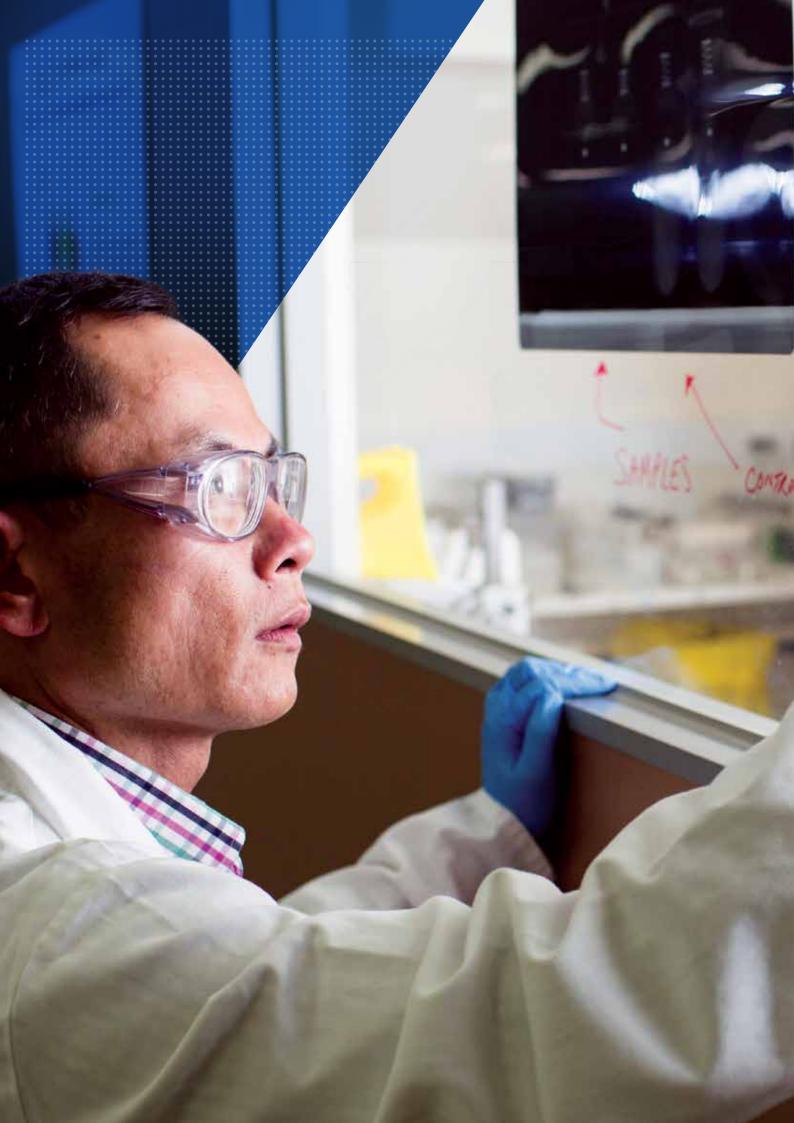


# ANNUAL REPORT 2015

1 2







- 2 Company Overview
- 4 Business Snapshot
- 6 Chairman's Address
- 7 CEO and Managing Director's Report
- 9 Operating Review
- 16 Board of Directors & Senior Management
- 18 Corporate Governance Statement
- 24 Directors' Report
- 30 Remuneration Report (Audited)
- 35 Auditor's Independence Declaration
- 36 Consolidated Statement of Comprehensive Income
- **37** Consolidated Statement of Financial Position
- **38** Consolidated Statement of Changes in Equity
- **39** Consolidated Statement of Cash Flows
- 40 Notes to the Financial Statements
- 62 Directors' Declaration
- 63 Independent Auditor's Report
- 65 Shareholder Information
- 68 Glossary
- 69 Corporate Directory

ACRUX (ASX: ACR) IS AN AUSTRALIAN DRUG DELIVERY COMPANY, DEVELOPING AND COMMERCIALISING A RANGE OF PATIENT-PREFERRED PHARMACEUTICAL PRODUCTS FOR GLOBAL MARKETS. USING INNOVATIVE TECHNOLOGY, OUR DRUGS CAN BE ADMINISTERED THROUGH THE SKIN OR NAILS, BOTH TOPICALLY AND TRANSDERMALLY.

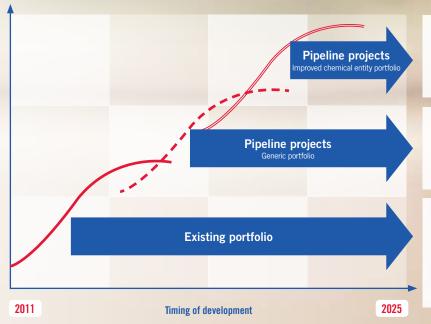
# COMPANY PROFILE

#### ACRUX (ASX: ACR) IS AN AUSTRALIAN DRUG DELIVERY COMPANY, DEVELOPING AND COMMERCIALISING A RANGE OF PATIENT-PREFERRED PHARMACEUTICAL PRODUCTS FOR GLOBAL MARKETS. USING INNOVATIVE TECHNOLOGY, OUR DRUGS CAN BE ADMINISTERED THROUGH THE SKIN OR NAILS, BOTH TOPICALLY AND TRANSDERMALLY.

Acrux has three products marketed by licensees within major markets around the world, as well as additional products at earlier stages of development. Our unique technology, used in marketed products such as Axiron<sup>®</sup>, Evamist<sup>®</sup> and Lenzetto<sup>®</sup>, are based on fast-drying, low volume, accurately-dosed solutions containing penetration enhancers, that when applied topically, deposit the drugs through the skin with long-lasting effects.

We are currently developing a range of generic and patent-preferred products. Acrux has on-site laboratories, a Good Manufacturing Practice (GMP) manufacturing suite, clinical and the commercial experience to facilitate these development projects.

# **GROWTH STRATEGY**



Acrux is building a diversified portfolio, maximising its existing assets and developing both proprietary and generic projects for longer term growth. Each growth wave provides a different investment profile, formulation development cycle and clinical and regulatory program. Acrux will continue to commercialise its products with corporate partners. The timing of partnerships will be assessed to accommodate investment requirements and capital returns to shareholders.

#### Wave 3: Improved chemical entity portfolio

- Proprietary product portfolio with intellectual property protection
- Reformulation with superior product profiles for unmet patient needs

#### Wave 2: Generic portfolio

- Product candidates identified
- Abbreviated regulatory and clinical pathways

#### Wave 1: Extend products from our existing portfolio

- Estradiol launch outside the United States
- New distributor (Perrigo) for Estradiol within
- the United States
   Continued growth of Axiron sales outside the United States
- Improved product life cycle management



# BUSINESS MILESTONES

# \$11.1M

ACRUX RECORDS ITS 6TH CONSECUTIVE PROFITABLE YEAR: NPAT OF \$11.1 MILLION FOR THE YEAR ENDED 30 JUNE 2015

ESTRADIOL SPRAY LENZETTO REGULATORY APPROVAL GRANTED IN EUROPE \$23.1M

#### **STRONG BALANCE SHEET**

CASH RESERVES OF \$23.1 MILLION AT 30 JUNE 2015

#### **GENERIC PORTFOLIO**

TOPICAL AND TRANSDERMAL GENERICS PORTFOLIO **IDENTIFIED AND DEVELOPMENT INITIATED** 

#### NSAID

NON-STEROIDAL ANTI-INFLAMMATORY DRUG PROPRIETARY PORTFOLIO: SUPERIOR FORMULATIONS DEVELOPED

# \$1.02

TOTAL CAPITAL RETURNED TO SHAREHOLDERS VIA DIVIDEND **OVER THE LAST 5 YEARS:** \$1.02/SHARE

# BUSINESS SNAPSHOT

### **FINANCIAL METRICS**

	2014/15	2013/14	2012/13	2011/12
Final dividend per share	6 cents	8 cents	8 cents	8 cents
Special dividend per share	-	12 cents	_	_
Earnings per share	6.7 cents	16.8 cents	4.2 cents	4.4 cents
Cash (million)	\$23.1	\$25.8	\$22.8	\$30.0
Net profit after tax (million)	\$11.1	\$28.0	\$6.9	\$7.4
Revenue (million)	\$25.4	\$53.9	\$16.7	\$10.7

### **BUSINESS HIGHLIGHTS**

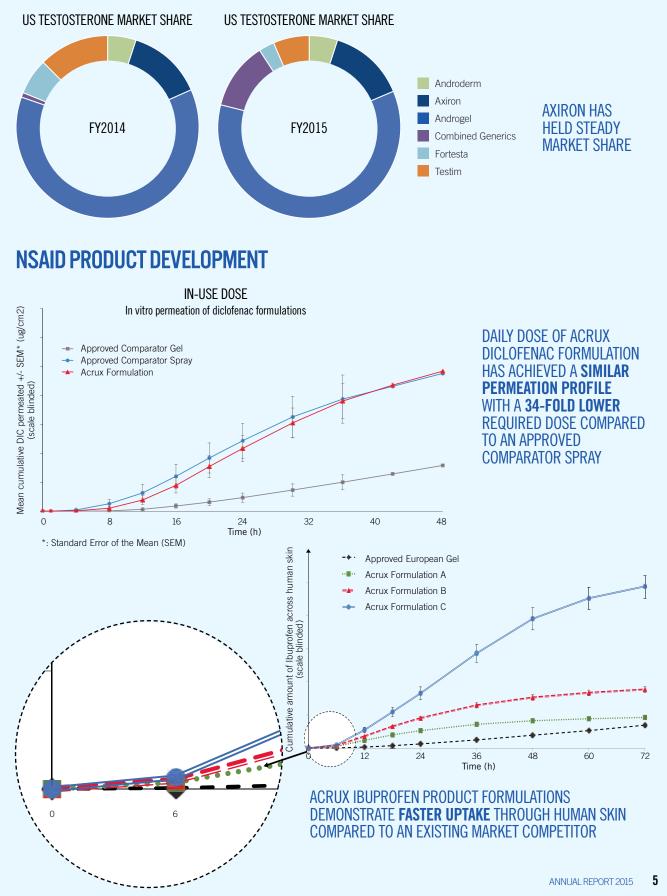
- Earnings per share 6.7 cents, facilitating a final dividend payment of 6 cents per share, fully-franked
- Board-endorsed strategy with a clear focus on diversifying our product pipeline and creating future growth opportunities utilising the Acrux technology platform
- Good progress on our onychomycosis program, targeting a once daily treatment with a superior drug permeation profile
- Topical and transdermal generics pipeline identified and development initiated
- Superior permeation profiles demonstrated with formulation of non-steroidal anti-inflammatory drugs (NSAID), compared to market leaders
- ► Acrux net profit after tax (NPAT) of \$11.1 million (2014: \$28.0 million). Profit in the prior year was higher as milestone payments were received in 2014
- Royalty income of \$24.6 million (2014: \$24.7 million). Declines in the sales volumes of Axiron were largely offset by improvements in the AUD\$:USD\$ exchange rate
- Cash reserves: \$23.1 million (2014: \$25.8 million) after payment of dividends in the current and prior financial years. Acrux does not have any debt facilities
- Regulatory approval for Lenzetto (estradiol spray) granted in Europe

### **BUSINESS OUTLOOK FOR 2015/16**

- Launch of Lenzetto in Europe, Acrux's unique estradiol spray for treating post-menopausal symptoms which is licensed exclusively in Europe to Gedeon Richter
- 2016 National Formulary status for Axiron has been secured at two of the largest commercial prescription benefit managers (PBMs)
- ► Axiron anticipated to maintain market share during the 2016 financial year, with stabilisation of prescription volumes over the first half 2015 calendar year
- Progression of development programs for multiple product candidates with no material change to ongoing cash operating cost needs (until one or more projects enters into clinical trials)



### **UNITED STATES TESTOSTERONE MARKET SHARE**





Ross Dobinson

THE STABILISATION OF THE TESTOSTERONE MARKET AND RESULTING ROYALTY REVENUE STREAM FOR AXIRON WILL BE ABLE TO FUND FURTHER DEVELOPMENT WORK ON OUR PRODUCT PIPELINE.

# CHAIRMAN'S ADDRESS

#### ON BEHALF OF THE BOARD, I WOULD LIKE TO PRESENT TO YOU THE 2015 ANNUAL REPORT FOR ACRUX LIMITED.

We continue to have a strong cash position and were pleased to have announced a 6 cent fullyfranked dividend for the year ended 30 June 2015.

Your Board has endorsed a business strategy which will result in the Company having a more balanced asset portfolio. Our portfolio includes development programs which are expected to generate new intellectual property, as well as programs which will be able to achieve product commercialisation through generic regulatory pathways. This revised portfolio will enable us to diversify our earnings base in the future and broaden our future income streams.

The market for Axiron appears to have stabilised since the publication of the Drug Safety Communication by the Food and Drug Administration (FDA) in the United States in March 2015. Since then, labelling changes have been implemented for all testosterone products. Sponsors of marketed testosterone products are in dialogue with the FDA over a long term safety trial. The stabilisation of the testosterone market and resulting royalty revenue stream for Axiron will be able to fund further development work on our product pipeline. Since our last Annual Report, Perrigo Company plc has been appointed as the distributor for Evamist in the US, resulting in a more effective distribution franchise for the product. In Europe, Gedeon Richter has received a number of regulatory approvals for Lenzetto. Evamist and Lenzetto are the US and European trademarks respectively for our proprietary estradiol spray.

We continue to progress development of an antifungal therapeutic for onychomycosis. Subject to the results of work currently being undertaken as part of the development program, new intellectual property is expected to be generated. In a separate initiative, we have made significant progress with superior formulations of two nonsteroidal anti-inflammatory drugs.

As evidenced by this list of developments since our last annual report, Michael Kotsanis and the senior management team have had a very active year since Michael's appointment as CEO. Acrux is well positioned for continued regeneration following the disruption of the US testosterone replacement therapy market.

Ross Dobinson Chairman



# CEO AND MANAGING DIRECTOR'S REPORT



Michael Kotsanis

It is my pleasure to summarise the status of our key activities through my Chief Executive Officer's Review for the first time since joining Acrux in November 2014. Since my appointment to Acrux the senior management team has invested significant time reviewing the Company's corporate strategy and related activities, our development pipeline and organisational structure.

We have implemented significant changes throughout the Company, including in our pipeline focus, our organisational structure and our strategy. We have been mindful of the need to balance our development spend on commercially attractive development projects with a return to shareholders through the payment of a fully-franked dividend of 6 cents for the 2015 financial year.

# Product development pipeline

It is incumbent upon us to diversify our business and offset our reliance on Axiron as a key value driver within the Company. Our strategy has been refined and will continue to evolve. A key element has been to re-focus our development efforts. We have evaluated the use of our transdermal technology on a substantial number of development opportunities and to date have identified a commercially attractive portfolio of projects. We continue to focus on key pipeline assets including the development of a product for onychomycosis, for which we are leveraging our existing internal skills, technology and laboratory facilities. Our focus on this project has been to develop formulations that have enhanced nail penetration and we have assessed a number of different antifungals for that purpose. with successful nail permeation seen with several of these antifungals. However, our goal is not just improved permeation of the antifungal to the site of the nail infection, but a superior delivery profile, which will allow us to predict clinical success with a greater order of precision. Our work here continues. We have also commenced work on a number of generic transdermal and topical product development opportunities. These opportunities represent exciting additions to the pipeline, with lower development risks that have shorter development timelines and lower development costs than those needed for novel drugs.

The development progress we made throughout the year on our two NSAID projects has yielded very encouraging skin permeation results, with superior permeation profiles to the leading products that are commercially available in major markets. This is another demonstration of our capabilities in the transdermal drug delivery field.

#### **Transdermal capabilities**

Acrux is one of the few Australian biotech companies to have commercialised human prescription pharmaceutical products. This gives us the confidence to develop additional products utilising our proven capabilities to drive further shareholder value for the Company.

We continue to evaluate additional projects for our transdermal technology. The quality of these opportunities and the due diligence we conduct in understanding and evaluating the technical and commercial feasibility is paramount prior to embarking on any development work. We will continue to evaluate new product concepts carefully.

#### Axiron

Our attention within our commercialised portfolio is naturally focused on Axiron (our testosterone replacement therapy), which currently provides the bulk of our royalty income. Whilst there have been regulatory assessments in a number of markets where Axiron is sold, the most impactful assessment has been by the FDA in the United States, which is where over 90% of our sales occur. The FDA published a Drug Safety Communication in March 2015.

## CEO AND MANAGING DIRECTOR'S REPORT

CONTINUED

Safety concerns over the testosterone drug class impacted sales volumes of the testosterone replacement therapy market (including Axiron) in 2014. However, Axiron volume trends to date in calendar year 2015 appear to have stabilised. We have been pleased with the continued growth of Axiron sales in Canada, Brazil, Germany, Australia and South Korea. Our royalty stream for Axiron is paid in US dollars and the Australian dollar exchange rate has helped our year on year royalties to remain relatively stable.

#### Estradiol Spray European Launch

We look forward to the launch of our estradiol product in Europe later in the 2016 financial year and were excited to achieve the first of the country regulatory approvals in Europe in recent weeks. This generated an important financial milestone and we believe our partner (Gedeon Richter, which has a strong women's health franchise) is well positioned to execute its sales and marketing strategy. Subsequent sales will generate royalties for Acrux.

We look forward to communicating news of the various country launches of our estradiol product over coming months, as well as reporting on meaningful progress with our development projects.

#### Changes to the Management Team

We have made some important additions and changes in our management team during the year:

- Sharon Papworth commenced with Acrux as CFO and Company Secretary in September 2014. Having previously held senior finance roles at ASX and US listed organisations, Sharon's experience spans industries including pharmaceuticals, media, fast-moving consumer goods and professional services.
- Felicia Colagrande was promoted to Product Development and Technical Affairs Director in February 2015. Felicia has a broad background in pharmaceutical operations, dermal drug development, quality control, analytical development and production. She has 25 years' experience in the pharmaceutical/ biotech industry and joined Acrux in 2001.
- Charles O'Sullivan was appointed as Portfolio Director in July 2015. He is an experienced healthcare executive, with a strong background in the pharmaceutical industry, gained over 20 years in both senior executive and clinical roles with large multinational pharma businesses.

In summary, I am excited by the opportunities we are pursuing and see significant upside for the Company in the coming years.

Michael Kotsanis CEO and Managing Director

ACRUX IS ONE OF THE FEW AUSTRALIAN BIOTECH COMPANIES TO HAVE COMMERCIALISED HUMAN PRESCRIPTION PHARMACEUTICAL PRODUCTS. THIS GIVES US THE CONFIDENCE TO DEVELOP ADDITIONAL PRODUCTS UTILISING OUR PROVEN CAPABILITIES TO DRIVE FURTHER SHAREHOLDER VALUE FOR THE COMPANY.



# OPERATING REVIEW

Acrux Pipe	eline	Formulation Design	Pre-clinical Development	Phase I c	Phase II	Phase III	Registration	Commercial	
Marketed Produced Indication(s)	ucts Product name								
Hypogonadism	Axiron®								Lilly
Menopausal symptoms	Estradiol MDTS® (USA) — Evamist®								Silly Perrigo
Post-operative pain in dogs	Recuvyra®								Elanco
Product Pipelin	ne Product name								
Menopausal symptoms	Estradiol MDTS®* (Europe) – Lenzetto®							¢	GEDEON RICHTER
Antifungal (Onychomycosis)	ACR-065								
Pain and inflamation (Diclofenac)	ACR-046								
Pain and inflamation (Ibuprofen)	ACR-048								
Identified multiple generics	Various								
Initial generic portfolio	Undisclosed								
Companion animal health	Undisclosed							c	Elanco
*Ex-US licensees	for Estradiol include 0	Gedeon Richte	r, Aspen, Drea	am Pharma, V	ifor. Trademar	ks vary by co	untry/region.	1 1	

#### **Onychomycosis**

Acrux continues to develop a topical antifungal product for the treatment of onychomycosis (fungal infection in fingernails and toenails). It is anticipated that the product will be a once daily application that provides better efficacy than the current lead comparator product. In parallel with ongoing preclinical studies, the clinical trial design and regulatory pathway for the product are being planned.

#### **Dispute with Hexima**

Our dispute with Hexima over the antifungal collaboration agreement remains formally unresolved. This does not affect our current onychomycosis program.

**OPERATING REVIEW** 

# **OPERATING REVIEW**

CONTINUED



ACRUX IS BUILDING A DIVERSIFIED PRODUCT PORTFOLIO BASED ON MAKING CAPITAL RETURNS, MAINTAINING SUSTAINABLE MARKET ADVANTAGES AND PROVIDING CLEAR BENEFITS TO PATIENTS, PHYSICIANS AND HEALTHCARE PAYERS.

#### Pain

Acrux's proprietary topical NSAID products for pain have completed formulation design.

#### Diclofenac

Based on preclinical studies, the daily dose of Acrux Diclofenac formulation has achieved a similar permeation profile with a 34-fold lower dose requirement compared to an approved comparator spray. In addition, the permeation profile is such that the dose would support a once daily application. Current competitors' products require at least a twice daily application to maintain the drug delivery profile. This differential feature provides a significant improvement over existing products.

#### Ibuprofen

Early studies indicate that Acrux's ibuprofen product formulations demonstrate a significantly faster uptake through human skin relative to existing competitors, which would result in a much faster onset of pain relief. Our product delivery profile also supports a once daily application, providing a significant improvement over currently approved products.

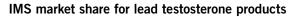
With both of these NSAID opportunities, Acrux intends to work closely with prospective corporate partners that are both capable and committed to further development and marketing in key territories.

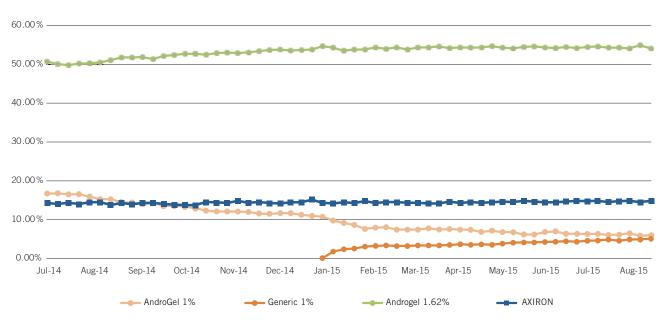


#### Generics

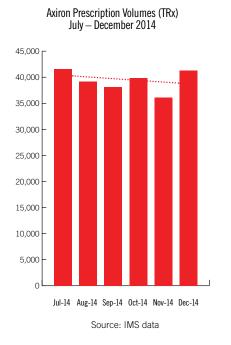
The first wave of topical and transdermal generic product opportunities has been identified and product development has been initiated. The local market value of the initial 12 products identified has market sales of US\$2.4 billion in countries we are targeting. For competitive reasons the pipeline remains undisclosed.

#### Axiron

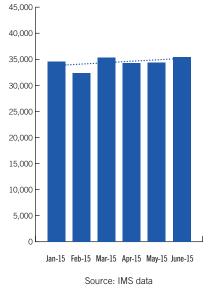




#### Axiron TRx (prescription volume) for financial year 2014/15



#### Axiron Prescription Volumes (TRx) January – June 2015



Axiron's net sales for the 2014/15 financial year totaled US\$155.4 million compared to US\$181.1 million in the prior year. Our royalty stream for Axiron is paid in US dollars and the Australian/US dollar exchange rate has helped our year on year-royalties to remain stable. Royalty receipts from Axiron were \$24.3 million, compared to \$24.5 million in the prior year.

Axiron's sales volumes have remained relatively steady throughout the 2015 calendar year. Axrion's market share for both new prescriptions and total prescriptions for the last financial quarter was consistent with the prior quarter. The introduction of 1% generics of competitors' formulations through FY2015 has had no impact on Axiron's market share. **OPERATING REVIEW** 

# OPERATING REVIEW



THE 2016 NATIONAL FORMULARY STATUS FOR AXIRON HAS BEEN SECURED AT TWO OF THE LARGEST COMMERCIAL PRESCRIPTION BENEFIT MANAGERS (PBM).

#### **Axiron FDA Update**

In March 2015, the Food and Drug Administration released a Communication 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". These class labelling changes were implemented for all testosterone products in June 2015. Sponsors of marketed testosterone products in the United States are in dialogue with the FDA over a long term safety trial. The protocols for this are being planned with finalisation expected in mid-2016.

#### **Axiron EMA Update**

In November 2014, the European Medicines Agency (EMA) released a statement regarding the use of Testosterone Replacement Therapy in Europe, titled: "No consistent evidence of an increased risk of heart problems with testosterone medicines". The committee considered that the benefits of testosterone continue to outweigh its risks but recommended that testosterone-containing medicine should only be used where lack of testosterone has been confirmed by signs and symptoms as well as laboratory tests. Labelling changes were not required for Axiron in Europe.



#### **Axiron Litigation**

The Acrux patent concerning the underarm administration of testosterone formulations was granted by the United States Patent and Trademark Office (USPTO) in May 2013. In the United States, Axiron is now protected by a number of patents which have expiry dates of 2030, 2027, 2026 and 2017. The patents cover 3 different aspects of the product, including the formulation and delivery method, administration to the underarm and the physical applicator. In May 2013, November 2013, December 2014 and July 2015, Acrux DDS Pty Ltd (a wholly-owned subsidiary of Acrux Ltd.) together with Eli Lilly and Company ("Lilly") filed lawsuits in the United States District Court for the Southern District of Indiana against 1) Perrigo Israel Pharmaceuticals Limited, 2) Watson Laboratories Inc. ("Activis"), 3) Amneal Pharmaceuticals LLC and 4) Lupin Pharmaceuticals Inc., respectively for infringement of issued patents covering Axiron. In each instance, the patents are owned by Acrux DDS and are exclusively licensed to Lilly. The lawsuits were filed in response to notice letters sent by each company regarding its filing with the United States 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 United States patents that include claims relating to the application of testosterone formulations to the underarm and to the applicator used to apply Axiron. Activis further includes paragraph IV certifications with respect to United States patents that include claims relating to the quick-drying formulation. A Paragraph IV certification alleges invalidity, unenforceability and/or noninfringement of a patent.

Throughout 2014, a number of pending product liability lawsuits were filed against Acrux and 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 pretrial 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.

#### **Estradiol Spray**

The first product developed by Acrux was an estradiol spray for women to treat the symptoms of menopause. The spray was approved by the FDA in 2007 and launched into the US market in 2008. Branded Evamist, the spray is now distributed in the United States by Perrigo Company plc. Evamist US net sales are currently approximately US\$10 million per annum.

In June 2013, Acrux appointed Gedeon Richter to commercialise the product in certain ex-US markets and received US\$1 million upon signing the agreement. In September 2015, Gedeon Richter and Acrux announced that the product, named Lenzetto, received multiple regulatory approvals in European territories, triggering milestone payments totaling US\$2 million. These approvals of Lenzetto were granted after the European decentralised procedure (DCP) was completed with the first country approval triggering a milestone payment of US\$ 1 million and the second and third approvals triggering milestone payments of US\$ 0.5 million each. Initial launches are planned for the first half of calendar year 2016 following pricing and reimbursement approvals.

Finance	30 June 2015 \$m	30 June 2014 \$m	30 June 2013 \$m	30 June 2012 \$m
Product agreement revenue	24.6	53.4	15.5	9.0
Interest, grant and other income	0.8	0.5	1.2	1.7
Total revenue	25.4	53.9	16.7	10.7
Royalties payable	(0.9)	(1.8)	(0.5)	(0.3)
Capitalised development amortisation	(1.3)	(1.3)	(1.3)	(0.2)
Other expenditure	(6.4)	(6.9)	(4.8)	(5.3)
Total expenditure	(8.6)	(10.0)	(6.6)	(5.8)
Profit before tax	16.8	43.9	10.0	4.9
Income tax (expense)/benefit	(5.7)	(15.9)	(3.1)	2.5
Profit after tax	11.1	28.0	6.9	7.4
Earnings per share	6.7 cents	16.8 cents	4.2 cents	4.4 cents
Net cash inflow/(outflow)	10.5	36.3	6.3	(2.5)
Dividend paid	(13.3)	(33.3)	(13.4)	(0.6)
Net cash	23.1	25.8	22.8	30.0

**OPERATING REVIEW** 

# **OPERATING REVIEW**

CONTINUED



**ACRUX GENERATES INCOME FROM** COMMERCIALISED PRODUCTS. IS **CASHFLOW POSITIVE** AND MAINTAINS A LOW OPERATING COST BASE.

#### 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). No milestones were recognised during the year (2014: \$28.7 million). The prior year revenue included two one-off milestones - firstly. \$28.0 million (US\$25 million) from Lilly for Axiron sales exceeding US\$100 million during the 2014 calendar year and secondly, a \$0.7 million (US\$0.6 million) milestone from Gedeon Richter following the first European regulatory filing for Acrux's estradiol spray in Europe. Interest income contributed \$0.6 million (2014: \$0.5 million).

#### **Expenses**

Operating expenditure decreased to \$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 decreased product income. 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). Directors' fees decreased to \$0.4 million (2014: \$0.6 million) while employee benefits expense increased to \$2.7 million (2014: \$2.3 million). Professional fees increased to \$0.7 million (2014: \$0.3 million) as a result of investment in strategic advice, 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.

Income tax expense for the financial year was \$5.7 million (2014: \$15.9 million) representing approximately 33.8% of profit before income tax. Acrux Limited is a Pooled Development Fund (PDF). The income tax expense recorded is the result of the tax effect particular to a PDF. PDFs are taxed at 15% on operating income. Subsidiaries of a PDF are taxed at 30% on operating income. Groups containing a PDF are not permitted to consolidate for tax purposes. Further information regarding income tax expense is provided at Note 1(j) of the notes to the financial statements following.

#### Cash flow

Cash reserves at the end of the financial year were \$23.1 million (2014: \$25.8 million). Net cash outflow over the period totaled \$2.9 million (2014: a net cash inflow of \$3.0 million was recorded).

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

Cash receipts from product agreements decreased to \$25.2 million (2014: \$53.4 million) with no milestones received. 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 (2014: \$10.8 million).

#### Outlook

Acrux generates income from commercialised products, is cashflow positive and maintains a low operating cost base.

#### **Operating cost base**

Acrux will continue to progress its product pipeline. The annual cash operating expenditure to execute our preclinical program is expected to remain consistent with the 2015 financial year, being \$5.5 million. This excludes Monash royalty payments and non-cash items. This expenditure covers maintenance of the Company's operations, research and development, and intellectual property expenses. Royalty payments due to Monash Investment Trust cease in February 2017. The expenditure profile of the business will naturally increase as projects enter into clinical trials. Acrux will update the market accordingly prior to this occurring.

#### **Royalties**

In the short term, Acrux will derive the majority of its revenue under its global license agreement with Lilly for the marketing and distribution of Axiron. Royalty income will increase from our estradiol products. In the US, Perrigo has been appointed as the distributor through Perrigo's women's health franchise. As noted previously, Acrux announced the approval of Lenzetto, Acrux's estradiol spray for the relief of menopausal symptoms for women, licensed exclusively to Gedeon Richter in Europe. Launch in Europe is expected in the first half of calendar 2016.

#### Milestones

Under our agreements, Acrux may also be eligible to receive milestones for defined product achievements. During the quarter ended September 2015, Acrux announced that a US\$2 million milestone was earned upon receipt of regulatory approvals for Lenzetto in Europe. Sales of Axiron are not anticipated to trigger a sales based milestone during 2016, however a revenue based milestone payment of US\$50 million is payable upon Axiron achieving an undisclosed global sales hurdle. Acrux may be eligible for further milestone payments totaling US\$120 million over the four financial years commencing 2018/19.

#### **Risk and uncertainty**

Forward-looking statements are subject to risks and uncertainties and have been made throughout this report. Such statements involve known and unknown risks and important factors that may cause the actual results, performance or achievements of Acrux to be materially different from statements made in this report.

## **BOARD OF DIRECTORS & SENIOR MANAGEMENT**



Ross Dobinson BBus Non-Executive Chairman

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.



Bruce Parncutt BSc, MBA Non-Executive Director

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, capitalraisings, 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.



Tim Oldham BSc.Hons, LLB Hons, PhD Non-Executive Director

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).



Michael Kotsanis BSc, MBus Managing Director and Chief Executive Officer

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.





#### **Sharon Papworth**

B.Com, CA Chief Financial Officer and Company Secretary

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.



Nina Webster Ph.D., M.IP.Law, MBA Commercial Director

Nina has over twenty years in the pharmaceutical industry, with leadership roles in business development, project management, intellectual property portfolio management, research and development and general management. Most recently, Nina spent two years with Immuron Limited where, as Director of Commercialisation and Intellectual Property, she was responsible for the intellectual property portfolio and research & development. Prior to this, Nina spent ten years with Acrux Limited as Director of Business Development, responsible for the strategic identification, development and maintenance of commercial partnerships globally, and six years in research and development at Wyeth in the UK, gaining experience from formulation development through to pharmaceutical scale-up and technology transfer. Nina holds a Ph.D in Pharmaceutics from Cardiff University, a Bachelor degree in Pharmacology, a Masters degree in Intellectual Property Law from Melbourne University and an MBA from RMIT.



Felicia Colagrande BSc(Hons) Product Development and Technical Affairs Director

Felicia was appointed Product Development and **Technical Affairs Director** in February 2015. Felicia has a broad background in pharmaceutical operations, dermal drug development, quality control, analytical development and production. Felicia leads and facilitates all technical aspects of pharmaceutical product development including R&D, analytical development, clinical development, project management and CMC development, with a focus on exploiting and optimizing the company's drug delivery technology. She has 25 years' experience in the pharmaceutical/ biotech industry and joined Acrux in 2001. She has previously held positions at Faulding Pharmaceuticals. the Department of Clinical Pharmacology and Therapeutics at the Austin Hospital, Silliker-Microtech Laboratories and was an Adjunct Appointee Lecturer with the Faculty of Pharmacy and Pharmaceutical Sciences atMonash University. Felicia has a Bachelor of Science degree (with Honours) from La Trobe University.

#### **CORPORATE GOVERNANCE STATEMENT**

## CORPORATE GOVERNANCE STATEMENT

This statement summarises the corporate governance policies and procedures adopted by the Board and discloses the extent to which the Company has followed the Australian Securities Exchange (ASX) Corporate Governance Council's Corporate Governance Principles and Recommendations ("ASX Principles") during and since the reporting period.

The Company's corporate governance principles, details of which can be found on the Company's website (www.acrux. com.au), comprise:

- statement of corporate governance principles
- ► code of conduct
- ► Board Charter
- ► Audit and Risk Committee Charter
- Human Capital and Nomination Committee Charter
- continuous disclosure and shareholder reporting policy
- share trading policy
- whistle-blower policy
- diversity policy

#### 1. The Board of Directors

#### 1.1 Board Role and Charter

The Board has the primary responsibility for guiding and monitoring the business and affairs of the Company, including compliance with the Company's corporate governance objectives. The Board's role is set out in the Board Charter, which establishes the relationship between the Board and Management and describes their respective functions and responsibilities. The Board is responsible for the oversight and performance of the Company, including matters such as:

- evaluating, approving and monitoring the strategic and financial plans and performance objectives of the Company;
- b. evaluating, approving and monitoring the annual budgets and business plans;
- evaluating, approving and monitoring major capital expenditure, capital management and all major corporate transactions including the issue of any securities of the Company;
- d. monitoring and approving all financial reports and all other reporting and external communications by the Company;
- e. evaluating Board and individual Director performance;
- f. appointing, removing and managing the performance of, and the succession planning for, a Chief Executive Officer or an Executive Director;
- g. overseeing and ratifying the terms of appointment including remuneration and, where appropriate, ratifying removal of Senior Management;
- h. monitoring Senior Management performance and their implementation of strategy and ensuring appropriate resources are available;

- i. monitoring the Company's performance in relation to maintaining appropriate standards of corporate governance;
- j. approving and monitoring the Company's risk management strategy including internal controls, accountability systems and their effectiveness.

The Board has delegated the day to day management of the Company to the Chief Executive Officer who, in turn, may delegate to Senior Management. The delegations to the Executive Director include:

- a. developing business plans, budgets and Company strategy for consideration by the Board and, to the extent approved by the Board, implementing those plans, budgets and strategy;
- operating the business of the Company within the parameters determined by the Board and keeping the Board promptly informed of all developments material to the Company and its business;
- c. identifying and managing operational risks and formulating strategies for managing those risks for consideration by the Board;
- d. managing the Company's financial and other reporting mechanisms and control and monitoring systems to ensure that they capture all relevant material information on a timely basis and are functioning effectively.

#### 1.2 Board Composition

The Board seeks to achieve a mix of skills and diversity that enables it to most effectively carry out the functions and responsibilities set out in the Board Charter. This includes:

- commercial and technical expertise and experience gained in the pharmaceutical industry;
- expertise and experience in business management and financial markets; and
- relevant relationships in the pharmaceutical industry and in the business community.

The current Board is made up of a Chairman (Ross Dobinson), two non-executive Directors (Bruce Parncutt and Timothy Oldham) and an Executive Director (Michael Kotsanis). Ross Dobinson was a founding Director of Acrux and he has been intimately involved with the development and implementation of the Company's strategy since the Company was founded. Timothy Oldham has extensive technical development and commercialisation skills in the life sciences sector. Bruce Parncutt has comprehensive commercial skills from his 40 years in investment management, investment banking and stockbroking. Michael Kotsanis is the Managing Director and has extensive global pharmaceutical industry experience.

The names of the Directors, the dates of their appointments, their non-executive, executive or independent status and whether they will seek election at the 2015 Annual General Meeting are set out in the table below. The details of their background, skills and experience are set out on page 26 of this report.



Name	Appointed / Retired	Non-Executive	Executive	Independent	Seeking election at 2015 AGM
Ross Dobinson	Appointed 1998	No <sup>(1)</sup>	Yes <sup>(1)</sup>	No	No <sup>(2)</sup>
Bruce Parncutt	Appointed 30 April 2012	Yes	No	Yes	Yes <sup>(3)</sup>
Timothy Oldham	Appointed 1 October 2013	Yes	No	Yes	No <sup>(2)</sup>
Michael Kotsanis	Appointed 1 November 2014	No	Yes	No	No <sup>(4)</sup>

(1) Ross Dobinson held the position of Executive Chairman from 1 July 2012 until Michael Kotsanis was appointed as Chief Executive Officer on 1 November 2014

(2) Ross Dobinson was re-elected and Timothy Oldham was elected on 21 November 2013

(3) Bruce Parncutt was elected on 22 November 2012

(4) Michael Kotsanis is the Managing Director

#### 1.3 Director Independence

Pursuant to the recommendations of ASX Principle 2, the Board Charter ideally requires the Board to include a majority of non-executive independent Directors, have a non-executive independent Chairman and to have different persons filling the roles of Chairman and Chief Executive Officer.

The Board appointed Ross Dobinson as Executive Chairman following the departure of the former Chief Executive Officer and Managing Director at the end of the 2012 financial year. Notwithstanding the Board Charter, the Board determined that with his extensive experience, the current needs of the Company were best served by appointing Ross into an executive role. Michael Kotsanis was subsequently appointed as Chief Executive Officer on 1 November 2015. Ross Dobinson has simultaneously ceased his executive responsibilities with the Company. In accordance with the recommendation of ASX Principle 2.5 and since the appointment of Michael Kotsanis, the roles of Chair and Chief Executive Officer were not exercised by the same individual.

The Chair is responsible for the leadership of the Board, for ensuring that the Board functions effectively and, where appropriate, communicating the views of the Board to the public. The Chair sets the agendas for Board meetings and manages the conduct of meetings by facilitating open discussion between Board members, between the Board and Management and with the public.

#### 1.4 Terms of Director Appointment

The non-executive Directors do not have formal letters of appointment. The Chairman and Managing Director have formal letters of appointment. Remuneration of the non-executive Directors, Managing Director and the terms of appointment of the Chairman are disclosed in the Remuneration Report.

#### 1.5 Access to Information and Independent Advice

All Directors have unrestricted access to employees of the Company and, subject to the law, access to all Company records and information held by the Company, its employees and advisors. The Board receives an agenda, detailed financial and operational reports and, where relevant, reports of the Board Committees for each Board meeting.

Each Director is entitled to obtain independent professional advice at the Company's expense for the purpose of assisting them in performing their duties. A Director who wishes to obtain such advice must first obtain the approval of the Chair (which approval must not be unreasonably withheld) and must provide the Chair with the reason for seeking such advice, the identity of the person from whom the advice will be sought and the likely cost of obtaining such advice. Except in certain circumstances detailed in the Board Charter, advice obtained in this manner is made available to the Board as a whole.

#### 1.6 Human Capital and Nomination Committee

The current members of the Human Capital and Nomination Committee of the Board are Timothy Oldham (Chair), Bruce Parncutt and Ross Dobinson. Ross Barrow held the position of Chair until he resigned on 25 February 2015. Ross Dobinson joined the Committee on 6 July 2015.

Since our last Annual Report, the Committee met once on 6 July on 2015, with all members attending. Members of the Committee are chosen having regard to their skills and experience in relation to the matters for which the Committee is responsible. Members of the Committee have unrestricted access to company records, Management and advisers and the external auditors.

## CORPORATE GOVERNANCE STATEMENT

#### CONTINUED

The Committee's role, which is set out in its Charter, in general terms is to:

- establish a formal and transparent procedure for the selection and appointment of new Directors to the Board;
- b. identify suitable candidates to fill Board vacancies as and when they arise and nominating candidates for the approval of the Board;
- consider processes for the orientation and education of new Directors and developing ongoing policies to facilitate continuing education and development of Directors;
- d. periodically assess the skills required for each Director to discharge competently the Director's duties;
- e. regularly review the structure, size and composition of the Board and the effectiveness of the Board as a whole;
- f. establish and conduct an appropriate evaluation of the Board's process and of existing Directors, including an evaluation of whether each Director is contributing the time required of him or her for Board duties;
- g. recommend to the Board a policy and framework for Senior Management's remuneration;
- h. review and monitor the implementation of the human resources plan of the Company and succession planning for Senior Management; and
- i. review and recommend to the Board the total individual remuneration package of each member of Senior Management, including any bonuses, incentive payments, and participation in any share or share option plans in accordance with the policy and framework for Senior Management's remuneration.

In accordance with the recommendations of ASX Principle 2.4, the Committee's Charter further provides that, where practical, a majority of the Committee must be independent non-executive Directors and the Chair must be a non-executive Director who is not the Chair of the Company. Executive Directors may not be members of the Committee. A further recommendation of ASX Principle 2.1 is that the Committee have at least 3 members. During the period 26 February to 5 July 2015, the Committee was made up of 2 members. On 6 July 2015 the Company appointed Ross Dobinson as a third member of the Human Capital and Nomination Committee. Mr. Dobinson relinquished executive responsibilities effective 1 November 2014.

The Company's Code of Conduct, which has been in place since 2005, contains a principle of equal opportunity to be applied in all human resource decisions and in the workplace environment. The Committee has supplemented the Code of Conduct principle by adopting a formal diversity policy. However, the Committee has not yet set measurable objectives for gender diversity. The workforce at Acrux is small and the majority of positions require specialist qualifications and experience. The Committee believes specific diversity objectives are impractical at this time. At the date of this report, Acrux's workforce numbered twenty four people, fifteen (63%) of whom were female. The Senior Management team consists of three female and one male members, while the four current Board members are male. The Committee and the Board will review the potential need for formal diversity objectives in future as the Company evolves.

#### 1.7 Audit and Risk Committee

The current members of the Audit and Risk Committee are Bruce Parncutt (Chair), Timothy Oldham and Ross Dobinson. Bruce and Tim held these positions during the financial year while Ross Dobinson joined the Audit and Risk Committee on 12 August 2015 to ensure the Committee contained at least 3 members. Ross Barrow was a member of the Audit and Risk Committee until he resigned on 25 February 2015. Members are chosen having regard to their skills and experience in relation to the matters for which the Committee is responsible. Members of the Committee have unrestricted access to company records, Senior Management, advisers and the external auditors.

The Committee's role, as set out in its Charter, in general terms is:

- overseeing the Company's system of financial reporting for the purpose of safeguarding its integrity, including viewing all regular financial reports and other formal announcements relating to the Company's financial performance prepared for release to the ASX, regulators and the public before making appropriate recommendations to the Board;
- b. determining the extent of internal audit activities required and monitor the effectiveness of those activities (note that the Committee has determined that the Company, due to its size, does not presently warrant establishing a separate internal audit function);
- c. monitoring the performance and activities of the external auditor including:
  - overseeing the process for the appointment, reappointment and removal of the external auditors (including audit engagement letters), overseeing the rotation of the principal audit partner and reviewing the level of the external auditors' fees;
  - assessing the performance and independence of the external auditors and the quality of the audit work performed;
  - requiring, reviewing and monitoring compliance with the audit plan of the external auditors, including the scope of the plan and the levels of financial statement materiality;
  - reviewing reports from the external auditors and meeting with the external auditors at least once annually in the absence of Management and also meeting with the external auditors as requested by the Board, the Committee or the external auditors; and
  - receiving, reviewing, developing and implementing policy on the engaging of the external auditors to supply non-audit services.



- d. overseeing and reviewing the Company's financial and risk Management compliance and internal control framework including:
  - overseeing the creation, implementation and maintenance of the risk management system of the Company and its controlled entities and their internal control framework, including information systems;
  - reviewing the effectiveness of the Company's implementation of its risk management systems and internal controls on an ongoing basis and reviewing the outcome of any non-financial audits;
  - requiring Management to report to the Board at least annually on whether the Company's material business risks are being managed effectively;
  - developing an understanding of the overall business environment, relevant laws and codes of importance to the Company and the programs that the Company has in place to provide reasonable assurance of compliance;
  - reviewing the Company's occupational health and safety policies and ensuring regular reporting to the Committee on issues related to occupational health and safety;
  - reviewing insurance coverage and claims trends;
  - ensuring that the Chief Executive Officer and the Chief Financial Officer state in writing to the Board annually that:
    - the Company's financial reports present a true and fair view, in all material respects, of the Company's financial condition and operational results and are in accordance with the relevant accounting standards;
    - the statement in (i) above is founded on a sound system of risk management and control which implements the policies adopted by the Board; and
    - the Company's risk management and internal compliance and control systems are operating efficiently and effectively in all material respects.

The Board has received the report from Management referred to above, advising whether the Company's material business risks are being managed effectively. The Board received the statement in writing referred to above from the Chief Executive Officer and the Chief Financial Officer on 12 August 2015. In accordance with the recommendations of ASX Principle 4.1, the Committee's Charter provides that the Committee have at least three members, Executive Directors may not be members of the Committee, a majority of the Committee must be independent Directors and the Chair must not be the Chair of the Company. During the period 26 February to 11 August 2015, the Committee was made up of 2 members. On 12 August 2015 the Company appointed Ross Dobinson as a third member of the Audit and Risk Committee. Mr. Dobinson relinquished executive responsibilities effective 1 November 2014.

#### **1.8 Director and Senior Management** Remuneration and Performance

The remuneration structure for Senior Management and Directors and the amounts paid to each during the year are set out in the Remuneration Report section of the Directors' Report on page 30.

Non-executive Directors are remunerated by way of fees only and do not participate in executive remuneration schemes, nor do they receive options, bonus payments or retirement benefits (other than statutory superannuation payments).

At the end of each financial year, the performance of Senior Executives against their personal goals is assessed and personal goals and development plans for the next financial year are set, to be aligned with the Company's objectives. The review of Senior Management team members is carried out by the Chief Executive Officer and the results are subject to further review and approval by the Human Capital and Nomination Committee. The review of the Chief Executive Officer's performance is carried out by the Human Capital and Nomination Committee and the Committee's remuneration recommendations are then approved by the Board. A performance evaluation in accordance with this process was undertaken in respect of the year ended 30 June 2015. A formal review of the performance of the Board and its Committees was not undertaken during the year ended 30 June 2015.

## CORPORATE GOVERNANCE STATEMENT

CONTINUED

#### 2. Disclosure and Communication

#### 2.1 Continuous Disclosure

The Board has approved a written continuous disclosure policy to ensure compliance with the ASX Listing Rules continuous disclosure requirements. This policy:

- a. gives guidance as to the information that may need to be disclosed;
- b. gives guidance for dealing with market analysts and the media;
- c. establishes regular reminders to Directors and Senior Management to actively consider whether there is any price sensitive information which needs disclosure;
- d. allocates responsibility for approving public disclosures and shareholder communications.

#### 2.2 Communications with Shareholders

The Board has approved, as part of the continuous disclosure policy, the Company's policy to promote effective communication with its shareholders. In addition to its disclosure obligations under the ASX Listing Rules, the Company communicates with its shareholders through a number of channels including:

- a. annual and half-yearly reports;
- b. regular shareholder updates conducted by teleconference;
- c. media releases, public announcements and investor briefings; and
- d. annual general meetings.

All the above communications are posted on the Company's website (www.acrux.com.au). Shareholders are encouraged to receive shareholder materials electronically and can do so by visiting our investor centre, located on the Company's website.

In addition the Company is committed to using general meetings of the Company to effectively communicate with shareholders and to allow reasonable opportunities for informed shareholder participation at these meetings. Where possible the Company will comply with the ASX Best Practice Guidelines for the content of notices of meeting. Further, the external auditor is requested to attend the annual general meeting and be available to answer shareholder questions about the conduct of the auditor's report. The Company is committed to further developing its communications strategies to optimise shareholder communication.

#### 3. Share Trading

Under the Company's share trading policy all employees and Directors of the Company and its related companies are prohibited from trading in the Company's shares if they are in possession of inside information. In addition, the Directors, Senior Executives and all other employees are prohibited from trading in the Company's shares during the period from the end of the financial year to the release of financial results to the market.

The Directors, the Company Secretary, persons reporting directly to the Chief Executive Officer (and their associated persons) and all other employees may not trade in shares in the Company without the approval of the Company Secretary (or the Chair in the case of the Company Secretary) and only if they have first given a statement that they are not in possession of material non-public information. Such approval expires after five business days.

#### 4. Conduct and Ethics

The Directors and Management of the Company and its controlled entities are committed to observing high standards of ethics and behaviour in all of the Company's activities, including the Company's interaction with its shareholders, employees, business partners, customers, suppliers, the community and the environment in which the Company operates.

The Company has adopted a Code of Conduct which provides the ethical and legal framework for how the Company will conduct its business and how the Company will relate to shareholders, employees, business partners, customers, suppliers, the community and the environment in which the Company operates. Issues covered by the Code of Conduct are:

- ▶ values
- compliance with laws
- fair dealing
- confidentiality and protection of Company assets
- conflicts of interest
- shareholders and the financial community
- trading in Company securities
- equal opportunity
- ▶ health, safety and environment
- reporting non-compliance and grievances
- compliance with taxation laws
- bribes and financial inducements
- political donations



In addition the Company has adopted a whistleblower policy. The purpose of this policy is to encourage the reporting of conduct by employees of the Company and other persons with whom the Company deals closely where the interests of others, including the public, or of the Company itself are at risk. The conduct covered by the policy is conduct that is:

- a. illegal, dishonest, fraudulent or corrupt;
- b. in breach of Commonwealth or state legislation or local authority by-laws;
- c. in breach of applicable industry practices, such as Good Laboratory Practice, Good Clinical Practice or Good Manufacturing Practice;
- d. unethical (being either a breach of the Company's Code of Conduct or generally);
- e. gross mismanagement;
- f. a serious or substantial waste of resources;
- g. an unsafe work practice;
- h. failure to comply with agreements with the Company's commercial partners;
- i. a breach of proper environmental practice;
- j. other serious improper conduct;
- k. any other conduct that may cause financial or non-financial loss to the Company or otherwise be detrimental to the interests of the Company

# **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<sup>®</sup> 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 commercialsiation of high value therapies. Details will 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 whollyowned 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-raisings, 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.

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#### **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:

				Committee M	leetings	
	Directors' M	eetings	Audit & F	Risk	Human Ca & Nominat	
Directors	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 <sup>1</sup>	4	4	2	2	_	_
T Oldham	5	5	2	2	_	_
M Kotsanis <sup>2</sup>	3	3	-	1*	-	-

<sup>1</sup> Resigned 25 February 2015.

<sup>2</sup> 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

# **REMUNERATION REPORT (AUDITED)**

FOR THE YEAR ENDED 30 JUNE 2015

The Directors present the consolidated entity's 2015 remuneration report which details the remuneration information for Acrux Limited's Non-Executive Chairman, Non-Executive Directors and other key management personnel.

#### **Human Capital and Nomination Committee**

The Human Capital and Nomination Committee carries out the following functions in relation to the remuneration of senior management:

- a. recommending to the Board a policy and framework for senior employees' remuneration which should aim to set remuneration which:
  - i. is competitive, fair and designed to attract employees of high quality, experience and integrity;
  - ii. motivates senior employees to pursue the long term growth and success of the Company within the appropriate control framework; and
  - establishes a clear relationship between the performance of senior management and their remuneration;
- reviewing and recommending to the Board the total individual remuneration package of each member of senior management (including an executive Director), including any bonuses, incentive payments, and participation (including the level of participation) in any share or share option plans in accordance with the policy and framework for senior employees' remuneration;
- c. reviewing benchmarks against which salary reviews are made;
- reviewing and recommending the establishment and terms of any employee share or share option plan or other incentive plan and recommending any changes to the Board;
- e. reviewing and recommending on the superannuation arrangements of the Company and its controlled entities; and
- f. ensuring that equity-based senior management remuneration is made in accordance with thresholds set in plans approved by shareholders.

#### **Remuneration Policy**

The main principles of the Company's remuneration policy are:

- remuneration is set at levels intended to attract and retain good performers and to motivate and reward them to continually advance the business of the Company;
- remuneration is structured to reward employees both for superior performance and for increasing long term shareholder value; and
- rewards are linked to the achievement of business objectives as set by the Board.

#### **Remuneration Structure**

The remuneration of employees is structured in two parts:

- Fixed Remuneration, which comprises salary, superannuation and other benefits in lieu of salary; and
- Variable Remuneration, which may comprise a short term incentive in the form of cash and a long term incentive in the form of options under the employee share option plan (ESOP). All permanent staff are eligible to participate in the short term incentive plan and the ESOP. However the level of participation varies according to the level of seniority and the ability to influence the performance of the business.

The Company aims to set the level of fixed remuneration at market levels for comparable jobs in the industry in which the Company operates, based on market sources. The Company then aims to set the short and long term incentives to provide for top performers to be remunerated at the upper end of the market, subject to the overall performance of the Company measured against the goals set by the Board.

The aim of both the short term and long term incentive plans is to drive performance to successfully implement annual business plans and to increase shareholder value. No advice from a remuneration consultant was sought during the financial year for the Company's remuneration structure.

#### Short Term Incentive Plan

The purpose of the short term incentive plan is to reward achievement of business objectives on a year by year basis. Each financial year the Board, in conjunction with senior management, sets the business objectives aimed to be achieved during the year to implement the Company's business plan.

The business objectives are clearly defined outcomes in product development and commercialisation, achievement of which can be readily and objectively measured at the end of the financial year. Measurement of achievement of the business objectives does not involve comparison with factors external to the Company.

Achievement of each objective is expected to create immediate value for shareholders, or secure a material step towards value that will crystallise in a future period. Shareholder returns in the form of tax-free dividends are shown in the table below. Comparison of the achievement of objectives and shareholder returns for an individual year is not meaningful, because the value may crystallise in a future year.



Financial year	Closing share price (\$)	Share price increase/ (decrease) (\$)	Dividend (\$ per share)
2007/08	1.22		
2008/09	1.13	(0.09)	_
2009/10	1.81	0.68	_
2010/11	3.39	1.58	0.60
2011/12	4.25	0.86	0.08
2012/13	3.51	(0.74)	0.08
2013/14	1.01	(2.50)	0.20
2014/15	0.85	(0.16)	0.06

There are different levels of the short term incentive plan, with senior executives, other than the Chief Executive Officer, able to achieve annual incentives of up to 24% of fixed remuneration.

The key principles of the plan are:

- Payments under the short term incentive plan are at the discretion of the Board.
- The amount of at-risk remuneration payable under the short term incentive plan is dependent upon the overall level of achievement of the year's business objectives.
- The Board assesses the level of achievement of the business objectives at the end of the year.
- For staff other than senior executives, achievement of personal objectives set for the financial year may also form part of their assessment for short term incentive plan payments.

#### Long Term Incentive Plans

The purpose of the long term incentive plan is to align the interests of senior executives and other employees more closely with those of the shareholders towards long term sustained superior performance. Long term incentive plan instruments are designed to meet the requirements of ASX Listing Rules and the Company's status as a Pooled Development Fund. There are two long term incentive plans, comprising options to acquire ordinary shares.

The employee share option plan is subject to the following terms:

- The options expire three years after grant;
- ► The options lapse on termination of employment, other than through death or redundancy; and
- ► The exercise price was set at a 25% premium to the volume weighted average market price of the Company's shares 5 days prior to 31 July 2013.

The Chief Executive Officer share option plan is subject to the following terms:

- The options expire three years after grant;
- The options lapse on termination of employment, other than through death or redundancy; and
- The exercise price is set at a 25% premium to the volume weighted average market price of the Company's shares 5 days prior to grant and comprise 3 tranches.
  - ► Tranche 1 was granted on 3 February 2015;
  - ► Tranche 2 was granted on 22 July 2015; and
  - Tranche 3 eligibility will be assessed by the Board on or after 22 July 2016.

The Board evaluates the effectiveness of existing and potential long term incentive plans as the business environment changes.

# Remuneration and Termination Entitlements of Senior Management

Senior executives have no fixed term of employment and either party may terminate the employment contract on periods of written notice of three months. The employment contracts contain no other entitlement to termination benefits in addition to statutory entitlements.

Names and positions held by executives of the consolidated entity in office at any time during the financial year are:

Executives	Position
M Kotsanis	Chief Executive Officer – Commenced 3 November 2014
S Papworth	Chief Financial Officer and Company Secretary – Commenced 29 September 2014
N Webster	Commercial Director – Commenced 1 July 2013
F Colagrande	Product Development and Technical Affairs Director – Commenced 15 February 2015
C Blower	Chief Operating Officer – Resigned 15 August 2014
T Di Pietro	Chief Financial Officer and Company Secretary – Resigned 31 October 2014

#### Share Options

### (a) Compensation Options: Granted and vested during the year

A total of 2,000,000 share options were issued by Acrux Limited to the Chief Executive Officer, Mr. Kotsanis, on 3 February 2015, following shareholder approval at the Extraordinary General Meeting held on the same date.

### (b) Shares issued on exercise of compensation options

No ordinary shares were issued to Directors or Executives on exercise of compensation options during or since the end of the financial year.

# **REMUNERATION REPORT (AUDITED)**

#### CONTINUED

Details of the remuneration of the Executives are set out in the following table:

	Primary		Post Employment	Termination Benefits	Equity	Total	Equity as % of Total	Bonus as % of Total
	Salary \$	Bonus* \$	Super \$	\$	Options \$	\$	%	%
2015								
M Kotsanis <sup>1</sup>	254,150	68,668	12,522	-	760,000	1,095,340	69%	6%
S Papworth <sup>2</sup>	158,304	27,874	14,174	-	-	200,352	0%	14%
F Colagrande <sup>3</sup>	158,837	28,031	16,356	-		203,224	0%	14%
N Webster <sup>4</sup>	114,324	20,030	11,956	_		146,310	0%	14%
	685,615	144,603	55,008	-	760,000	1,645,226	46%	9%
2014								
J Pilcher <sup>5</sup>	61,033	-	4,444	_	-	65,477	0%	0%
C Blower <sup>6</sup>	253,112	25,736	17,775	_	107,500	404,123	27%	6%
T Di Pietro <sup>7</sup>	179,354	18,622	17,431	-	75,250	290,657	26%	6%
N Webster <sup>4</sup>	111,253	11,533	11,387	_	75,250	209,423	36%	6%
	604,752	55,891	51,037	_	258,000	969,680	27%	6%

\* Bonus relates to the achievement of objectives for the financial year. The amount of bonus earned was 100% of the maximum amount payable for the 2014/15 financial year and 40% for the 2013/14 financial year.

<sup>1</sup> Appointed Chief Executive Officer and Managing Director 1 November 2014.

<sup>2</sup> Appointed Chief Financial Officer and Company Secretary 29 September 2014.

<sup>3</sup> Appointed Product Development and Technical Affairs Director 15 February 2015.

<sup>4</sup> Appointed Commercial Director 1 July 2013.

<sup>5</sup> Resigned as Chief Financial Officer and Company Secretary 16 August 2013.

<sup>6</sup> Resigned as Chief Operating Officer 15 August 2014.

<sup>7</sup> Resigned as Chief Financial Officer and Company Secretary 31 October 2014.

#### **Remuneration of Directors**

The Human Capital and Nomination Committee considers the level of remuneration necessary to attract and retain Directors with the skills and experience required by the Company at its stage of development. The Committee makes recommendations to the Board, for approval by the shareholders, at the following Annual General Meeting.

The director and management services of the Non-Executive Chairman Ross Dobinson are provided by Espasia Pty Ltd. The contract for services can be terminated by either party by giving three months' notice in writing. For the 2014/15 financial year the contract provided for fees of \$118,000 per annum in respect of director services, \$200,000 per annum in respect of executive services performed 1 July 2014 to 31 October 2014 and an additional payment of up to 60% of the executive services, dependent on the achievement of objectives, set by the Board. The Board has absolute discretion over the amount of the additional payment.

For the 2014/15 financial year Non-Executive Directors' fees were \$76,650 per annum, including superannuation, for each Non-Executive Director. At the 2004 Annual General Meeting shareholders set the maximum aggregate amount of Non-Executive Directors' fees at \$450,000. In addition Non-Executive Directors are entitled to reimbursement of reasonable expenses incurred by them on Company business.

No retirement allowances are paid to Non-Executive Directors. No equity based remuneration is paid to Non-Executive Directors. Non-Executive Directors do not receive any additional remuneration for being members of Board Committees.



The remuneration of each person who held the position of Director at any time during the financial year is set out in the following table:

	Primary		Post Employment	Termination Benefits	Equity	Total	Equity as % of Total	Bonus as % of Total
	Fees \$	Bonus* \$	Super \$	\$	Options \$	\$	%	%
2015								
R Dobinson <sup>1</sup>	232,667	32,000	_	_	-	264,667	0%	12%
B Parncutt	70,000	-	6,650	_	_	76,650	0%	0%
R Barrow	46,667	-	4,433	_	_	51,100	0%	0%
T Oldham <sup>2</sup>	70,000	-	6,650	_	_	76,650	0%	0%
	419,334	32,000	17,733	-	_	469,067	0%	7%
2014								
R Dobinson <sup>1</sup>	318,000	48,000	_	_	98,463	464,463	21%	10%
B Parncutt	70,000	-	6,475	_	-	76,475	0%	0%
R Barrow	70,000	-	6,475	_	_	76,475	0%	0%
T Oldham <sup>2</sup>	52,500	-	4,856	-	-	57,356	0%	0%
	510,500	48,000	17,806	_	98,463	674,769	15%	7%

\* Bonus relates to the achievement of objectives for the financial year. The amount of bonus earned was 100% of the maximum amount payable for the 2014/15 financial year and 40% for the 2013/14 financial year.

<sup>1</sup> Appointed Non-Executive Chairman post appointment of the Chief Executive Officer, November 2014. Previously Executive Chairman from 1 July 2012.

<sup>2</sup> Appointed Non-Executive Director 1 October 2013.

Mr. Kotsanis was appointed Chief Executive Officer and Managing Director, November 2014. The remuneration details of Mr. Kotsanis have been disclosed in the executive remuneration table.

#### Number of Shares held by Key Management Personnel

Directors and Executives	Balance 7/1/2014	Granted as Remuneration	Options Exercised	Net Change Other	Balance 6/30/2015
Directors					
R Dobinson <sup>1</sup>	1,372,593	_	-	-	1,372,593
B Parncutt	718,137	_	_	_	718,137
R Barrow	17,375	_	_	_	17,375
T Oldham	15,750	-	-	-	15,750
Executives					
C Blower <sup>2</sup>	33,000	_	_	(33,000)	_
T Di Pietro <sup>3</sup>	10,290	_	_	(10,290)	-
N Webster <sup>4</sup>	6,100	_	_	_	6,100
F Colagrande⁵	1,500				1,500
Total	2,174,745	_	-	(43,290)	2,131,455

<sup>1</sup> Appointed Non-Executive Chairman post appointment of the Chief Executive Officer, November 2014. Previously Executive Chairman from 1 July 2012.

<sup>2</sup> Appointed Chief Operating Officer 16 August 2013 and resigned as Chief Operating Officer 15 August 2014.

<sup>3</sup> Resigned as Chief Financial Officer and Company Secretary 31 October 2014.

<sup>4</sup> Appointed Commercial Director 1 July 2013.

<sup>5</sup> Appointed Product Development and Technical Affairs Director 15 February 2015.

# **REMUNERATION REPORT (AUDITED)**

CONTINUED

#### Number of Employee Share Options held by Key Management Personnel

Directors and Executives	Balance 7/1/2014	Granted as Remuneration	Options Exercised	Net Change Other	Balance 6/30/2015
Directors			·		
R Dobinson <sup>1</sup>	600,000	_	_	-	600,000
B Parncutt	_	_	-	-	-
R Barrow	-	_	_	-	-
T Oldham	_	-	-	-	-
Executives					
M Kotsanis <sup>2</sup>	-	2,000,000	_	-	2,000,000
S Papworth <sup>3</sup>	_	_	-	-	-
N Webster	175,000	_	-	-	175,000
F Colagrande <sup>4</sup>	140,000	_	-	-	140,000
C Blower <sup>5</sup>	250,000	_	-	(250,000)	-
T Di Pietro <sup>6</sup>	175,000	-	-	(175,000)	-
Total	1,340,000	2,000,000	-	(425,000)	2,915,000

<sup>1</sup> Appointed Non-Executive Chairman post appointment of the Chief Executive Officer on 1 November 2014. Previously Executive Chairman from 1 July 2012.

<sup>2</sup> Appointed Chief Executive Officer November 2014.

<sup>3</sup> Resigned as Chief Financial Officer and Company Secretary 29 September 2014.

<sup>4</sup> Product Development and Technical Affairs Director 15 February 2015.

<sup>5</sup> Appointed Chief Operating Officer 16 August 2013 and resigned as Chief Operating Officer 15 August 2014.

<sup>6</sup> Resigned as Chief Financial Officer and Company Secretary 31 October 2014.

#### Voting and Comments made at the Company's 2014 Annual General Meeting (AGM)

At the Company's most recent AGM, a resolution to adopt the prior year remuneration report was put to the vote and at least 75% of 'yes' votes were cast for adoption of that report. No comments were made on the remuneration report that was considered at the AGM.

The company held an EGM during the year, at which a resolution to adopt the CEO Share Option Plan was put to a vote and at least 75% of 'yes' votes were cast for adoption of the Plan.

This is the end of the audited remuneration report.

#### **Rounding of Amounts**

The amounts contained in the report and in the financial report have been rounded to the nearest \$1,000 (where rounding is applicable) under the option available to the company under ASIC Class Order 98/0100. The Company is an entity to which the Class Order applies.

Signed in accordance with a resolution of the Directors.

**R Dobinson** Non-Executive Chairman Melbourne Dated this 12<sup>th</sup> day of August 2015

**B Parncutt** Director Melbourne Dated this 12<sup>th</sup> day of August 2015



# **AUDITOR'S INDEPENDENCE DECLARATION**

FOR THE YEAR ENDED 30 JUNE 2015

PITCHER PARTNERS ACRUX LIMITED AND CONTROLLED ENTITIES ABN 72 082 001 152 AUDITOR'S INDEPENDENCE DECLARATION TO THE DIRECTORS OF ACRUX LIMITED AND CONTROLLED ENTITIES In relation to the independent audit for the year ended 30 June 2015, to the best of my knowledge and belief there have been: (i) No contraventions of the auditor independence requirements of the Corporations Act 2001; and (ii) No contraventions of any applicable code of professional conduct. 1:61th s sm S SCHONBERG **PITCHER PARTNERS** Melbourne Partner Date 13 August 2015 An independent Victorian Partnership ABN 27 975 255 196 Level 19, 15 William Street, Melbourne VIC 3000 Liability limited by a scheme approved under Professional Standards Legislation Pitcher Partners is an association of independent firms Melbourne | Sydney | Perth | Adelaide | Brisbane| Newcastle An independent member of Baker Tilly International

# CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

FOR THE YEAR ENDED 30 JUNE 2015

	Notes	2015 \$'000	2014 \$'000
Revenue	4	25,368	53,859
Employee benefits expense	5	(2,686)	(2,346)
Share options expense		(760)	(638)
External research and development expenses	5	(705)	(756)
Directors' fees		(431)	(576)
Professional fees		(716)	(324)
Royalty expense		(859)	(1,827)
Occupancy expenses		(412)	(414)
Depreciation and amortisation expenses	5	(1,425)	(1,413)
Foreign exchange loss		-	(1,239)
Other expenses		(568)	(469)
		(8,562)	(10,002)
Profit before income tax		16,806	43,857
Income tax expense	6	(5,676)	(15,887)
Profit for the year		11,130	27,970
Total comprehensive income for the year		11,130	27,970
Total comprehensive income attributable to:			
Members of the parent	17	11,130	27,970
Non-controlling interest	18	-	_
		11,130	27,970
Basic earnings per share (cents per share)	8	6.70	16.80
Diluted earnings per share (cents per share)	8	6.70	16.80



# **CONSOLIDATED STATEMENT OF FINANCIAL POSITION**

AS AT 30 JUNE 2015

	Notes	2015 \$'000	2014 \$'000
Current Assets			
Cash and cash equivalents	9	23,068	25,775
Receivables	10	4,943	5,604
Total Current Assets		28,011	31,379
Non-Current Assets			
Plant and equipment	11	92	78
Intangible assets	12	20,392	21,764
Total Non-Current Assets		20,484	21,842
Total Assets		48,495	53,221
Current Liabilities			
Current tax payable	6	1,764	4,526
Payables	13	1,150	1,129
Short term provisions	14	288	401
Total Current Liabilities		3,202	6,056
Non-Current Liabilities			
Deferred tax liabilities	6	4,649	5,097
Long term provisions	14	19	11
Total Non-Current Liabilities		4,668	5,108
Total Liabilities		7,870	11,164
Net Assets		40,625	42,057
Equity			
Contributed equity	15	95,873	95,873
Reserves	17(a)	1,194	638
Accummulated Losses	17(b)	(56,442)	(54,454)
Equity attributable to the owners of Acrux Limited		40,625	42,057
Non-controlling interests	18		_
Total Equity		40,625	42,057

# **CONSOLIDATED STATEMENT OF CHANGES IN EQUITY**

FOR THE YEAR ENDED 30 JUNE 2015

	Notes	Contributed Equity \$'000	Reserves \$'000	Accumulated Losses \$'000	Total Equity \$'000
Balance as at 1 July 2013		95,873	-	(49,120)	46,753
Profit for the period		_	-	27,970	27,970
Total comprehensive income for the year		-	_	27,970	27,970
Transactions with owners in their capacity as owners:					
Contributions	15(b)	_	-	_	-
Employee Share Options Expense	17(a)	_	638	_	638
Dividends Paid	7	_	-	(33,304)	(33,304)
Total transactions with owners in their capacity as owners		_	638	(33,304)	(32,666)
Balance as at 30 June 2014		95,873	638	(54,454)	42,057
Balance as at 1 July 2014		95,873	638	(54,454)	42,057
Profit for the period		_	-	11,130	11,130
Total comprehensive income for the year		-	-	11,130	11,130
Transactions with owners in their capacity as owners:					
Contributions	15(b)	_	_	_	-
Employee Share Options Expense	17(a)	_	760	_	760
Vested Employee Share Options that lapsed during the period	17	_	(204)	204	_
Dividends Paid	7	-	_	(13,322)	(13,322)
Total transactions with owners in their capacity as owners		_	556	(13,118)	(12,562)
Balance as at 30 June 2015		95,873	1,194	(56,442)	40,625



# CONSOLIDATED STATEMENT OF CASH FLOWS

FOR THE YEAR ENDED 30 JUNE 2015

		Consolidate	d Entity	
	Notes	2015 \$'000	2014 \$'000	
Cash Flows from Operating Activities				
Receipts from product agreements		25,203	53,425	
Payments to suppliers and employees		(6,460)	(6,737)	
Interest received		639	450	
Grant income received		23	21	
Taxes paid		(8,886)	(10,788)	
Net Cash Flows provided by Operating Activities	19(a)	10,519	36,371	
Cash Flows from Investing Activities				
Cash Flows from Investing Activities			(22)	
Purchase of plant and equipment		(66)	(39)	
Net Cash Flows used in Investing Activities		(66)	(39)	
Cash Flows from Financing Activities				
Net proceeds from issues of ordinary shares		_	-	
Dividends paid		(13,322)	(33,346)	
Net Cash Flows used in Financing Activities		(13,322)	(33,346)	
Net Increase/(Decrease) in Cash Held		(2,869)	2,986	
Foreign exchange differences on cash holdings		162	(51)	
Add cash at the beginning of the year		25,775	22,840	
Cash at end of Year	19(b)	23,068	25,775	

FOR THE YEAR ENDED 30 JUNE 2015

# Note 1: Statement of Significant Accounting Policies

The following is a summary of significant accounting policies adopted by the consolidated entity in the preparation and presentation of the financial report. The accounting policies have been consistently applied, unless otherwise stated.

### (a) Basis of presentation of the financial report

This financial report is a general purpose financial report that has been prepared in accordance with Australian Accounting Standards, Interpretations and other authoritative pronouncements of the Australian Accounting Standards Board and the *Corporations Act 2001*.

The financial report covers Acrux Limited and its controlled entities as a consolidated entity. Acrux Limited is a company limited by shares, incorporated and domiciled in Australia. Acrux Limited is a for-profit entity for the purpose of preparing the financial statements.

The financial report was authorised for issue by the Directors as at the date of the Directors' report.

#### Compliance with IFRS

The consolidated financial statements of Acrux Limited also comply with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB).

### Historical Cost Convention

The financial report has been prepared under the historical cost convention, as modified by revaluations to fair value for certain classes of assets as described in the accounting policies.

#### Critical Accounting Estimates

The preparation of the financial report requires the use of certain estimates and judgements in applying the entity's accounting policies. Those estimates and judgements significant to the financial report are disclosed in Note 2.

### (b) Going concern

The financial report has been prepared on a going concern basis.

During the year ended 30 June 2015 the consolidated entity reported an operating profit after tax of \$11.1 million (2014: \$28.0 million) and at the reporting date total assets exceeded total liabilities by \$40.6 million (2014: \$42.1 million).

### (c) Principles of consolidation

The consolidated financial statements are those of the consolidated entity, comprising the financial statements of the parent entity and of all entities, which the parent controls. The group controls an entity where it is exposed, or has rights, to variable returns from its involvement with the entity and has the ability to effect those returns through its power over the entity.

The financial statements of subsidiaries are prepared for the same reporting period as the parent entity, using consistent accounting policies. Adjustments are made to bring into line any dissimilar accounting policies, which may exist.

All inter-company balances and transactions, including any unrealised profits or losses have been eliminated on consolidation. Subsidiaries are consolidated from the date on which control is established and are derecognised from the date that control ceases.

Non-controlling interests in the results of the subsidiaries are shown separately in the consolidated statement of comprehensive income and consolidated statement of financial position respectively.

#### (d) Revenue

Revenue from product agreements is made up of milestone payments and revenue relating to product sales. Revenue from milestone payments is recognised upon completion of the milestone, which is the trigger point for the right to receive the revenue. Revenue relating to product sales, such as royalties and distribution fees, is recognised in the period in which the sales occur.

Interest revenue is recognised when it becomes receivable on a proportional basis taking into account the interest rate applicable to the financial assets.

Revenue from rendering of services to customers is recognised in the period in which the service was performed for the customer.

Government grants are recognised at fair value where there is a reasonable assurance that the grant will be received and all grant conditions will be met. Revenue from the receipt of contracted grants is recognised in the period the monies associated with the grants are expensed.

Other revenue is recognised as received or over the time period to which it relates.

All revenue is stated net of the amount of goods and services tax (GST).

### (e) Cash and cash equivalents

Cash and cash equivalents include cash on hand and at banks, short term deposits with an original maturity of three months or less, held at call with financial institutions.

### (f) Plant and equipment

#### Cost and Valuation

Each class of plant and equipment is carried at cost less, where applicable, any accumulated depreciation and any accumulated impairment losses. At each balance date the carrying amount of each asset is reviewed to ensure that it does not differ materially from the asset's fair value at reporting date. Where necessary, the asset is revalued to reflect its fair value.



#### Depreciation

The depreciable amount of all fixed assets are calculated on a straight line basis over their estimated useful lives to the entity commencing from the time the asset is held ready for use.

Leasehold improvements are depreciated over the shorter of either the unexpired period of the lease or the estimated useful lives of the improvements.

The useful lives for each class of assets are:

	2015	2014
Leasehold improvements:	5 to 20 years	Not Applicable
Plant and equipment:	2.5 to 14 years	2.5 to 14 years

### (g) Leases

Leases are classified at their inception as either operating or finance leases based on the economic substance of the agreement so as to reflect the risks and rewards incidental to ownership.

#### Operating Leases

Lease payments for operating leases are recognised as an expense on a straight-line basis over the term of the lease.

#### (h) Intangibles

The intangible assets are recognised at cost at the date of acquisition. The balances are reviewed annually and any balances representing probable future benefits that are no longer anticipated are written off.

#### Intellectual Property

Acquired intellectual property is initially recorded at cost. Intellectual property with a finite life is carried at cost less any accumulated amortisation and any impairment losses. The intellectual property is amortised over the useful life of the relevant patents. Amortisation expense is included in 'Depreciation and amortisation expenses' of the Statement of Comprehensive Income.

#### Research and Development

Expenditure during the research phase of a project is recognised as an expense when incurred. Product development costs are capitalised only when each of the following specific criteria has been satisfied:

- 1. Technical feasibility of completing development of the product and obtaining approval by regulatory authorities.
- 2. Ability to secure a commercial partner for the product.
- Availability of adequate technical, financial and other resources to complete development of the product, obtain regulatory approval and secure a commercial partner.
- 4. Reliable measurement of expenditure attributable to the product during its development.
- 5. High probability of the product entering a major pharmaceutical market.

Capitalised development costs have a finite life and are amortised on a systematic basis over the period from when the product becomes available for use and cease at the earlier of the date that the asset is classified as held for sale (or included in a disposal group that is classified as held for sale) in accordance with AASB 5 Non-current assets held for sale and discontinued operations and the date that the asset is derecognised.

The estimated useful life and total economic benefit for each asset are reviewed at least annually. The useful life of capitalised development costs for Axiron, for which amortisation has commenced, is approximately 18 years. Amortisation expense is included in 'Depreciation and amortisation expenses' of the Statement of Comprehensive Income.

#### (i) Impairment of non-financial assets

Assets with an indefinite useful life are not amortised but are tested annually for impairment in accordance with *AASB 136 Impairment of assets*. Assets subject to annual depreciation or amortisation are reviewed for impairment whenever events or circumstances arise that indicate that the carrying amount of the asset may be impaired.

An impairment loss is recognised where the carrying amount of the asset exceeds its recoverable amount. The recoverable amount of an asset is defined as the higher of its fair value less costs to dispose and its value in use.

#### (j) Income tax

Current income tax expense or revenue is the tax payable on the current period's taxable income based on the applicable income tax rate adjusted by changes in deferred tax assets and liabilities.

Deferred tax assets and liabilities are recognised for temporary differences at the applicable tax rates when the assets are expected to be recovered or liabilities are settled. No deferred tax asset or liability is recognised in relation to temporary differences if they arose in a transaction, other than a business combination, that at the time of the transaction did not affect either accounting profit or taxable profit or loss.

Deferred tax assets are recognised for deductible temporary differences and unused tax losses only when it is probable that future taxable amounts will be available to utilise those temporary differences and losses.

Current and deferred tax balances attributable to amounts recognised directly in equity are also recognised directly in equity.

The parent entity, Acrux Limited is a Pooled Development Fund (PDF):

- ► PDFs are taxed at 15% on income and gains from investments in small to medium enterprises;
- ▶ PDFs are taxed at 25% on other income; and
- ► PDFs are not permitted to consolidate for tax purposes.

FOR THE YEAR ENDED 30 JUNE 2015

# Note 1: Statement of Significant Accounting Policies (continued)

The subsidiary companies of Acrux Limited are subject to the general corporate company tax rate of 30%. At 30 June 2014 Acrux Limited's tax paying subsidiaries had utilised all accumulated tax losses. The majority of the consolidated entity's taxable income is earned by these subsidiary companies.

Income tax expense for the financial year was \$5.7 million (2014: \$15.9 million) representing approximately 33.8% of profit before income tax. The parent entity, Acrux Limited, received franked dividends totaling \$19.0 million from subsidiary companies. The parent entity's tax rate payable on this income is 15% however the franked dividends include an imputed tax credit of 30%. The excess franking credits convert to tax losses that can be used in future periods to offset taxable income. For accounting purposes the entity has not recognised a tax asset for these carried forward tax losses as the current operating structure of the entity is unlikely to produce the quantum of future taxable income to enable Acrux Limited to utilise these carried forward losses.

### (k) Provisions

Provisions are recognised when the consolidated entity has a legal or constructive obligation, as a result of past events, for which it is probable that an outflow of economic benefits will result and that outflow can be reliably measured.

### (I) Employee benefits

Provision is made for employee benefits accumulated as a result of employees rendering services up to the reporting date. These benefits include wages and salaries, annual leave and long service leave.

Liabilities arising in respect of wages and salaries, annual leave and any other employee benefits expected to be settled within twelve months of the reporting date are measured at their nominal amounts based on remuneration rates which are expected to be paid when the liability is settled. All other employee benefit liabilities are measured at the present value of the estimated future cash outflow to be made in respect of services provided by employees up to the reporting date.

Contributions are made by the consolidated entity to employee superannuation funds and are charged as expenses when the obligation to pay them arises.

### Bonus

The consolidated entity recognises a provision when a bonus is payable in accordance with the employee's contract of employment, and the amount can be reliably measured.

### Share-based Payments

The consolidated entity operates an employee share option plan. The fair value of the options is recognised as an expense in the Statement of Comprehensive Income in the period(s) during which the employee becomes entitled to exercise the options. The fair value of options at grant date is determined using a Binomial option pricing model, and is recognised as an employee expense over the period during which the employees become entitled to the option (the vesting period).

### Termination Benefits

Termination benefits are payable when employment of an employee is terminated before the normal retirement date.

The consolidated entity recognises a provision for termination benefits when entitlement to contractual benefits arises or when the entity can no longer withdraw the offer of non-contractual benefits.

### (m) Comparatives

Where necessary, comparative information has been reclassified and repositioned for consistency with current year disclosures.

### (n) Financial instruments

#### Non-derivative Financial Instruments

#### Financial Assets

Non-derivative financial assets consist of trade and other receivables and cash and cash equivalents. Financial assets are tested for impairment at each financial year end to establish whether there is any objective evidence for impairment. Trade receivables are carried at full amounts due less any provision for impairment. A provision for impairment is recognised when collection of the full amount is no longer probable. Amounts receivable from other debtors are carried at full amounts due. Other debtors are normally settled 30 days from month end unless there is a specific contract, which specifies an alternative date. Amounts receivable from related parties are carried at full amounts due.

Non-listed investments in controlled entities, for which fair value cannot be reliably measured, are carried at cost and tested for impairment.

#### Financial Liabilities

Non-derivative financial liabilities include trade payables, other creditors and inter-company balances.

Liabilities are recognised for amounts to be paid in the future for goods and services received, whether or not billed to the consolidated entity. Trade liabilities are normally settled 30 days from month end.

#### Derivative Financial Instruments

The consolidated entity has used and could continue to use derivative financial instruments to hedge its risk exposures from foreign currency exchange rate movements.

Such derivatives are measured at fair value and changes in value are recognised immediately in profit or loss.



### (o) Foreign currency translations and balances

#### Functional and Presentation Currency

The financial statements of each of the consolidated entity's subsidiaries are measured using the currency of the primary economic environment in which that entity operates (the functional currency). The consolidated financial statements are presented in Australian dollars, which is the consolidated entity's functional and presentation currency.

#### Transactions and Balances

Transactions in foreign currencies of entities within the consolidated group are translated into functional currency at the rate of exchange ruling at the date of the transaction.

Foreign currency monetary items that are outstanding at the reporting date (other than monetary items arising under foreign currency contracts where the exchange rate for that monetary item is fixed in the contract) are translated using the spot rate at the end of the financial year. Except for certain currency hedges, all resulting exchange differences arising on settlement or re-statement are recognised as revenues and expenses for the financial year.

#### (p) Goods and services tax (GST)

Revenues, expenses and assets are recognised net of the amount of GST, except where the amount of GST incurred is not recoverable from the Australian Tax Office. In these circumstances the GST is recognised as part of the cost of acquisition of the asset or as part of an item of expense. Receivables and payables in the balance sheet are shown inclusive of GST.

Cash flows are presented in the statement of cash flows on a gross basis.

#### (q) Rounding amounts

The parent entity and the consolidated entity have applied the relief available under ASIC Class Order CO 98/0100 and accordingly, amounts in the consolidated financial statements and Directors' report have been rounded off to the nearest thousand dollars, or in certain cases, to the nearest dollar.

# (r) Accounting standards issued but not yet effective at 30 June 2015

AASB 15 Revenue from contracts with customers AASB 15 introduces a five step process for revenue recognition with the core principle being for entities to recognise revenue to depict the transfer of goods or services to customers in amounts that reflect the consideration (that is, payment) to which the entity expects to be entitled in exchange for those goods or services. The five step approach is as follows:

- Step 1: Identify the contracts with the customer;
- ► Step 2: Identify the separate performance obligations;
- Step 3: Determine the transaction price;
- ▶ Step 4: Allocate the transaction price; and
- Step 5: Recognise revenue when a performance obligation is satisfied.

AASB 15 will also result in enhanced disclosures about revenue, provide guidance for transactions that were not previously addressed comprehensively (for example, service revenue and contract modifications) and improve guidance for multiple-element arrangements.

The effective date is annual reporting periods beginning on or after 1 January 2017.

The changes in revenue recognition requirements in AASB 15 may cause changes to the timing and amount of revenue recorded in the financial statements as well as additional disclosures. The impact of AASB 15 has not yet been quantified.

#### AASB 9 Financial Instruments

Significant revisions to the classification and measurement of financial assets, reducing the number of categories and simplifying the measurement choices, including the removal of impairment testing of assets measured at fair value. The amortised cost model is available for debt assets meeting both business model and cash flow characteristics tests. All investments in equity instruments using AASB 9 are to be measured at fair value.

AASB 9 amends measurement rules for financial liabilities that the entity elects to measure at fair value through profit or loss. Changes in fair value attributable to changes in the entity's own credit risk are presented in other comprehensive income.

Chapter 6 *Hedge Accounting* supersedes the general hedge accounting requirements in AASB 139 *Financial Instruments: Recognition and Measurement*, which many consider to be too rules-based and arbitrary. Chapter 6 requirements include a new approach to hedge accounting that is intended to more closely align hedge accounting with risk management activities undertaken by entities when hedging financial and non-financial risks. Some of the key changes from AASB 139 are as follows:

- to allow hedge accounting of risk components of nonfinancial items that are identifiable and measurable (many of which were prohibited from being designated as hedged items under AASB 139);
- changes in the accounting for the time value of options, the forward element of a forward contract and foreign-currency basis spreads designated as hedging instruments; and
- modification of the requirements for effectiveness testing (including removal of the 'brightline' effectiveness test that offset for hedging must be in the range 80-125%).

Revised disclosures about an entity's hedge accounting have also been added to AASB 7 *Financial Instruments: Disclosures.* 

FOR THE YEAR ENDED 30 JUNE 2015

# Note 1: Statement of Significant Accounting Policies (continued)

Impairment of assets is now based on expected losses in AASB 9 which requires entities to measure:

- the 12-month expected credit losses (expected credit losses that result from those default events on the financial instrument that are possible within 12 months after the reporting date); or
- full lifetime expected credit losses (expected credit losses that result from all possible default events over the life of the financial instrument.

The effective date is annual reporting periods beginning on or after 1 January 2018.

The available-for-sale investments held will be classified as fair value through other comprehensive income and will no longer be subject to impairment testing. The impairment loss recognised in the current year financial statements in relation to these statements was nil. Hedge accounting is likely to be applied to more of the entity's transactions in future transactions – the impact on the reported financial position and performance is dependent on the volume and value of future derivatives. Other impacts on the reported financial position and performance have not yet been determined.

# Note 2: Critical Accounting Estimates and Judgements

Certain accounting estimates and assumptions concerning the future, which, by definition, will seldom represent actual results. Estimates and assumptions based on future events have a significant inherent risk, and where future events are not as anticipated there could be a material impact on the carrying amount of assets and liabilities, discussed below:

### (a) Income tax

Income tax benefits are based on the assumption that no adverse change will occur in the income tax legislation and the anticipation that the group will derive sufficient future assessable income to enable the benefit to be realised and that it will comply with the conditions of deductibility imposed by the law.

Deferred tax assets are recognised for deductable temporary differences as management considers that it is probable that future tax profits will be available to utilise those temporary differences.

### (b) Impairment testing

The Company uses discounted cash flow models to determine that the parent entity's investments in and loans to its subsidiaries, and the capitalised development costs in the consolidated entity, are not being carried at a value that is materially in excess of recoverable value. The models value each product or potential product by estimating future cash flows and discounting the future net cash flows for the probability of successful commercialisation, as well as for the time value of money using a discount rate of 12%. Revenue from a product is estimated using current market data and projections of market growth and potential market share.

#### (c) Employee benefits

Calculation of long term employment benefits requires estimation of the retention of staff, future remuneration levels and timing of the settlement of the benefits. These estimates are based on historical trends.

#### (d) Share based payments

The group operates an employee share option plan. The bonus element over the exercise price for the grant of options is recognised as an expense in the Statement of Comprehensive Income in the period(s) when the benefit is earned. The value of the bonus element is calculated using a Binomial option pricing model. This model requires the input of a number of variables including an estimate of future volatility and a risk free interest rate. Volatility is estimated based on the historical movements in the Company's share price since listing on the Australian Stock Exchange. The risk free interest rate is the Reserve Bank of Australia's cash rate at the options grant date.

# Note 3: Financial Instruments and Financial Risks

The consolidated entity is exposed to a variety of financial risks comprising:

- (a) Interest rate risk
- (b) Currency risk
- (c) Credit risk
- (d) Liquidity risk
- (e) Fair Values

The Board of Directors have overall responsibility for identifying and managing operational and financial risks.

#### (a) Interest rate risk

Interest rate risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate as a result of changes in market interest rates.

The consolidated entity's exposure to interest rate risks and the effective interest rates of financial assets and financial liabilities at 30 June 2015 are shown in the table on the following page. Cash is the only financial asset or liability that is exposed to interest rate risk. A change in the average effective interest rate of 1% would change the net profit and equity of the consolidated entity by approximately \$0.2 million (2014: \$0.2 million).



	Floating rat		Fixed inte maturi 1 year	ng in:	Non in bear		Total ca amount a Balance	s per the	Weigh average e interest	ffective
Financial Instruments	2015 \$'000	2014 \$'000	2015 \$'000	2014 \$'000	2015 \$'000	2014 \$'000	2015 \$'000	2014 \$'000	2015 %	2014 %
(i) Financial assets										
Cash	19,067	2,774	4,000	23,000	1	1	23,068	25,775	2.9	2.2
Receivables	_	-	_	_	4,943	5,604	4,943	5,604		
Total financial assets	19,067	2,774	4,000	23,000	4,944	5,605	28,011	31,379		
(ii) Financial liabilities										
Trade creditors	-	_	_	-	106	217	106	217		
Sundry creditors and accruals		_	_	_	1,044	912	1,044	912		
Total financial liabilities	-	-	-	_	1,150	1,129	1,150	1,129		

At 30 June 2015, the consolidated entity had financial instruments with carrying amounts as shown in the following table:

\* The weighted average interest rate is calculated by dividing interest income for year over the average cash balance held.

### (b) Currency risk

Currency risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in foreign exchange rates.

The consolidated entity is exposed to material currency risks due to revenue denominated in US dollars. Currency risk management strategies are regularly reviewed.

Bank accounts denominated in US dollars are maintained in order to facilitate receipts and payments. Cash reserves at 30 June 2015 included \$0.2 million (2014: \$0.2 million) denominated in US dollars. A change of 10% in the AUD/USD exchange rate at 30 June 2015 would have immaterial impact on the net profit and equity of the consolidated entity.

The balance of receivables at 30 June 2015 includes the right to receive US\$3.6 million (2014: US\$5.2 million) of Axiron royalties for the fourth quarter of the 2014/15 financial year. A change of 10% in the AUD/USD exchange rate at 30 June 2015 would change the consolidated net profit and equity by approximately \$0.4 million (2014: \$0.6 million).

During the reporting period, exchange rate risk was managed by eliminating US dollar revenue in excess of US dollar expenditure through spot and short-term forward sales of US dollars. The consolidated entity does not enter into forward exchange contracts. At balance date, there were nil (2014: nil) forward exchange contracts.

The accounting policy for forward exchange contracts is detailed in Note 1(n).

In future periods, material amounts of revenue are expected to be received in US dollars as royalties and potential sales milestone payments under the Axiron agreement are payable in US dollars.

### (c) Credit risk

Credit risk is the risk that one party to a financial instrument will cause a financial loss for the other party by failing to discharge an obligation. The maximum exposure to credit risk of recognised financial assets at balance date, excluding the value of any collateral or other security, is the carrying amount of those assets, net of any provisions for impairment of those assets, as disclosed in consolidated statement of financial position and notes to the consolidated financial statements.

Cash reserves form the majority of the consolidated entity's financial assets at 30 June 2015. Acrux Limited is a Pooled Development Fund. The Pooled Development Fund Act restricts the investment of cash reserves to deposits with an Australian bank licensed to take deposits. This policy is also followed for all cash held by the other companies within the consolidated entity.

At 30 June 2015 the consolidated entity had a material credit risk exposure to Eli Lilly and Company and its subsidiaries. The receivables recorded on the consolidated entity's balance sheet contains an amount of AUD\$4.7 million due from Eli Lilly under the license agreement for the commercialisation of Axiron. During future reporting periods, the consolidated entity is expected to continue to have a material credit exposure to Eli Lilly and Company and its subsidiaries, due to the royalties and milestone payments expected. At 30 June 2015, Eli Lilly's credit ratings were AA- (S&P) and A2 (Moodys). The credit rating and financial health of Eli Lilly are monitored regularly. The grant of the license under the license agreement is subject to payment by Eli Lilly of the amounts in accordance with the agreement.

FOR THE YEAR ENDED 30 JUNE 2015

# Note 3: Financial Instruments and Financial Risks (continued)

### (d) Liquidity risk

Liquidity risk is the risk that an entity will encounter difficulty in meeting obligations associated with financial liabilities.

The financial liabilities of the consolidated entity at the balance date are all expected to mature within three months of the balance date. The consolidated entity has sufficient cash reserves, \$23.1 million (2014: \$25.7 million) to settle these liabilities and to fund operating expenditure for the foreseeable future. The consolidated entity does not have an overdraft or loan facility. The maturity profile of the consolidated entity's cash term deposits is actively managed and compared with forecast liabilities to ensure that sufficient cash is available to settle liabilities as they fall due.

#### (e) Fair values

The fair value of financial assets and financial liabilities approximates their carrying amounts as disclosed in the consolidated statement of financial position and notes to the consolidated financial statements.

Financial asset and liabilities measured and recognised at fair value have been determined by the following fair value measurement hierarchy:

- Level 1: Quoted prices (unadjusted) in active markets for identical assets or liabilities
- Level 2: Input other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly
- Level 3: Inputs for the asset or liability that are not based on observable market data

Forward exchange contracts are level 2 on the fair value hierarchy.

	2015 \$'000	2014 \$'000
Revenues from operating activities		
Revenue from product agreements	24,616	53,368
Grant revenue	23	21
Total revenues from operating activities	24,639	53,389
Other revenues		
Interest	564	470
Foreign exchange gain	165	_
Total revenues from non-operating activities	729	470
Total revenues from continuing operations	25,368	53,859

# Note 4: Revenue



# Note 5: Profit from Continuing Operations

	Notes	2015 \$'000	2014 \$'000
Profit from continuing operations before income tax has been determined after the following specific expenses:			
Employee benefits expense			
Wages and salaries		2,329	2,050
Workers' compensation costs		8	6
Superannuation costs		181	172
Payroll taxes		109	92
Training expenses		59	26
Total employee benefits expense		2,686	2,346
Depreciation of non-current assets			
Plant and equipment		52	40
Total depreciation of non-current assets		52	40
Amortisation of non-current assets			
Intellectual property		95	95
Research and development		1,278	1,278
Total amortisation of non-current assets		1,373	1,373
Total depreciation and amortisation expenses		1,425	1,413
Rental expense on operating leases		294	282
External research and development expenses		705	756

FOR THE YEAR ENDED 30 JUNE 2015

# Note 6: Income Tax

	2015 \$'000	2014 \$'000
(a) Income tax recognised in profit or loss:		
Current tax	5,949	13,749
Deferred tax	(448)	2,237
(Over)/under provision in prior years	175	(99)
Income tax expense/(credit) attributable to profit	5,676	15,887
(b) Reconciliation of income tax expense		
The prima facie tax payable on profit before income tax is reconciled to the income tax expense as follows:		
Profit before tax from continuing operations	16,806	43,857
Prima facie income tax payable on profit before income tax at 30.0% (2014: 30.0%)	5,042	13,157
Add/(subtract) tax effect:		
Parent entity 15% tax rate <sup>1</sup>	208	233
Parent entity tax on unfranked dividend income	-	2,925
Parent entity net adjustment on franked dividend income	(2,092)	(3,000)
Non deductible expenses	270	128
Research and development tax incentive	(59)	(52)
Foreign tax credits written off	-	(10)
Over provision in prior years	175	(22)
Tax losses and temporary differences not brought to account	2,132	2,518
	634	2,720
Income tax expense attributable to profit	5,676	15,877
(c) Current tax		
Opening balance	4,526	1,675
(Over)/under provision in prior years	175	(110)
Provision for current year	5,949	13,870
Tax losses transferred from deferred tax	0	(121)
Tax payments	(8,886)	(10,788)
Current tax liability	1,764	4,526

<sup>1</sup> The parent entity, Acrux Limited is a Pooled Development Fund (PDF):

- PDF's are taxed at 15% on income and gains from investments in small to medium enterprises;

- PDF's are taxed at 25% on other income; and

- PDFs are not permitted to consolidate for tax purposes.



	2015 \$'000	2014 \$'000
(d) Deferred tax		
Deferred tax relates to the following:		
Deferred tax assets		
The balance comprises:		
Accruals and provisions	90	145
Leasehold improvements	183	195
Patent expenses	799	711
Exchange differences	-	15
Share issue expenses	-	1
Tax losses	92	_
	1,164	1,067
Deferred tax liabilities		
The balance comprises:		
Exchange differences	35	-
Intangible assets	5,749	6,133
Accrued interest	8	31
Prepayments	21	-
	5,813	6,164
Net deferred tax assets/(liabilities)	(4,649)	(5,097)
(e) Deferred tax assets not brought to account		
Temporary differences	2	10
Tax losses	10,443	8,311
	10,445	8,321

# (a) Dividends paid

Dividends paid at 8 cents per share, franked (2014: 20 cents per share, unfranked)	13,322	33,304
Balance of franking account on a tax paid basis at financial year-end adjusted for franking		
credits arising from payment of provision for income tax and dividends recognised as		
receivables, franking debits arising from payment of proposed dividends and any credits that		
may be prevented from distribution in subsequent years:	42,188	33,337

FOR THE YEAR ENDED 30 JUNE 2015

# Note 8: Earnings Per Share

	2015 \$'000	2014 \$'000
Profit from continuing operations	11,130	27,970
Profit used in calculating basic and diluted earnings per share	11,130	27,970
	No. of shares	No. of shares
Weighted average number of ordinary shares used in calculating basic earnings per share	166,521,711	166,521,711
Effect of dilutive securities:		
Employee Share Options	-	-
Adjusted weighted average number of ordinary shares used in calculating diluted earnings per share	166,521,711	166,521,711
Basic earnings per share (cents)	6.70	16.80
Diluted earnings per share (cents)	6.70	16.80

# Note 9: Cash and Cash Equivalent

	2015 \$'000	2014 \$'000
Cash at bank	19,068	2,775
Deposits at call	4,000	23,000
	23,068	25,775

# Note 10: Receivables

	2015 \$'000	2014 \$'000
CURRENT		
Trade receivables	4,760	5,347
Other receivables	66	141
Prepayments	117	116
	4,943	5,604

### (a) Provision for impairment

No trade receivables are past due and all trade receivables are non interest bearing with 30 or 60 day terms. An impairment loss is recognised when there is objective evidence that an individual trade receivable is impaired. No impairment losses have been recognised for reported periods. All trade receivables are expected to be received within trading terms.



# Note 11: Plant and Equipment

	Notes	2015 \$'000	2014 \$'000
Leasehold Improvements			
At cost		1,119	1,115
Accumulated amortisation		(1,115)	(1,115)
Total leasehold improvements	11(a)	4	_
Plant and Equipment			
At cost		213	166
Accumulated depreciation		(125)	(88)
Total plant and equipment	11(a)	88	78
Total plant and equipment		92	78

# (a) Reconciliations

Reconciliations of the carrying amounts of plant and equipment at the beginning and end of the current financial year:

	2015 \$'000	2014 \$'000
Leasehold improvements		
Carrying amount at beginning	-	-
Additions	4	-
Amortisation expense	-	-
	4	-
Plant and equipment		
Carrying amount at beginning	78	93
Additions	62	25
Disposals	-	-
Depreciation expense	(52)	(40)
	88	78

FOR THE YEAR ENDED 30 JUNE 2015

# Note 12: Intangible Assets

	Notes	2015 \$'000	2014 \$'000
Intellectual Property			
At cost		1,200	1,200
Accumulated amortisation		(1,044)	(949)
	12(a)	156	251
Capitalised Development			
Ellavie™			
External research and development expenses		766	766
Employee benefits capitalised		169	169
Other capitalised amounts		136	136
	12(a)	1,071	1,071
Axiron™			
External research and development expenses		17,415	17,415
Employee benefits capitalised		3,353	3,353
Other capitalised amounts		2,403	2,403
Accumulated amortisation		(4,006)	(2,729)
	12(a)	19,165	20,442
Net carrying amount		20,236	21,513
Total intangible assets		20,392	21,764

### (a) Reconciliations

Reconciliations of the carrying amounts of intellectual property and capitalised development at the beginning and end of the current financial year.

	2015 \$'000	2014 \$'000
Intellectual Property		
Carrying amount at beginning	251	346
Amortisation expense	(95)	(95)
	156	251
Capitalised Development		
Ellavie <sup>™</sup>		
Carrying amount at beginning	1,071	1,071
Additions	_	_
	1,071	1,071
Axiron™		
Carrying amount at beginning	20,442	21,720
Additions	-	_
Amortisation	(1,277)	(1,278)
	19,165	20,442

The remaining useful life of Axiron Capitalised Development is approximately 15 years.



# Note 13: Payables

	2015 \$'000	2014 \$'000
Current		
Trade creditors	106	217
Sundry creditors and accruals	1,044	912
	1,150	1,129
Note 14: Provisions		
	2015 \$'000	2014 \$'000

	\$'000	\$1000
Current		
Employee entitlements	288	401
Non-Current		
Employee entitlements	19	11
Aggregate employee entitlements liability	307	412

# Note 15: Contributed Equity

	2015		2014		
	No. of Shares	\$'000	No. of Shares	\$'000	
(a) Issued and paid up capital					
Ordinary shares fully paid	166,521,711	95,873	166,521,711	95,873	
(b) Movements in shares on issue					
Beginning of the financial year	166,521,711	95,873	166,521,711	95,873	
Issued during the year:					
- Employee share option plans	-	-	-	-	
Less Capital Raising Expenses	-	-	-	-	
Fair value of shares issued on exercise of employee share options	-	-	-	-	
Contributions from share issues	-	_	_	-	
At reporting date	166,521,711	95,873	166,521,711	95,873	

### (c) Share Options

### Employee Share Option Plan

The consolidated entity operates an employee share option plan. During the financial year no options were exercised (2014 Nil), 2,000,000 new options were issued under the plan during the financial year (2014: 1,855,000). Options hold no participation rights, but shares issued on exercise of options rank equally with existing shares. At 30 June 2015 2,915,000 options were held by key management personnel (2014: 1,340,000).

FOR THE YEAR ENDED 30 JUNE 2015

# Note 15: Contributed Equity (continued)

The closing market value of an ordinary Acrux Limited share on the Australian Stock Exchange at 30 June 2015 was \$0.85.

	2015 No.	2014 No.
(i) Movement in the number of share options held under Employee Share Option Plan are as follows:		
Opening balance	1,855,000	-
Granted during the year	2,000,000	1,855,000
Exercised during the year	-	-
Lapsed during the year	(475,000)	-
Closing balance	3,380,000	1,855,000
	\$'000	\$'000
(ii) Details of share options exercised during the year:		
Proceeds from shares issued	-	-
Fair value as at issue date of shares issued during the year	-	-

	2015 No.	2014 No.
Key Management Personnel	425,000	_
Employee	50,000	-
Lapsed during the year	475,000	-

# (d) Capital management

When managing capital, the Directors' objective is to ensure the entity continues as a going concern as well as to maintain optimal returns to shareholders and benefits for other stakeholders.

During 2015, the Board paid dividends of \$13.3 million (2014: \$33.3 million). The amounts and ratio of future dividends have not been determined.

# Note 16: Share Based Payments

# (a) Employee share option plan

Details of the options granted are provided below:

2	2014	Exercise	Balance at the beginning of	Granted during the	Exercised during the	Expired during the	Balance at the end of	Exercisable at the end of
Grant date	Expiry date	price	the year	year	year	year	the year	the year
7/31/2013	7/31/2016	\$4.30	1,255,000	-	_	(475,000)	780,000	780,000
11/21/2013	7/31/2016	\$4.30	600,000	_	_	_	600,000	600,000
2/3/2015	2/3/2018	\$1.32	_	2,000,000	_	_	2,000,000	2,000,000
				2,000,000	_	(475,000)	3,380,000	3,380,000



The weighted average remaining contractual life for share options outstanding at the end of the period was 1.98 years.

The fair value of the options granted on 3 February 2015 was 38 cents per option at the date of grant. Fair value was determined using the binomial option pricing model. The following inputs were utilised:

Exercise price: \$1.32 Grant date: 3 February 2015 Expiry date: 3 February 2018 Share price at grant date: \$1.45 Expected price volatility of the company's shares: 57% Expected dividend yield: 8.99%

The fair value of the options granted on 31 July 2013 was 43 cents per option. Fair value was determined using the binomial option pricing model. The following inputs were utilised:

Exercise price: \$4.30 Grant date: 31 July 2013 Expiry date: 31 July 2016 Share price at grant date: \$3.35 Expected price volatility of the company's shares: 38% Expected dividend yield: 5% Risk-free interest rate: 2.52%

The fair value of the options granted on 21 November 2013 was 16 cents per option. Fair value was determined using the binomial option pricing model. The following inputs were utilised:

Exercise price: \$4.30 Grant date: 21 November 2013 Expiry date: 31 July 2016 Share price at grant date: \$2.56 Expected price volatility of the company's shares: 37% Expected dividend yield: 5.0% Risk-free interest rate: 3.08%

### (b) Expenses recognised from share-based payment transactions

The expense recognised in relation to the share-based payment transactions was recorded within share options expense in the statement of comprehensive income were as follows:

	2015 \$'000	2014 \$'000
Options issued under the employee share option plan	760	638
Total expenses recognised from share based payment transactions	760	638

FOR THE YEAR ENDED 30 JUNE 2015

# Note 17: Reserves and Accumulated Losses

	Notes	2015 \$'000	2014 \$'000
Share based payment reserve	17(a)	1,194	638
Accumulated losses	17(b)	(56,442)	(54,454)
(a) Share based payment reserve			
(i) Nature and purpose of reserve			
This reserve is used to record the value of equity benefit provided to employees and directors as part of their remuneration. Refer Note 15 for details.			
(ii) Movement in reserve			
Balance at the beginning of year		638	_
Transfer fair value of employee shares options to share capital		_	_
Employee share option expense for the period (including adjustment for service conditions not met)		760	638
Vested employee share options previously expensed, that lapsed during the period		(204)	_
Balance at end of year		1,194	638
(b) Accumulated losses			
Balance at the beginning of year		(54,454)	(49,120)
Vested employee share options that lapsed during the period		204	-
Net profit attributable to members of Acrux Limited		11,130	27,970
Accumulated losses at reporting date		(43,120)	(21,150)
Dividends paid		(13,322)	(33,304)
Accumulated losses at reporting date		(56,442)	(54,454)

# Note 18: Non-Controlling Interests

The consolidated entity holds nil (2014: nil) Non-controlling interests at balance date.



# Note 19: Cash Flow Information

	2015 \$'000	2014 \$'000
(a) Reconciliation of the cash flow from operations with profit after income tax:		
Profit from ordinary activities after income tax	11,130	27,970
Non-Cash Items		
Depreciation and amortisation	1,425	1,413
Share options expense	760	638
Unrealised foreign exchange gains	(163)	107
Changes in assets and liabilities		
Increase/(decrease) in tax liabilities	(2,762)	2,851
Decrease/(increase) in trade and other receivables	661	1,221
Increase/(decrease) in payables	21	(127)
Increase/(decrease) in employee entitlements	(105)	61
Increase/(decrease) in deferred taxes	(448)	2,237
	(611)	8,401
Net cash (outflows)/inflows from operating activities	10,519	36,371
(b) Reconciliation of cash		
Cash at the end of the financial year as shown in the statement of cash flows is reconciled to the related items in the statement of financial position is as follows:		
- Cash at bank	19,068	2,775
- At call deposits with financial institutions	4,000	23,000
Closing cash balance	23,068	25,775

### (c) Credit stand-by arrangement and loan facilities

The consolidated entity has credit card facilities with the National Australia Bank and American Express available to the extent of \$161,000 (2014: \$101,000). As at 30 June 2015 the consolidated entity had unused facilities of \$147,599 (2014: \$93,153).

FOR THE YEAR ENDED 30 JUNE 2015

# Note 20: Commitments

	2015 \$'000	2014 \$'000
Lease expenditure commitments		
Operating leases (non-cancellable)		
(i) Non cancellable operating leases contracted for but not capitalised in the accounts:		
(ii) Minimum lease payments		
- Not later than one year	302	294
- Later than one year and not later than five years	606	908
Aggregate lease expenditure contracted for at reporting date	908	1,202

The operating lease relates to office, laboratory and warehouse facilities for which the lease was renewed by Acrux DDS Pty Ltd for a period of 4 years from 1 June 2014, with an option to extend for a further period of 4 years. The lease contract contains market review clauses in the event that Acrux DDS Pty Ltd exercises its option to renew. The company does not have an option to purchase the leased asset at the expiry of the lease period.

# Note 21: Key Management Personnel Compensation

Details of Key Management Personnel Compensation are contained within the Remuneration Report section of the Director's Report. A breakdown of the aggregate components of Key Management Personnel's compensation is provided below:

	2015 \$'000	2014 \$'000
Compensation by category:		
Short-term employment benefits	1,282	1,219
Post-employment benefits	73	69
Termination benefits	-	-
Equity	760	356
	2,115	1,644

### Note 22: Loans to Key Management Personnel

There were no loans made to Key Management Personnel during the reporting period.

# Note 23: Related Party Disclosures

### Wholly-owned group transactions

### Loans

Loans were made by Acrux Limited to its subsidiaries under normal terms and conditions. The aggregate amounts receivable from controlled entities by the parent entity at the end of the reporting period were nil (2014: nil).

Non-interesting bearing loans were made by Acrux Commercial Pty Ltd to its subsidiary, Fempharm Pty Ltd. The aggregate amount receivable from Fempharm Pty Ltd at the end of the reporting period was \$4,895,370 (2014: \$4,486,184).

#### Other transactions with Key Management Personnel and their personally-related entities

Acrux DDS Pty Ltd, a wholly owned subsidiary of Acrux Limited, entered into two research and commercialisation collaboration agreements with Hexima Limited on 8 October 2013. Ross Dobinson was previously the Executive Chairman of Hexima Limited. During the reporting period Acrux DDS Pty Ltd received nil (2014: \$5,260.37) from Hexima for the reimbursement of expenses directly related to the collaboration agreements. At the end of the reporting period there were no amounts outstanding to be paid to or received from Hexima.

Any payments made to Key Management Personnel during the financial year, other than remuneration entitlements, related to the reimbursement of business expenses incurred on behalf of Acrux Limited and its subsidiaries.



# Note 24: Auditor's Remuneration

	2015 \$'000	2014 \$'000
Amounts paid and payable to Pitcher Partners for:		
(i) Audit and other assurance services		
<ul> <li>An audit or review of the financial report of the entity and any other entity in the consolidated entity</li> </ul>	106	92
- Other assurance services	13	-
	119	92

# Note 25: Segment Information

The consolidated entity operates as a single operating segment. Internal management reporting systems present financial information as a single segment. The segment derives its revenue from developing and commercialising products using unique technology to administer drugs through the skin.

### Additional information on revenue:

	2015 \$'000	2014 \$'000
Product/Service		
Axiron	24,255	52,528
Other revenue	1,113	1,331
Total revenue	25,368	53,859
Country of Origin		
Australia	752	491
Outside Australia:		
Switzerland	24,255	52,528
United States	144	169
Other	217	671
	25,368	53,859

FOR THE YEAR ENDED 30 JUNE 2015

### **Note 26: Parent Entity Details**

Summarised presentation of the parent entity, Acrux Limited, financial statements:

	Parent E	Parent Entity	
	2015 \$'000	2014 \$'000	
(a) Summarised statement of financial position			
Assets			
Current assets	6,204	523	
Non-current assets	19,000	19,000	
Total assets	25,204	19,523	
Liabilities			
Current liabilities	924	296	
Non-current liabilities	_	-	
Total liabilities	924	296	
Net assets	24,280	19,227	
Equity			
Share capital	95,873	95,873	
Profit reserve	4,293	-	
Accumulated losses	(77,080)	(77,284)	
Share based payments reserve	1,194	638	
Total equity	24,280	19,227	
(b) Summarised statement of comprehensive income			
Profit for the year	17,615	29,530	
Other comprehensive income for the year	-	-	
Total comprehensive income for the year	17,615	29,530	



# **Note 27: Controlled Entities**

		Percentag	e Owned
	Country of Incorporation	2015	2014
Parent Entity:			
Acrux Limited	Australia		
Subsidiaries of Acrux Limited			
Acrux DDS Pty Ltd	Australia	100%	100%
Acrux Pharma Pty Ltd	Australia	100%	100%
Acrux Commercial Pty Ltd	Australia	100%	100%
Subsidiaries of Acrux Commercial Pty Ltd			
Fempharm Pty Ltd	Australia	100%	100%

# Note 28: Contingencies

There were no contingencies at 30 June 2015 (2014: Nil).

# Note 29: Subsequent 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.

There has been no other matter or circumstance, which has arisen since 30 June 2015 that has significantly affected or may significantly affect:

(a) the operations, in financial years subsequent to 30 June 2015, of the consolidated entity, or

(b) the results of those operations, or

(c) the state of affairs, in financial years subsequent to 30 June 2015, of the consolidated entity.

# **Note 30: Company Details**

The registered office of the company is: Acrux Limited 103 – 113 Stanley Street West Melbourne VIC 3003

# **DIRECTORS' DECLARATION**

The Directors declare that the financial statements and notes set out on 24 to 61 in accordance with the *Corporations Act 2001*:

- (a) Comply with Accounting Standards and the *Corporations Regulations 2001*, and other mandatory professional reporting requirements;
- (b) As stated in Note 1(a) the consolidated financial statements also comply with International Financial Reporting Standards; and
- (c) Give a true and fair view of the financial position of the consolidated entity as at 30 June 2015 and of its performance for the year ended on that date.

In the Directors' opinion there are reasonable grounds to believe that Acrux Limited will be able to pay its debts as and when they become due and payable.

This declaration has been made after receiving the declarations required to be made by the Chief Executive Officer and Chief Financial Officer to the Directors in accordance with sections 295A of the *Corporations Act 2001* for the financial year ending 30 June 2015.

This declaration is made in accordance with a resolution of the Directors.

)

R Dobinson Non-Executive Chairman Melbourne Dated this 12<sup>th</sup> day of August 2015

**B Parncutt** Director Melbourne Dated this 12<sup>th</sup> day of August 2015



# **INDEPENDENT AUDITOR'S REPORT**



ACRUX LIMITED ABN 72 082 001 152 AND CONTROLLED ENTITIES

INDEPENDENT AUDITOR'S REPORT TO THE MEMBERS OF ACRUX LIMITED

#### **Report on the Financial Report**

We have audited the accompanying financial report of Acrux Limited and its controlled entities, which comprises the consolidated statement of financial position as at 30 June 2015, the consolidated statement of comprehensive income, consolidated statement of changes in equity and consolidated statement of cash flows for the year then ended, notes comprising a summary of significant accounting policies and other explanatory information, and the directors' declaration of the consolidated entity comprising the company and the entities it controlled at the year's end or from time to time during the financial year.

#### Directors' Responsibility for the Financial Report

The directors of the company are responsible for the preparation of the financial report that gives a true and fair view in accordance with Australian Accounting Standards and the *Corporations Act 2001* and for such internal control as the directors determine is necessary to enable the preparation of the financial report that gives a true and fair view and is free from material misstatement, whether due to fraud or error. In Note 1, the directors also state, in accordance with Accounting Standard AASB 101 *Presentation of Financial Statements*, that the financial statements comply with *International Financial Reporting Standards*.

#### Auditor's Responsibility

Our responsibility is to express an opinion on the financial report based on our audit. We conducted our audit in accordance with Australian Auditing Standards. Those standards require that we comply with relevant ethical requirements relating to audit engagements and plan and perform the audit to obtain reasonable assurance about whether the financial report is free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial report. The procedures selected depend on the auditor's judgement, including the assessment of the risks of material misstatement of the financial report, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the company's preparation of the financial report that gives a true and fair view in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by the directors, as well as evaluating the overall presentation of the financial report.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

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# **INDEPENDENT AUDITOR'S REPORT**

CONTINUED

ACRUX LIMITED ABN 72 082 001 152 AND CONTROLLED ENTITIES PITCHER PARTNERS

#### INDEPENDENT AUDITOR'S REPORT TO THE MEMBERS OF ACRUX LIMITED

#### Independence

In conducting our audit, we have complied with the independence requirements of the *Corporations Act* 2001.

#### Opinion

In our opinion:

- (a) the financial report of Acrux Limited and controlled entities is in accordance with the *Corporations Act 2001*, including:
  - (i) giving a true and fair view of the consolidated entity's financial position as at 30 June 2015 and of its performance and its cash flows for the year ended on that date; and
  - (ii) complying with Australian Accounting Standards and the Corporations Regulations 2001; and
- (b) the consolidated financial report also complies with *International Financial Reporting Standards* as disclosed in Note 1.

#### **Report on the Remuneration Report**

We have audited the Remuneration Report included in pages 30 to 34 of the directors' report for the year ended 30 June 2015. The directors of the company are responsible for the preparation and presentation of the Remuneration Report in accordance with section 300A of the *Corporations Act 2001*. Our responsibility is to express an opinion on the Remuneration Report, based on our audit conducted in accordance with Australian Auditing Standards.

#### Opinion

In our opinion, the Remuneration Report of Acrux Limited and controlled entities for the year ended 30 June 2015 complies with section 300A of the *Corporations Act 2001*.

s rm

S SCHONBERG Partner 13 August 2015

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PITCHER PARTNERS Melbourne

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# **SHAREHOLDER INFORMATION**

Additional information required by Australian Securities Exchange Listing Rules and not disclosed elsewhere in this report, as at 11 September 2015:

### **Shareholders**

The Company has 166,521,711 ordinary fully paid shares on issue, held by 8,529 shareholders and 4,380,000 options outstanding, held by 14 people. The Company does not have any other shares or options or other equity securities on issue. The holders of ordinary shares are entitled to receive dividends as declared from time to time and are entitled to one vote per share at shareholders' meetings. No voting rights attach to the options.

All fully paid ordinary shares are quoted on the Australian Securities Exchange. No other equity securities of the Company are quoted on the Australian Securities Exchange. The Company has not had, and neither is there currently, any on-market buy back.

# **Distribution Schedule**

The following is a distribution schedule of the number of holders of fully paid ordinary shares in the Company within the bands of holding specified by the ASX Listing Rules:

Category	Number of Shareholders	Percentage	Shares
1 to 1,000 shares	1,771	0.63%	1,041,682
1,001 to 5,000 shares	3,330	5.78%	9,619,994
5,001 to 10,000 shares	1,505	7.30%	12,161,967
10,001 to 100,000 shares	1,782	29.66%	49,394,170
100,001 shares and over	141	56.63%	94,303,898
Total	8,529	100.00%	166,521,711

1,198 shareholders hold less than a marketable parcel of fully paid ordinary shares (being the Company's main class of securities), based on the market price at the date set out above.

# **Substantial Holders**

Name	Number of Equity Securities Held
Allan Gray Australia Pty Limited	23,640,122

Under the ASX Listing Rules "Substantial Holder" means, in general terms, a person who either alone or with their associates has an interest in 5% or more of the voting shares of the Company.

# **SHAREHOLDER INFORMATION**

CONTINUED

# Twenty Largest Holders of Fully Paid Ordinary Shares in Acrux Limited

	Shareholder	Number of Fully Paid Ordinary Shares	Percentage of Total Capital
1	CITICORP NOMINEES PTY LIMITED	13,874,890	8.33%
2	J P MORGAN NOMINEES AUSTRALIA LIMITED	13,841,266	8.31%
3	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED	12,840,464	7.71%
4	NATIONAL NOMINEES LIMITED	5,115,028	3.07%
5	BRISPOT NOMINEES PTY LTD	2,183,604	1.31%
6	MR IAN VICTOR LANCINI & MRS DEBRA ANN LANCINI	2,045,000	1.23%
7	DURBIN SUPERANNUATION PTY LTD	1,895,000	1.14%
8	HISHENK PTY LTD	1,655,000	0.99%
9	DORVELL PTY LTD	1,513,640	0.91%
10	ASIA UNION INVESTMENTS PTY LIMITED	1,500,000	0.90%
11	BOND STREET CUSTODIANS LIMITED	1,257,295	0.76%
12	ASIA UNION INVESTMENTS PTY LTD	1,200,000	0.72%
13	BNP PARIBAS NOMS PTY LTD	889,267	0.53%
14	BOND STREET CUSTODIANS LIMITED	876,923	0.53%
15	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED - A/C 3	850,604	0.51%
16	CS FOURTH NOMINEES PTY LTD	815,104	0.49%
17	C M ABBOTT PTY LIMITED	800,000	0.48%
18	LOREMELL PTY LIMITED	764,716	0.46%
19	MR LOUIS PIERRE LEDGER	701,500	0.42%
20	MR WILLIAM GEORGE JEPHCOTT	655,000	0.39%
		65,274,301	39.20%

### Market Listing

Acrux Limited is quoted on the Australian Securities Exchange (ASX). Share prices can be obtained from most Australian national newspapers and from the ASX website (www.asx.com.au). The shares of the Company are not quoted on any other stock exchange. The following are the share prices for the end of each quarter of the financial year ending 30 June 2015:

Quarter ended 30 September 2014	\$1.54
Quarter ended 31 December 2014	\$1.28
Quarter ended 31 March 2015	\$0.86
Quarter ended 30 June 2015	\$0.85

The closing share price on 11 September 2015 was 61 cents



# **Pooled Development Fund**

The information set out below is of a general nature only and may vary from person to person (dependent on their circumstances). Any shareholder or prospective shareholder should obtain their own taxation advice, rather than relying on this summary.

Acrux Limited is a Pooled Development Fund (PDF) that has been registered under the *Pooled Development Fund Act 1992* ("the PDF Act") since 7 July 1999. A PDF is a company that is resident in Australia, and is registered and regulated by the PDF Registration Board in accordance with the PDF Act.

Shareholders in the Company will be entitled to concessionary tax treatment in Australia for income and capital gains derived in connection with their shareholding. The concessionary tax treatment should be available to investors that hold their interests directly and indirectly through non-corporate trusts and partnerships.

Gains realised by an investor on the disposal of shares in the Company will not be included in the investor's assessable income in Australia. This is because:

- Where the gain on sale would be ordinary income of the investor, the gain will be treated as exempt income; and
- Where the gain on sale would be a capital gain it is specifically excluded from the capital gains tax provisions of the Tax Act.

Equally, an investor will not be entitled to any deduction or capital loss on the sale of the Company's shares.

Shares held in a PDF cannot be held as trading stock. Accordingly, share traders cannot treat PDF shares as trading stock.

Unfranked dividends received by an Australian resident shareholder from the Company will be exempt from tax in the hands of the shareholder. Franked dividends will also be exempt from tax unless the shareholder elects to treat the franked dividend as taxable. Broadly, Australian resident shareholders who hold the Company's shares at risk (in accordance with the Tax Act) for 45 days or more may elect to treat franked dividends paid by the Company as assessable income, and claim the tax offset available in respect of the dividend. The tax offset will be equal to the franking credit attaching to the dividend received. Where the tax offset available exceeds the shareholder's highest marginal tax rate, the shareholder may be entitled to receive a refund of tax in respect of the excess franking credit.

Australian corporate tax entities are entitled to benefit from the franking credits attaching to the franked portion of the dividends paid by the Company, irrespective of whether the corporate tax entity treats the dividend as exempt income or elects to treat it as assessable income. Accordingly, an Australian corporate may credit its franking account with franking credits attaching to a dividend from the Company regardless of whether or not they have elected to treat the dividend as exempt or assessable income.

Dividends paid by Acrux to non-residents will not be subject to withholding tax regardless of whether or not they are franked or unfranked.

Should the Company cease to be a PDF, each shareholder will be deemed to have sold their shares immediately before the Company ceased to be a PDF and to have acquired the shares at their market value immediately after the Company ceased to be a PDF. Any gain or loss realised on the sale after that time, calculated by reference to the deemed acquisition cost, will be subject to the general provisions of the Tax Act and any such gain may be included in the shareholder's assessable income.

# GLOSSARY

Term	Abbreviation	Description
Abbreviated New Drug Application	ANDA	An Abbreviated New Drug Application (ANDA) contains data which, when submitted to the FDA's Center for Drug Evaluation and Research, Office of Generic Drugs, provides for the review and ultimate approval of a generic drug product. Once approved, an applicant may manufacture and market the generic drug product to provide a safe, effective, low cost alternative to the branded drugs.
		A generic drug product is one that is comparable to an innovator drug product in dosage form, strength, route of administration, quality, performance characteristics and intended use.
Axiron®		Brand name for Acrux's unique testosterone replacement therapy solution product licensed globally to Lilly and which is approved in various countries. The Axiron® trademark is owned Lilly.
Decentralised Procedure	DCP	A regulatory application in Europe for marketing authorisation is submitted simultaneously to the competent authorities within the European Union. At the end of the DCP procedure, the draft Assessment Report, labelling and package leaflet, as proposed by the Reference Member State, may be approved.
Diclofenac		Diclofenac is a commonly used nonsteroidal anti-inflammatory drug (NSAID).
Elanco		Elanco provides products and knowledge services to improve animal health and food animal production in more than 70 countries around the world. The company has nearly 7,000 employees worldwide. Founded in 1954, Elanco is a division of Eli Lilly and Company. Worldwide headquarters and research facilities are located in Greenfield, Indiana.
Eli Lilly and Company	Lilly	Lilly is a global healthcare leader that unites caring with discovery to make life better for people around the world. Lilly was founded more than a century ago and are committed to creating high-quality medicines that meet real needs. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism.
Ellavie®		Alternative brand name for Acrux's estradiol spray product. The Ellavie® trademark is owned by Acrux.
Estradiol		Estradiol is a form of estrogen, a female sex hormone produced by the ovaries. Estrogen is necessary for many processes in the body.
Estrogen		Generic term for any substance, natural or synthetic, that exerts biologic effects characteristic of estrogenic hormones.
European Medicines Agency	EMA	European Union agency responsible for the protection of public and animal health through the scientific evaluation and supervision of medicines.
Evamist®		Brand name for Acrux's unique estradiol spray product in the United States. The Evamist® trademark is owned by Lumara Health.
Food and Drug Administration	FDA	The FDA is responsible for protecting and promoting public health through the regulation and supervision of prescription, over-the-counter pharmaceutical drugs (medications), vaccines, biopharmaceuticals and veterinary products in the United States.
Gedeon Richter		Gedeon Richter Plc., headquartered in Budapest/Hungary, is a major pharmaceutical company in Central Eastern Europe, with an expanding direct presence in Western Europe. Richter's consolidated sales were approximately EUR 1.1 billion (US\$ 1.5 billion), while its market capitalization amounted to EUR 2.1 billion (US\$ 2.5 billion) in 2014. The product portfolio of Richter covers a broad range of therapeutic areas, including gynaecology, central nervous system, and cardiovascular areas. Richter is a significant player in the female healthcare field worldwide.
Generic		A generic medicine is a medicine that provides the same quality, safety and efficacy as the original brand name product which undergoes strict scrutiny before it is licensed and given market approval by national regulatory authorities.
Hypogonadism		Hypogonadism occurs when the body's sex glands produce little or no hormones. In men, these glands (gonads) are the testes.
Ibuprofen		Ibuprofen is a commonly used nonsteroidal anti-inflammatory drug (NSAID).
Lenzetto®		Brand name for Acrux's unique estradiol spray in the European Union. The Lenzetto® trademark is owned by Gedeon Richter.
Net profit after tax	NPAT	Total amount earned during the financial reporting period after deducting income tax expense. The financial statements are audited and comply with relevant accounting principles, taxation laws and accounting standards.
Non-steroidal anti-inflammatory drug	NSAID	All nonsteroidal anti-inflammatory drugs (NSAIDs) differ in structure but they all have similar antipyretic, anti- inflammatory and analgesic properties. NSAIDs work by blocking the variant forms of the cyclooxygenase (COX) enzyme, inhibiting production of prostaglandins and thromboxanes, which are produced as part of the body's inflammatory response.
NRx		New prescriptions over a period of time
Onychomycosis		Onychomycosis is a fungal infection of the toenails or fingernails that may involve any component of the nail unit, including the matrix, bed, or plate. Onychomycosis can cause pain, discomfort, and disfigurement and may produce serious physical and occupational limitations, as well as reducing quality of life.
Perrigo		Perrigo Company Plc., is a top five global over-the-counter ("OTC") consumer goods and leading specialty pharmaceutical company. It is one of the world's largest manufacturers of OTC healthcare products and suppliers of infant formulas for the store brand market.
Testosterone		Testosterone is a naturally occurring sex hormone that is produced in a man's testicles.
Topical		Topical is a route of administration wherein active pharmaceutical ingredients are applied to, or affect a localised area of the surface of the body.
Transdermal		Transdermal is a route of administration wherein active pharmaceutical ingredients are delivered across the skin for systemic distribution. Examples include Axiron, Evamist and Lenzetto.
TRx		Total number of prescriptions over a period of time



# **CORPORATE DIRECTORY**



# Acrux Limited and Subsidiary Companies

103-113 Stanley Street West Melbourne Victoria 3003 Australia

T: + 61 3 8379 0100
www.linkedin.com/company/acrux
www.acrux.com.au
Australian Stock Exchange code "ACR"

Information about the Company, including disclosures to the Australian Stock Exchange, can be found on the Company's website. If you require further information about Acrux, please contact the Chief Financial Officer & Company Secretary on +61 3 8379 0100.

### Share Registry

Link Market Services Level 1 333 Collins Street Melbourne Victoria 3000 Australia Locked Bag A14 Sydney South NSW 1235 Australia

Toll-free: 1300 554 474 (Australia only) International: +61 1300 554 474

- F: (02) 9287 0303
- F: (02) 9287 0309 (for proxy voting)
- E: registrars@linkmarketservices.com.au
- W: www.linkmarketservices.com.au



### Acrux Limited

103–113 Stanley Street West Melbourne Victoria 3003 Australia

T: + 61 3 8379 0100 www.linkedin.com/company/acrux

