



ASX and Media Release

Viralytics Annual Report and Full Year Financial Results

26 August 2015, Sydney, Australia: Viralytics Limited (ASX: VLA, OTCQX: VRACY) has released its Annual Report including financial results for the year ended 30 June 2015.

FINANCIAL RESULTS

Net cash used in operating activities for the Year	\$4.5 million
Cash position at the end of the Year	\$21.6 million
Reported loss	\$4.3 million

OPERATIONAL HIGHLIGHTS

In 2015, Viralytics accelerated and broadened its clinical development program for CAVATAK™, as described in the following summary of the highlights of the year. Further detail is provided in the *Review of Operations* in the Directors Report.

CAVATAK Phase 2 CALM Melanoma Clinical Trial (USA)

- Impressive final data were presented at the American Society of Clinical Oncology Annual Meeting in June 2015. According to the CALM trial results, 22 of the 57 (38.6%) patients achieved immune-related Progression-Free Survival (irPFS) at six months – more than doubling the target of 10 of 54 evaluable patients to reach this endpoint.
- In addition, investigators reported an overall response rate in 16 of 57 (28%) patients and durable responses, persisting for 6 months or more, in 21% of patients. These included responses in some patients who had progressed on other agents such as T-VEC and ipilimumab.
- A one-year survival rate of 43 of 57 (75%) patients with a median overall survival of 26 months was achieved in a challenging population with advanced, intractable disease. Importantly, CAVATAK was well tolerated, with no grade 3 or 4 treatment-related adverse events.
- Anti-cancer activity was also observed in non-injected distant cancers, including lung and liver metastases, suggesting CAVATAK's ability to trigger an anti-tumour immune response.



CAVATAK Phase 2 CALM Melanoma Clinical Trial (USA) – Extension Cohort

- Preliminary results of this 13-patient extension study, initiated to enable a deeper understanding of the role of CAVATAK in triggering an immune response against cancer cells, showed anti-cancer immune activity in tumour tissue biopsies taken from melanoma lesions after CAVATAK administration.
- Specifically, evidence suggests that CAVATAK induces key immune cells (such as T lymphocytes) to infiltrate the tumour tissue, and also upregulates important receptors (such as PDL1) on cancer cells – demonstrating CAVATAK's potential complementary activity when combined with other immunotherapies such as checkpoint inhibitors.

CAVATAK Phase 1/2 STORM Multi-dose Intravenous Clinical Trial (UK)

- Initial results of the STORM trial, being conducted at three leading cancer centres in the UK including the Royal Marsden in London, show that multiple intravenous infusions of CAVATAK have produced possible tumour-specific viral replication in some patients with advanced melanoma, non-small cell lung, bladder and prostate cancer. Moreover, additional indications of anti-tumour activity in some lesions have been associated with escalating doses of CAVATAK.
- The intravenous administration of CAVATAK has been well tolerated, with no grade 3 or 4 product-related adverse events. The third cohort of patients is now underway using the highest dose of CAVATAK and includes the assessment of tumour tissue biopsies. Initial results indicate the presence of CAVATAK in tumour biopsies from first two melanoma patients.

CAVATAK Phase 1 CANON Non-Muscle Invasive Bladder Cancer Clinical Trial (UK)

- The CANON study was initiated in January 2015 to evaluate the safety and tolerability of CAVATAK administered alone, and in combination with a sub-therapeutic dose of the standard chemotherapy, mitomycin C, in 30 to 40 patients with non-muscle invasive bladder cancer.
- Early results from first three patients demonstrated that the intravesicular administration (via catheter into the bladder) of CAVATAK was well tolerated, and was able to produce widespread virus replication in the tumour as well as viral-induced cancer cell death.
- The second stage of the trial will investigate the combination of CAVATAK and mitomycin C.



CAVATAK Phase 1b MITCI Combination Clinical Trial - CAVATAK and Ipilimumab in Melanoma (USA)

- The MITCI trial of CAVATAK administered in combination with YERVOY®¹(ipilimumab) in late-stage melanoma patients was announced in December 2014.
- The trial, designed to assess the safety and tolerability of CAVATAK administered in combination with Yervoy in 26 late-stage melanoma patients, will also evaluate evidence of anti-cancer activity, including response rates and bio-markers of anti-tumour immunity.
- No results have been released as of the date of this report.

CORPORATE OUTLOOK

- With \$21.6 million cash at 30 June 2015, Viralytics is well funded.
- The company is building a compelling data package through its CALM, STORM, CANON, MITCI, and future clinical trials, with the aim of attracting pharmaceutical partners interested in adding an oncolytic virus to their oncology portfolio. In this way, Viralytics intends to achieve a significant commercial outcome from its innovative technology.

“Viralytics made strong progress in the 2015 financial year, as we continued to advance CAVATAK as a new oncolytic immunotherapy with the potential to benefit patients across a range of cancer types – both as a monotherapy and in combination with other immunotherapies,” stated Dr Malcolm McColl, Managing Director and Chief Executive Officer of Viralytics. “The data generated in the past year have been impressive, further strengthening our position for a successful commercial transaction involving CAVATAK in the future.”

¹ YERVOY® is a registered trademark of Bristol-Myers Squibb Company



About Viralytics Ltd:

Viralytics is developing oncolytic immunotherapy treatments for a range of cancers. The company's lead investigational product, CAVATAK™, is currently being studied in Phase 1 and 2 clinical trials for the treatment of melanoma, as well as prostate, bladder and lung cancers. CAVATAK is a proprietary formulation of the common cold Coxsackievirus Type A21 (CVA21) that preferentially binds to specific 'receptor' proteins highly expressed on multiple cancer types. CAVATAK acts to kill both local and metastatic cancer cells through cell lysis and the potential generation of an immune response against the cancer cells – a two-pronged mechanism of action known as oncolytic immunotherapy.

Based in Sydney Australia, the company is listed on the Australian Securities Exchange (ASX: VLA) while Viralytics' ADRs also trade under VRACY on the US OTCQX International market. For more information, please visit www.viralytics.com.

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