accelerated time to market and market exclusivity for CAVATAK™ for a seven-year period. In addition, the Company received a Notice of Allowance by the U.S patent office on its core EVATAK™ technology.

In preparation for Phase II CAVATAK™ trials, the Company is reviewing its toxicology results with the U.S. FDA and seeking their input for the design of upcoming studies. By laying the groundwork for a future FDA submission now, Viralytics accelerates its progress towards commercialization and enhances shareholder value. The Company has also commissioned a U.S. specialist manufacturer to commence design and scale-up of CAVATAK™ production at their GMP facility. In addition to advancing CAVATAK™ clinical development, Viralytics is gathering evidence supporting the oncolytic action of its next product EVATAK™.

EVATAK™ targets cancer cells with a different surface molecule than CAVATAK™ and may thus offer an alternative strategy and potential treatment for different cancer types. Initial EVATAK™ research has focused on ovarian and prostate cancer models.



The Company's research team is led by Dr. Darren Shafren, Associate Professor of Virology in the Faculty of Health, University of Newcastle. Through its relationship with the University of Newcastle, Viralytics gains access to leading edge research facilities and infrastructure that would cost millions of dollars to replicate. The Company's research team consists of up to 12 scientists.

Viralytics has demonstrated the ability to advance its products and clinical programs while spending much less than competitors. During FY 2008, the Company raised AU$3.1 million to support its ongoing research program, progressed two Phase I clinical trials of CAVATAK™ and reduced cash outflows to only AU$3.0 million. In contrast, many of the Company's competitors are spending millions of dollars each month to achieve the same level of progress. Viralytics' focus on the bottom line increases the likelihood that its development efforts will culminate in marketable products and makes the Company more attractive to potential partners and investors.

The Company also strengthened its Board of Directors by adding two independent U.S.-based non-executive directors whose broad-based pharmaceutical industry experience and extensive network of contacts may assist Viralytics in securing international licensing agreements for its technology. To assist in this process, the Company appointed a representative experienced in international partnering, licensing, collaborations and mergers and acquisitions as its Business Development Representative in October 2008

Viralytics additional appeal as a biotechnology investment include international recognition of its technology through prominent peer reviewed journals, a broad new product pipeline, an international collaboration with a leading brain cancer expert and a skilled Management team and Board of Directors. In addition, the Company's equity investments in other healthcare companies help diversify its intellectual property portfolio and create an additional source of income.

Publications

Melanoma

Au, G.G., Lindberg, A.M., Barry, R.D., Shafren, D.R., 2005. Oncolysis of vascular malignant human melanoma tumors by Coxsackie A21. *Int. J. Oncol. 6, 1471-1476*

Shafren, D.R., Au, G.G., Nguyen, T., Newcombe, N.G., haley, E.S., Beagley, L., Johansson, E.S., Hersey, P., Barry, R.D., 2004. Therapy of malignant human melanoma tumors by a common cold producing enterovirus, Coxsackievirus A21. *Clin. Can. Res. 10, 53-60*

Breast Cancer

Skelding, K.A., Barry, R.D., Shafren, D.R., 2008. Systemic targeting of metastatic human breast tumor xenografts by Coxsackievirus A21. *Breast Cancer Res Treat. [Epud ahead of print]*

Prostate Cancer

Berry, L.J., Au, G.G., Barry, R.D., Shafren, D.R., 2008. Potent oncolytic activity of human enteroviruses against human prostate cancer. *Prostate 68(6), 577-587*

Ovarian Cancer

Shafren, D.R., Sylvester, D., Johansson, E.S., Campbell, I.G., Barry, R.D., 2005. Oncolysis of human ovarian cancers by Echovirus Type 1. *Int. J. Cancer 115, 320-328*

Multiple Melanoma

Au, G.G., Lincz, L.F., Enno, A., Shafren, D.R., 2007. Oncolytic Coxsackievirus A21 as a novel therapy for multiple myeloma. *Br J. Hematology, 137(2) 133-141.*

Income Statement

For the Fiscal Period Ending *Currency*	Restated 12 months Jun-30-2005 *AUD*	Reclassified 12 months Jun-30-2006 *AUD*	12 months Jun-30-2007 *AUD*	12 months Jun-30-2008 *AUD*
Revenue	0.419	-	-	-
Other Revenue	0.164	0.027	0.359	-
Total Revenue	**0.583**	**0.027**	**0.359**	-
Cost Of Goods Sold	0.224	0.245	0.348	0.306
Gross Profit	**0.359**	**(0.218)**	**0.011**	**(0.306)**
Selling General & Admin Exp.	2.469	2.856	1.523	1.364
Stock-Based Compensation	1.058	0.046	-	-
R & D Exp.	1.816	2.408	1.85	1.838
Depreciation & Amort.	0.11	0.171	0.158	0.139
Amort. of Goodwill and Intangibles	1.68	2.29	0.304	0.382
Other Operating Expense/(Income)	-	-	-	-
Other Operating Exp., Total	**7.133**	**7.771**	**3.835**	**3.723**
Operating Income	**(6.774)**	**(7.989)**	**(3.824)**	**(4.029)**
Interest Expense	-	(0.012)	(0.005)	(0.007)
Interest and Invest. Income	0.119	0.043	0.163	0.154
Net Interest Exp.	**0.119**	**0.031**	**0.158**	**0.147**
Income/(Loss) from Affiliates	(0.64)	(1.314)	(0.225)	-
Other Non-Operating Inc. (Exp.)	-	-	-	-
EBT Excl. Unusual Items	**(7.294)**	**(9.272)**	**(3.892)**	**(3.882)**
Impairment of Goodwill	-	-	-	-
Gain (Loss) On Sale Of Invest.	(0.704)	-	(0.304)	0.201
Other Unusual Items	-	-	-	-
EBT Incl. Unusual Items	**(7.999)**	**(9.272)**	**(4.196)**	**(3.681)**
Income Tax Expense	-	-	-	-
Minority Int. in Earnings	1.044	-	-	-
Earnings from Cont. Ops.	**(6.955)**	**(9.272)**	**(4.196)**	**(3.681)**
Earnings of Discontinued Ops.	-	-	-	-
Extraord. Item & Account. Change	-	-	-	-
Net Income	**(6.955)**	**(9.272)**	**(4.196)**	**(3.681)**
Pref. Dividends and Other Adj.	-	-	-	-
NI to Common Incl Extra Items	**(6.955)**	**(9.272)**	**(4.196)**	**(3.681)**
NI to Common Excl. Extra Items	**(6.955)**	**(9.272)**	**(4.196)**	**(3.681)**
Per Share Items				
Basic EPS	(0.057)	(0.06)	(0.018)	(0.014)
Basic EPS Excl. Extra Items	(0.057)	(0.06)	(0.018)	(0.014)
Weighted Avg. Basic Shares Out.	122.673	155.828	228.539	260.546
Diluted EPS	(0.057)	(0.06)	(0.018)	(0.014)
Diluted EPS Excl. Extra Items	(0.057)	(0.06)	(0.018)	(0.014)
Weighted Avg. Diluted Shares Out.	122.673	155.828	228.539	260.546
Normalized Basic EPS	(0.037)	(0.037)	(0.011)	(0.009)
Normalized Diluted EPS	(0.037)	(0.037)	(0.011)	(0.009)
Dividends per Share	NA	NA	NA	NA
Common Shares per ADR	30.0	30.0	30.0	30.0
Supplemental Items				
EBITDA	(4.984)	(5.529)	(3.363)	(3.507)
EBITA	(5.094)	(5.699)	(3.521)	(3.647)
EBIT	(6.774)	(7.989)	(3.824)	(4.029)
EBITDAR	(4.902)	NA	NA	NA
As Reported Total Revenue*	0.703	0.07	0.522	0.355
Effective Tax Rate %	NA	NA	NA	NA
Normalized Net Income	(4.559)	(5.795)	(2.432)	(2.427)
Filing Date	Oct-23-2006	Oct-29-2007	Sep-04-2008	Sep-04-2008
Restatement Type	RSA	RCA	NC	O
Calculation Type	REP	REP	REP	REP
Supplemental Operating Expense Items				
General and Administrative Exp.	1.156	1.19	1.004	0.602
R&D Exp.	1.816	2.408	1.85	1.838
Net Rental Exp.	0.082	NA	NA	NA
Stock-Based Comp., Unallocated	1.058	0.046	-	-
Stock-Based Comp., Total	**1.058**	**0.046**	-	-

Balance Sheet

Balance Sheet as of: *Currency*	Restated Jun-30-2005 *AUD*	Jun-30-2006 *AUD*	Jun-30-2007 *AUD*	Jun-30-2008 *AUD*
ASSETS				
Cash And Equivalents	1.408	3.357	1.881	2.847
Total Cash & ST Investments	**1.408**	**3.357**	**1.881**	**2.847**
Accounts Receivable	0.001	-	-	-
Other Receivables	0.447	0.325	0.421	0.062
Total Receivables	**0.448**	**0.325**	**0.421**	**0.062**
Inventory	-	-	-	-
Prepaid Exp.	-	0.184	0.146	0.07
Other Current Assets	-	-	-	-
Total Current Assets	**1.856**	**3.866**	**2.448**	**2.979**
Gross Property, Plant & Equipment	0.755	0.824	0.837	0.845
Accumulated Depreciation	(0.09)	(0.259)	(0.395)	(0.532)
Net Property, Plant & Equipment	**0.665**	**0.566**	**0.441**	**0.313**
Long-term Investments	3.658	4.749	4.296	1.2
Other Intangibles	2.902	3.146	5.05	4.667
Other Long-Term Assets	0.056	0.056	0.017	0.017
Total Assets	**9.136**	**12.383**	**12.252**	**9.176**
LIABILITIES				
Accounts Payable	0.143	2.381	0.277	0.178
Accrued Exp.	0.023	-	-	-
Other Current Liabilities	0.267	0.469	0.279	0.303
Total Current Liabilities	**0.433**	**2.849**	**0.556**	**0.482**
Minority Interest	-	-	-	-
Other Non-Current Liabilities	-	-	-	-
Total Liabilities	**0.433**	**2.849**	**0.556**	**0.482**
Common Stock	25.904	33.56	39.918	42.998
Additional Paid In Capital	-	-	-	-
Retained Earnings	(18.258)	(27.531)	(31.726)	(35.407)
Treasury Stock	-	-	-	-
Comprehensive Inc. and Other	1.058	3.504	3.504	1.104
Total Common Equity	**8.703**	**9.533**	**11.696**	**8.694**
Total Equity	**8.703**	**9.533**	**11.696**	**8.694**
Total Liabilities And Equity	**9.136**	**12.383**	**12.252**	**9.176**
Supplemental Items				
Total Shares Out. on Filing Date	143.24	194.436	240.847	281.222
Total Shares Out. on Balance Sheet Date	143.24	194.436	240.847	281.222
Book Value/Share	0.06	0.05	0.05	0.03
Tangible Book Value	5.801	6.387	6.646	4.027
TangBV/Share	0.04	0.03	0.03	0.01
Total Debt	0	0	0	0
Net Debt	(1.408)	(3.357)	(1.881)	(2.847)
Debt Equivalent Oper. Leases	0.659	NA	NA	NA
Total Minority Interest	NA	NA	NA	NA
Equity Method Investments	2.458	1.149	NA	NA
Inventory Method	NA	NA	NA	NA
Machinery	0.755	0.824	0.837	0.845
Full Time Employees	NA	6	NA	NA
Part-Time Employees	NA	2	NA	NA
Filing Date	Oct-23-2006	Oct-29-2007	Sep-04-2008	Sep-04-2008

Cash Flow

For the Fiscal Period Ending *Currency*	Restated 12 months Jun-30-2005 *AUD*	12 months Jun-30-2006 *AUD*	12 months Jun-30-2007 *AUD*	12 months Jun-30-2008 *AUD*
Net Income	**(7.999)**	**(9.272)**	**(4.196)**	**(3.681)**
Depreciation & Amort.	0.11	0.171	0.158	0.139
Amort. of Goodwill and Intangibles	1.68	2.29	0.304	0.382
Depreciation & Amort., Total	**1.79**	**2.461**	**0.462**	**0.522**
(Gain) Loss From Sale Of Assets	-	0.005	0.009	0.007
(Gain) Loss On Sale Of Invest.	0.704	-	0.302	(0.201)
(Income) Loss on Equity Invest.	0.64	1.314	0.225	-
Stock-Based Compensation	1.058	0.046	-	-
Other Operating Activities	-	0.021	-	-
Change in Acc. Receivable	0.037	(0.061)	(0.132)	0.359
Change In Inventories	0.225	-	-	-
Change in Acc. Payable	(0.083)	0.149	(0.084)	(0.074)
Change in Other Net Operating Assets	(0.216)	-	0.074	0.076
Cash from Ops.	**(3.844)**	**(5.339)**	**(3.34)**	**(2.993)**
Capital Expenditure	(0.64)	(0.076)	(0.044)	(0.018)
Sale of Property, Plant, and Equipment	-	-	0.001	-
Cash Acquisitions	-	-	-	-
Divestitures	(1.271)	-	-	-
Sale (Purchase) of Intangible assets	(3.06)	-	(2.0)	-
Invest. in Marketable & Equity Securt.	(0.844)	(0.005)	(0.075)	0.898
Net (Inc.) Dec. in Loans Originated/Sold	-	-	-	-
Other Investing Activities	(0.056)	0.017	0.04	-
Cash from Investing	**(5.871)**	**(0.064)**	**(2.078)**	**0.88**
Short Term Debt Issued	-	-	-	-
Long-Term Debt Issued	-	0.55	-	-
Total Debt Issued	-	**0.55**	-	-
Short Term Debt Repaid	-	-	-	-
Long-Term Debt Repaid	-	-	-	-
Total Debt Repaid	-	-	-	-
Issuance of Common Stock	9.48	6.957	4.461	3.23
Total Dividends Paid	-	-	-	-
Special Dividend Paid	-	-	-	-
Other Financing Activities	(0.394)	(0.154)	(0.519)	(0.15)
Cash from Financing	**9.086**	**7.353**	**3.942**	**3.08**
Net Change in Cash	**(0.63)**	**1.949**	**(1.476)**	**0.966**
Supplemental Items				
Cash Interest Paid	NA	NA	NA	NA
Cash Taxes Paid	NA	NA	NA	NA
Levered Free Cash Flow	(5.542)	(0.261)	(6.327)	(1.658)
Unlevered Free Cash Flow	(5.542)	(0.254)	(6.324)	(1.654)
Change in Net Working Capital	(0.602)	(2.355)	2.351	(0.36)
Net Debt Issued	NA	0.55	NA	NA
Filing Date	Oct-23-2006	Oct-29-2007	Sep-04-2008	Sep-04-2008

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