

21 August 2012

ASX / MEDIA ANNOUNCEMENT

Alchemia Announces Audited Financial Results for the 2012 Financial Year

Alchemia, Brisbane, Australia (ASX:ACL), today announces its audited financial results for the financial year to 30 June 2012.

Alchemia's Chief Executive Officer and Managing Director, Dr Pete Smith stated that the financial year to June 2012 in many ways should be viewed as a landmark year in the development of Alchemia Limited and its consolidated entities ("Alchemia" or the "Group"), and certainly one where the Group was able to drive forward a number of plans and programs.

"As we prepare for the receipt of our first profits from sales of fondaparinux and for the demerger and listing of Audeo Oncology Inc. ("Audeo Oncology"), we are well positioned to deliver outcomes and value to shareholders. Highlights of the year include:

- **July:** Approval of generic fondaparinux by the US Food and Drug Administration and the subsequent launch by our global marketing partner Dr Reddy's Laboratories ("Dr Reddy's")
- **September:** Initiation of recruitment to an investigator-sponsored clinical study of HA-Irinotecan vs irinotecan in Extensive Stage Small Cell Lung Cancer
- **November:** Successful completion of an oversubscribed \$16m fundraising to sophisticated US and Australian investors
- **November:** Announcement of proposed plans to demerge and list Alchemia's oncology assets as a separate company
- **December:** Successful completion of a Share Placement Plan to shareholders raising \$5m
- **January:** Recruitment of first patient to the pivotal Phase III clinical trial of HA-Irinotecan in 2nd line metastatic colorectal cancer
- **February:** Grant of further US patents protecting the process for synthesizing generic fondaparinux
- **April:** Filing for approval of fondaparinux in the EU by Dr Reddy's through the EMA mutual recognition process
- **June:** Incorporation of Audeo Oncology, Inc in the US, in preparation for the demerger of Alchemia Limited's oncology assets.

"The approval and successful launch of generic fondaparinux in the US in the first half of the financial year is a major achievement for the company and testament to the huge effort of many people in Alchemia, Dr Reddy's and the many other companies with whom we have worked and collaborated over the years. It proved to be an exceptionally challenging project both at the technical level and at the corporate level as we grappled with a protracted review time with the regulatory authorities. While the delays certainly did not aid the development of the company, the support of our shareholders and the ongoing dedication of our staff have ensured that the value we perceive across all of our programs has been preserved. At the Annual General Meeting in November 2011 we said that Alchemia was, at last, on the front foot. The excellent progress made since that meeting speaks for itself and considerable advances are anticipated for the current financial year."

Brisbane Head Office
Alchemia Limited
(ACN 071 666 334 ABN 43 071 666 334)
3 Hi –Tech Court Brisbane Technology Park
Eight Mile Plains QLD 4113 Australia
PO Box 4851 Eight Mile Plains QLD 4113
T: 61 7 3340 0200 F: 61 7 3340 0222

Melbourne Office
Alchemia Oncology Pty Limited
(ACN 058 390 953 ABN 60 058 390 953)
Room D130, Building 13D
Department of Biochemistry and Molecular Biology, Monash University,
Wellington Road, Clayton, VIC 3800, Australia
T: 61 3 9905 3760 F: 61 3 9905 3726

“We believe that HyACT is a broadly applicable platform technology that has the potential for enhancing the efficacy of a range of anti-cancer drugs in a number of different cancer indications.”

“We expect our VAST small molecule drug discovery technology will give us the ability to research and develop new anti-cancer drug candidates. Currently this technology has been deployed in several collaborations with pharmaceutical companies, including Amgen, Inc and Genentech Inc., and research institutes, including the University of Queensland, the Institute of Molecular Biology, Brisbane, the Monash Institute of Pharmacological Science and the Walter and Eliza Hall Institute, exploring its capability and application in non-cancer therapeutic areas. These collaborations are exploiting the chemistry and molecular diversity offered by the VAST technology and diversity scanning array by addressing known targets in an innovative way.”

Operating Results for the Year

The Group reported a net loss of \$15.1 million for the 2012 financial year, up from \$13.4 million loss in 2011.

Total income for the period was \$0.7 million, down by \$0.6 million from the previous period (2011: \$1.3 million). This decrease was driven predominantly by lower grant income received from the Queensland State Government under the Smart State Innovation Fund for the Company's collaboration with (i) Monash Institute of Pharmaceutical Science to discover new drug candidates for G-Protein coupled receptors (NIRAP) and (ii) University of Queensland to discover novel opioid analgesics with reduced side effects (RIPP). Interest income was down on the corresponding period due to lower cash balances in interest bearing term deposits.

Operating expenditure of \$16.2 million was slightly higher than the corresponding period (2011: \$15.1 million). The 2012 expenditure represents funding of ongoing research and development programs together with \$5.7 million on the HA-Irinotecan Phase III trial.

Other expenses include the impact of foreign exchange movements. In the current period the Group recognised a \$0.4 million exchange gain arising from the exchange movement on the US dollar bank accounts and foreign currency denominated payables.

The consolidated cash position of the group over the reporting period has seen a net increase in cash balances, from \$5.6 million as at 30 June 2011 to \$14.0 million as at 30 June 2012 due to capital raising activities in November and December 2011, which raised \$20 million (net) through the issue of 88 million shares. Net cash outflows from operating activities in the current year, which totalled \$11.8 million, was slightly up from last year's \$11.1 million.

The Group has an established treasury function responsible for tracking and monitoring the Group's cash position against forecasts. This allows management to proactively accelerate or decelerate programs based upon its cash position and anticipated changes, through financing or other activities, in that position.

Generic Fondaparinux

Fondaparinux is an anticoagulant drug used in the prevention and treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE); it is mainly used after major surgery such as knee and hip replacements. The branded version of the drug, Arixtra was launched in the US in 2003 by Sanofi, a year after the patents on the drug expired. Sanofi had used all of the patent life of the drug working out how to make it at scale. Following

Brisbane Head Office
Alchemia Limited
(ACN 071 666 334 ABN 43 071 666 334)
3 Hi-Tech Court Brisbane Technology Park
Eight Mile Plains QLD 4113 Australia
PO Box 4851 Eight Mile Plains QLD 4113
T: 61 7 3340 0200 F: 61 7 3340 0222

Melbourne Office
Alchemia Oncology Pty Limited
(ACN 058 390 953 ABN 60 058 390 953)
Room D130, Building 13D
Department of Biochemistry and Molecular Biology, Monash University,
Wellington Road, Clayton, VIC 3800, Australia
T: 61 3 9905 3760 F: 61 3 9905 3726

the merger of Sanofi with Aventis, the drug was sold to GlaxoSmithKline which, like its predecessor, continued to invest heavily in clinical development of the drug. The protection from generics was not from patents but the incredible complexity of the synthesis of the active molecule. In March 2009, our partner, Dr Reddy's, filed an Abbreviated New Drug Application (ANDA) for the approval of fondaparinux manufactured using Alchemia's proprietary process.

Fondaparinux was approved in July 2011 and almost immediately Dr Reddy's started to ship product. Shortly thereafter, GSK launched an Authorized Generic (AG) through Apotex. An AG does not need to go through an approval process as it is simply a rebadged version of the branded drug. Alchemia receives 50% of profits from the sales of fondaparinux in the territory after certain development costs have been recouped by our partner. We expect to start receiving profits from fondaparinux in the first half of the financial year 2013 following the repayment of those costs under the terms of our agreement. Market share in the retail segment of the market has been strong with Dr Reddy's now commanding a 41% share of prescriptions and dollars sold. Market share in the hospital segment is expected to increase through the year.

Application for approval in the European Union was filed with the European Medicines Agency (EMA) in April 2012, shortly after the expiry of 10 years of data exclusivity. Approval times in the EU are generally shorter than in the US and launch is anticipated sometime in the calendar year 2013. Dr Reddy's also has rights to commercialize fondaparinux outside of North America under the terms of our 'Rest of World' agreement. Commercialization will principally focus on markets where Arixtra is already selling and where our fondaparinux can be sold as a typical generic drug.

Chemists at Alchemia and at Dr Reddy's continue to focus on optimizing the synthetic route for fondaparinux in order to maximize profitability. This, along with the exploitation of the hospital sector in the US and new markets should result in a pattern of increasing receipts by Alchemia.

HyACT Technology

Each of our current product candidates combines HyACT with a known anti-cancer drug. HyACT uses hyaluronic acid, or HA, which delivers additional drug to the tumour and promotes uptake of the drug into the tumour cells. HyACT binds to the activated receptor CD44, a naturally occurring HA receptor, which has been shown in numerous studies to be present in high levels in many prevalent solid tumour cancer types but, more importantly, is generally not activated in healthy tissue. CD44 over-expression is associated with more aggressive, metastatic tumours and is also a marker for treatment-resistant cancer stem cells. "Cancer stem cells," sometimes referred to as tumour-initiating cells, is a term used to describe a small subset of cells within the tumour that, although not actual stem cells, demonstrate stem cell-like characteristics. Cancer stem cells are generally more resistant to current chemotherapy regimens than cancer cells, and their persistence after therapy is thought to be one of the key reasons for disease progression and treatment failure. We believe, based on preclinical studies, that the CD44 receptor-based mechanism has the potential for improving the effectiveness of drugs combining HyACT with an anti-cancer drug, which we refer to as HyACT-targeted drugs. In preclinical studies, HyACT-targeted drugs delivered at least double the dose of anti-cancer drug to the tumour when compared with the drug alone. Our *in vitro* studies have shown that HyACT significantly increases drug uptake into cancer cells. Finally, preclinical studies have also shown HyACT-targeted chemotherapies are more potent than the original drug at killing cancer stem cells and other CD44-expressing cells.

Our lead product candidate is HyACT-targeted irinotecan, or HA-Irinotecan, for the treatment of mCRC. Irinotecan, which is marketed in major markets by Pfizer as Camptosar, is an off-patent chemotherapy drug

Brisbane Head Office
Alchemia Limited
(ACN 071 666 334 ABN 43 071 666 334)
3 Hi –Tech Court Brisbane Technology Park
Eight Mile Plains QLD 4113 Australia
PO Box 4851 Eight Mile Plains QLD 4113
T: 61 7 3340 0200 F: 61 7 3340 0222

Melbourne Office
Alchemia Oncology Pty Limited
(ACN 058 390 953 ABN 60 058 390 953)
Room D130, Building 13D
Department of Biochemistry and Molecular Biology, Monash University,
Wellington Road, Clayton, VIC 3800, Australia
T: 61 3 9905 3760 F: 61 3 9905 3726

widely used in the treatment of mCRC. In a 76 patient, randomized Phase II clinical trial of HA-Irinotecan compared with irinotecan alone, HA-Irinotecan was able to double the time it took for patients' tumours to grow (also known as progression free survival, or PFS) in mCRC patients. After having consultations with the U.S. Food and Drug Administration, or FDA and the EMA, we commenced a pivotal Phase III clinical trial testing HA-Irinotecan in patients with mCRC in November 2011. Recruitment and enrolment of patients for the clinical trial was initially slow, but is currently on track and we have increased the number of trial sites. This trial is designed to recruit 390 irinotecan-naïve, second and third line patients and will directly compare HA-Irinotecan with irinotecan alone, in both cases as components of the FOLFIRI chemotherapy regimen (leucovorin, 5-fluorouracil and irinotecan).

In addition, a Phase II clinical trial of HA-Irinotecan in SCLC started recruitment in September 2011. This investigator-sponsored trial will examine the clinical benefits of HA-Irinotecan compared with irinotecan alone, as well as the direct effect of HA-Irinotecan on cancer stem cells and other aggressive cancer cell populations through analysis of tumour biopsies. The objective of this Phase II trial is to demonstrate that, by targeting the CD44 receptor on cancer stem cells, HA-Irinotecan may enhance the killing of the cancer stem cell and cancer cell populations, which may ultimately translate into increased patient survival. We are participating in this investigator-sponsored trial primarily because of the potential to further validate the HyACT technology and the data on HA-Irinotecan's activity on cancer stem cells that it may provide. We currently do not intend to pursue further clinical trials or commercialization of HA-Irinotecan for the treatment of SCLC.

VAST™ Drug Discovery

The VAST technology is based on high throughput, synthetic chemistry on pyranose scaffolds and comprises an array of compounds, which due to their rigidity and high chirality (compound shape), can enable the systematic exploration of new drugs. In 2009, we completed the synthesis of a diversity scanning array, or DSA, a suite of approximately 14,000 pyranose-based compounds that systematically arrange typical binding groups in a broad range of possible three-dimensional orientations. This array has the ability to identify the shape and functional requirements of molecules that modulate a target.

We expect VAST small molecule drug discovery technology will give us the ability to research and develop new anti-cancer drug candidates. This technology has been deployed in several collaborations with pharmaceutical companies, including Amgen, Inc and Genentech Inc., and research institutes, including the University of Queensland, the Institute of Molecular Biology, Brisbane and Monash Institute of Pharmacological Science and the Walter and Eliza Hall Institute exploring its capability and application in non-cancer therapeutic areas. These collaborations are exploiting the chemistry and molecular diversity offered by the VAST technology and diversity scanning array, or DSA, by addressing known targets in an innovative way. We plan to initiate programs to study inflammation pathways associated with cancer stem cells and cancer metabolism with a target involved in HA synthesis. These programs are intended to make use of the selectivity and compound efficiency of the VAST technology. Our VAST programs are run on a business model designed to limit our cash expenditures through the use of partnerships and, if and when available, government grants. These programs include the allosteric modulation of family B G-protein coupled receptors for chronic obstructive pulmonary disease and type II diabetes, as well as opioid receptor agonists and ion channel inhibitors for pain.

Brisbane Head Office
Alchemia Limited
(ACN 071 666 334 ABN 43 071 666 334)
3 Hi-Tech Court Brisbane Technology Park
Eight Mile Plains QLD 4113 Australia
PO Box 4851 Eight Mile Plains QLD 4113
T: 61 7 3340 0200 F: 61 7 3340 0222

Melbourne Office
Alchemia Oncology Pty Limited
(ACN 058 390 953 ABN 60 058 390 953)
Room D130, Building 13D
Department of Biochemistry and Molecular Biology, Monash University,
Wellington Road, Clayton, VIC 3800, Australia
T: 61 3 9905 3760 F: 61 3 9905 3726

Outlook

The ongoing support of the Company's shareholders, its Board of Directors, and its employees, has enabled the Company to make significant progress, including obtaining approval of its first product, fondaparinux. The board looks forward with excitement to one of the most exciting fiscal years for the Company. In the coming year, Alchemia expects to be in receipt of its first revenues from the sale by Dr Reddy's of its generic fondaparinux in the USA and the possible demerger and listing of its oncology business on the NASDAQ. This together with the Phase III oncology trial, places the Group in a position to make significant progress over the next twelve months and unlock significant value for our shareholders and stakeholders.

Ends

Brisbane Head Office
Alchemia Limited
(ACN 071 666 334 ABN 43 071 666 334)
3 Hi –Tech Court Brisbane Technology Park
Eight Mile Plains QLD 4113 Australia
PO Box 4851 Eight Mile Plains QLD 4113
T: 61 7 3340 0200 **F:** 61 7 3340 0222

Melbourne Office
Alchemia Oncology Pty Limited
(ACN 058 390 953 ABN 60 058 390 953)
Room D130, Building 13D
Department of Biochemistry and Molecular Biology, Monash University,
Wellington Road, Clayton, VIC 3800, Australia
T: 61 3 9905 3760 **F:** 61 3 9905 3726

About Alchemia Limited – www.alchemia.com.au

Alchemia is a drug discovery and development Company founded on its chemistry expertise. The Company's lead drug is fondaparinux (a generic version of GlaxoSmithKline's Arixtra®, a synthetic anticoagulant mainly used for the prevention of deep vein thrombosis), which, following approval by the US FDA, has been launched by Dr Reddy's Laboratories in the USA. Alchemia's pipeline of assets is built on two platform technologies: HyACT® (targeted cancer delivery) and VAST® (drug discovery). The primary objective of the HyACT® technology is to develop a new generation of anti-cancer drugs which demonstrate better efficacy. The lead product from the HyACT® platform is HA-Irinotecan for which a pivotal phase III clinical trial has been prepared for metastatic colorectal cancer. Dosing of patients commenced in 2012. In addition, Alchemia has successfully initiated an investigator-sponsored Phase II trial to examine the effects of HA-Irinotecan on cancer stem cells in patients with small cell lung cancer. The Company has also taken two other anti-cancer products – HA-Doxorubicin (doxorubicin and hyaluronic acid) and HA-Fluorouracil (5-fluorouracil and hyaluronic acid) – successfully into Phase I clinical testing.

For further information:

Dr Pete Smith
Chief Executive Officer
Alchemia Limited
Tel: +61 7 3340 0200

Charles Walker
Chief Financial Officer
Alchemia Limited
Tel: +61 7 3340 0200

Brisbane Head Office
Alchemia Limited
(ACN 071 666 334 ABN 43 071 666 334)
3 Hi –Tech Court Brisbane Technology Park
Eight Mile Plains QLD 4113 Australia
PO Box 4851 Eight Mile Plains QLD 4113
T: 61 7 3340 0200 **F:** 61 7 3340 0222

Melbourne Office
Alchemia Oncology Pty Limited
(ACN 058 390 953 ABN 60 058 390 953)
Room D130, Building 13D
Department of Biochemistry and Molecular Biology, Monash University,
Wellington Road, Clayton, VIC 3800, Australia
T: 61 3 9905 3760 **F:** 61 3 9905 3726