

SECURITIES AND EXCHANGE COMMISSION

FORM SUPPL

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20 August 2008



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Division of Corporate Finance
Office of International Corporation Finance
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SIES
Mail Processing
Section

AUG 29 2008

Washington, DC
103

Attention: Mr. Elliot Staffin

Re: *Osiron*
~~Viralytics Limited~~
12g3-2(b) Information
File No. 82-34945

SUPPL

Dear Mr. Staffin

Enclosed please find information that Viralytics Limited is required to furnish to the Securities and Exchange Commission pursuant to Rule 12g3-2(b) of the Securities Exchange Act of 1934, as amended.

The attached documents are being furnished with the understanding that:

- they will not be deemed "filed" with the Securities and Exchange Commission or otherwise subject to the liabilities of Section 18 of the Securities Exchange Act; and
- neither this letter nor the furnishing of such documents shall constitute an admission for any purpose that Viralytics Limited is subject to the Securities Exchange Act.

If you have any questions or comments, please call the undersigned on telephone 61 2 9499 3200.

Bryan Dulhunty
Executive Chairman

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ASX Release

Date: 20 August 2008

Subject: Phase I clinical trial of CAVATAK™ in Melanoma patients - Completion of the second patient group and approval to commence administration to the last group of patients.

Viralytics is pleased to announce the successful completion of administration of CAVATAK™ to the second group of patients in its Phase I clinical trial in late stage Melanoma. The company has also received approval from the Drug Safety Monitoring Committee (DSMC) to commence escalated dose administration of CAVATAK™ to the three patients of the final group in the trial.

This third and final group of patients will receive a 10 - fold higher dose (2×10^9 TCID₅₀) than the second group and 100 - fold higher than the first group of patients.

The company has now administered CAVATAK™ to a total of 13 patients in all trials to date.

Administration of CAVATAK™ to the first two groups of patients in this study has determined that:

1. There were no severe adverse events considered to be related to the study medication or causing withdrawal from the study.
2. Two injections of CAVATAK™ at a combined dose up to 2×10^8 TCID₅₀ into one subcutaneous lesion in patients with Stage IV metastatic Melanoma appears to be well tolerated.
3. Virus can be detected in some patients up to 5 weeks post injection potentially indicating viral replication.

The primary objective of this Phase I clinical trial is to determine safety. Secondary endpoints indicating early stage therapeutic activity will be determined through the assessment of tumour size and signs of viral replication.

To date, all of the Melanoma patients treated appear to have tolerated either a single or multiple intratumoural injections of CAVATAK™ up to a combined dose of 2×10^8 TCID₅₀.

Viralytics has a second trial currently underway that recently completed intravenous dosing of two Prostate patients. This completes the first group in the Intravenous Phase I trial of Prostate, Breast and Melanoma patients and will subsequently commence administration to the second group in the trial.

“Clinicians are encouraged by the results and progress of our trials. We are seeing this reflected in acceleration of patient recruitment and interest in designing new studies to test CAVATAK™ in other cancer types” said Phillip Altman, Director of Clinical Development.

While these preliminary findings are encouraging, it is still too early to draw conclusions regarding the clinical efficacy of CAVATAK™ at this stage.

Phillip Altman
Director of Clinical Development and Regulatory Affairs

About the Trial - Phase I, open label study of CAVATAK™ given intratumourally in Stage IV Melanoma

The primary aim of the study is to determine the safety of CAVATAK™.

The secondary objectives include:

1. Evaluating the clinical activity of CAVATAK™ on injected nodules and
2. Evaluating the action of CAVATAK™ on non-injected tumours.

The study will include 9 patients (3 cohorts each of 3 patients). Patients will be injected intratumourally with two doses of CAVATAK™ 48 hours apart. The first cohort will receive the same dose as received by patients in Viralytics' first 3 patient Phase I Melanoma trial completed in June 2006. The second and third cohorts will receive increasingly higher doses of CAVATAK™. Dosing levels will be; Cohort 1: 2×10^7 TCID₅₀, Cohort 2: 2×10^8 TCID₅₀ and Cohort 3: 2×10^9 TCID₅₀.

About Viralytics Ltd.

Viralytics is listed on the Australian Stock Exchange (ASX code: VLA), Viralytics ADR trades under VRACY on the OTC market in the USA. Viralytics' principal asset is the intellectual property relating to CAVATAK™, an Oncolytic Virus technology. CAVATAK™ is the trade name for Viralytics' proprietary formulation of the Coxsackievirus Type A21 (CVA21). CVA21 is a human virus that occurs naturally in the community. CVA21 attaches to the outside of a cell, using a specific 'receptor' on the cell's surface (like a key fitting a lock). CVA21 uses two receptors to infect cells, intercellular adhesion molecule-1 (ICAM-1) and/or decay accelerating factor (DAF). Both of these receptor proteins have been demonstrated to be highly expressed on multiple cancer types, including: melanoma, prostate cancer, breast cancer, multiple myeloma and others.

Dear Shareholder,

Since our newsletter in December 2007, we have continued to advance the clinical development of CAVATAK™ while preparing the Phase II clinical program of our lead product.

Recent Achievements

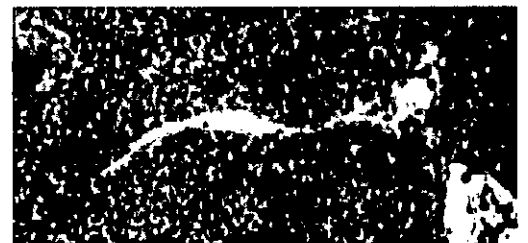
2008 has seen strong progress of the company's clinical program and the rapid construction of key components of the business necessary for international recognition of our product development. Key achievements in the first half of this year include:

- Raising the total number of patients dosed with CAVATAK™ to 13 patients to date providing valuable human data.
- Completion of the second of three groups of patients in our Phase I intratumoural trial (Melanoma) of CAVATAK™. We are now recruiting patients for our last group in this trial at a dose 100 times higher than the first dose.
- Completion of the first group of patients in our Phase I intravenous trial (Melanoma, Prostate and Breast cancer). We have received approval for treatment of the next group with multiple injections of CAVATAK™ and are currently recruiting patients.
- Granting of the company's core patent in the US and Notice of Allowance of the patent in Europe securing the company's intellectual property.
- Strengthening of the management team with Stephen Goodall joining to consolidate the business planning and management activities and lead the manufacturing scale up and non-clinical projects.
- Commissioned a US specialist manufacturer to commence design and scale up of CAVATAK™ production in their FDA approved facilities to service future clinical requirements.
- Held discussions with the US Food and Drug Administration (FDA) to review the company's toxicology results and future studies providing guidance to the non-clinical program.

The Need For Better Cancer Treatments

Cancer is the leading cause of death in the United States, and the number of people dying from cancer is increasing. The need for better cancer treatments is therefore a major public health concern. Current cancer treatments, such as chemotherapy and radiation therapy, often have significant side effects and are not always effective. There is a need for new, more targeted and effective cancer treatments. CAVATAK™ is a novel, targeted cancer treatment that is designed to target and destroy cancer cells. It is a virus-like particle (VLP) that is engineered to target and destroy cancer cells. CAVATAK™ is a novel, targeted cancer treatment that is designed to target and destroy cancer cells. It is a virus-like particle (VLP) that is engineered to target and destroy cancer cells.

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400 x photomicrograph of a Melanoma tumour biopsy. The tumour cells (blue) produce the ICAM-1 molecule (brown) used by CAVATAK™ to target, infect and destroy the cancer cells.

Clinical Development

We have now administered CAVATAK™ to 13 patients in our clinical programs and our two current trials are being conducted in two independent hospitals. The company's first pilot studies completed in 2006 treated 5 melanoma patients with a single intratumoural dose of CAVATAK™. The treatment was well tolerated and led the direction for new dose escalation studies that have been successfully progressed in the last six months.

Melanoma - Intratumoural Treatment

Direct injection of CAVATAK™ into tumours lets us assess the performance of the virus without its dilution around the rest of the patient's body. In late stage Melanoma, surface tumours are easily accessed by the doctor to see the injection site and monitor the tumour after treatment.

Our current study is designed to progressively increase the dose with each new group of patients, starting with 2 doses $\times 10^7$ TCID₅₀ and rising 100 fold to 2 doses $\times 10^9$ TCID₅₀. Patients in the study have stage IV melanoma, an aggressive stage of the disease which has not responded to all other treatments.

We have now finished the first two groups of patients, each with three patients. After treating the first six patients in the study we have:

- Reached an intratumoural dose of 2 doses $\times 10^9$ TCID₅₀
- Observed no drug related serious adverse events
- Noted that the treatment was well tolerated by all patients
- Been able to measure the presence of virus up to 4-5 weeks post-injection in some patient samples
- Obtained approval to treat the final group of patients at the highest dose in the trial

Prostate, Breast & Melanoma - Intravenous Treatment

When a cancer metastasizes, cells start to migrate around the patient's body and start new tumours in remote locations such as lymph nodes and vital organs. Intravenous delivery of CAVATAK™ will allow the virus to travel throughout the patient and attack these remote tumours.

Our Phase I intravenous trial progressively increases the dose, and number of doses to patients with late stage cancer and monitor patients for their tolerance to CAVATAK™.

This is the first time anyone has ever injected the CAVATAK™ virus intravenously. After treating the first group of two patients we have:

- Administered an intravenous dose of 10^6 TCID₅₀
- Observed no drug related serious adverse events
- Noted that the treatment was well tolerated by both patients
- Obtained approval to treat the second group with two doses of CAVATAK™

The Development Process

Phase II Preparations

In June this year, Viralytics moved to have its development program come under the oversight of the FDA. The FDA can contribute significantly to the efficient development of novel therapies, such as viruses, and so maximize the value of the product when entering licensing negotiations. Steps taken this year to enhance the quality of our program include:

- Engaging the specialist advice of two world leading toxicologists
- Conducting reviews of the existing and planned toxicology studies in meetings with the FDA
- Contracting a US specialist manufacturer to scale up and produce CAVATAK™ suitable for FDA approved Phase II clinical trials.

Pipeline	RESEARCH	PRECLINICAL	PHASE I	PHASE II
CAVATAK™ Melanoma IT				
CAVATAK™ Melanoma IV				
CAVATAK™ Breast IV				
CAVATAK™ Prostate IV				
CAVATAK™ Glioma				
CAVATAK™ Multiple Myeloma				
EVATAK™ Ovarian				
EVATAK™ Prostate				
GVA 08				
GVA 09				
GVA 13				

Research & Development

Our Research team at the University of Newcastle have continued to advance the knowledge and science of our oncolytic virus products over the past 6 months. In addition to the progress described below, the team have continued to prepare virus for the clinical studies and performed a range of patient testing services in support of the trials.

Intellectual Property

The Viralytics IP was reinforced in April this year when our core patent protecting our panel of Coxsackieviruses was granted in the US. This broad cover patent covers not only CAVATAK™ but three other viruses and secures the value of our program development. We also received Notice of Allowance for this patent from the European Patent office.

Publications

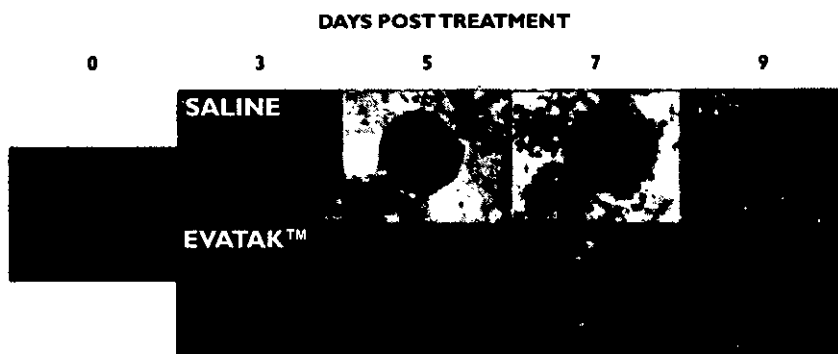
Publication of research by our staff at Uni of Newcastle in the article "Systemic targeting of metastatic human breast tumor xenografts by Coxsackievirus A21" in February highlights the pre-clinical effectiveness of our virus in attacking the most prevalent cancer in women.

Our publication "Potent Oncolytic activity of human enteroviruses against human prostate cancer" was published in February to describe the pre-clinical anti-cancer activity of CAVATAK™, EVATAK™ and CVA21-DAFv against laboratory cultures of prostate cancer cells and prostate tumours in mice. This information shows the breadth of the VLA pipeline.

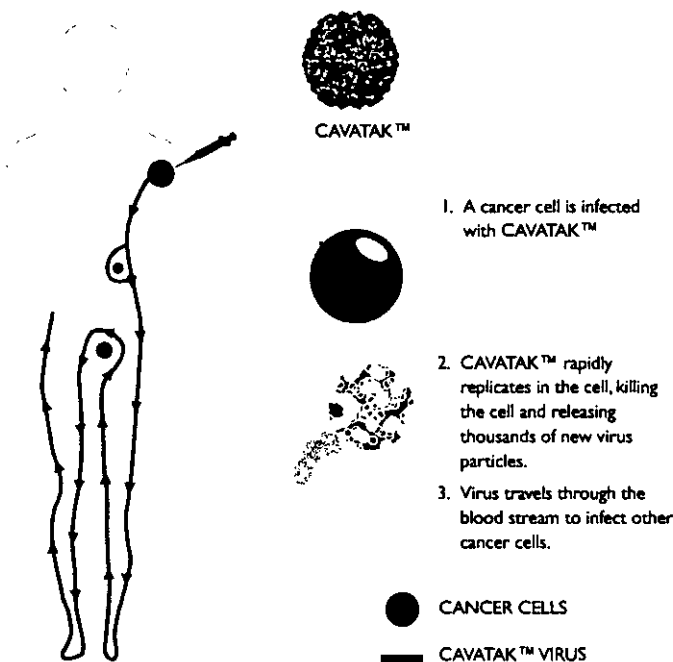
Scientific Advisors

Our Scientific Advisory Board held their regular scientific review in March to provide direction and comment to the scientists and company directors. Our scientists gave presentations of their work covering all their new results in the laboratory and clinical trials. The rigorous interrogation by the SAB (consisting of Professor Chris Burrell, Professor Eric Gowans and Professor Ian Campbell) ensured details of the work was thoroughly challenged. The SAB praised the scientists for the clarity of their work and rigor of their science. Suggestions and directions of the SAB have been integrated within the research program.

Research Directions: EVATAK™



Three dimensional culture of ovarian cancer cells (shown in purple and blue), challenged with either Saline control or EVATAK™ showing the complete destruction of the tumour mass within nine days.



Direct intratumoural injection of CAVATAK™ results in infection and destruction of tumour cells releasing progeny virus into the patient blood stream to target other tumours within the patient's body.

Company Management

Viralytics has assembled a core management team of experienced professionals to manage each of the key areas of the business.

The Viralytics Team

(from left to right)

Roberta Karpathy PhD

Operations Director

Coordinating the production and clinical testing programs in Newcastle.

Stephen Goodall MSc,MBA

Chief Operating Officer

Coordinating the business and project plans and responsible for manufacturing and non-clinical studies.

Bryan Dulhunty CA

Chairman and CEO

Leading the company's direction and management team while taking direct responsibility for finance, governance and shareholder relations.

Darren Shafren PhD

Chief Scientific Officer

Leading the research team in Newcastle and responsible for science and intellectual property.

Phillip Altman PhD

Director of Clinical Development and Regulatory Affairs

Developing and coordinating the clinical program and responsible for regulatory affairs and clinical trials.



More with Less

Viralytics is managed by a small team of experienced professionals. We take pride in maintaining a lean and efficient operation. This keeps overheads low and allows for effective decision making and the ability to adapt quickly to exploit opportunities and accelerate the company's progress.

At year end we record an unaudited cash balance of \$2.65 million, which is adequate to handle our short term program. Since the change in management in 2006, we have reduced the company's annual cash outflow by approximately 65%, from \$5.3m in 2006 to a current projected level of \$3 million. At the same time we have accelerated preclinical and clinical programs. We expect significant data from our Phase I program within the next 6 months.

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