

DIRECTORS' REPORT

FOR THE YEAR ENDED 30 JUNE 2015

The Directors present their report together with the financial report of the consolidated entity, consisting of Acrux Limited and the entities it controlled for the financial year ended 30 June 2015 and the independent auditor's report thereon. This financial report has been prepared in accordance with Australian Accounting Standards.

Principal Activities

The principal activities of the consolidated entity during the financial year were the development and commercialisation of healthcare products. There has been no significant change in the nature of these activities during the financial year.

Operating Results

The consolidated profit, after income tax, attributable to the members of Acrux Limited was \$11.1 million (2014: \$28.0 million). Diluted earnings per share were 6.7 cents (2014: 16.8 cents).

Review of Operations

A review of the operations of the consolidated entity during the financial year and the results of those operations are as follows:

Vision

Acrux is an innovative Australian drug delivery business developing and commercialising a range of patient-preferred products for global markets, using unique proprietary technology to administer drugs.

Business Strategy

Acrux's strategy is to create new human pharmaceutical products by combining proven drugs and new chemical entities with innovative delivery technologies. Using proven drugs means that the development time is usually shorter and the risk and expenditure lower than is typical for new drug development. Intellectual property (IP) remains an important cornerstone of our product development strategy both in terms of creating new IP (where relevant), and ensuring freedom to operate in the fields in which we develop products.

Acrux's development skills are used to progress a range of products through clinical and regulatory milestones, before commercialising them in global markets through selected commercial partners, who provide expertise in the particular market. The value of each product is shared with the partner.

Operating Results

The consolidated profit before tax was \$16.8 million (2014: \$43.9 million). The consolidated profit after tax was \$11.1 million (2014: \$28.0 million).

Revenue

Total revenue for the financial year was \$25.4 million (2014: \$53.9 million). Revenue from product agreements was \$24.6 million (2014: \$53.4 million) and comprises royalty revenue of \$24.6 million (2014: \$24.7 million) and milestones. No milestones were received during the financial year (2014: \$28.7 million). Further milestones may be generated from meeting contractual milestones in future years. Interest income contributed \$0.6 million (2014: \$0.5 million). Royalty revenue from Axiron® was \$24.3 million (2014: \$24.5 million).

Operating Expenditure

Operating expenditure totalled \$8.6 million (2014: \$10.0 million). Royalty payments due to Monash Investment Trust decreased to \$0.9 million (2014: \$1.8 million), in line with the reduction in product income. Employee benefits expense increased to \$2.7 million (2014: \$2.3 million), the result of a general increase in staff salaries in line with CPI and the recruitment of the new Chief Executive Officer. Directors' fees decreased to \$0.4 million (2014: \$0.6 million) due to the Chairman relinquishing his Executive capacity and the resignation of one Non-Executive Director during the year. Professional fees increased to \$0.7 million (2014: \$0.3 million), the result of investment in the consolidated entities strategy coupled with legal costs incurred in the dispute with Hexima. A non-cash expense of \$0.8 million (2014: \$0.6 million) was recorded for employee share options granted during the reporting period, as required by accounting standard AASB 2. The continued strength of the US dollar against the Australian dollar resulted in a favourable conversion of product income, which is received in US dollars. No foreign exchange losses were recorded during the financial year (2014: \$1.2 million). Foreign exchange gains totalled \$0.2 million (2014: \$nil).

Income tax expense for the financial year was \$5.7 million (2014 \$15.9 million), in line with the reduction in consolidated profit before income tax. Further details of the income tax expense are provided at Note 1(j) of the financial report which follows the Director's Report.

Cash Flow

Net cash provided by operating activities totalled \$10.5 million (2014: \$36.4 million). Net cash outflow for the financial year was \$2.9 million (2014: a net cash inflow of \$3.0 million was recorded). Cash reserves at 30 June 2015 were \$23.1 million (30 June 2014: \$25.8 million).

Receipts from product agreements totalled \$25.2 million (2014: \$53.4 million) comprising royalty income \$24.4 million (2014: \$24.7 million) with no milestones received (2014: \$28.7 million). Interest receipts added \$0.6 million (2014: \$0.5 million). Payments to suppliers and employees decreased to \$6.5 million (2014: \$6.7 million). Income taxes paid decreased to \$8.9 million from the \$10.8 million recorded in the 2014 financial year.

The outflow of cash recorded for financing activities represents the payment of \$13.3 million (2014: \$33.3 million) of dividends to shareholders, comprising the 8 cent final dividend for the 2013/14 financial year.

Contributed Equity

There were no changes to contributed equity during the financial year.

The number of outstanding employee share options on issue at the end of the reporting period was 3,380,000 (30 June 2014: 1,855,000), representing 2.0% of the issued share capital. These options are exercisable under two schemes, 1,380,000 at \$4.30 per share and 2,000,000 at \$1.32 per share.

Key Events During the Year

- ▶ In addition to preclinical work on project in development, Acrux explored opportunities on a series of generic projects utilising Acrux's proven transdermal and topical technology.
- ▶ Evamist technology transfer has been completed with Gedeon Richter likely to receive national approvals and launch during the quarter ended March 2016.
- ▶ Axiron's net sales for the 2014/15 financial year totalled US\$155.4 million, down from US\$181.1 million in the prior year.
- ▶ The Food and Drug Administration (FDA) released a statement regarding the use of Testosterone Replacement Therapy in the US, titled "FDA Cautions About Using Testosterone Products for Low Testosterone Due to Aging; Requires Labeling Change to Inform of Possible Increased Risk of Heart Attack And Stroke."
- ▶ Acrux and Eli Lilly filed a lawsuit in the United States against Amneal Pharmaceuticals LLC., Lupin Pharmaceuticals Inc. for infringement of issued US patents covering Axiron.

Significant Changes in the State of Affairs

There have been no significant changes in the state of affairs of the consolidated entity during the year.

After Balance Date Events

The Board resolved to issue 1,000,000 Options to the Chief Executive Officer, Mr. Kotsanis on 22 July 2015 at an exercise price of \$1.11 per share. The Options comprise the long term incentive component of the remuneration package for the Chief Executive Officer and were issued pursuant to the terms of the Chief Executive Officer Share Option Plan, which was approved at the Acrux Limited Extraordinary General Meeting on 3 February 2015. Shares allocated on exercise of the Options will rank equally from the date of exercise.

No other matters or circumstances have arisen since the end of the financial year that have significantly affected or may significantly affect the operations of the consolidated entity, the results of those operations, or the state of affairs of the consolidated entity in future financial years.

Likely Developments

For the foreseeable future, the consolidated entity's financial results will be materially influenced by the sales performance of Axiron in the United States and/or development of the consolidated entity's product pipeline, involving transition of pipeline products from preclinical activities to clinical trial initiation.

Under a license agreement with Eli Lilly, the consolidated entity receives royalties on worldwide sales of Axiron by Eli Lilly and it is eligible to receive potential sales milestone payments of up to US\$170 million.

Development of the consolidated entity's pipeline is progressing, the key focus being development of formulations for world wide commercialisation of high value therapies. Details will be released as and when projects in the consolidated entity's pipeline progress through the development life cycle.

Environmental Regulation

The consolidated entity's operations are subject to certain environmental regulations under the laws of the Commonwealth and of the State. Details of the consolidated entity's performance in relation to such environmental regulations are as follows:

Laboratory Waste

In order to ensure compliance with the Environment Protection Act 1970, the consolidated entity engages an external waste management consultant. This consultant has ISO 14001:2004 Certified Environmental Management to ensure compliance with the legislative requirements. The consultant issues an EPA Transport Certificate at every collection of waste to ensure safe collection, transport, delivery and disposal/recycling procedures.

Trade Water Waste

An agreement exists with City West Water to ensure compliance under the Water Industry Act 1994 and Water Industry Regulations 1995. This agreement ensures that the acceptance of trade waste into the sewage network is managed effectively and that City West Water is aware of the type and quantities of waste disposed of by the consolidated entity.

The Directors are not aware of any breaches during the period covered by this report.

DIRECTORS' REPORT

CONTINUED

Dividend Paid, Recommended and Declared

A final fully-franked dividend for the 2013/14 financial year of 8 cents per share, totaling \$13.3 million, was paid during the reporting period. On 12 August 2015, the Directors resolved to declare a final dividend to shareholders of 6 cents per share, fully-franked. The total amount of the dividend, based on the number of shares on issue at 30 June 2015 and at the date of this report, is \$10.0 million.

Share Options

Unissued ordinary shares of Acrux Limited under option at the date of this report are as follows:

| Date options granted | Number of unissued ordinary shares under option | Issue price of shares | Expiry date of the options |
|----------------------|---|-----------------------|----------------------------|
| 31 July 2013 | 780,000 | \$4.30 | July 2016 |
| 21 November 2013 | 600,000 | \$4.30 | July 2016 |
| 3 February 2015 | 2,000,000 | \$1.32 | February 2018 |
| 3,380,000 | | | |

No option holder has any right under the options to participate in any other share issue of the Company.

A total of 2,000,000 options over unissued ordinary shares were granted to the CEO during the financial year.

Shares Issued on Exercise of Options

There were no shares issued during the financial year from the exercise of share options.

Indemnification and Insurance of Directors and Officers

During the financial year, the consolidated entity has paid premiums in respect of an insurance contract to indemnify officers against liabilities that may arise from their position as officers of the Company and its controlled entities. Officers indemnified include the company secretary, all Directors and all executive officers participating in the management of the Company and its controlled entities. Further disclosure required under section 300(9) of the *Corporations Act 2001* is prohibited under the terms of the insurance contract.

Proceedings on Behalf of the Consolidated Entity

In May 2013, November 2013, December 2014 and July 2015, Acrux DDS Pty Ltd together with Eli Lilly and Company filed lawsuits in the United States District Court for the Southern District of Indiana against 1) Perrigo Israel Pharmaceuticals Limited ("Perrigo"), 2) Watson Laboratories Inc. ("Actavis"), 3) Amneal Pharmaceuticals LLC ("Amneal") and 4) Lupin Pharmaceuticals Inc. ("Lupin"), respectively for infringement of issued patents covering Axiron. In each instance, the patents are owned by Acrux DDS, a wholly-owned subsidiary of Acrux Limited and exclusively licensed to Lilly. The lawsuits were filed in response to notice letters sent by each company regarding its filing with the US Food and Drug Administration of an Abbreviated New Drug Application ("ANDA") for a Testosterone Metered Dose Transdermal Solution. The letters each stated that the respective ANDAs contain Paragraph IV certifications with respect to US Patent's that include claims relating to the application of testosterone formulations to the underarm and to the applicator used to apply Axiron. Actavis further includes paragraph IV certifications with respect to US patents that include claims relating to the quick-drying formulation. A Paragraph IV certification alleges invalidity, unenforceability and/or non-infringement of a patent.

Through 2014, a number of pending product liability lawsuits were filed against Acrux and Eli Lilly in the United States District Court for the Northern District of Illinois, including claims that assert injury caused by testosterone replacement therapy. These cases, brought by private plaintiffs, were consolidated for pre-trial purposes in the United States District Court for the Northern District of Illinois under the Multi-District Litigation Rules as Testosterone Replacement Therapy Products Liability Litigation, MDL No. 2545.

Information on Directors and Company Secretary

The qualifications, experience and special responsibilities of each person who has been a Director of Acrux Limited at any time during or since 1 July 2014 is provided below, together with details of the company secretary as at the year end. The Directors have been in office since the start of the financial year to the date of this report unless otherwise stated.

R Dobinson
(Director since March 1998)

Responsibilities

From November 2014, Non-Executive Chairman; 1 July 2012, Executive Chairman; prior to 1 July 2012, Non-Executive Chairman.

Qualifications

BBus

Experience

Ross has been a Director since 1998 and was appointed Chairman in January 2006 and then Executive Chairman from 1 July 2012 to October 2014. He is a founder and former CEO of Acrux. Ross has a background in investment banking and stockbroking. He is currently Managing Director of TSL Group Ltd, a corporate advisory company specialising in establishing and advising life sciences companies. He was a founding Director of Starpharma Holdings Limited (ASX: SPL) since May 1997, former Executive Chairman of Hexima Limited which was listed on the ASX from July 2010 to June 2011, former Chairman of TPI Enterprises Limited (ASX:TPE), a former Director of Roc Oil Company Limited (ASX: ROC) and a former Director of Racing Victoria Limited.

B Parncutt
(Director since April 2012)

Responsibilities

Non-Executive Director, member of the Human Capital and Nomination Committee and Chair of the Audit and Risk Committee with financial qualification.

Qualifications

BSc, MBA

Experience

Bruce joined the board on 30 April 2012. His career spans over 40 years' in investment management, investment banking and stockbroking including seven years as Chief Executive of listed securities firm McIntosh Securities (1990-1996) and three years as Senior Vice President of Merrill Lynch (1997-1999). His experience includes extensive involvement in financial analysis, merger and acquisition transactions, capital-raising, and investment in companies across a broad spectrum from early stage to mature public companies. He holds a Bachelor of Science, an MBA, and is a Member of the Financial Services Institute of Australasia. Bruce is Chairman of the investment and corporate advisory firm Lion Capital. He is President of The National Gallery of Victoria and a Board Member of the NGV Foundation and the Australian Ballet Company. He was previously a Director of ASX listed Stuart Petroleum Limited (from Aug 2010 to May 2011) and was Director of McIntosh Securities Limited, Australian Stock Exchange Ltd and Vision Systems Ltd for varying periods prior to 1 July 2010.

T Oldham
(Director since October 2013)

Responsibilities

Non-Executive Director, member of the Audit and Risk Committee and Chair of the Human Capital and Nomination Committee (commencing July 2015).

Qualifications

BSc.Hons, LLB Hons, PhD

Experience

Tim joined the board in October 2013. He has more than a decade of life sciences business development, alliance management and sales and marketing experience in Europe, Asia and Australia. He is CEO and Managing Director of Cell Therapies Pty Ltd, a leading Asia Pacific provider of collection, manufacturing, delivery and distribution capabilities for stem cell therapies and regenerative medicine and was President of Asia Pacific for Hospira Inc. (2007 to 2012), having held a variety of senior management roles with Mayne Pharma (2002 to 2007) prior to its acquisition by Hospira. These roles encompassed the development and commercialisation of pharmaceuticals, devices, biologics and cellular therapies. Prior to this, Dr. Oldham was an engagement manager with McKinsey & Co (1997 to 2001). Tim has been chairman of the European Generic Medicines Association Biosimilars and Biotechnology Committee, a Director of the Generic Medicines Industry Association and a member of the Pharmaceutical Industry Strategy Group. He is also a Director of iSonea Ltd (ASX: ISN).

R Barrow
(Director from April 2012 to February 2015)

Responsibilities

Non-Executive Director, Chair of the Human Capital and Nomination Committee and member of the Audit and Risk Committee.

Qualifications

BSc.Hons, MBA

Experience

Ross joined the board on 1 April 2012. He has extensive experience in the life sciences sector. Ross was Chief Operating Officer and a director of Vision BioSystems Limited during the period when the company became a leader in the global histopathology market. Following acquisition by Danaher Corporation, Ross played a pivotal role overseeing the global integration of the company with Danaher's subsidiary, Leica Microsystems GmbH. Ross is currently the Chief Executive Officer and a director of Paranta Biosciences Limited.

DIRECTORS' REPORT

CONTINUED

M Kotsanis (Managing Director from 1 November 2014)

Responsibilities

Managing Director and Chief Executive Officer.

Qualifications

BSc.MBus

Experience

Michael commenced as CEO and Managing Director of Acrux in November, 2014. He has over 25 years' of experience in the pharmaceutical industry and has significant senior leadership experience across the global pharmaceutical markets. Michael was formerly the Chief Commercial Officer for Synthon Holding BV, a specialty pharmaceutical company based in The Netherlands, a position he held from mid-2010. Prior to Synthon, he served as President, Europe, Middle East and Africa, for Hospira, the global leader in generic injectable pharmaceuticals. Michael joined Hospira following its acquisition of Mayne Pharma in 2007, where he served as President Asia Pacific from 2002. He joined Mayne following their acquisition of Faulding Pharmaceuticals in 2001, where he held responsibility for commercial activities in Australia and New Zealand. Prior to Faulding, Michael held a variety of sales and marketing positions with Boehringer Ingelheim over an 11 year period. Michael earned a bachelor's degree in science from Monash University, and a master's degree in business from the University of Technology, Sydney.

S Papworth (Company Secretary from 29 September 2014)

Responsibilities

Chief Financial Officer and Company Secretary.

Qualifications

B.Com, CA.

Experience

Sharon commenced with Acrux as CFO and Company Secretary in September 2014. She has 18 years' of finance experience, leading both commercial and technical functions. Having previously held senior finance roles at ASX and US listed organisations, Sharon's experience spans across industries including Pharmaceuticals, Media, Fast Moving Consumer Goods and professional services. Prior to joining Acrux, Sharon was General Manager Finance at Salmat Limited (2010-2014) and Regional Financial Controller for Australia and New Zealand at Hospira (2004-2010), initially joining Mayne Pharma prior to its acquisition by Hospira. These roles supported business growth strategies, providing financial advisory and leadership. Sharon commenced her career at KPMG in the audit division and worked with a broad range of clients including ASX listed entities. Sharon is a Chartered Accountant who also holds a Bachelor of Commerce with majors in Accounting and Marketing.

Directors' Meetings

The number of meetings of the Board of Directors and of each Board Committee held during the financial year and the numbers of meetings attended by each Director were as follows:

| Directors | Committee Meetings | | | | | |
|-------------------------|---------------------------|-----------------|---------------------------|-----------------|------------------------------|-----------------|
| | Directors' Meetings | | Audit & Risk | | Human Capital & Nomination** | |
| | Number eligible to attend | Number attended | Number eligible to attend | Number attended | Number eligible to attend | Number attended |
| R Dobinson | 5 | 5 | — | 2* | — | — |
| B Parncutt | 5 | 5 | 2 | 2 | — | — |
| R Barrow ¹ | 4 | 4 | 2 | 2 | — | — |
| T Oldham | 5 | 5 | 2 | 2 | — | — |
| M Kotsanis ² | 3 | 3 | — | 1* | — | — |

¹ Resigned 25 February 2015.

² Appointed Managing Director 1 November 2014.

* Attended by invitation.

** The Human Capital and Nomination Committee met on 6 July 2015. During the year the Committee discussed the appointment of the Chief Executive Officer including setting of remuneration and performance metrics.

Directors' and Executives' Interests in Shares and Options

Directors' and Executives' relevant interests in shares of Acrux Limited and options over shares in the Company as at 30 June 2015 are detailed below:

| | Total No. of Shares | Total No. of Options |
|-------------------|------------------------|-------------------------|
| Directors | | |
| R Dobinson | 1,372,593 | 600,000 |
| B Parncutt | 718,137 | – |
| R Barrow | 17,375 | – |
| T Oldham | 15,750 | – |
| M Kotsanis | – | 2,000,000 |
| Executives | | |
| N Webster | 6,100 | 175,000 |
| F Colagrande | 1,500 | 140,000 |
| Total | 2,131,455 | 2,915,000 |

Directors' Interests in Contracts

Directors' interests in contracts are disclosed in Note 23 to the financial statements.

Auditor's Independence Declaration

A copy of the auditor's independence declaration as required under section 307C of the *Corporations Act 2001* in relation to the audit for the financial year is provided with this report.

Non-Audit Services

Non-audit services are approved by resolution of the Audit Committee and approval is provided in writing to the Board of Directors. Non-audit services provided by the auditors of the consolidated entity during the year, Pitcher Partners (Melbourne) and network firms of Pitcher Partners are detailed below.

| | 2015 \$ | 2014 \$ |
|---|---------------|------------|
| Amounts paid or payable to Pitcher Partners (Melbourne) for non-audit services: | 12,500 | Nil |
| Amounts paid or payable to network firms of Pitcher Partners for non-audit services: | Nil | Nil |
| Amounts paid or payable to non-related auditors of group entities for non-audit services: | Nil | Nil |
| Total auditors' remuneration for non-audit services | 12,500 | Nil |