Actinogen LIMITED
ACN 086 778 476

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23 October 2014
ASX Release

Actinogen Limited (ASX: ACW)

September Quarter Appendix 4C & Commentary

The Board of Actinogen Limited (ASX: ACW) would like to update the Company's shareholders and the market on its activities over the last quarter.

Corticrine Limited

On 27th August 2014, the Company signed a sale and purchase agreement to acquire 100% of Corticrine Ltd, a pharmaceutical company focused on the development of new therapies for Alzheimer's dementia. The Board of Directors is extremely pleased to have secured a project of such calibre and potential, and believe that the transaction will transform Actinogen into a clinical stage company with an asset that has the potential to become the long awaited treatment for Alzheimer's dementia, a multi-billion dollar market.

Overview:

- Corticrine is a mid-stage pharmaceutical R&D company focused on the development of novel treatments for disease modification and prevention in Alzheimer's dementia. It is a spin-out company from Edinburgh BioQuarter, the commercialisation arm of the College of Medicine and Veterinary Medicine of the University of Edinburgh in the United Kingdom.
- Corticrine has licensed worldwide development and commercialisation rights from the University of Edinburgh to UE2343 which is in clinical development for Alzheimer's disease.
- With significant support from the Seeding Drug Discovery program of the Wellcome Trust, the University of Edinburgh has successfully completed a Phase 1 single ascending dose (SAD) study of UE2343 in healthy human volunteers. UE2343 was well tolerated in humans with no serious adverse events.
- According to the World Health Organization 18M people affected globally with Alzheimer's with 5.1M in the US alone. The market could possibly surpass $20B USD with the approval of the new drug.
- New management team and advisory board are in place and ready to take the project forward. Near term value inflection point – a Phase 1b multiple ascending dose study and Phase 2a proof-of-concept study in patients with mild cognitive impairment.
- Capital raising of $2M to accompany the acquisition resulting in available working capital of approximately $3M.

Overview of the Transaction:

Subject to shareholder approval, Actinogen will:

- Issue 125,000,000 new ACW fully paid ordinary shares.
- Raise an additional $2M via the placement of 100M shares at $0.02. The placement will be managed by Perth based, Forrest Capital. 50 million shares of the placement will be issued immediately, without shareholder approval, using the Company's share issue capacity under ASX Listing Rule 7.1 and 7.1 A, with the balance subject to shareholder approval at the annual general meeting of shareholders on 19 November 2014

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Proposed Board Changes:

On approval of the Corticrine transaction, the following changes will be made to the Board of Directors:

Appointment of Dr Jason Loveridge (founder of Corticrine) – Non-Executive Director

Dr Loveridge brings extensive experience in developing clinical stage biotechnology companies to the Board of Actinogen. Dr Loveridge will oversee the clinical progress of UE2343 and will provide the necessary liaison between Actinogen and the Scientific Advisors of the Company.

Appointment of Mr Martin Rogers – Non-Executive Chairman

Mr Rogers is a well-recognized Australian biotechnology entrepreneur and executive. The appointment of Mr Rogers will add substantial capital markets experience to the current Board of the Company.

Other

In other Board changes, current Non-Executive Director Mr Daniel Parasiliti will retire from the board at the conclusion of the acquisition. Dr Brendan de Kauwe and Dr Anton Uvarov will remain with the company in a Non-Executive role.

The Board would like to thank Mr Parasiliti for the support and efforts during his tenure as board member of Actinogen Ltd.

Appointment of Clinical Advisors:

On approval of the Corticrine transaction, the Company will appoint the following:

Professor Alan Boyd

Professor Alan Boyd is a co-founder of Corticrine Ltd. Alan began his 30 years' pharmaceutical career with Glaxo Group Research Ltd. From 1988 he led ICI's cardiovascular medical research team, later assuming the role of Director of Clinical and Medical Affairs at ICI Pharma, Canada. In 1999, after four years as Head of Medical Research for Zeneca Pharmaceuticals (now Astra Zeneca), he became Director of Research and Development for Ark Therapeutics Ltd where he was responsible for the development of their gene based medicines portfolio. In 2005 Alan set up Boyd Consultants. The focus of which is to aid and support early stage life-science based companies.

A graduate in Biochemistry and Medicine from the University of Birmingham, UK Professor Boyd is a Vice-President of the Faculty of Pharmaceutical Medicine, Royal College of Physicians, UK. Professor Boyd is also an Honorary Professor in the College of Medical and Dental Sciences at the University of Birmingham Medical School.

Professor Brian Walker

Brian Walker is clinical Professor of Endocrinology and Head of the University of Edinburgh/British Heart Foundation Centre for Cardiovascular Science.

His prolific translational research over 20 years has concerned the role of glucocorticoids in metabolic syndrome and cardiovascular disease. He published the original description of 11β-HSD1 as an amplifier of glucocorticoid action, identifying this enzyme as a prime therapeutic target (Corticrine lead compound, UE2343 is a patented novel inhibitor of 11β-HSD1).

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Professor Walker co-chairs the CORtisol NETwork (CORNET) international consortium that has conducted GWAS metanalyses for cortisol. He is Co-Director of the Edinburgh Clinical Academic Training (ECAT) scheme, mentor to its many recruits in various disciplines, former chair of the development group of the Edinburgh MSc in Translational Medicine, and has been a member of the Wellcome Trust's Clinical Interview Committee since 2007. He has extensive experience collaborating with and advising for pharmaceutical R&D.

Cancer Stem Cell Stem Project

One of Actinogen's lead therapeutic programs is focused on discovering and developing drugs to treat brain cancer and potentially other oncological diseases by the targeted killing of cancer stem cells (CSCs). In February the Company announced it had entered into a research agreement with Curtin University to conduct further studies on the Company's CSC Project.

Cancer stem cells have been reported in many human tumours and are classified as a highly tumorigenic subpopulation that drives tumour formation, proliferation and metastasis. CSCs share a variety of biological properties with normal stem cells such as capacity for self-renewal and propagation of differentiated progeny. However, CSCs differ from normal stem cells in their inherent resistance mechanisms against radiation- and chemotherapy-induced cancer cell death, enabling them to survive and initiate tumour recurrence. Despite their potential clinical importance, the regulation of CSCs at the molecular level is not well-understood and no drugs specifically targeting CSCs been developed to date. However, recent research in brain tumours has identified a CD133+ cell population as a cancer stem cell population, giving the way to some targeted therapeutic approaches.

In its previous experiments Actinogen has tested a total of 11 actinomycetes' supernatants against U87MG and U125MG neurospheres (free floating clusters rich in stem cells). The results have demonstrated that two isolates killed the whole cell population (ACN 5059 and ACN 5086). Cells which had died due to supernatant treatment had a high percentage of CD133+ cells, and thus actinomycete isolates ACN 5059 and ACN 5086 can be assumed to target CD133+ cells.

Currently, Actinogen and Curtin University are examining the effects of actinomycete isolates on cell viability in four different GBM (glioblastomamultiforme, a type of brain tumour) cell lines (U138, U87, A172 and LN18) using additional new techniques and assays. To confirm the activity is specific against cancer stem cells, the cells were grown in conditions that provide for the development of sphere formation.

Identification of CSCs within these cultures was based upon the presence of the cell surface markers CD133 and CD44. The isolates were then tested on their ability to induce cell death in cultures enriched with CD133 and CD44 positive cells.

The first study was conducted in the laboratory of Professor Arun Dharmarajan using methodologies established by his research group. The results demonstrated substantial reduction of proliferation in CSC populations in GBM cell lines (A172, U138, U87, U373). In addition, CSC sphere disruption, cell anchorage, and cell death were observed with different isolates for the CSCs across all four cell lines. This data is consistent with our previous internal results and supports the strong anti-cancer activity of some of the actinomycetes isolates.

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Professor Dharmarajan is among world leading scientists in the area of cancer stem cell research and is a discoverer of secreted frizzled-related protein 4 (sFRP4) that was recently shown to inhibit cancer stem cell proliferation in several tumours including the brain (Warrier et al (2014), Oncology Research, 21(2), 93-102).

Antibiotic Research Project

The Company continues its focus on drug development via its Antibiotic Research Project; with its scientific team currently conducting trials at its new laboratory premises at Murdoch University's State Agricultural Biotechnology Centre (SABC), Western Australia.

Antibiotic-resistant bacteria are becoming an increasing global problem, with much research and investment directed to discovering new effective agents and treatment modalities. Infections caused by resistant microorganisms often fail to respond to the standard treatment, resulting in prolonged illness and greater risk of death. The death rate for patients with serious infections treated in hospitals is about twice that in patients with infections caused by non-resistant bacteria. A high percentage of hospital-acquired infections are caused by highly resistant bacteria such as methicillin-resistant *Staphylococcus aureus* (MRSA), vancomycin resistant enterococci (VRE) and *Clostridium difficile.*

The Company has identified the importance of continuing the research in this field due to the global demand for new potential agents and on the back of positive initial results conducted on numerous strains of bacteria, in particular MRSA and VRE.

Actinogen owns a private existing database of over 6000 actinomycetes. Previously, the library has been screened to identify actinomycetes able to produce compounds with antimicrobial activity against resistant strains. The actinomycetes are then tested for activity against the MRSA panel, VRE, *Candida spp*., *Pseudomonas aeruginosa* and the anaerobic pathogen *Clostridium difficile.*

These testing panels consist of clinical isolates of microorganisms that have developed serious antibiotic resistance patterns and can therefore be used to increase the likelihood of finding new antibiotics.

Actinogen employs a series of screening tests which become more stringent. Primary screening is a rapid test to detect the production on solid agar of an isolate producing an antibiotic directed to one or more of the test organisms outlined above. Secondary screening is then carried out on known antibiotic producing isolates, in liquid culture. Once actinomycetes with antimicrobial activity against the clinical test isolates have been identified, Actinogen then tries to identify the active compound from public literature and databases. If the compound cannot be matched to an existing substance, it is sent to an independent laboratory to obtain a molecular structure.

In the Actinogen library 69 isolates have shown activity against the entire MSRA panel, 11 isolates have shown activity against the entire *Candida spp*. panel and 58 isolates have shown activity against VRE. Each compound with activity against the MRSA panel and *Clostridium difficile* has the potential to become a new antibiotic; however extensive further testing is required in order for this to be established.

The research team has inoculated the previously identified isolates and is currently retesting these for activity against MRSA, *Candida spp.* and *C. difficile*. Of particular interest are the antimicrobial actinomycete isolates that produce unidentifiable active compounds. Future work will include isolating and testing the active compound using HPLC and fraction collection. If the isolation of the active compound is successful, it may be sent to an independent laboratory for further characterisation.

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Collaborative and Royalty Agreement with Leaf Energy Ltd (ASX: LER)

On 23 December 2013, the Company announced that it had signed a Collaborative and Royalty Agreement with ASX listed company Leaf Energy Ltd, where LER will fund the further studies in the Company's Bioethanol Project; in which the Company previously identified strains of actinomycetes capable of producing cellulase(s). Cellulase(s) are enzymes used to breakdown cellulose from plant material, papers and industrial waste glycerols (Biomass), and are an important step in the production of second generation bioethanols.

The traditional method of producing cellulases is very costly and requires significant capital for infrastructure, requiring an anaerobic and high temperature and pressure environment ACW's can produce cellulases in an aerobic environment at low temperature and pressure and at significantly lower costs

ACWs enzyme production method is complimentary to LER's Glycerol Pre-treatment Process which uses cheap, recyclable glycerol at low temperature and pressure, in a simple and highly effective process

The trial has now been completed by Company's scientific team, and the results are now being examined with the view to discuss further collaborative work. LER now has the option to contribute further funding towards additional trials to explore the potential synergy of other actinomycetes in the Company's library.

The Company will grant LER the rights to exclusive uses of any of the methods of production solely developed as part of the collaborative process in return for a net profit royalty on LER's future licensing arrangements.

The potential market opportunity is very large, with LER's Glycerol Pre-treatment process requiring a fracture of the costs and infrastructure to current worldwide methods and processing facilities, having a highly scalable business model with licensing into multiple territories and markets, and providing for excellent environmental credentials with large carbon savings.

-end-

Dr Brendan de Kauwe
Executive Chairman
Actinogen Limited

About Actinogen Limited
Actinogen Limited (ASX: ACW)

Actinogen is a clinical stage Australian biotechnology company focused on the development of novel treatments for Alzheimer's Disease (AD) and other major age-related neurodegenerative disorders. Actinogen's lead candidate UE2343 is a small molecule inhibitor of 11-beta-hydroxysteroid dehydrogenase (11β-HSD1) an enzyme that reduces cortisone to the active hormone cortisol that activates glucocorticoid receptors. There is evidence for a role of glucocorticoids and hypothalamus-pituitary–adrenal axis dysfunction in AD that includes both cortisol-induced neurotoxicity on the hippocampal formation and acute ongoing impairment of cognition. UE2343 was discovered in 2007 at the laboratory of Professor Brian Walker at the University of Edinburgh. Subsequently, the University received significant support from the Wellcome Trust's Seeding Drug Discovery program to advance UE2343 into early clinical development.

In addition, the company has an early stage drug discovery program focused on developing drugs to treat brain cancer and potentially other oncological diseases by the targeted killing of cancer stem cells (CSCs). The first study was conducted in collaboration with Curtin University and the results demonstrated substantial reduction of proliferation in CSCs populations in glioblastoma cell lines.

Rule 4.7B

Appendix 4C

Quarterly report for entities admitted on the basis of commitments

Introduced 31/03/00 Amended 30/09/01, 24/10/05, 17/12/10

Name of entity

ACTINOGEN LIMITED

ABN	Quarter ended ("current quarter")
14 086 778 476	30 September 2014

Consolidated statement of cash flows

	Cash flows related to operating activities	Current quarter $A'000	Year to date (3 months) $A'000
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) staff costs	(9)	(9)
	(b) advertising and marketing	-	-
	(c) research and development	(53)	(53)
	(d) leased assets	-	-
	(e) other working capital	(109)	(109)
	(f) corporate reconstruction costs	-	-
1.3	Dividends received	-	-
1.4	Interest and other items of a similar nature received	7	7
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Other (R&D tax rebate)		
	Net operating cash flows	**(164)**	**(164)**

+ See chapter 19 for defined terms.

		Current quarter $A'000	Year to date (3 months) $A'000
1.8	Net operating cash flows (carried forward)	**(164)**	**(164)**
	Cash flows related to investing activities		
1.9	Payment for acquisition of:		
	(a) businesses (item 5)	-	-
	(b) equity investments	-	-
	(c) intellectual property	-	-
	(d) physical non-current assets	-	-
	(e) other non-current assets	-	-
1.10	Proceeds from disposal of:		
	(a) businesses (item 5)	-	-
	(b) equity investments	-	-
	(c) intellectual property	-	-
	(d) physical non-current assets	-	-
	(e) other non-current assets	-	-
1.11	Loans to other entities	(21)	(21)
1.12	Loans repaid by other entities	-	-
1.13	Other (provide details if material)	-	-
	Net investing cash flows	**(21)**	**(21)**
1.14	**Total operating and investing cash flows**	**(185)**	**(185)**
	Cash flows related to financing activities		
1.15	Proceeds from issues of shares, options (net of capital raising costs)	995	995
1.16	Proceeds from sale of forfeited shares	-	-
1.17	Proceeds from borrowings	-	-
1.18	Repayment of borrowings		
1.19	Dividends paid	-	-
1.20	Other – share application monies re proposed Tranche 2 Placement	35	35
	Net financing cash flows	**1,030**	**1,030**
	Net increase (decrease) in cash held	845	845
1.21	Cash at beginning of quarter/year to date	1,128	1,128
1.22	Exchange rate adjustments to item 1.20	-	-
1.23	**Cash at end of quarter**	**1,973**	**1,973**

+ See chapter 19 for defined terms.

Payments to directors of the entity and associates of the directors

Payments to related entities of the entity and associates of the related entities

		Current quarter $A'000
1.24	Aggregate amount of payments to the parties included in item 1.2	36
1.25	Aggregate amount of loans from the parties included in item 1.11	-

1.26 Explanation necessary for an understanding of the transactions

1.24 – payments relate to Directors Fees paid during the quarter.

Non-cash financing and investing activities

2.1 Details of financing and investing transactions which have had a material effect on consolidated assets and liabilities but did not involve cash flows

N/A

2.2 Details of outlays made by other entities to establish or increase their share in businesses in which the reporting entity has an interest

N/A

Financing facilities available

Add notes as necessary for an understanding of the position.

		Amount available $A'000	Amount used $A'000
3.1	Loan facilities	-	-
3.2	Credit standby arrangements	-	-

+ See chapter 19 for defined terms.

Reconciliation of cash

Reconciliation of cash at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts is as follows.		Current quarter $A'000	Previous quarter $A'000
4.1	Cash on hand and at bank	22	22
4.2	Deposits at call	1,951	1,951
4.3	Bank overdraft	-	-
4.4	Other (provide details)	-	-
	Total: cash at end of quarter (item 1.23)	1,973	1,973

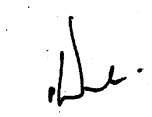
Acquisitions and disposals of business entities

		Acquisitions *(Item 1.9(a))*	Disposals *(Item 1.10(a))*
5.1	Name of entity	Nil	Nil
5.2	Place of incorporation or registration		
5.3	Consideration for acquisition or disposal		
5.4	Total net assets		
5.5	Nature of business		

Compliance statement

1 This statement has been prepared under accounting policies which comply with accounting standards as defined in the Corporations Act (except to the extent that information is not required because of note 2) or other standards acceptable to ASX.

2 This statement does give a true and fair view of the matters disclosed.

Sign here:  Date: 23 October 2014

Company Secretary

Print name: Peter Webse

+ See chapter 19 for defined terms.

Notes

1. The quarterly report provides a basis for informing the market how the entity's activities have been financed for the past quarter and the effect on its cash position. An entity wanting to disclose additional information is encouraged to do so, in a note or notes attached to this report.

2. The definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report except for any additional disclosure requirements requested by AASB 107 that are not already itemised in this report.

3. **Accounting Standards.** ASX will accept, for example, the use of International Financial Reporting Standards for foreign entities. If the standards used do not address a topic, the Australian standard on that topic (if any) must be complied with.

+ See chapter 19 for defined terms.