Oncolytic Immunotherapies for Difficult-to-Treat Cancers
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Positioned for Growth

- Lead product CAVATAK™ with demonstrated potential in a range of indications and treatment settings
- Opportunity for use as monotherapy or in combination with new ‘blockbuster’ agents
- Transformational $27M capital raise in 2014 from international healthcare institutions
- Resources to conduct key global clinical trials
- Corporate strategy to license, partner or sell at key value point

**CALM:**
Success in Phase 2 melanoma clinical trial (US)

**STORM:**
Initiated Phase 1/2 in solid tumour cancers (UK)

**Next Phase 2 melanoma trial:**
Late Planning Stage
# Strong Financial Foundation

<table>
<thead>
<tr>
<th>Key Statistics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ticker Code</td>
</tr>
<tr>
<td>ASX: VLA OTCQX: VRACY</td>
</tr>
<tr>
<td>Share Price (October 15)</td>
</tr>
<tr>
<td>A$0.28</td>
</tr>
<tr>
<td>Market Capitalisation</td>
</tr>
<tr>
<td>A$51.5M</td>
</tr>
<tr>
<td>Trading Range (12 month)</td>
</tr>
<tr>
<td>A$ 0.26-0.37</td>
</tr>
<tr>
<td>Institutional investors</td>
</tr>
<tr>
<td>45%</td>
</tr>
<tr>
<td>Cash position (June 30, 2014)</td>
</tr>
<tr>
<td>A$24.3M</td>
</tr>
<tr>
<td>Net operating cashburn 2013/14</td>
</tr>
<tr>
<td>A$5.5M</td>
</tr>
</tbody>
</table>

- Strong institutional register
- Leading specialist healthcare institutional investors

![Pie chart showing distribution of funds](image.png)
Cancer Immunotherapy: Emerging, High-Value Therapeutic Platform

• Rapidly emerging field, transforming cancer therapy

• Value highlighted by Amgen acquisition of Biovex (TVec™) in 2011
  – US $425 million cash upfront
  – US $575 million future milestone payments

• Multiple recent commercial transactions and collaborations

• Roche, GSK, Astra Zeneca, BMS, Merck all active in this field

• Cancer immunotherapy annual revenues could exceed US $35 billion by 2023*

Opportunities for CAVATAK™ in multiple settings including combination with new agents

Leerink Swann
October 2013 review:
“50% of all cancer treatment could involve immunotherapy within the next decade.”

‘Science’ Magazine
Cancer immunotherapy – Breakthrough of the Year 2013

* Citigroup report 2013
CAVATAK™
Lead Product, Many Potential Indications

- Proprietary formulation of Coxsackievirus A 21
- Targeted to specific receptor overexpressed on cancer cells (ICAM-1)
- Kills local and metastatic cells by both oncolytic and immunotherapeutic activity
- Potential application across a range of cancer types:
  - Intratumoural – melanoma
  - Intravenous – melanoma, prostate, lung, metastatic bladder
  - Intravesical – non-muscle invasive bladder cancer
- Well tolerated in patients - no treatment-related grade 3 or 4 adverse events
- Potential as monotherapy or with other agents
- Manufactured under cGMP at SAFC, California
CAVATAK™ Local and Systemic Activity

1. **Oncolytic lysis** and death of cancer cell
   - CAVATAK™ released from tumour (repeats)
   - CAVATAK™ binds externally to tumour cells
   - infects
   - replicates and destroys

2. **Viral induced tumor inflammation**

3. **Stimulation of host-immune response** against cancer cells
Melanoma – First Target for CAVATAK™

- Melanoma - potentially fatal malignant skin tumour that can spread throughout the body
- Ranked 5th in US for new cases per annum
- Promising new agents approved BUT sub-optimal activity, drug resistance and toxicity remain issues
- Big pharma race to find complementary agents
- Unmet need for well tolerated agents as monotherapy for earlier stage disease

Opportunities for effective, well tolerated products with potential monotherapy or combination use

STRONG OPPORTUNITIES FOR BRANDED PRODUCTS:

- **BMS Yervoy™**
  - 2011 launch – $960M sales in 2013

- **Roche Zelboraf™**
  - 2011 launch – $400M sales in 2013

- **Merck Keytruda™**
  - US launch September 2014
  - forecast sales of $6Bn by 2025#

* Leerink Swann 2014
CLINICAL TRIAL PROGRESS

CALM Phase 2 Melanoma Study

STORM Phase 1/2 Study
CAVATAK™ – Phase 2 CALM Melanoma Study
(CAVATAK IN LATE STAGE MELANOMA)

54 evaluable Stage IIC and IV melanoma patients
at least 1 injectable lesion

10 series of multi-intratumoral CAVATAK™ injections
(up to $3 \times 10^8$ TCID$_{50}$)
Day 1,3,5,8,22,43,64,85,106,127

YES
Day 169 (w24) irPFS

NO

Eligible for Extension study
9 series of multi-intratumoral CAVATAK™ injections
(up to $3 \times 10^8$ TCID$_{50}$)
q21 days

NO

6 Weeks later, confirm Disease progression

YES

Observation only

- 11 leading US cancer centres. Also participated in Amgen
  / Biovex studies
- Primary endpoint achieved in first 30 evaluable patients
- Responses in injected and metastatic (non injected) tumours
- Well tolerated
- Results presented to global conferences
**CAVATAK™ / Biovex OncoVex™ results**

<table>
<thead>
<tr>
<th></th>
<th>Viralytics CAVATAK™ Phase 2 CALM Melanoma Interim Data *</th>
<th>Biovex OncoVex™ Phase 2 Melanoma Final Data ^</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Number of patients</strong></td>
<td>57</td>
<td>50</td>
</tr>
<tr>
<td><strong>Stage of Disease</strong></td>
<td>IIIC-IV</td>
<td>IIIC-IV</td>
</tr>
<tr>
<td><strong>ir Progression-Free Survival - 6 months</strong></td>
<td>39% (22/57)</td>
<td>Not reported</td>
</tr>
<tr>
<td><strong>ir Progression-Free Survival - 3 months</strong></td>
<td>50%#</td>
<td>50% ^^</td>
</tr>
<tr>
<td><strong>One-year survival rate</strong></td>
<td>73% (33/45)</td>
<td>58%</td>
</tr>
<tr>
<td><strong>Overall Response Rate</strong></td>
<td>28% (16/57)</td>
<td>26% (13/50)</td>
</tr>
<tr>
<td><strong>Median Time to Response (TTR) Onset</strong></td>
<td>2.8 months</td>
<td>Not reported **</td>
</tr>
<tr>
<td><strong>Activity in injected and non injected lesions</strong></td>
<td>☑</td>
<td>☑</td>
</tr>
<tr>
<td><strong>No grade 3 or 4 drug-related adverse events</strong></td>
<td>☑</td>
<td>☑</td>
</tr>
<tr>
<td><strong>Met primary endpoint prior to full enrolment</strong></td>
<td>☑</td>
<td>☑</td>
</tr>
</tbody>
</table>

* Interim data lodged with ASX and Investigator assessed (refer ASX announcement for full details)


# 50% irPFS when assessed in 38 patients in November 2013

**Median TTR reported at 4.1 months in Phase 3 trial ESMO 2013
CAVATAK™ — Well Tolerated in Clinical Testing

CAVATAK-related adverse events+

<table>
<thead>
<tr>
<th>AE Term</th>
<th>*Grade 1 n(%)</th>
<th>Grade 2 n(%)</th>
<th>Grade 3 n(%)</th>
<th>Grade 4 n(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injection site pain</td>
<td>16 (35%)</td>
<td>2 (4%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tiredness (fatigue)</td>
<td>15 (33%)</td>
<td>2 (4%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chills</td>
<td>15 (33%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pyrexia</td>
<td>7 (15%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Injection site erythema</td>
<td>7 (15%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Myalgia</td>
<td>6 (13%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Headache</td>
<td>5 (11%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hyperhidrosis</td>
<td>5 (11%)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

+ Preliminary analysis, adverse events from 46 of the 57 treated patients;
* Only Grade 1 AE's occurring in ≥ 10% of patients are listed.

No drug-related grade 3 or 4 or serious adverse events

Toxicity is a well recognized shortcoming of both existing therapies and new cancer immunotherapies
Male with cutaneous melanoma on the chest. Injection in chest lesions.

Histopathological analysis confirmed complete melanoma regression.

CALM Phase 2 trial
LOCAL-INJECTED LESION RESPONSES

Baseline

Day 127

Courtesy Dr R Andtbacka, Lead Study Investigator, Huntsman Cancer Institute as presented at ASCO 2014
Male with metastatic melanoma to the leg. Injection in leg lesions.

Courtesy Dr R Andtbacka, Lead Study Investigator, Huntsman Cancer Institute as presented at ASCO 2014
## CALM Phase 2 trial

**NON-INJECTED CHEST WALL DISTANT LESION RESPONSE**

<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
<th>Circumference (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screening</td>
<td>Non-injected</td>
<td>0.6 cm</td>
</tr>
<tr>
<td>Day 262 (37 wks)</td>
<td>Ext. Injection 5</td>
<td>0 cm</td>
</tr>
<tr>
<td>Day 130 (18 wks)</td>
<td>Injection 10</td>
<td>1.1 cm</td>
</tr>
</tbody>
</table>

Male with metastatic melanoma to the chest. Injection in cutaneous metastatic arm lesion

Courtesy Dr R Andtbacka, Lead Study Investigator, Huntsman Cancer Institute as presented at ASCO 2014
Male with metastatic melanoma to left neck and lungs. Injection in left neck.

Baseline

Injected

Day 86

Non-injected

1.0 x 0.8 cm

0.5 x 0.2 cm

1.3 x 0.9 cm

0.6 x 0.5 cm

Courtesy Dr R Andtbacka, Lead Study Investigator, Huntsman Cancer Institute as presented at ASCO 2014
CAVATAK™
CALM Melanoma Study – Next Steps

- Successful study with primary endpoint achieved
- Significantly exceeded target endpoints
- Extension study to enhance understanding of immunotherapeutic activity
- Survival data on all patients in Q1 2015
- Follow-on trials in late planning stage

Strong data flow to drive partnering discussions
CAVATAK™ — STORM Phase 1/2 Study (SYSTEMIC TREATMENT OF RESISTANT MALIGNANCIES)

- Trial Initiated. Planned ~30 late stage cancer patients
  - Advanced melanoma, prostate, lung and metastatic bladder cancers
- Leading oncologists at prestigious UK cancer centres
- Multiple intravenous dosing with and without standard chemotherapy (e.g. docetaxel)
- Well tolerated in first two cohorts (6 patients)
- Third cohort (highest dose level) underway
- Preliminary results from early 2015 through early 2016

Potential to significantly broaden applications and expand partnering discussions

<table>
<thead>
<tr>
<th>Cancer Type</th>
<th>Rank *</th>
<th>Estimated New Cases in the US in 2014 *</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prostate</td>
<td>1&lt;sup&gt;st&lt;/sup&gt;</td>
<td>233,000</td>
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<tr>
<td>Lung</td>
<td>3&lt;sup&gt;rd&lt;/sup&gt;</td>
<td>224,210</td>
</tr>
<tr>
<td>Melanoma</td>
<td>5&lt;sup&gt;th&lt;/sup&gt;</td>
<td>76,100</td>
</tr>
<tr>
<td>Bladder</td>
<td>6&lt;sup&gt;th&lt;/sup&gt;</td>
<td>74,690</td>
</tr>
</tbody>
</table>

* USA National Cancer Institute, 2014
Deep Clinical Development Experience

Dr Darren Shafren  
*Chief Scientific Officer, inventor of CAVATAK™*

25 years' experience in oncolytic virotherapy and cancer cell interactions

Dr Leonard Post  
*Director*

Biomarin CSO  
formerly Onyx, Biovex

Extensive experience including Nexavar™ from IND through FDA approval for kidney cancer

Dr Robert Andtbacka  
*CALM Phase 2 Principal Investigator*

Huntsman Cancer Institute, University of Utah

Dr Keith Flaherty  
*Scientific Advisory Board*

Massachusetts General Hospital Cancer Center

Professor Merrick Ross  
*Independent Clinical Consultant*

MD Anderson Cancer Center, Houston, Texas

Professor Kevin Harrington  
*STORM trial Investigator*

The Royal Marsden, London

Dr Brendan Curti  
*CALM Phase 2 Investigator*

Providence Cancer Center  
Portland, USA

Professor Hardev Pandha  
*STORM trial Principal Investigator*

University of Surrey
FUTURE CLINICAL PROGRAM

- Melanoma – Multiple Opportunities
- Bladder – CANON Trial
CAVATAK™
Phase 2 Melanoma Studies

• Build on CALM study results
• Trial options
  – Combination with new agents in late-stage patients
    • Checkpoint inhibitors (anti-CTLA-4 and/or anti-PD1)
    • Targeted molecules (BRAF/MEK inhibitors)
  – Administration prior to surgery in early-stage patients
• Strong pharma interest in new combinations and well tolerated monotherapy
• Clinical studies in late planning stage

“CAVATAK™’s activity and tolerability in these late-stage melanoma patients is impressive. Given this growing body of clinical and pre-clinical data, CAVATAK™ appears to be an excellent candidate for development, either as a single agent in earlier disease, or in combination with other new therapies, including anti-PD-1 and other checkpoint inhibitors. I look forward to contributing to the further clinical development of this promising immunotherapy agent.”

Dr Robert Andtbacka Huntsman Cancer Institute

“Given the activity and tolerance profile witnessed to date, the combination of CAVATAK™ with other new targeted therapies has exciting potential in advanced stage melanoma patients. I look forward to seeing what CAVATAK can add to our current treatment standards in randomized trials.”

Dr Keith Flaherty – Massachusetts General Hospital Cancer Center
Preclinical Assessment of Combination of Intratumoural CAVATAK and Anti-PD-1 Antibody in mice

Implant B16-ICAM-1* melanoma cells into left flank

Day 0

Treatment with CAVATAK or saline intratumoral (i.t) + anti-PD-1 or control mAb intraperitoneal (i.p)

6 9 12 15

19 26

31

Implant B16 melanoma cells into right flank

33 40

Treatment with i.t CAVATAK or saline

B16-ICAM-1 melanoma cells (Primary tumor)

CAVATAK i.t

anti-PD-1 mAb

B16 cells re-challenge (Secondary tumor)

* B16-ICAM-1 cells are murine melanoma B16 cells stably transfected to express human ICAM-1 to allow CVA21 binding and cell infection
Preclinical Assessment of Combination of Intratumoural CAVATAK and Anti-PD-1 Antibody In mice

Spider plots of individual primary B16-ICAM-1 tumor growth

0% Tumor-free 0% Tumor-free 0% Tumor-free 75% Tumor-free

B16-ICAM-1 melanoma (Primary treated tumor)

Study Day 45

Shafren et al ESMO 2014
Preclinical Assessment of Combination of Intratumoural CAVATAK and Anti-PD-1 Antibody in mice

Incidence of palpable secondary B16 tumor *

![Graph showing incidence of palpable secondary B16 tumor](graph)

Survival

![Graph showing survival](graph)

Similar responses seen when CAVATAK used in combination with anti-CTLA4 antibody (murine form of ipilimumab - Yervoy™)

* Preliminary on-going analysis
CAVATAK Combined with Checkpoint Inhibitors

- Combination of CAVATAK and anti-PD1 or anti-CTLA-4 mAb is well tolerated
- Significant anti-tumor activity using a combination of CAVATAK and anti-PD-1 or anti-CTLA-4 in a pre-clinical mouse model
- Evaluation of a combination of CAVATAK and anti-PD-1 or anti-CTLA-4 mAb in advanced melanoma patients is warranted
- Checkpoint inhibitors, likely backbone of immunotherapy with forecast annual sales of $35Bn by 2023 (Citibank)
- Checkpoint inhibitors active across a range of cancer types, including melanoma, lung and bladder cancer and potential synergy with CAVATAK

Anti-PD1 mAb approved in USA (Keytruda™ Merck) and Japan (Ono Pharmaceutical) in late stage melanoma patients

Merck, Astra Zeneca, BMS and Roche have anti-PD1 / PDL1 mAb in development for melanoma and other cancer types

Anti-CTLA4 mAb approved globally (Yervoy - BMS) in late stage melanoma patients

Astra Zeneca has anti-CTLA-4 in development
Checkpoint inhibitors

Room to Improve through Combination with New Therapies

Yervoy™ 2011 launch – $960M sales in 2013

Courtesy of Professor K. Harrington – ESMO 2014

Checkpoints inhibitors important new agents in melanoma and other cancer types

Big Pharma focused on improving activity of these agents through combination therapy

Goal: to enhance performance with manageable toxicity

Also potential to enhance activity of targeted agents (BRAF / MEK inhibitors)
CAVATAK™ — CANON Phase 1 study
(CAVATAK in NON-MUSCLE INVASIVE BLADDER CANCER)

- Common cancer with high unmet need
- Significant costs to health care system - $200,000/patient
- No treatment advances in the last decade
- Need for non-toxic effective agents
- CAVATAK active in preclinical studies, in particular in combination with chemotherapy
- Phase 1 study initiate in Q1 2015
- Intravesical CAVATAK +/- mitomycin C in frontline NMIBC
- 18 – 30 patients in 2 stages at Royal Surrey Hospital

Potential to broaden partnering discussions

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</tr>
</tbody>
</table>

* USA National Cancer Institute, 2014
Current CAVATAK clinical trial program

**Intratumoural**
- Phase 2: CALM study
  - Advanced melanoma
  - \( N=57 \)

**Intravenous**
- Phase 1/2: STORM study
  - Advanced melanoma, NSCLC, Bladder and Prostate cancer
  - \( N=30 \)

**Intravesicular**
- Phase 1: CANON study
  - Non-muscle invasive bladder cancer
  - \( N=30 \)

- Phase 2 (in final planning)
  - Monotherapy or combination studies with immune checkpoint inhibitors and/or targeted small molecules

- Phase 2: CALM extension cohort
  - Advanced melanoma
  - \( N=12 \)
## Expected News Flow

<table>
<thead>
<tr>
<th>Event</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Presentation at AACR, ASCO and ESMO conferences</td>
<td>Achieved</td>
</tr>
<tr>
<td>Top-line results CALM Phase 2 melanoma study</td>
<td>Achieved</td>
</tr>
<tr>
<td>Initiate extension cohort in CALM study</td>
<td>Achieved</td>
</tr>
<tr>
<td>Initiate combination studies in melanoma patients</td>
<td>Q1 2015</td>
</tr>
<tr>
<td>Initial results first stage of STORM phase 1/2 study</td>
<td>Q1 2015</td>
</tr>
<tr>
<td>Survival data CALM Phase 2 melanoma study</td>
<td>Q1 2015</td>
</tr>
<tr>
<td>Initiate CANON Phase 1 bladder cancer study</td>
<td>Q1 2015</td>
</tr>
</tbody>
</table>
Compelling Near-Term Value Builders

- Lead product CAVATAK™ - potential in a range of cancer types
- Collaborating with leading oncologists in US and Europe
- Well funded following transformational $27M capital raise
- Impressive activity in CALM Study
- STORM Phase 1/2 trial in patients with solid tumour cancers
- Promising results in preclinical studies with blockbuster new agents
- Pharma company strong interest in combination strategies
- CAVATAK Phase 2 combination study planned for Q1 2015
- CANON Phase 1 bladder cancer trial planned for Q1 2015
- Data from multiple clinical trials to drive partnering discussions and shareholder value
- Recent high value transactions in cancer immunotherapy

Corporate strategy to build value through to licensing or partnering transaction

Success in Phase 2 CALM melanoma trial

- Primary endpoint achieved September 2013
- Significantly exceeded key endpoints
- Activity in metastatic (secondary) tumours
- Well tolerated with no drug-related serious adverse events
- Potential application as monotherapy or in combination with blockbuster new agents
Thank You

Dr Malcolm McColl
Managing Director

Email: malcolm.mccoll@viralytics.com
Web: www.viralytics.com