

Annual Report

DELIVERED
OUTCOMES

2021



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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 risk and important factors that may cause the actual results, performance or achievements of Acrux to be materially different from statements made in this report.

A scientist wearing a white lab coat, a white surgical mask, and a white hairnet is working in a laboratory. They are holding a small vial and looking at it intently. The background is slightly blurred, showing other laboratory equipment and bottles. The overall color scheme is a soft, warm pinkish-red.

MISSION

ACRUX IS A
PHARMACEUTICAL
COMPANY DEDICATED
TO DEVELOPING AND
COMMERCIALISING
GENERIC TOPICAL
PRESCRIPTION
PHARMACEUTICALS.

WHO WE ARE

Acrux (ASX: ACR) is a pharmaceutical company dedicated to developing and commercialising generic transdermal and topical pharmaceuticals. Incorporated in 1998 and using in house facilities and capabilities, Acrux has successfully developed and commercialised through licensees a number of topically applied pharmaceutical products now on market in the US and Europe. Acrux is expanding its range of topical generic products for the US market by leveraging its on-site laboratories, GMP manufacturing suite, clinical and commercial experience to bring affordable products to market. Acrux encourages collaboration and is well positioned to discuss partnering and product development.

KEY HIGHLIGHTS

Revenue

\$5.15m

Up 31%
on prior year

Market
Capitalisation

\$36.83m

Up 51%
on prior year

Cash
Reserves

\$15.27m

Up 66%
on prior year

Approved
Products

5

Up from 2
on prior year

R&D Incentive
Rebate

\$3.42m

Up 47%
on prior year

Net Assets

\$18.47m

Up 44%
on prior year

FDA Approvals received			Launched
January 2021 Testosterone Topical Solution USP, 30mg per actuation	June 2021 Generic Jublia® Efinaconazole Topical Solution 10%	July 2021 Generic EMLA® Cream (Lidocaine 2.5% and Prilocaine 2.5%)	August 2021 Testosterone Topical Solution USP, 30mg per actuation by licensee Dash Pharmaceuticals

CHAIRMAN'S ADDRESS



At our last AGM we confirmed the importance of having multiple distribution partners for our growing product pipeline and we identified our four key 2021 financial year objectives. These were: continued revenue growth from existing products, having three additional products submitted for FDA approval, the commercial launch of two products and the execution of two key licensing contracts. The four objectives for the 2022 financial year were also specified with the same level of granularity.

Due to the logistics disruption caused by Covid (both domestic and international) on the timely availability of freight, raw materials, staff, our seven contract manufacturing organisations and a range of other factors, the Company has had to extend the timeframe to meet its FY '21 targets. The testosterone solution product was ready for launch in August 2021. The commercial launch of prilocaine/lidocaine cream is expected in FY '22.

The Company has made solid progress towards achieving our FY '22 targets of further revenue growth from existing products, becoming cashflow positive by the close of calendar year 2022, the growth of new products in development and having additional products submitted for FDA review. As we have announced previously, we have submitted 5 ANDAs to the FDA for review and we have received three approvals to date. We are expecting to file several new ANDAs in calendar 2022. As a result of the experience with these products we are refining our approaches to both the selection and development of both the products we have in active development and for future generic drug candidates.

The capital raising completed by the Company last January secured the funding required for the continued development and expansion of our product portfolio, which is essential in enabling us to achieve our future targets. Acrux's skill sets in product development have been recognised by industry peers who have approached Acrux regarding the joint development of some of the more complex generic targets. These initiatives provide additional product development funding and diversification that Acrux would not necessarily have pursued independently.

We have enhanced the Board skillset through the appointment of Don Brumley, a former Ernst & Young partner with extensive experience in our market sector.

While it has been an extremely challenging year, we have made very significant progress in broadening our product portfolio and initiating the commercialisation of those products through establishing a solid distribution network in the US market.

A handwritten signature in black ink, appearing to read 'Ross Dobinson', with a long horizontal flourish extending to the right.

Ross Dobinson
Chairman

CEO & MANAGING DIRECTOR'S REPORT



Our key focus is on the continuing transformation of Acrux into a company with a diversified on-market portfolio and a broad pipeline of commercially valued products.

The second half of the financial year saw Acrux prepare for launch of its first abbreviated new drug application (ANDA) in the United States. The testosterone solution product was approved by the FDA in January 2021. The past months have been focussed on the successful execution of the commercial batches required for launch and associated process validation routinely required by the FDA. Acrux expects to announce that the product will be launched in the near term in the United States adding to the portfolio of products that Acrux has commercialised.

Acrux also received FDA approval for efinaconazole solution 10% and prilocaine/lidocaine cream 2.5%/2.5%, with both products approved in mid 2021. The Company is currently planning the launch of the prilocaine/lidocaine cream product.

Acrux has continued to focus on the development and registration of prescription topical pharmaceuticals that are generics of existing drugs in the United States. FDA requirements for the development of topical generics require different skill sets and approaches to bioequivalence when compared to the larger oral and injectable sectors of the US pharmaceutical market. The FDA characterises the development and bioequivalence of topical generics as complex and indeed some of the in-vitro bioequivalence techniques that generic companies are required to develop are known within the industry and Acrux as being technically challenging with significant barriers to successful execution. The Company has spent considerable effort in developing its expertise in these areas and uses both in house capabilities as well as a network of external non-clinical research organisations to assist in demonstrating bioequivalence of the products it develops compared to the reference listed drug in the United States.

Our approach to the evolution of our pipeline is based on the thorough assessment of new product development candidates as well as the financial and human resource capacity of our organisation. Our planning approach to development of new products has evolved and for new projects now takes into account our learnings from prior development projects and incorporates increased development discovery work to identify and pro-actively assess critical development issues. We know that when we choose to develop products that have few or zero generics approved, with no patent protection and annual sales that make the product attractive for development by other companies, that there are often reasons why zero or limited numbers of generics exist. Usually, the reason is based on a challenging set of formulation characteristics as well as a challenging array of bioequivalence techniques required by the FDA. To Acrux, these challenges are also opportunities and are the reason that Acrux receives numerous in-bound contacts from other generic companies, from the United States and other regions, who are interested in licensing our products for commercialisation in the United States and other countries. The majority of our products that are in development have been licensed to commercial partners for commercialisation, however, we always welcome contact from other potential licensees and actively engage with these companies to discuss other non-partnered products.

Acrux completed a Capital Raise during the Christmas and New Year period and we are grateful to existing and new shareholders for their support. The capital raised will be used to fund an expanded product pipeline and to commercialise our products.

The Company added an additional two new development projects to its pipeline during the year and our development work on these new projects has begun. Our pipeline of existing products also matured during the FY '21 financial year.

Two additional ANDA products were submitted to the FDA for review and three ANDA products that were filed prior to this financial year have now been approved by the FDA. These are important milestones and show the capability of Acrux to develop products through to and including FDA submission and approval.

CEO & MANAGING DIRECTOR'S REPORT CONTINUED

In total, the company has 15 ANDA products partially or fully developed in its portfolio. Of these, 10 products are in active development at Acrux or are in the process of technical transfer to one of our seven contracted manufacturing partners. This number of products in active development excludes those products under review or approved by the FDA.

Acrux development portfolio of generic topical prescription products (ANDAs)

	FY20	FY21	To 25 August 2021
FDA approved*	-	2	3
Under review by FDA**	3	2	2
Under development	10	11	10
Total products in portfolio	13	15	15

* Excludes estradiol products which are approved and marketed in the United States and Europe.

** Including Acrux ANDA products submitted prior to the period.

LOOKING FORWARD

Acrux expects to commercialise two products in the FY22 financial year and receiving a regular share of profits from our commercial partners from these products. We also look forward to receiving FDA feedback and ultimately approval on the products that are currently under evaluation.

Based on current project plans the Company expects to submit several additional ANDA products with the FDA for evaluation during the 2022 calendar year.

The Acrux team have continued operating with the added complexity of the COVID-19 pandemic. Our laboratory team have continued their work from the company's laboratory, whilst administrative staff largely worked from home throughout the financial year. The challenges that Acrux faced with the pandemic were similar to those faced by

many companies in the pharmaceutical sector. Sourcing materials and supply chain activities have become more difficult, costly and time consuming than in the past. Acrux development projects now involve many contract manufacturers, raw material sources and commercial partners outside Australia and this has added to the complexity in planning and executing each project. Continuity with some service providers has been periodically disrupted by COVID-19 through temporary impacts on their ability to provide a continuous service in their country or state of operations. Where possible, Acrux has planned for contingencies including the assessment of alternate service providers and alternate locations of operations, although this has not always been a realistic option. The broader Acrux team has progressed its pipeline whilst also dealing with the personal and professional challenges that COVID-19 has provided to the healthcare and general community in Australia and globally.

I would like to personally thank the Acrux team of employees and the Board for their continued efforts and focus on moving our pipeline of valued projects forward and to the commercialisation of these products.



Michael Kotsanis
Chief Executive Officer and Managing Director





Manufacture of Testosterone Topical Solution USP, 30mg per actuation

DIRECTORS' REPORT

For The Year Ended 30 June 2021

The Board of Directors of the consolidated entity consisting of Acrux Limited ('Acrux') and its controlled entities (collectively the 'Group') has pleasure in presenting their report for the financial year ended 30 June 2021. To comply with the provisions of the *Corporations Act 2001*, the directors report as follows:

DIRECTORS

The following persons were Directors of Acrux during or since the end of the year are:

Ross Dobinson	Chairman	
Geoffrey Brooke	Non-executive Director	
Don Brumley	Non-executive Director	Appointed 4 June 2021
Norman Gray	Non-executive Director	Resigned 4 June 2021
Timothy Oldham	Non-executive Director	
Michael Kotsanis	Managing Director and Chief Executive Officer	

Directors have been in office since the start of the financial year to the date of this report unless otherwise stated.

PRINCIPAL ACTIVITIES

The principal activities of the Group during the financial year were developing and commercialising a portfolio of generic topical prescription pharmaceutical products which use dermal and transdermal drug delivery technology. There has been no significant change in the nature of these activities during the financial year.

REVIEW OF OPERATIONS

A review of the operations of the Group during the year and the results of these operations are as follows:

Summary of Financial Performance

	2021 \$'000	2020 \$'000
Revenue from licensing agreements	1,337	1,253
R&D tax incentive rebate	3,421	2,327
Other revenue	398	365
Total revenue	5,156	3,945
Net loss after tax	(12,629)	(9,471)
Basic earnings per share	(5.75) cents	(5.65) cents
Cash on hand	15,270	9,206

The consolidated loss after income tax attributable to the members of Acrux Limited was \$12.629 million (2020 loss: \$9.471 million).

Key Events During Year

Strong technical progression has been made on a number of products in the product pipeline with 2 new products added to the pipeline during the year. Importantly, 3 ANDAs have been approved by the FDA since the last report:

- In January 2021 FDA approval was received for topical testosterone solution, 30mg/1.5mL a generic to Perrigo's testosterone topical solution, 30mg/1.5mL. An exclusive sales, marketing and distribution agreement has been signed with Dash Pharmaceuticals and IQVIA reports annual sales of US\$20million for the 12 months to June 2021 for this product;
- In June 2021 FDA approval was received for a generic version of Jublia® (efinaconazole) topical solution, 10%. For the 12 months to June 2021 IQVIA reports annual sales of US\$260 million for this product; and
- In July 2021 FDA approval was received for a generic EMLA® cream (Lidocaine 2.5% and Prilocaine 2.5%). An exclusive sales, marketing and distribution agreement has been executed and IQVIA reports annual sales for the 12 months to June 2021 of US\$23 million for this product.

Further to these 3 products which have been approved by the FDA, as at the date of writing, Acrux has a pipeline of 10 products under active development plus an additional 2 products which have been submitted and are under current review by the FDA.

In order to support Acrux's growing product development pipeline, commercialisation activity and working capital requirements, a \$17.747 million capital raise was concluded in February 2021 through Share Placements to institutional and sophisticated investors (\$7.815 million) and a Share Purchase Plan (\$9.932 million).

Business Strategy

Acrux continues to expand its range of topical generic products under development leveraging its on-site laboratories, GMP manufacturing suite and clinical and commercial experience. At the date of this report, the Group has 15 generic topical products in various stages of development and commercialisation, including three for which approval has been granted by the FDA and 2 where an FDA submission is under review. A significant proportion of the products under development currently have no or few generic alternatives marketed in the United States and the annual addressable market value in the United States of the pipeline exceeds US\$1.2 billion, as reported by IQVIA as at June 2021.

Sales, marketing and distribution agreements have been signed for 2 of the products recently approved by the FDA and launch planning for these products is well underway.

Commercialised products and co-development agreements

Estradiol spray, European Union and other markets

Acrux has licensed its Estradiol spray to Gedeon Richter for sale in the European Union and other markets under the Lenzetto® brand. Lenzetto® was launched in 2016 and is now sold in over 30 countries across the European Union and other markets in the Middle East and Africa.

Acrux's revenue share income from Estradiol has grown to \$1.025 million, an increase of 25% year on year, and is expected to continue to grow as Gedeon Richter increases its market share in existing countries and launches the product into new countries.

Estradiol spray has been licensed to Perrigo for sale in the United States where the product is marketed under the Evamist® brand. Evamist® revenue share income was in line with the prior year.

Other products in the Acrux portfolio of topical generics

In August 2020 Acrux entered an exclusive sales, marketing and distribution agreement for its generic version of EMLA® cream (Lidocaine 2.5% and Prilocaine 2.5%) and Acrux's Abbreviated New Drug Application (ANDA) was approved in July 2021. Based on IQVIA data, sales of EMLA® and its generic equivalents (against which Acrux's generic version will compete) were US\$23 million for the 12 months to the end of June 2021. Our partner is responsible for product commercialisation in the United States, including the coordination of commercial manufacturing and management of marketing and distribution. Acrux will share the profits generated from product sales.

In January 2021, the FDA approved Acrux's ANDA for generic topical testosterone solution, 30mg/1.5mL and in October 2020 Acrux entered an exclusive sales, marketing and distribution agreement in the United States. Our partner is responsible for commercialising the product, including coordinating commercial manufacturing, sales and distribution. Based on IQVIA data for the 12 months to June 2021, US sales generated by the product with which Acrux's generic will compete totalled USD\$20 million. Acrux will share the profits generated from the sales of the product.

In May 2020 Acrux signed an exclusive sales, marketing and distribution agreement for the United States to commercialise 6 products from Acrux's pipeline which are at various stages of development, subject to product approval by the FDA. Our partner will manage each FDA application, be the products' sponsor, and be responsible for commercial manufacturing as well as marketing and distribution. Acrux will continue to conduct the development, scientific and bioequivalence activities necessary to develop these products and to support the application for regulatory approval from the FDA. Following product launch, Acrux will share the gross profits generated from the sales of these products and the agreement has a 10-year term from launch of each product.

In June 2020 Acrux entered an exclusive product development and commercialisation agreement for one product and received an initial contractual milestone (\$0.210 million) in July 2020. Under the terms of the development and commercialisation agreement Acrux will continue to conduct development, scientific and bioequivalence activities necessary to develop the generic product and our partner will seek regulatory approval from the FDA and commercialise the product in the United States. Based on IQVIA data, US sales generated by the product with which Acrux's generic will compete exceeded USD\$250 million for the 12 months to June 2021. Acrux will share the development costs and the profits generated from the sales of the product.

Acrux has 15 products in its portfolio of generic topical ANDA products targeting the US market.

Having recently received FDA approval for 3 of these ANDAs, Acrux currently has 2 further products under FDA review. There are 10 products under active development by Acrux and is preparing for additional regulatory submissions for products from this portfolio that will be submitted in calendar year 2022.

GROUP PERFORMANCE

The following table summarises the Group's performance and key performance indicators:

	2021	2020	2019	2018	2017
Revenue (\$'000's)	5,156	3,945	5,286	3,432	23,934
(Loss)/profit before tax (\$'000)	(12,432)	(9,385)	(8,335)	(16,125)	(94)
Dividends to shareholders	-	-	-	-	-
Share Price at end of the year (cents)	13.0	14.5	18.0	14.5	21.5
Basic earnings/(loss) per share (cents)	(5.75)	(5.65)	(5.00)	(8.52)	(0.15)
Number of Ordinary Shares on Issue	283,305,394	168,583,515	166,577,711	166,521,711	166,521,711
Market Capitalisation (\$million)	36.83	24.44	29.98	24.15	35.80

OPERATING RESULTS

The consolidated loss before tax was \$12.432 million (2020: loss \$9.385 million) attributable to an increase in product development expenses incurred to progress the Group's generic pipeline. The consolidated loss after tax was \$12.629 million (2020 loss: \$9.471 million).

Revenue

Revenue and other income for the year increased by \$1.211 million or 31% to \$5.156 million (2020: \$3.945 million). The revenue increase is predominantly attributable to the R&D Tax Incentive Rebate from the Australian Taxation Office which at \$3.421 million is an increase of \$1.094 million on the prior reporting period. As at 30 June 2021, \$2.824 million is receivable, including \$0.353 million in relation to Overseas Finding applications relating to product development activities conducted in the 2020/21 financial year.

Revenue from product licensing agreements totalled \$1.337 million and is comprised of:

- Revenue share income of \$1.092 million (up by 17%) in relation to licensee sales of Estradiol spray. Revenue share received in relation to sales of Lenzetto[®] by our partner for territories in Europe and certain other countries, Gedeon Richter, continued to grow and contributed \$1.025 million (an increase of 25%) revenue share income. Royalties from the sale of Evamist[®] by our US partner Perrigo was similar to the prior year at \$0.067 million; and
- Contractual milestone revenue of \$0.245 million (2020: \$0.362 million) received following achievement of a contractual milestone of a product development and commercialisation agreement during the reporting period.

Additionally, \$0.364 million was received from the Australian Federal government in the form of COVID-19 relief programs, including JobKeeper support, and interest received on cash deposits was \$0.034 million (2020: \$0.216 million).

Expenses

Due to expenses associated with the progression of pipeline projects, total operating expenditure for the year increased by \$4.258 million, or 32% to \$17.588 million. The key driver was a year on year increase in External R&D costs by \$3.816 million to \$8,928 million reflecting costs which include contract manufacturer engagement, API (Active Pharmaceutical Ingredient) procurement for the manufacture of exhibit batches and engagement of clinical research organisations to conduct bioequivalence assessments. Employee benefits expense totalled \$5.418 million (2020: \$5.075 million).

Cash flow

During the year, Acrux's cash reserves increased from \$9.206 million to \$15.270 million following the capital raising completed in February 2021 adding \$17.747 million for the purpose of supporting Acrux's growing product development pipeline, commercialisation activities and working capital requirements.

Cash received from licensing agreements for the year was \$1.228 million (2020: \$1.093 million) and revenue from the Federal Government's R&D tax incentive rebate also increased to \$2.924 million (2020: \$2.015 million). The Group also received \$0.364 million (2020 \$0.1 million) in COVID relief payments.

The Group paid \$15.785 million to suppliers and employees (2020: \$11.666 million) to continue investment in our product development pipeline.

DIVIDENDS

The Directors have not declared a dividend for the 2021 financial year (2020: nil).

SIGNIFICANT CHANGES IN THE STATE OF AFFAIRS

On 11th March 2020 the World Health Organisation declared the global outbreak of a novel coronavirus, known as COVID-19, as a global pandemic. Acrux has largely maintained its operational activity through 2020 and 2021, implementing a range of precautionary measures in accordance with the Victorian Government recommendations. While the broader economy has been impacted significantly, the Group has experienced a limited financial impact from the COVID-19 operating environment although there have been instances where operations at contract research organisations (CROs) and contract manufacturing organisations ('CMOs') have been impacted resulting in some delays to product development project timelines. There have been no significant implications to operational revenue or expenditure in the current period. There may be longer term implications beyond the balance date, the extent of which the Group cannot currently estimate.

In the opinion of the Directors, there have been no significant changes in the state of affairs of the Group during the financial year not otherwise disclosed in this report or the financial statements.

AFTER BALANCE DATE EVENTS

On 28 July 2021 the Company received FDA approval of generic EMLA® Cream, Lidocaine and Prilocaine 2.5%. This is the Company's third ANDA to be approved and total addressable market size reported in IQVIA data for the 12 months to June 2021 is US \$23 million.

No other matter or circumstance has arisen since 30 June 2021 that has significantly affected the Group's operations, results or state of affairs, or may do so in future years.

FUTURE DEVELOPMENTS

Acrux will continue to pursue and execute its strategy of developing a diversified, financially attractive portfolio of generic topical prescription products. Acrux's future financial results will be materially influenced by its ability to commercialise the products currently within its development pipeline, as well as to evaluate and select attractive products to add to the pipeline.

COURT PROCEEDINGS

Since 2014, a number of product liability lawsuits have been 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. The conduct of the lawsuits is not expected to have a material impact on Acrux's operating expenditure.

In June Almirall LLC initiated patent litigation against Acrux in the U.S. District Court for the District of New Jersey, regarding the Company's Paragraph IV Abbreviated New Drug Application (ANDA) for Dapsone Gel 7.5% (a generic version of Aczone® Gel, 7.5%), asserting U.S. Patent No. 9,517,219 ("the '219 patent"), one of two patents listed in the FDA Orange Book for Aczone® Gel, 7.5%. Acrux's Paragraph IV certification asserts that the '219 patent is invalid, unenforceable and/or would not be infringed by Acrux's ANDA product. This action is expected and formally initiates the patent litigation process under the Hatch-Waxman Act.

ENVIRONMENTAL REGULATIONS

Acrux's operations are subject to environmental regulations under the laws of the Commonwealth and of the State of Victoria, including:

- *Laboratory Waste* – To ensure legislative compliance with the Environment Protection Act 1970 an external waste management consultant with ISO 14001:2015 Certification for Environmental Management. An EPA Transport Certificate is issued at each waste collection 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 2006. This agreement ensures 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.

The Directors consider Acrux has complied with all applicable environmental regulations throughout the year ended 30 June 2021 and no related issues have arisen since the end of the financial year to the date of this report.

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 2020 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.



Ross Dobinson
(Director since
March 1998)

Responsibilities

Non-executive Chairman and member of the Audit and Risk Committee.

Qualifications

BBus (Acc)

Experience

Ross has been a Director since 1998, was appointed Chairman in January 2006 and then Executive Chairman from July 2012 to October 2014. He is a founder and former CEO of Acrux.

Ross has a background in investment banking and stockbroking. He was formerly a Director of Reliance Worldwide Corporation (ASX: RWC). He was also previously a founding Director of Starpharma Holdings Limited (ASX: SPL), Executive Chairman of Hexima Limited (ASX: HXL), Chairman of TPI Enterprises Limited (now Palla Pharma Ltd. ASX: PAL), Director of Roc Oil Company Limited (ASX: ROC) and a Director of Racing Victoria Limited.



Tim 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.

Qualifications

BSc (Hons), LLB (Hons), PhD

Experience

Tim joined the Board in October 2013. He has 20 years of life sciences business development, alliance management and sales and marketing experience in Europe, Asia and Australia. Tim is the CEO and Managing Director at AdAlta Ltd (ASX: 1AD). AdAlta is a clinical stage biotech company developing an innovative range of new antibody-like drugs. Prior to this, he was Executive Leader of Tijan Ventures, an advisory business focussed on growing life sciences companies through strategic advisory and interim leadership services and acquiring cell and gene therapy assets. He was previously CEO and Managing Director of Cell Therapies Pty Ltd and President of Asia Pacific for Hospira, Inc., having held a variety of senior management roles with Mayne Pharma Ltd prior to its acquisition by Hospira. These roles encompassed the development and commercialisation of generic pharmaceuticals, devices, biologics and cellular therapies. Tim began his business career as an engagement manager with McKinsey & Company.

Tim is a Non-executive Director of BioMelbourne Network Inc and has been chairman of the European Generic Medicines Association Biosimilars and Biotechnology Committee, a Non-executive Director of the Alliance for Regenerative Medicine and a Non-executive Director of the Generic Medicines Industry Association. He has also been a Director of Respiro Ltd (ASX: RSH).



Geoff Brooke
(Director since
June 2016)

Responsibilities

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

Qualifications

MBBS, MBA

Experience

Geoff joined the Board in June 2016. He founded GBS Venture Partners Pty Ltd in 1996 and has more than 20 years of venture capital experience. In January 2014, he reduced his involvement in GBS and is now special adviser to the firm and its funds. Geoff was formally President of Medvest Inc., a US-based early-stage venture capital group he founded with Johnson & Johnson. Geoff's experience includes company formation and acquisitions, as well as public listings on the NYSE, NASDAQ and ASX exchanges. He commenced in March 2017 as Chairman of Actinogen Medical Limited (ASX: ACW) and has been a founder, executive and director of private and public companies. In August 2020 Geoff commenced as Chairman of Cynata Therapeutics Limited (ASX: CYP). From 2009 until 2015, he was an independent director of the Victoria WorkCover Authority.

Geoff is licensed in clinical medicine by the Medical Board of Victoria, Australia and his post-graduate work was in anaesthetics and intensive care. He earned his Bachelor of Medicine/Surgery from the University of Melbourne, Australia and a Master of Business Administration from IMEDE (now IMD) in Lausanne, Switzerland.



Don Brumley
(Director since June 2021)

Responsibilities

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

Qualifications

FCA, AICD

Experience

Don has 30 years' experience as a senior partner of Ernst & Young, Oceania. He has extensive experience in IPOs, transactions and audit and has advised and worked with Boards of organisations ranging from some of the largest in Australia to fast growing entrepreneurial and medium sized organisations. Don was the Oceania IPO Leader at Ernst & Young and worked with clients listing on the Australian, US, UK and key Asian stock exchanges. He held positions as Biotech Markets Leader, National Leader of Strategic Growth Markets and on the Board of Partners of Ernst & Young.

He is a Fellow of Chartered Accountants Australia & New Zealand and is a member of the Australian Institute of Company Directors. He was previously a non-executive director of Murray River Organics Group Ltd (ASX: MRG) and Chairman and non-executive director of Bio-Gene Technology Ltd (ASX: BGT).



Michael Kotsanis
(Director since
November 2014)

Responsibilities

Managing Director and Chief Executive Officer

Qualifications

BSc, MBus

Experience

Michael is a seasoned executive with over 30 years of experience in the pharmaceutical industry and has significant senior leadership experience across the global pharmaceutical markets. He was formerly the Chief Commercial Officer and a Board Member of Synthon Holding BV, a Dutch based pharmaceutical company with global revenue over EUR250 million. Prior to Synthon, he served as President, Europe, Middle East and Africa, for Hospira and where he was responsible for delivering over US\$500 million in annual revenue. Hospira was the global leader in generic injectable pharmaceuticals prior to its acquisition by Pfizer. Michael joined Hospira following its acquisition of Mayne Pharma in 2007, where he had served as President, Asia Pacific. He joined Mayne following their acquisition of FH Faulding in 2001, where he held responsibility for commercial activities of the pharmaceutical business in Australia and New Zealand. Prior to Faulding, Michael held a variety of sales and marketing positions with a German multinational pharmaceutical company over an 11 year period.

Michael was formerly a Board Member of the European Generics Association and a Director of the Generic Medicines Industry Association of Australia. Michael earned a Bachelor of Science from Monash University, Melbourne, a Graduate Diploma in Business from Edith Cowan University, Perth and a Master of Business from the University of Technology, Sydney. Michael is also a Non-executive Director of IDT Australia Limited (ASX: IDT).

Norman Gray

(Director since
November 2019,
resigned June 2021)

Responsibilities

Non-executive Director and member of the Human Capital and Nomination Committee

Qualifications

FAICD, Fellow of the Australia College of Defence and Strategic Studies

Experience

Norman consults to businesses to assist execution of business strategies. He has been Chief Executive Officer of Box Hill Institute and Centre for Adult Education and Chief Operating Officer and Executive Director of Network Operations of Public Transport Victoria, a State Statutory Authority. Norman was of Chief Executive Officer and Managing Director of Thales Australia, a large system engineering company and provider of solutions for the commercial and defence sectors.

Norman has had a long career in the Department of Defence, serving in The Royal Australian Air Force and rising to the rank of Air Vice Marshall. His service was recognised in June 1993 when he was made a Member of the Order of Australia. Norman is a Fellow of the Australian Institute of Company Directors, a former Member of the Business Council of Australia and has held a number of Board positions including the Royal Flying Doctor Service.



Joanna Johnson
(Company Secretary since June 2021)

Responsibilities

Chief Financial Officer and Company Secretary

Qualifications

CA, BEc, Grad Dip Management

Experience

Joanna commenced at Acrux as Chief Financial Officer and Company Secretary in June 2021 and is a member of the Institute of Chartered Accountants Australia and New Zealand. She is an experienced Company Secretary and has extensive experience in the pharmaceuticals industry, having held senior financial leadership positions at IDT Australia Ltd, Generic Health Pty Ltd, Hospira Inc, Mayne Pharma Ltd and FH Faulding Ltd.

She has led both small and large finance teams, both nationally and internationally, through all aspects of reporting, business planning, budgeting, forecasting and analysis as well as equity capital raising, taxation, corporate compliance and investor relations.

DIRECTORS MEETINGS

The number of Directors meetings (including meetings of committees of Directors) and the number of meetings attended by each of the Directors of Acrux Limited during the financial year were:

	Committee Meetings					
	Board		Audit and Risk		Human Capital and Nomination	
	Held ¹	Attended	Held ¹	Attended	Held ¹	Attended
Ross Dobinson	6	6	2	2	-	-
Geoffrey Brooke	6	5	2	2	2	2
Don Brumley ²	1	1	-	-	-	-
Norman Gray ³	5	5	-	-	-	-
Timothy Oldham	6	6	2	2	2	2
Michael Kotsanis	6	6	-	-	-	-

- The number of meetings held during the period where the Director was a member of the Board or Committee. Directors who are not members of Committees are invited to and also attend Committee meetings.
- Mr Brumley was appointed to the Audit and Risk Committee and the Human Capital and Nomination Committee on 20 June 2021.
- Mr Gray was a member of the Human Capital and Nomination Committee for the period 20 December 2020 until his resignation on 4 June 2021 but no Committee meetings were held during this period.

INFORMATION ON SENIOR MANAGEMENT



Felicia Colagrande
(Product Development and
Technical Affairs Director
since February 2015)

Qualifications

BSc (Hons), MBA

Experience

Felicia has a broad background in pharmaceutical operations, topical drug development, analytical development and production. Felicia leads and facilitates all technical aspects of pharmaceutical product development including R&D, formulation development, analytical development, CMC development and Technology Transfer, with a focus on generic topical product development and exploiting the company's drug delivery technology.

Felicia has 27 years' experience in the pharmaceutical/biotech industry, joining Acrux in 2001. Felicia 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 at Monash University. Felicia has a Bachelor of Science degree (with Honours) from La Trobe University and an MBA from the Australian Institute of Business.



Mark Hyman
(Project and Technical
Development Director
since July 2020)

Qualifications

BSc

Experience

Mark has a diverse background in the pharmaceutical and medical device industry. Following a pharmacokinetic research role with Melbourne University, Mark has more than 30 years' industry experience, previously holding leadership positions in Quality, Manufacturing, Logistics & Operations, Product Development, Project Management and Commercial Development.

Mark's experience spans prescription and consumer health, proprietary and generic products across topical, oral and injectable dose forms and drug infusion systems. With specialty expertise in project and technical management, Mark has a deep background in technology transfer and organisation development to establish comprehensive product development, portfolio and project management processes. Mark has a Bachelor of Science degree in Chemistry and Pharmacology from Monash University.



Charles O'Sullivan
(Portfolio Director
since July 2015)

Qualifications

BPharm

Experience

Charles is an experienced healthcare executive with senior and international roles in scientific affairs, medical affairs, health economics and government affairs. Prior to Acrux, Charles was Asia Pacific Director of Medical and Government Affairs for Hospira (now Pfizer). Other pharmaceutical industry roles were at Mayne Pharma (Pricing and Reimbursement Manager), GSK and Zeneca Pharmaceuticals. Additional external roles include former Director of the Generic Medicines Industry Association of Australia (now the Generic and Biosimilar Association) and membership of a number of industry and government working parties.

As a qualified pharmacist, Charles has senior experience in the public hospital sector including pharmacy management and key committee membership including Bio-Ethics Committees and Drug and Therapeutics Committees. Charles has a Bachelor of Pharmacy degree from Monash University and a Graduate Diploma of Epidemiology and Biostatistics from Melbourne University.

DIRECTORS' AND SENIOR MANAGERMENTS' INTERESTS IN EQUITY INSTRUMENTS

Directors' and senior managements' relevant interests in equity instruments of the Company as at the date of this report are detailed below:

	Number of shares	Number of rights
Directors		
Ross Dobinson	3,308,284	571,670
Geoff Brooke	474,221	663,332
Don Brumley ¹	500,000	-
Tim Oldham ¹	223,539	743,332
Michael Kotsanis	1,511,083	3,000,000
Senior management		
Felicia Colagrande	126,500	420,000
Mark Hyman	27,882	178,595
Joanna Johnson	-	-
Charles O'Sullivan	405,000	140,000
Total	6,576,509	5,716,929

1. Including related party interests.

RIGHTS

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

Date rights granted	Number of unissued ordinary shares under rights	Value at grant date	Exercise price	Expiry date of the right
14 November 2017	3,000,000	\$0.17	\$0.00	November 2024
25 January 2018	97,000	\$0.17	\$0.00	January 2025
23 November 2018	320,000	\$0.19	\$0.00	January 2023
4 February 2019	381,000	\$0.18	\$0.00	February 2026
9 December 2019	1,658,334	\$0.185	\$0.00	November 2026
3 February 2020	300,190	\$0.185	\$0.00	February 2027
4 February 2021	596,824	\$0.17	\$0.00	February 2028
	6,353,348			

INDEMNIFICATION AND INSURANCE OF DIRECTORS, OFFICERS AND AUDITORS

During the financial year, the consolidated entity paid a premium in respect of an insurance contract to indemnify officers against liabilities that may arise from their positions as officers of the Group. Officers who are indemnified include the Company Secretary, all Directors and all executive officers participating in the management of the Group to the extent permitted by the *Corporations Act 2001*. The contract of insurance prohibits public disclosure of the nature of the liability and the amount of the premium.

REMUNERATION REPORT (AUDITED)

The Directors of the Group are pleased to present the following Remuneration Report which forms part of the Report of Directors and has been prepared in accordance with s300A of the *Corporations Act 2001*.

The Remuneration Report has been audited as required by s308 (3C) of the *Corporations Act 2001* and sets out remuneration information for the Group's key management personnel who have authority and responsibility for planning, directing and controlling the Group's activities, directly or indirectly, including any Director (whether executive or otherwise) and the broader remuneration policies and philosophy adopted by the Board.

REMUNERATION POLICY

The Human Capital and Nomination Committee is responsible for recommending to the Board the framework of the Group's remuneration, including participation in any employee security or other incentive plan. The Charter of the Human Capital and Nomination Committee can be viewed on the Company website; www.acrux.com.au.

The main principles of the Group's remuneration policy are to:

- remunerate at levels intended to attract, retain, motivate and reward good performance;
- structure remuneration to reward employees for both superior performance and increasing long term shareholder value; and
- formally link rewards to the achievement of business objectives as determined and assessed by the Board.

There were no significant changes to remuneration policies during the year.

REMUNERATION STRUCTURE

Remuneration of employees is structured in two parts:

- Fixed remuneration, comprising salary, superannuation and other benefits which may be provided in lieu of salary; and
- Variable remuneration, comprising a short term incentive in the form of a cash bonus and a long term incentive in the form of an equity instrument issued under the Omnibus Equity Plan.

The Group aims to establish fixed remuneration in accordance with market rates for comparable jobs in the industry sector. Short and long term incentive plans are in place to reward superior achievement, subject to achievement of objectives set and assessed by the Board.

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. On an annual basis the Board, in consultation with senior management, establishes the business objectives. Each objective is expected to either create value for shareholders or represent material progress towards enhancing long term shareholder value and includes clearly defined outcomes for product development and commercialisation. Achievement or non-achievement of business objectives are objectively measured at the end of the financial year.

Under the short term incentive plan, senior management (other than the Chief Executive Officer) may receive annual cash incentives of up to 24% of their fixed remuneration. The Chief Executive Officer may receive annual cash incentives of up to 25% of his fixed remuneration, and this can be varied by Board discretion.

The key principles of the short term incentive plan are:

- payments are at the discretion of the Board;
- the amount of at-risk remuneration payable is dependent upon achievement of the year's business objectives; and
- the Board assesses the level of achievement of the business objectives at the end of the financial year.

LONG TERM INCENTIVE PLAN

The purpose of the long-term incentive plan is to align the interests of senior management and other employees more closely with those of shareholders in terms of achieving sustainable, long term superior performance. Long term incentive plans have been designed to comply with both the requirements of ASX Listing Rules and the *Pooled Development Funds Act 1992*.

The Omnibus Equity Plan ('OEP') is applicable for all employees including the Chief Executive Officer and was approved by shareholders at the 2020 Annual General Meeting. Grants of securities under the OEP are subject to the following terms:

A. Chief Executive Officer ('CEO')

- At the 2017 AGM, 4 million performance rights were approved for issue for nil consideration, vesting in 4 equal tranches, with each successive tranche vesting at the end of each of the 4 years after grant. Each grant of performance rights vests after one year, provided the total shareholder return (TSR) over that period is equal to or greater than 12% and the CEO remains employed by the Group;
- Each performance right carries the right to one ordinary share in the Acrux Ltd;
- Tranches that do not vest in any year of the cycle may be "rolled over" into the next year and are subject to an additional 12% TSR hurdle. There will be no "roll-over" after the fourth year; and
- The rights expire 7 years after granting.

B. Senior management

- The Board has chosen to issue performance rights to senior management for nil consideration, granted based on a four-year cycle;
- Each grant of performance rights will vest after one year, provided the total shareholder return (TSR) over that period is equal to or greater than 12% and the employee remains employed by the Group;
- Each performance right carries the right to one ordinary share in the Acrux Ltd;
- Tranches that do not vest in any year of the cycle may be "rolled over" into the next year of the cycle and will be subject to an additional 12% TSR hurdle. There will be no "roll-over" after the fourth year; and
- The rights expire 7 years after grant.

C. Directors

- At the 2018 AGM, rights equivalent to 10% of cash fees payable to Directors were approved by shareholders for issue, in lieu of an increase in cash fees. The rights vest over four years commencing 1 January 2018
- At the 2019 AGM, rights equivalent to 50% of cash fees payable to Directors were approved for issue. Shareholders approved the issue of rights to Directors for nil consideration on the basis of a three-year cycle;
- Each right carries the right to one ordinary share in the Acrux Ltd;
- Each grant of rights will vest quarterly, provided that the Director has been continuously engaged from the grant date to the vesting date; and
- The rights expire 7 years after grant.

D. Employees

- The Board may issue \$1000 worth of tax exempt ordinary shares to employees, other than Senior Management, each year at nil cost;
- Each grant of tax exempt ordinary shares will be held in escrow for a period of 3 years; and
- There are no vesting conditions and if an employee ceases employment with the Group the shares vest immediately.

Further details of Share based payments is provided in Note 18 to the accounts.

REMUNERATION REPORT (AUDITED) CONTINUED

REMUNERATION OF DIRECTORS

The Human Capital and Nomination Committee determines the level of remuneration necessary to attract and retain Directors who have the skills and experience required by the Group at its stage of development. The Committee makes recommendations to the Board, which subsequently puts those recommendations for approval by the shareholders at the following Annual General Meeting.

For the 2021 financial year, the total value of fees paid to Non-executive Directors' was set at \$70,000 per annum plus superannuation and plus rights that vest over a four year period that were approved by shareholders at the 2018 AGM in lieu of a fee increase of 10%. At the 2019 AGM shareholders resolved for this remuneration to be paid in both cash and equity within the terms of the OEP. Equity has been issued to Directors in the form of Rights which subject to service criteria, vest quarterly over a 3 year period with the final tranche due to vest on 16 November 2022. Rights which are unvested at the time of retirement of a Director are cancelled and rights are issued to newly appointed Directors after shareholder approval has been received at the AGM following their appointment.

The value of these Rights over the 3 year vesting period has been estimated using Black-Scholes methodology and this value is taken to account over the vesting period. Whilst the Rights vest equally over time the accounting expense has been calculated to decline progressively over the vesting period. In the prior comparative period the value of Directors rights expensed totalled \$232,546. The remaining value to be taken to account for the reporting period 30 June 2022 will be lower than the current and prior periods.

In addition, there has been a change of accounting policy applied to how the value of Rights has been reported in the remuneration table. For the prior reporting period the values reported reflect the full value of the rights issued and to be brought to account over the 3 year period, whereas in the current reporting period the value of expense for the financial year has been reflected.

Director services of the Non-executive Chairman Ross Dobinson are provided by Espasia Pty Ltd. This services contract can be terminated by either party after giving three months' notice in writing. For the 2021 financial year this services contract for the Non-executive Chairman provided for the total value of Director's fees to be \$118,000 per annum, paid in both cash and equity.

The maximum aggregate of Non-executive Directors' annual fees is \$450,000, approved at the 2004 Annual General Meeting. Non-executive Directors are entitled to be reimbursed for reasonable expenses incurred on Group business. No retirement allowances are paid and Directors do not receive additional remuneration for membership of Board Committees.

The remuneration of each person who held the position of Non-executive Director at any time during the financial year is outlined in the following table:

	Director Fee Payments \$	Short Term Incentive \$	Post Employment Super- annuation \$	Share based Payments (Rights) ⁴ \$	Total Remuneration \$
2021					
Ross Dobinson (Chair)	59,000	-	-	74,358	133,358
Geoff Brooke	35,000	-	6,650	43,314	84,964
Don Brumley ¹	2,558	-	486	2,917	5,961
Norman Gray ²	32,622	-	6,198	59,500	98,320
Timothy Oldham	35,000	-	6,650	43,314	84,964
	164,180	-	19,984	223,403	407,567

2020	Director Fee Payments \$	Short Term Incentive \$	Post Employment Super-annuation \$	Share based Payments (Rights) ⁴ \$	Total Remuneration \$
Ross Dobinson (Chair)	83,583	-	-	181,917	265,500
Geoff Brooke	49,583	-	6,650	107,916	164,149
Norman Gray ²	20,417	-	3,879	-	24,296
Simon Green ³	29,167	-	2,771	-	31,938
Timothy Oldham	49,583	-	6,650	107,916	164,149
	232,333	-	19,950	397,749	650,032

1. Appointed Non-executive Director 4 June 2021.

2. Resigned as Non-executive Director 4 June 2021.

3. Resigned as Non-executive Director 28 November 2019.

4. For the period ended 30 June 2021, the value of rights has been attributed to directors at the time the rights have vested and consistent with the manner in which they have been recorded in the financial statements. In previous periods the full value of rights was reported at the time the rights were issued whilst they vest over a period up to 3 years, in accordance with directors' service provisions.

Mr Michael Kotsanis was appointed Chief Executive Officer and Managing Director in November 2014. As an Executive Director his remuneration details are disclosed in the senior management remuneration table.

REMUNERATION AND TERMINATION ENTITLEMENTS OF SENIOR MANAGEMENT

Senior management have no fixed term of employment and employment contracts may be terminated by either party based on periods of written notice ranging between one and six months. Employment contracts contain no entitlement to termination benefits beyond statutory entitlements.

Names and positions held by senior management of the Group in office at any time during the financial year are:

Michael Kotsanis	Chief Executive Officer and Managing Director	
Deborah Ambrosini	Chief Financial Officer & Company Secretary	Until 25 June 2021
Felicia Colagrande	Product Development and Technical Affairs Director	
Mark Hyman	Project and Technical Development Director	From 1 July 2020
Joanna Johnson	Chief Financial Officer & Company Secretary	Commenced 16 June 2021
Charles O'Sullivan	Portfolio Director	

Unless otherwise stated, senior management have been in office since the start of the financial year until the date of this report.

DIRECTORS' REPORT CONTINUED

REMUNERATION REPORT (AUDITED) CONTINUED

REMUNERATION OF SENIOR MANAGEMENT

Details of the remuneration of the Group's Senior Management are set out in the following table:

	Primary		Post Employment	Long Term Benefit	Other	Share Based Payments	Total Remuneration	Equity as % Total	Bonus as % Total
	Salary ⁵	Short Term Incentive ⁶	Super-annuation	Long Service Leave		Performance Rights			
	\$	\$	\$	\$	\$	\$	\$	%	%
2021									
Michael Kotsanis ¹	468,313	92,408	21,694	8,153	-	54,852	645,420	8%	14%
Deborah Ambrosini ²	270,755	-	27,088	(4,532)	62,044	5,306	360,661	1%	-
Felicia Colagrande	237,214	31,468	21,151	5,006	-	20,714	315,552	7%	10%
Mark Hyman ³	229,173	30,404	20,709	6,296	-	7,726	294,307	3%	10%
Joanna Johnson ⁴	9,659	-	966	-	-	-	10,625	-	-
Charles O'Sullivan	229,173	30,404	20,619	4,018	-	20,714	304,928	7%	10%
	1,444,287	184,684	112,227	18,941	62,044	109,312	1,931,493	6%	10%
2020									
Michael Kotsanis	452,499	28,312	21,003	8,201	-	-	510,015	0%	6%
Deborah Ambrosini	254,363	18,970	21,003	4,213	-	21,237	319,786	7%	6%
Felicia Colagrande	215,061	9,594	20,858	3,728	-	21,237	270,478	8%	4%
Charles O'Sullivan	207,384	9,259	20,313	4,974	-	21,237	263,167	8%	4%
	1,129,307	66,135	83,177	21,116	-	63,711	1,363,446	5%	5%

1. As outlined in the Long Term Incentive Plan section above, as CEO and Managing Director, Mr Kotsanis was issued with 4,000,000 performance rights in November 2017. The full value of those performance rights was valued using a Monte Carlo valuation model and the value was disclosed in full in the remuneration table for the financial year ended 30 June 2018. For the current reporting period the annual value of expense was \$54,852.

2. Chief Financial Officer and Company Secretary until 25 June 2021. Other remuneration includes salary in lieu of notice period and final payment of annual leave.

3. Promoted to Project and Technical Development Director 1 July 2020.

4. Chief Financial Officer and Company Secretary commenced 16 June 2021.

5. Salary has been calculated as ordinary salary payments, including annual leave and sick leave, and consistent with individual employment contracts plus their statutory entitlement of 20 days of annual leave accrued. In the prior period Salary was calculated as ordinary salary payments plus the movement in the Provision for Annual Leave applicable to individual employees.

6. A short term incentive may be paid based on assessment of achievement of corporate objectives agreed at the beginning of the financial year. For the financial year ended 30 June 2021, achievement of these objectives has been assessed by the Board at 85% and these accrued balances have been paid in August 2021.

EQUITY INSTRUMENTS HELD BY KEY MANAGEMENT PERSONNEL

Ordinary Shares

The number of ordinary shares held by Directors and key management personnel ("KMP") at financial year end is set out in the following table:

	Balance 1 July 2020	Acquired through placement/Share Purchase Plan	Rights exercised	Other	Balance 30 June 2021
Directors					
Ross Dobinson	1,987,481	831,083	489,720	-	3,308,284
Geoff Brooke ⁵	155,750	318,471	-	-	474,221
Don Brumley ^{1,5}	n/a	-	-	500,000	500,000
Norman Gray ²	-	127,389	350,001	-	n/a
Tim Oldham ⁵	96,150	127,389	-	-	223,539
Senior Management					
Michael Kotsanis	1,000,000	511,083	-	-	1,511,083
Deborah Ambrosini ³	-	-	140,000	-	n/a
Felicia Colagrande	126,500	-	-	-	126,500
Mark Hyman ⁴	n/a	-	-	27,882	27,882
Joanna Johnson	-	-	-	-	-
Charles O'Sullivan	-	-	405,000	-	405,000
	3,365,881	1,915,415	1,384,721	527,882	6,576,509

1. Appointed as Non-executive Director 4 June 2021 and held 500,000 ordinary shares at the time of commencement.

2. Resigned as Non-executive Director 4 June 2021, transactions and holdings of ordinary shares are reported until the date of his resignation.

3. Chief Financial Officer and Company Secretary to 23 June 2021, transactions and holdings are reported until her final date of employment.

4. Promoted to Project and Technical Development Director 1 July 2020 and held 27,882 ordinary shares at the date he became a KMP.

5. Includes relevant interests under the control of the KMP, these ordinary shares are held both directly and through controlled entities.

RIGHTS

(a) Compensation Performance Rights: Granted and vested during the year

4,000,000 performance rights were issued by Acrux Ltd to the Chief Executive Officer, Mr Michael Kotsanis, on 14 November 2017 under the OEP, having been approved by shareholders at the 2017 Annual General Meeting. Performance rights vest upon the Group achieving performance metrics approved by the Board and his continued employment. Performance rights will vest after one year, provided the total shareholder return (TSR) over that period is equal to or greater than 12%.

Under the terms of the OEP, 751,419 performance rights were issued by Acrux Ltd to eligible employees, including but not limited to KMP, on 4 February 2021. Performance rights issued to eligible employees vest upon the Group achieving performance metrics approved by the Board as well as their continued employment.

(b) Rights issued to Directors as a component of compensation

699,999 rights were granted to Mr Norman Gray within the terms of the OEP and were issued after shareholder approval was received at the 2020 Annual General Meeting. Mr Gray, who was appointed to the Board in November 2019, received 50% of his cash remuneration as equity in the form of rights granted for a period of 3 years from the date of his appointment. The rights vested on a quarterly basis in arrears and unvested rights were cancelled following his resignation as a Director.

(c) Shares issued on exercise of rights

545,000 ordinary shares were issued to eligible employees after performance rights were exercised during or since the end of the financial year.

839,721 ordinary shares were issued to Directors after rights were exercised.

DIRECTORS' REPORT CONTINUED

REMUNERATION REPORT (AUDITED) CONTINUED

The number of rights held by KMP is set out in the following table:

	Balance at 1 July 2020	Granted as remuneration	Rights exercised	Lapsed/ Cancelled	Balance 30 June 2021	Value of rights granted \$
Directors						
Ross Dobinson	1,061,390	-	489,720	-	571,670	-
Geoff Brooke	663,332	-	-	-	663,332	-
Don Brumley ¹	-	-	-	-	-	-
Norman Gray ²	-	699,999	350,001	349,998	-	119,000
Tim Oldham	743,332	-	-	-	743,332	-
Executives						
Michael Kotsanis	3,000,000	-	-	-	3,000,000	-
Deborah Ambrosini ³	140,000	140,000	140,000	140,000	-	19,740
Felicia Colagrande	280,000	140,000	-	-	420,000	19,740
Mark Hyman	38,595	140,000	-	-	178,595	19,740
Joanna Johnson	-	-	-	-	-	-
Charles O'Sullivan	405,000	140,000	405,000	-	140,000	19,740
	6,331,649	1,259,999	1,384,721	489,998	5,716,929	197,960

1. Appointed Non-executive Director 4 June 2021, initial grant of rights to be put to the 2021 AGM for approval.

2. Rights granted following approval at 2020 AGM. Resigned as Non-executive Director 4 June 2021, unvested rights cancelled.

3. Chief Financial Officer and Company Secretary until 23 June 2021, unvested rights cancelled.

VOTING AND COMMENTS MADE AT THE COMPANY'S 2020 ANNUAL GENERAL MEETING (AGM)

At the Company's 2020 Annual General Meeting, a resolution to adopt the prior year's Remuneration Report was put to the vote and fewer than 25% of the votes cast on the resolution to adopt the 2020 Remuneration Report were cast against the resolution. No comments were made at the AGM by shareholders in relation to the Remuneration Report.

This is the end of the audited remuneration report.

NON-AUDIT SERVICES

Non-audit services are recommended by resolution of the Audit and Risk Committee and approval is granted by the Board of Directors. Non-audit services provided by the auditor, namely Pitcher Partners (Melbourne) and their network firms are detailed below. Directors are satisfied that the provision of the non-audit services during the year by the auditors is compatible with the general standard of independence for auditors imposed by the *Corporations Act 2001* for the following reasons:

- all non-audit services were subject to the Group's corporate governance procedures and have been reviewed and approved by the Audit and Risk Committee to ensure they do not impact on the integrity and objectivity of the auditor; and
- the non-audit services provided do not undermine the general principles relating to auditor independence as set out in *APES 110 Code of Ethics for Professional Accountants (including independence standards)* issued by the Accounting Professional & Ethical Standards Board, including reviewing or auditing the auditors' own work, acting in a management or decision making capacity for the Group, acting as an advocate for the Group, or jointly sharing economic risks and rewards.

	2021 \$	2020 \$
Amount paid or payable to Pitcher Partners (Melbourne) for non-audit services	48,730	18,645
Amount paid or payable to network firms of Pitcher Partners for non-audit services	-	-
	48,730	18,645

AUDITOR INDEPENDENCE DECLARATION

A copy of the Auditor's Independence Declaration as required under section 307C of the *Corporation Act 2001* in relation to the audit for the financial year is included after this report.

ROUNDING OF AMOUNTS

The Company is a company of the kind referred to in *ASIC Corporations (Rounding in Financial/Directors' Reports) Instrument 2016/191*, dated 24 March 2016, and in accordance with that Corporations Instrument, amounts in the Directors' Report and the financial statements have been rounded to the nearest one thousand dollars, unless otherwise indicated.


DIRECTORS RESOLUTION

This report is made in accordance with a resolution of the Directors made pursuant to s298(2) of the *Corporations Act 2001*.



Ross Dobinson
Non-executive Chairman

Melbourne
25 August 2021



Don Brumley
Non-executive Director

Melbourne
25 August 2021

AUDITOR'S INDEPENDENCE DECLARATION TO THE DIRECTORS OF ACRUX LIMITED



ACRUX LIMITED AUDITOR'S INDEPENDENCE DECLARATION TO THE DIRECTORS OF ACRUX LIMITED

In relation to the independent audit for the year ended 30 June 2021, 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 APES 110 *Code of Ethics for Professional Accountants (including Independence Standards)*.

This declaration is in respect of AcruX Limited and the entities it controlled during the year.

A handwritten signature in black ink, appearing to be "NR Bull".

N R BULL
Partner
25 August 2021

A handwritten signature in black ink, appearing to be "Pitcher Partners".

PITCHER PARTNERS
Melbourne

CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

For the Year Ended 30 June 2021

	Note	Consolidated	
		2021 \$'000	2020 \$'000
Revenue from licensing agreements	4	1,337	1,253
Other revenue	4	3,819	2,692
		5,156	3,945
Employee benefits expense	5	(5,418)	(5,075)
Directors' fees		(184)	(252)
Securities based payment expense	18(c)	(507)	(385)
Depreciation and amortisation expenses	5	(665)	(708)
Occupancy expenses		(247)	(226)
External research and development expenses		(8,928)	(5,012)
Professional fees		(644)	(444)
Other expenses		(995)	(1,228)
Total expenses		(17,588)	(13,330)
Loss before income tax		(12,432)	(9,385)
Income tax expense	6	(197)	(86)
Net loss for the year		(12,629)	(9,471)
Total comprehensive loss for the year		(12,629)	(9,471)
Total comprehensive loss attributable to:			
Members of the parent entity	19(b)	(12,629)	(9,471)
Non-controlling interest	21	-	-
		(12,629)	(9,471)
Loss per share for loss attributable to the equity holders of the parent entity:			
Basic loss per share	8	(5.75) cents	(5.65) cents
Diluted loss per share	8	(5.75) cents	(5.65) cents

The statement should be read in conjunction with the notes to these financial statements.

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

As at 30 June 2021

	Note	Consolidated	
		30 June 2021 \$'000	30 June 2020 \$'000
Current Assets			
Cash and cash equivalents	9	15,270	9,206
Receivables	10	3,159	2,559
Other current assets	11	165	577
Total Current Assets		18,594	12,342
Non-Current Assets			
Plant and equipment	12	538	761
Intangible assets	13	482	589
Deferred tax asset	6	1,607	1,805
Lease assets	14	2,106	2,339
Total Non-Current Assets		4,733	5,494
Total Assets		23,327	17,836
Current Liabilities			
Payables	15	1,780	1,878
Provisions	16	801	620
Lease liabilities	14	185	167
Total Current Liabilities		2,766	2,665
Non-Current Liabilities			
Provisions	16	41	88
Lease liabilities	14	2,049	2,234
Total Non-Current Liabilities		2,090	2,322
Total Liabilities		4,856	4,987
Net Assets		18,471	12,849
Equity			
Contributed equity	17	114,213	96,137
Reserves	19(a)	8,147	7,972
Retained earnings	19(b)	(103,889)	(91,260)
Equity attributable to equity holders of the Parent		18,471	12,849
Non-controlling interests	21	-	-
Total Equity		18,471	12,849

The statement should be read in conjunction with the notes to these financial statements.

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

For the Year Ended 30 June 2021

	Note	Contributed equity \$'000	Reserves \$'000	Retained earnings \$'000	Total equity \$'000
Balance as at 1 July 2019		95,879	8,029	(81,972)	21,936
Loss for the period		-	-	(9,471)	(9,471)
Total comprehensive loss for the year		-	-	(9,471)	(9,471)
Transactions with owners in their capacity as owners:					
Employee share scheme	19(a)	30	126	-	156
Performance rights exercised	17(b)	228	-	-	228
Employee share options lapsed during the year	19(a)	-	(183)	183	-
Balance as at 30 June 2020		96,137	7,972	(91,260)	12,849

	Note	Contributed equity \$'000	Reserves \$'000	Retained earnings \$'000	Total equity \$'000
Balance as at 1 July 2020		96,137	7,972	(91,260)	12,849
Loss for the period		-	-	(12,629)	(12,629)
Total comprehensive loss for the year		-	-	(12,629)	(12,629)
Transactions with owners in their capacity as owners					
Employee share scheme	19(a)	28	175	-	203
Performance rights exercised	17(b)	301	-	-	301
Capital Raising	17(b)	17,747	-	-	17,747
Balance as at 30 June 2021		114,213	8,147	(103,889)	18,471

The statement should be read in conjunction with the notes to these financial statements.

CONSOLIDATED STATEMENT OF CASHFLOWS

For the Year Ended 30 June 2021

	Note	Consolidated	
		30 June 2021 \$'000	30 June 2020 \$'000
Cash flows from operating activities			
Receipts from product agreements		1,228	1,093
Payments to suppliers and employees		(15,785)	(11,666)
Interest received		40	216
Finance costs		(185)	(191)
Research and development tax incentive rebate		2,924	2,015
Government support received (COVID-19)		364	-
Net cash used in operating activities	20(a)	(11,414)	(8,533)
Cash flows from investing activities			
Proceeds from property, plant and equipment		-	4
Payment for property, plant and equipment		(102)	(258)
Net cash used in investing activities		(102)	(254)
Cash flows from financing activities			
Proceeds from capital raising		17,747	-
Lease liability principal repayments		(167)	(159)
Net proceeds from financing activities		17,580	(159)
Net increase/(decrease) in cash and cash equivalents		6,064	(8,946)
Cash and cash equivalents at beginning of year		9,206	18,152
Cash at the end of the year	20(b)	15,270	9,206

The statement should be read in conjunction with the notes to these financial statements.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

For the Year Ended 30 June 2021

1. STATEMENT OF SIGNIFICANT ACCOUNTING POLICIES

The following are the significant accounting policies adopted by the Group in the preparation and presentation of the financial report. The accounting policies have been consistently applied, unless otherwise stated.

(a) Basis of preparation

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

Australian Accounting Standards set out accounting policies that the AASB has concluded would result in a financial report containing relevant and reliable information about transactions, events and conditions to which they apply. Material accounting policies adopted in the preparation of this financial report are presented below. They have been consistently applied unless otherwise stated.

This financial report covers Acrux Limited and controlled entities as a Group. Acrux Limited is a company limited by shares, incorporated and domiciled in Australia. The address of Acrux Limited's registered office and principal place of business is 103-113 Stanley Street, West Melbourne, Victoria, 3003.

Acrux Limited is a for-profit entity for the purpose of preparing the financial statements.

The financial report was approved by the Directors as at the date of the Directors' report.

Compliance with IFRS

The financial report of Acrux Limited complies 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 and liabilities as described in the accounting policies.

Fair value measurement

For financial reporting purposes, 'fair value' is the price that would be received to sell an asset, or paid to transfer a liability, in an orderly transaction between market participants (under current market conditions) at the measurement date, regardless of whether that price is directly observable or estimated using another valuation technique.

When estimating the fair value of an asset or liability, the entity uses valuation techniques that are appropriate in the circumstances and for which sufficient data are available to measure fair value, maximising the use of relevant observable inputs and minimising the use of unobservable inputs.

Inputs to valuation techniques used to measure fair value are categorised into three levels according to the extent to which the inputs are observable:

- Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities that the entity can access at the measurement date.
- Level 2 inputs are inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly.
- Level 3 inputs are unobservable inputs for the asset or liability.

Significant accounting estimates and judgements

The preparation of the financial report requires the use of certain estimates and judgements in applying the Group's accounting policies. Those estimates and judgements significant to the financial report are disclosed in the notes to the consolidated financial statements.

(b) Going Concern Basis of Preparation

The financial report has been prepared on a going concern basis. During the year ended 30 June 2021 the Group reported an operating loss after tax of \$12.629 million (2020: loss \$9.471 million) and at the reporting date held cash reserves of \$15.270 million with total assets exceeding total liabilities by \$18.471 million (2020: \$12.849 million).

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS CONTINUED

Directors have prepared cash flow projections for twelve months beyond the date of approval of these financial statements.

This projection indicates that the Group is expected to continue normal business operations, within available cash reserves, with headroom, through the forecast period. Key projection assumptions include:

- continued eligibility of product development expenditure for the Research and Development tax incentive rebate;
- receipt of milestone payments and profit share income in line with executed licensing contracts and growth expectations; and
- progression of the generic product pipeline supporting future product launches.

Based on the forecasts, the Directors believe that it remains appropriate to prepare the financial statements on a going concern basis.

(c) Principles of Consolidation

The consolidated financial statements are those of the Group, comprising the financial statements of the parent entity and of all the entities which the parent entity controls. The Group controls an entity when it is exposed to, or has rights over, variable returns from its involvement with the entity and has the ability to affect those returns through its power to direct the activities of the entity. Financial statements of subsidiaries are prepared for the same reporting period as the parent entity, using consistent accounting policies.

All inter-company balances and transactions, including any unrealised profits or losses, between Group companies have been eliminated on consolidation. Subsidiaries are consolidated from the date on which control is established and are not recognised from the date that control ceases.

Equity interests in a subsidiary not attributable, directly or indirectly, to the Group are presented as non-controlling interests. Non-controlling interests are initially recognised either at fair value or at the non-controlling interests' proportionate share of the acquired entity's net identifiable assets. This decision is made on an acquisition-by-acquisition basis. Non-controlling interests in the results of subsidiaries are shown separately in the Consolidated Statement of Profit or Loss and Other Comprehensive Income and Consolidated Statement of Financial Position.

(d) 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 at least annually or 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 estimated recoverable amount. The estimated recoverable amount of an asset is defined as the higher of its fair value less costs to dispose and its value in use. An Impairment loss is disclosed as a separate line item on the Consolidated Statement of Comprehensive Income.

(e) Comparatives

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

(f) Financial instruments

Initial recognition and measurement

Financial assets and financial liabilities are recognised when the Group becomes a party to the contractual provisions of the instrument. For financial assets, this is equivalent to the date that the Group commits itself to either the purchase or sale of the asset (i.e. trade date accounting is adopted).

Financial instruments are initially measured at fair value adjusted for transaction costs, except where the instrument is classified as fair value through profit or loss, in which case transaction costs are immediately recognised as expenses in profit or loss.

Classification of financial assets

Financial assets recognised by the Group are measured in their entirety at either amortised cost or fair value, subject to their classification and whether the Group irrevocably designates the financial asset on initial recognition at fair value through other comprehensive income ('FVtOCI') in accordance with the relevant criteria in *AASB 9 Financial Instruments*.

Financial assets not irrevocably designated on initial recognition at FVtOCI are classified and measured at amortised cost, FVtOCI or fair value through profit or loss ('FVtPL') on the basis of both:

- (a) the Group's business model for managing the financial assets; and
- (b) the contractual cash flow characteristics of the financial asset.

Impairment of financial assets

Receivables from contracts with customers and contract assets are tested for impairment using the 'expected credit loss' impairment model. The simplified approach under *AASB 9 Financial Instruments* is applied to measure the allowance for credit losses for both receivables from contracts with customers and contract assets. The allowance for credit losses is determined on the basis of the lifetime expected credit losses of the financial asset which represent the credit losses that are expected to result from default events over the expected life of the financial asset.

Financial Liabilities

Non-derivative financial liabilities include trade payables, other creditors and inter-company balances. Liabilities are recognised for future payments for goods and services received, whether or not these have been billed to the Group. Trade liabilities are normally settled 30 days from month end.

(g) Foreign currency translation and balances

Functional and presentation currency

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

Transactions and balances

Transactions in foreign currencies within the Group are translated into functional currency at the rate of exchange prevailing at the date of the transaction.

Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation of monetary assets and liabilities denominated in foreign currency at year end exchange rates are recognised in profit or loss. Except for any currency hedges, all resulting exchange differences arising on settlement or re-statement are recognised as revenues or expenses for the financial year.

(h) Revenue Recognition

The accounting policies for the Group's revenue from contracts with customers are explained in Note 4.

(i) 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. The net amount of GST recoverable from, or payable to, the Australian Tax Office is included with other receivables or payables in the balance sheet.

Cash flows are presented in the Consolidated Statement of Cashflows on a gross basis.

(j) Rounding amounts

The Company and the Group is of a kind referred to in ASIC Corporations (Rounding in Financial/Directors' Reports) Instrument 2016/191, dated 24 March 2016, issued by the Australian Securities and Investments Commission relating to the "rounding off" of amounts in the financial statements. Amounts in the financial statements have been rounded off in accordance with the Class Order to the nearest thousand dollars, or in certain cases, to the nearest dollar.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS CONTINUED

(k) New and revised Accounting Standards effective at 30 June 2021

No new or revised Australian Accounting Standards have been applied for the first time to the annual reporting period commencing 1 July 2020.

(l) Accounting Standards issued but not yet effective

Certain new standards and interpretations have been issued but are not yet mandatory and have not yet been applied by the Group. These standards are not expected to have a material effect on the Group in current or future reporting periods.

2. SIGNIFICANT ACCOUNTING ESTIMATES AND JUDGEMENTS

Preparation of these financial statements requires the Group to make estimates and judgements that may affect the reported values of assets, liabilities, revenues and expenses. Management continually evaluates estimates and judgements based on historical experience and other factors it believes to be reasonable under the circumstances, including expectations of future events that may have a financial impact on the entity. The following critical judgements have been made in application of the Group's accounting policies and have the most significant effect on amounts recognised in the Group's financial statements:

(a) Income tax

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

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

(b) Impairment testing

The Group has prepared discounted cash flow models to evaluate and determine that capitalised product development costs are not being carried at a value that is materially in excess of the assets' recoverable value. Each product is valued by estimating future cash flows which are discounted for risks specific to the assets as well as for the time value of money. The following approach and assumptions have been applied:

- product revenue is estimated using current market data and projections of market volumes, product price and market share, adjusted for the impact of potential competitors entering the market and based on external analysis of the market effect of those competitors;
- cash flow forecasts are over 10 years; and
- cash flows have been discounted using an after tax rate of 12%.

The Group recorded a non-cash impairment loss of \$nil (2020: \$nil) for the financial year.

(c) Employee benefits

Long term employment benefits are valued at the present value of estimated future cash outflows which have been calculated based on evaluation of trends in relation to the retention of staff, future remuneration levels and the timing of the settlement of the benefits.

(d) Share based payments

The Group operates an OEP for issuance of rights to Directors and employees. The value of rights issued is recognised as an expense in the Consolidated Statement of Profit or Loss and Other Comprehensive Income in the period(s) when the benefit is earned. The value of the right is calculated at the time of issue using either a Monte Carlo or Black and Scholes simulation pricing model. The pricing 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 Acrux Limited's share price on the Australian Securities Exchange. The risk free interest rate is the Reserve Bank of Australia's cash rate at the options grant date(s).

3. FINANCIAL RISK MANAGEMENT

The Group is exposed to a variety of financial risks comprising:

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

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.

At reporting date the Group held \$15.270 million in operating bank accounts and short term deposits. As forecasted cashflows do not project the use of bank debt facilities the Group does not foresee a material sensitivity from interest rate fluctuations.

(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 Group is exposed to currency risks due to certain revenues and expenses being denominated in both US dollars and Euro. Currency risk management strategies are regularly reviewed.

Bank accounts denominated in US dollars and Euro are maintained to facilitate foreign currency receipts and payments. As at 30 June 2021, US dollar denominated cash reserves totalled A\$0.032 million (2020: A\$0.064 million) and Euro denominated cash reserves totalled A\$0.263 million (2020: A\$0.071 million). The balance of receivables as at 30 June 2021 includes the right to receive US\$0.01 million (2020: US\$0.01 million) USD denominated profit share income and EUR 0.182 million (2020: EUR 0.11 million) EUR denominated profit share income relating to partner sales recorded in the fourth quarter of the 2020/21 financial year. The balance of payables includes US\$0.153 million (2020: US\$0.227 million) and EUR 0.001 million (2020: EUR 0.025 million). A change in the AUD/USD and AUD/EUR exchange rates would have immaterial financial impact on the consolidated net profit/(loss) and equity of the Group (2020: immaterial).

The Group does not enter forward exchange contracts. At balance date, there were \$nil (2020: \$nil) forward exchange contracts. The accounting policy for forward exchange contracts is detailed in Note 1(g).

In future periods, revenues are expected to be received and costs are expected to continue to be incurred in foreign currency.

(c) Credit risk

Credit risk refers to the risk that a counterparty will default on its contractual obligations, resulting in a financial loss to the Company. The maximum exposure to credit risk of recognised financial assets at balance date 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.

Credit risk is closely managed and the Group has procedures to deal with credit worthy counterparties. Customer credit worthiness is reviewed and exposure to any one party is monitored. Potential credit loss is regularly assessed and a provision for expected credit losses would be raised if there was evidence that a debt was no longer collectible. The Company does not have a history of defaulted balances nor does it carry overdue debtor balances.

(d) Liquidity risk

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

The Group has Lease liabilities of \$0.185 million due within 12 months of the balance date and \$2.049 million due beyond 12 months from balance date. Other financial liabilities of the Group at the balance date are all expected to mature within three months of the balance date. The Group has cash reserves of \$15.270 million (2020: \$9.206 million), which are sufficient to settle these liabilities and to fund operating expenditure at planned levels for at least 15 months from the balance date based on current cashflow forecasts.

The maturity profile of the Group's cash term deposits is actively managed and compared with forecast liabilities to ensure that sufficient short term liquidity is available to settle liabilities as and when they fall due. The Group does not maintain an overdraft or loan facility.

4. REVENUE

	2021 \$'000	2020 \$'000
Revenue from contracts with customers		
Revenue from licensing agreements	1,337	1,253
Other revenues		
Interest	34	216
Grant revenue – R&D tax incentive rebate	3,421	2,327
Other revenue	364	149
Total revenue from non-operating activities	3,819	2,692
Total revenue from continuing operations	5,156	3,945

Key Accounting Policies

Revenue from contracts with customers

Revenue is derived from product licensing agreements in the form of contractual milestone and profit share receipts. Revenue from contractual milestones is recognised at the time of completion of the milestone, being the trigger point for the right to receive the revenue. Revenue relating to product sales, including profit share arrangements, is recognised in the period in which the sales occur.

Other revenues

Grants from the Government are recognised at fair value where there is reasonable assurance that the grant will be received, it can be reliably measured and the Group will comply with all conditions. As the Group can reliably estimate its R&D tax incentive rebate an accrual is recognised in the current year under Australian Accounting Standards. Revenue associated with the R&D tax incentive rebate is accrued at 43.5% of eligible R&D expenditure.

Interest revenue is recognised as it becomes receivable on a proportional basis after consideration of the applicable interest rate.

Other revenue is recognised as it has been received or, if it can be reliably estimated, over the period to which it relates. Other revenue includes \$0.364 million received from the Australian Federal government for JobKeeper and other support as part of their COVID-19 relief programmes.

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

5. LOSS FROM CONTINUING OPERATIONS

	2021 \$'000	2020 \$'000
Loss from continuing operations before income tax has been determined after the following specific expenses:		
Employee benefits expense		
Wages and salaries	4,574	4,237
Superannuation costs	400	370
Other employee benefits expense	444	468
Total employee benefits expense	5,418	5,075
Depreciation of non-current assets		
Right of use asset	233	201
Plant and equipment	322	397
Total depreciation of non-current assets	555	598
Amortisation of non-current assets		
Buildings	3	3
Capitalised research and development	107	107
Total amortisation of non-current assets	110	110
Total depreciation and amortisation of non-current assets	665	708

6. INCOME TAX

	2021 \$'000	2020 \$'000
(a) Income tax recognised in profit and loss		
Current tax	-	-
Deferred tax	197	86
Over/under provision in prior years	-	-
Income tax (benefit)/expense attributable to profit and loss	197	86
(b) Reconciliation of income tax (benefit)/expense		
The prima facie tax payable on loss before income tax is reconciled to the income tax (benefit)/expense as follows:		
Loss before tax from continuing operations	(12,432)	(9,385)
Prima facie income tax payable on loss before income tax at 26.0% (2020: 27.5%)	(3,232)	(2,581)
Add/(subtract) tax effect:		
Non-deductible expenses	132	109
Research and development tax incentive rebate	(890)	(640)
Non-assessable income	(13)	(14)
Impact of change in tax rate on Deferred tax asset	38	-
Tax losses not brought to account	4,106	3,125
Parent entity net adjustment and tax losses and temporary differences not brought to account	56	87
	3,429	2,667
Income tax (benefit)/expense attributable to loss	197	86
(c) Current tax		
Current tax (asset)/liability	-	-

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS CONTINUED

	2021 \$'000	2020 \$'000
(d) Deferred Tax		
<i>Deferred tax assets</i>		
The balance comprises:		
Accruals and provisions	197	192
Leasehold improvements and Plant and equipment	108	131
Plant and equipment under lease	33	17
Intangible Assets	1,068	1,136
Exchange differences	-	4
Tax losses and research and development offset	1,076	1,010
	2,482	2,490
<i>Deferred tax liabilities</i>		
The balance comprises:		
Intangible assets	(844)	(682)
Prepayments	(26)	(3)
Exchange differences	(5)	-
	(875)	(685)
Net deferred tax assets/(liabilities)	1,607	1,805
(e) Deferred tax assets not brought to account		
Temporary differences	(123)	(161)
Tax losses	19,385	17,388
	19,262	17,227

Key accounting policies

Current income tax expense/benefit 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 attributable to temporary differences and to unused tax losses.

Deferred tax assets and liabilities are recognised as temporary differences at the applicable tax rate when the assets are expected to be recovered or liabilities to be 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.

The subsidiary companies of Acrux Limited are subject to the general company tax rate of 26% (2020: 27.5%).

Income tax expense for the financial year was \$0.197 million (2020: \$0.086 million).

7. DIVIDENDS

	2021 \$'000	2020 \$'000
(a) Dividends paid and declared		
\$nil dividends were declared or paid during the financial year (2020: \$nil)	-	-
(b) Franking account		
Balance of franking account on a tax paid basis at financial year end, adjusted for franking credits arising from payment of income tax, franking debits from payment of dividends and any credits that may be prevented from distribution in subsequent year.	43,835	43,835

8. LOSS PER SHARE

	2021 \$'000	2020 \$'000
Loss from continuing operations	(12,629)	(9,471)
Loss used in calculating basic and diluted earnings per shares	(12,629)	(9,471)
	No. of shares	No. of shares
Weighted average number of ordinary shares used in calculating basic earnings per share	219,726,077	167,768,974
Effect of dilutive securities:	-	-
Adjusted weighted average number of ordinary shares used in calculating diluted earnings per share	219,726,077	167,768,974
Basic loss per share (cents)	5.75	5.65
Diluted loss per share (cents)	5.75	5.65

9. CASH AND CASH EQUIVALENTS

	2021 \$'000	2020 \$'000
Cash at bank	7,270	1,206
Deposits at call	8,000	8,000
	15,270	9,206

Key accounting policies

Cash and cash equivalents include bank deposits which are readily convertible to cash on hand and are used in the cash management function on a day-to-day basis.

10. RECEIVABLES

	2021 \$'000	2020 \$'000
Receivables from contracts with customers	288	190
Allowance for credit losses	-	-
	288	190
Other receivables	2,871	2,369
Allowance for credit losses	-	-
	2,871	2,369
	3,159	2,559

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS CONTINUED

Key accounting policies

Trade and other receivables arise from the transactions with customers and are normally settled within 30 days.

Impairment of receivables from contracts with customers and other receivables

The Group applies the simplified approach under *AASB 9 Financial Instruments* to measure the allowance for credit losses for receivables from contracts with customers and contract assets. Under this simplified approach, the Group determines losses on the basis of the expected lifetime of the instrument. After initial measurement, the collectability of receivable balances is reviewed on an ongoing basis and a provision raised if collection in full is no longer considered probable. Debts which are known to be uncollectable are written off. The Company does not have a history of collection delays, defaulted balances or client dispute and does not consider a provision for expected credit losses is necessary at this time.

11. OTHER CURRENT ASSETS

	2021 \$'000	2020 \$'000
Prepayments	165	577
	165	577

12. PLANT AND EQUIPMENT

	2021 \$'000	2020 \$'000
<i>Leasehold improvements</i>		
At cost	47	36
Accumulated amortisation	(15)	12
Total leasehold improvements	32	24
<i>Plant and equipment</i>		
At cost	1,916	1,825
Accumulated depreciation	(1,410)	(1,088)
Total plant and equipment	506	737
Total plant and equipment	538	761
Reconciliations of the carrying amounts of plant and equipment at the beginning and end of the current financial year:		
<i>Leasehold improvements</i>		
Carrying amount at the start of the year	24	27
Additions	11	-
Amortisation expense	(3)	(3)
Carrying amount at the end of the year	32	24
<i>Plant and equipment</i>		
Carrying amount at the start of the year	737	879
Additions	91	258
Disposals	-	(4)
Depreciation expense	(322)	(386)
Carrying amount at the end of the year	506	737

Key accounting policies

Cost and valuation

Each class of plant and equipment is carried at historical cost less applicable accumulated depreciation and accumulated impairment losses. Historical cost includes expenditure that is directly attributable to the acquisition of the items. At each balance date the carrying amount of each asset classification is reviewed to ensure that it does not differ materially from the asset classification's fair value at reporting date. Where necessary, assets are revalued to reflect fair value.

Depreciation

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

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

The useful lives for each class of assets are:

	2021	2020
Leasehold improvements	5 to 20 years	5 to 20 years
Plant and equipment	1 to 16 years	1 to 16 years

13. INTANGIBLE ASSETS

	2021 \$'000	2020 \$'000
Capitalised development		
External development expenditure capitalised	1,071	1,071
Accumulated amortisation	(589)	(482)
Total intangible assets	482	589
Reconciliation of the carrying amounts of external development expenditure at the beginning and end of the current financial year:		
<i>Estradiol</i>		
Carrying amount at the start of the year	589	696
Additions	-	-
Amortisation	(107)	(107)
Carrying amount at the end of the year	482	589

The remaining useful life of Capitalised Development relating to Estradiol is estimated at 5 years.

Key accounting policies

Intangible assets are recognised at cost at the date of acquisition. Balances are reviewed at least 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 and amortised from the time the asset is available for use. Intellectual property with a finite life is carried at cost less accumulated amortisation and any impairment losses. Intellectual property is amortised over the useful life of relevant patents. Amortisation expense is included in 'Depreciation and amortisation expenses' in the Statement of Comprehensive Income.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS CONTINUED

Research and Development

Product development costs are capitalised only when all of the following criteria can be demonstrated:

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;
3. 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; and
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 from the time the product becomes available for use until 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 remaining estimated useful life and total economic benefit for each asset are reviewed at least annually.

14. LEASE ASSETS AND LEASE LIABILITIES

The Group has an operating lease for occupancy of its office, laboratory and warehouse facilities. The lease was renewed by Acrux DDS Pty Limited for a period of 4 years from 1 June 2018, with a three options to extend for three 3 years each. There is no option to purchase at the end of the lease period.

	2021 \$'000	2020 \$'000
Leased assets		
Carrying amount of lease assets, by class of underlying asset:		
Buildings under lease arrangements		
At cost	2,409	2,409
Accumulated depreciation	(402)	(201)
	2,007	2,208
Plant and equipment under lease arrangements		
At cost	142	142
Accumulated depreciation	(43)	(11)
	99	131
	2,106	2,339
Reconciliation of carrying amount of Leased assets at the beginning and end of the financial year:		
Buildings under lease arrangements		
Carrying amount at the beginning of the period	2,208	2,409
Additions	-	-
Depreciation	(201)	(201)
Carrying amount at the end of the period	2,007	2,208
Plant and equipment under lease arrangements		
Carrying amount at the beginning of the period	131	-
Additions		142
Depreciation	(32)	(11)
Carrying amount at the end of the period	99	131

	2021 \$'000	2020 \$'000
Lease Liabilities		
Lease liabilities (current)	185	167
Lease liabilities (non-current)	2,049	2,234
Total carrying amount of lease liabilities	2,234	2,401
Lease expenses and cashflows		
Interest expense on lease liabilities	185	191
Depreciation expense on lease assets	233	212
Total cash outflow in relation to leases	352	351
Future commitments		
Future minimum lease payments to be made:		
– Not later than 1 year	344	
– Later than 1 year and not later than 5 years	1,317	
Aggregate of lease payments contracted for at reporting date	1,661	

Key accounting policies

The Group recognises a Leased asset at the date of lease commencement (other than leases of 12-months or less and leases of low value assets), representing its right to use the underlying asset and a Lease liability representing its obligation to make lease payments.

Leased assets are initially recognised at cost, comprising the amount of the initial measurement of the lease liability, any lease payments made at or before date of lease commencement, less any lease incentives received, any initial direct costs incurred by the Group and an estimate of costs to be incurred by the Group in dismantling and removing the underlying asset, restoring the site on which it is located or restoring the underlying asset to the condition required by the terms and conditions of the lease. Leased assets are depreciated over the shorter of the lease term and the estimated useful life of the underlying asset, consistent with the estimated consumption of the economic benefits of the underlying asset.

Subsequent to initial recognition, Leased assets are measured at cost (adjusted for any remeasurement of the associated lease liability), less accumulated depreciation and any accumulated impairment loss.

Lease liabilities are initially recognised at the present value of the future lease payments which are unpaid at the date of lease commencement. These lease payments are discounted at the interest rate implicit in the lease.

Subsequent to initial recognition, Lease liabilities are measured at the present value of the remaining lease payments that are unpaid at the reporting date. Lease liabilities are remeasured to reflect changes to lease terms, changes to lease payments and any lease modifications not accounted for as separate leases.

Interest expense on lease liabilities is recognised in profit or loss, presented as a component of finance costs.

Variable lease payments not included in the measurement of lease liabilities are recognised as an expense when incurred.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS CONTINUED

15. PAYABLES

	2021 \$'000	2020 \$'000
Current		
Trade payables	312	1,025
Sundry creditors and accruals	1,468	853
	1,780	1,878

Key accounting policies

These amounts represent liabilities for goods and services were provided to the Group prior to the end of the financial year and which are unpaid. Balances are unsecured and usually paid within 30 days of recognition. Trade and other payables are presented as current liabilities unless payment is not due withing 12 months of the reporting period.

Short term incentives

The Group recognises an accrual for short term incentives payable to staff in accordance with the employee's contract of employment and when the amount can be reliably measured.

Termination benefits

Termination benefits are payable when employment of an employee is terminated before the normal retirement date. The Group recognises a provision for termination benefits when an entitlement to contractual benefits arises or when the entity can no longer withdraw the offer of non-contractual benefits.

16. PROVISIONS

	2021 \$'000	2020 \$'000
Current		
Employee entitlements	801	620
Non-current		
Employee entitlements	41	88
Aggregate employee entitlements	842	708

Key accounting policies

Provisions are recognised when the Group 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 the outflow can be reliably measured.

Provision is made for employee entitlements accumulated as a result of employees rendering services up to the reporting date. These benefits include annual leave and long service leave. Liabilities arising in respect employee benefits expected to be settled within twelve months of the reporting date are measured at their nominal amounts based on remuneration rates expected to be paid when the liability is settled are presented as current employee entitlements on the balance sheet. 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 up to the reporting date and are presented as non-current employee entitlements on the balance sheet.

17. CONTRIBUTED EQUITY

	2021		2020	
	No. of shares	000's	No. of shares	000's
(a) Issued and paid up capital				
Ordinary shares fully paid	283,305,394	114,213	168,583,515	96,137
(b) Movements in ordinary shares on issue				
Beginning of the financial year	168,583,515	96,137	166,577,711	95,879
Issued during the year:				
Issue of shares – two tranche placements	49,777,982	7,815		
Issue of shares – Share Purchase Plan	63,298,095	9,932		
Conversion of rights under the Omnibus Equity Plan	1,498,438	301	1,829,344	228
Share issues under Omnibus Equity Plan	147,364	28	176,460	30
Value of ordinary shares issued during the year	114,721,879	18,076	2,005,804	258
Value of ordinary shares on issue at reporting date	283,305,394	114,213	168,583,515	96,137

(c) Rights

During the financial year 1,451,418 rights were issued under the OEP (2020: 2,804,095). Rights hold no participation rights, but shares issued on exercise of rights rank equally with existing shares. At 30 June 2021, 5,716,929 rights were held by key management personnel (2020: 6,331,649).

The closing market value of an ordinary Acrux Limited share on the Australian Securities Exchange at 30 June 2021 was 13.0 cents.

	2021	2020
(i) Movement in the number of rights held under Omnibus Equity Plan are as follows:		
Opening balance	6,943,556	6,235,000
Granted during the year	1,451,418	2,804,095
Exercised during the year	(1,498,438)	(1,829,344)
Lapsed during the financial year	(543,188)	(266,195)
Closing balance	6,353,348	6,943,556
(ii) Details of rights exercised during the financial year:		
Fair value as at issue date of shares issued during the financial year	301	228
(iii) Details of lapsed rights		
Key management personnel	489,998	83,600
Employees	53,190	182,595
Lapsed during the year	543,188	266,195

(d) Capital management

When managing capital, the Directors' objective is to ensure the entity continues as a going concern and optimises returns to shareholders and benefits for other stakeholders. During 2021 financial year, the Board paid dividends of \$nil (2020: \$nil).

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS CONTINUED

18. SHARE BASED PAYMENTS

(a) Omnibus Equity Plan

Details of rights granted are provided below:

Grant date	Expiry date	Balance at beginning of the year	Granted during the year	Exercised during the year	Expired during the year	Balance at the end of the year	Exercisable at the end of the year
14 November 2017	14 November 2024	3,000,000	-	-	-	3,000,000	-
25 January 2018	25 January 2025	237,000	-	(140,000)	-	97,000	97,000
23 November 2018	1 January 2023	400,000	-	(80,000)	-	320,000	160,000
4 February 2019	4 February 2026	598,000	-	(190,000)	27,000	381,000	381,000
9 December 2019	28 November 2026	2,068,054	-	(409,720)	-	1,658,334	583,332
3 February 2020	3 February 2027	640,502	-	(328,717)	11,595	300,190	300,190
17 November 2020	17 November 2027	-	699,999	(350,001)	349,998	-	-
4 February 2021	4 February 2028	-	751,419	-	154,595	596,824	-
		6,943,556	1,451,418	(1,498,438)	543,188	6,353,348	1,521,522

The fair value of the performance rights granted on 14 November 2017 was 12 cents per performance right at the date of grant.

Fair value was determined using the Monte Carlo simulation pricing model. The following inputs were utilised:

Grant date: 14 November 2017

Expiry date: 14 November 2024

Share price at grant date: \$0.17

Expected price volatility of the Company's shares calculated using the movement in the share price over a 36 month period: 63%

Expected dividend yield: nil

Risk free rate: 2.24%

The fair value of the performance rights granted on 25 January 2018 was 14 cents per performance right at the date of grant.

Fair value was determined using the Monte Carlo simulation pricing model. The following inputs were utilised:

Grant date: 25 January 2018

Expiry date: 25 January 2025

Share price at grant date: \$0.17

Expected price volatility of the Company's shares calculated using the movement in the share price over a 48 month period: 64%

Expected dividend yield: nil

Risk free rate: 2.45%

The fair value of the performance rights granted on 23 November 2018 was 19 cents per performance right at the date of grant.

Fair value was determined using the Monte Carlo simulation pricing model. The following inputs were utilised:

Grant date: 23 November 2018

Expiry date: 1 January 2023

Share price at grant date: \$0.19

Expected price volatility of the Company's shares calculated using the movement in the share price over a 36 month period: 68%

Expected dividend yield: nil

Risk free rate: 2.31%

The fair value of the performance rights granted on 4 February 2019 was 16 cents per performance right at the date of grant.

Fair value was determined using the Monte Carlo simulation pricing model. The following inputs were utilised:

Grant date: 4 February 2019

Expiry date: 4 February 2026

Share price at grant date: \$0.18

Expected price volatility of the Company's shares calculated using the movement in the share price over a 48 month period: 78%

Expected dividend yield: nil

Risk free rate: 1.82%

The fair value of the performance rights granted on 9 December 2019 was 18.5 cents per performance right at the date of grant.

Fair value was determined using the Monte Carlo simulation pricing model. The following inputs were utilised:

Grant date: 9 December 2019

Expiry date: 28 November 2026

Share price at grant date: \$0.185

Expected price volatility of the Company's shares calculated using the movement in the share price over a 36 month period: 64%

Expected dividend yield: nil

Risk free rate: 0.62%

The fair value of the performance rights granted on 4 February 2020 was 15 cents per performance right at the date of grant.

Fair value was determined using the Monte Carlo simulation pricing model. The following inputs were utilised:

Grant date: 4 February 2020

Expiry date: 4 February 2027

Share price at grant date: \$0.185

Expected price volatility of the Company's shares calculated using the movement in the share price over a 48 month period: 60%

Expected dividend yield: nil

Risk free rate: 0.65%

The fair value of the performance rights granted on 17 November 2020 was 17 cents per performance right at the date of grant.

The following inputs were utilised in determining the valuation:

Grant date: 17 November 2020

Expiry date: 17 November 2027

Share price at grant date: \$0.17

The fair value of the performance rights granted on 4 February 2021 was 14 cents per performance right at the date of grant.

Fair value was determined using the Monte Carlo simulation pricing model. The following inputs were utilised:

Grant date: 4 February 2021

Expiry date: 4 February 2028

Share price at grant date: \$0.17

Expected price volatility of the Company's shares calculated using the movement in the share price over a 48 month period: 69%

Expected dividend yield: nil

Risk free rate: 0.41%

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS CONTINUED

(c) Expenses recognised from share-based payment transactions

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

	2021 \$'000	2020 \$'000
Rights under the OEP	479	355
Issue of tax exempt ordinary shares to eligible employees	28	30
Total expenses recognised from securities based payment transactions	507	385

The Group operates an OEP which was approved by shareholders on 12 November 2020. On 4 February 2021, employees accepted 751,419 performance rights and 147,364 Exempt ordinary shares were issued to employees who did not receive performance rights. The performance rights and ordinary shares were issued at nil cost and hold no participation rights.

Ordinary shares issued on exercise of performance rights rank equally with existing ordinary shares. Performance rights vest annually, subject to performance hurdles being achieved. The Exempt shares will be escrowed for a period of 3 years from the date of issue.

Within the terms of the OEP and subject to approval of shareholders, rights are also issued to Directors comprising 50% of their remuneration.

Share-based payments

The fair value of the rights are recognised as an expense in the Consolidated Statement of Profit or Loss and Other Comprehensive Income in the period(s) during which the employee or Director becomes entitled to exercise the rights. The fair value of rights at grant date is determined using a Monte Carlo simulation pricing model and is recognised as an employee benefit expense over the period during which the employee or director became entitled to the performance rights (the vesting period).

19. RESERVES AND ACCUMULATED LOSSES

	2021 \$'000	2020 \$'000
Share based payment reserve	757	582
Profit reserve	7,390	7,390
Reserves	8,147	7,972
Accumulated losses	(103,889)	(91,260)

Share based payment reserve

(i) Nature and purpose of Share based payment reserve

This reserve is used to record the value of equity benefit provided to employees and Directors as part of their remuneration.

(ii) Movement in Share based payment reserve

Balance at the beginning of year	582	639
Employee performance rights expense for the year	175	126
Employee share options previously expensed, that lapsed during the year	-	(183)
Balance at end of year	757	582

	2021 \$'000	2020 \$'000
Profit Reserve		
<i>Nature and purpose of Profit reserve</i>		
This reserve is used to record the profits which have been generated by the Group.		
Accumulated losses		
<i>Movement in Accumulated losses</i>		
Balance at the beginning of year	(91,260)	(81,972)
Employee share options that lapsed during the year	-	183
Net loss attributable to members of Acrux Limited	(12,629)	(9,471)
Balance at end of year	(103,889)	(91,260)

20. CASHFLOW INFORMATION

	2021 \$'000	2020 \$'000
(a) Reconciliation of the cash flow from operations with loss after income tax:		
Loss from ordinary activities after income tax	(12,629)	(9,471)
Non-Cash Items		
Depreciation and amortisation	664	708
Share options expense	507	385
Changes in assets and liabilities		
(Increase)/decrease in trade and other receivables	(600)	(246)
(Increase)/decrease in other current assets	415	(81)
Increase/(decrease) in payables	(103)	6
Increase/(decrease) in employee entitlements	135	80
Increase/(decrease) in deferred tax assets	197	86
	1,215	938
Net cash (outflows)/inflows from operating activities	(11,414)	(8,533)
(b) Reconciliation of cash		
Cash at the end of the financial year as shown in the statement of cash flows and the Statement of financial position is as follows:		
Cash at bank	7,270	1,206
At call deposits with financial institutions	8,000	8,000
Closing cash balance	15,270	9,206

(c) Credit stand-by arrangement and loan facilities

The Group has credit card facilities with financial institutions available to the extent of \$120,000 (2020: \$120,000). As at 30 June 2021 the Group had unused facilities of \$101,311 (2020: \$100,736).

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS CONTINUED

21. NON-CONTROLLING INTERESTS

The Group holds \$nil (2020: nil) non-controlling interests at balance date.

22. 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:

	2021 \$	2020 \$
Short-term employment benefits	1,793,149	1,448,891
Post-employment benefits	213,197	103,127
Equity	332,714	461,460
	2,339,060	2,013,478

23. LOANS TO KEY MANAGEMENT PERSONNEL

No loans were made to Key Management Personnel during the financial year.

24. RELATED PARTY DISCLOSURES

Wholly owned Group transactions

Loans

Loans were made between Acrux Limited and 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 was \$13.399 million (2020: \$0.560 million).

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 \$0.366 million (2020: \$0.061 million).

Other transactions with Key Management Personnel and their personally related entities

Transactions of Directors and Key Management Personnel concerning shares in accordance with the OEP are disclosed the Directors' Report and are included in Note 17 and 18. There were no other transactions or contracts between the Company and Directors and Key Management Personnel in 2021 (2020: nil).

25. AUDITOR REMUNERATION

	2021 \$'000	2020 \$'000
Amounts paid and payable to Pitcher Partners for:		
An audit or review of the financial report of the entity and any other entity in the Group	78	86
Taxation compliance and consulting	49	19
Other non-audit services	-	-
	127	105

26. SEGMENT REPORTING

The Group operates as a single operating segment. Internal management reporting systems present financial information as a single segment. The segment derives revenue from developing and commercialising pharmaceutical products which administer drugs topically.

	2021 \$'000	2020 \$'000
Geographical segment information		
Australia	3,819	2,645
Europe and other countries	1,025	868
United States	312	432
	5,156	3,945
Revenue by product group and services provided		
Profit share received on commercialised products	1,092	937
Contractual milestones received in relation to development products	245	363
R&D Tax Incentive rebate	3,421	2,327
Other, including other government support and interest received	398	318
	5,156	3,945

27. CONTROLLED ENTITIES

	Country of Incorporation	2021	2020
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%

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS CONTINUED

28. PARENT ENTITY DETAILS

(a) Summarised statement of financial position of the parent entity, Acrux Limited

	Parent Entity	
	2021 \$'000	2021 \$'000
Assets		
Current assets	10,946	6,305
Non-current assets ¹	20,510	7,672
Total assets	31,456	13,977
Liabilities		
Current liabilities	381	249
Non-current liabilities	-	30
Total liabilities	381	279
Net assets	31,075	13,698
Equity		
Share capital	114,213	96,137
Profit reserve	7,390	7,390
Accumulated losses	(91,285)	(90,410)
Share based payments reserve	757	582
Total equity	31,075	13,698

1. Investment in subsidiaries are initially recognised at cost and are subsequently carried at the lower of cost or recoverable amount. If the carrying value exceeds the recoverable amount, an impairment loss is recognised in the profit or loss of the parent.

(b) Summarised statement of comprehensive income

	2021 \$'000	2020 \$'000
Loss for the financial year	(875)	(754)
Other comprehensive income for the financial year	-	-
Total comprehensive income for the financial year	(875)	(754)

29. CONTINGENCIES

There were no contingencies at 30 June 2021 (2020: nil).

30. SUBSEQUENT EVENTS

On 28 July the Company received FDA approval of generic EMLA® Cream, Lidocaine and Prilocaine 2.5%. This is the Company's third ANDA to be approved and total addressable market value reported in IQVIA data for the 12 months to June 2021 is UD \$23 million. An exclusive sales, marketing and distribution agreement for this product has been executed for this product.

No other matter or circumstance has arisen since 30 June 2021 that has significantly affected the Group's operations, results or state of affairs, or may do so in future years.

31. SIGNIFICANT CHANGES IN THE STATE OF AFFAIRS

On 11th March 2020 the World Health Organisation declared the outbreak of a novel coronavirus, known as 'coronavirus disease 2019' ('COVID-19') as a global pandemic. Acrux has largely maintained its operational activities through 2020 and 2021 and has implemented a series of precautionary measures in line with the Victorian Government recommendations including working from home provisions and activating business continuity plans internally and with business partners. Acrux has implemented a COVID Safe Plan which all employees and visitors must follow.

While the broader economy has been impacted significantly, the Group has experienced a limited impact from the COVID-19 operating environment. The COVID-19 operating environment has in some cases affected operations at our clinical research organisations (CROs) and CMOs that has caused delays to some projects. Whilst there have been no significant implications to either revenue or operational expenditure in the current period there may be longer term implications beyond the balance date, the extent of which the Company cannot estimate.

DIRECTORS' DECLARATION

The Directors of the company declare that:

1. In the Directors' opinion, the financial statements and notes thereto, as set out on pages 27 to 53, are in accordance with the *Corporations Act 2001* including:
 - (a) complying with Australian 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) giving a true and fair view of the financial position of the Group as at 30 June 2021 and of its performance for the year ended on that date.
2. 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 section 295A of the *Corporations Act 2001* for the financial year ending 30 June 2021.

Signed in accordance with a resolution of the Directors made pursuant to S295(5) of the *Corporations Act 2001*.



Ross Dobinson
Non-executive Chairman

Melbourne
25 August 2021



Don Brumley
Non-executive Director

Melbourne
25 August 2021

INDEPENDENT AUDITOR'S REPORT TO THE MEMBERS OF ACRUX LIMITED

ACRUX LIMITED
AND CONTROLLED ENTITIES
ABN 72 082 001 152



INDEPENDENT AUDITOR'S REPORT TO THE MEMBERS OF ACRUX LIMITED

Report on the Audit of the Financial Report

Opinion

We have audited the financial report of Acrux Limited "the Company" and its controlled entities "the Group", which comprises the consolidated statement of financial position as at 30 June 2021, the consolidated statement of profit or loss and other comprehensive income, the consolidated statement of changes in equity and the consolidated statement of cash flows for the year then ended, and notes to the financial statements, including a summary of significant accounting policies, and the directors' declaration.

In our opinion, the accompanying financial report of the Group is in accordance with the *Corporations Act 2001*, including:

- (a) giving a true and fair view of the Group's financial position as at 30 June 2021 and of its financial performance for the year then ended; and
- (b) complying with Australian Accounting Standards and the *Corporations Regulations 2001*.

Basis for Opinion

We conducted our audit in accordance with Australian Auditing Standards. Our responsibilities under those standards are further described in the *Auditor's Responsibilities for the Audit of the Financial Report* section of our report. We are independent of the Group in accordance with the auditor independence requirements of the *Corporations Act 2001* and the ethical requirements of the Accounting Professional and Ethical Standards Board's APES 110 *Code of Ethics for Professional Accountants (including Independence Standards)* "the Code" that are relevant to our audit of the financial report in Australia. We have also fulfilled our other ethical responsibilities in accordance with the Code.

We confirm that the independence declaration required by the *Corporations Act 2001*, which has been given to the directors of the Company, would be in the same terms if given to the directors as at the time of this auditor's report.

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

Key Audit Matters

Key audit matters are those matters that, in our professional judgement, were of most significance in our audit of the financial report of the current period. These matters were addressed in the context of our audit of the financial report as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters.

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ACRUX LIMITED
AND CONTROLLED ENTITIES
ABN 72 082 001 152



INDEPENDENT AUDITOR'S REPORT
TO THE MEMBERS OF
ACRUX LIMITED

Key Audit Matter

How our audit addressed the key audit matter

Assessment of impairment of Intangible Assets

Refer to page 28 consolidated statement of financial position, note 2(b) on page 34 and note 13 on page 41.

The Group has \$0.48 million (\$0.59 million as at 30 June 2020) of capitalised development costs as at 30 June 2021 after accumulated amortisation and impairment loss. We view intangible assets in relation to capitalised development costs to be a Key Audit Matter due to the management judgement required in making Discounted Cash Flow (DCF) model assumptions such as discount rate, growth rate, foreign exchange rate and forecast cashflows.

Our procedures included amongst others:

- Critically evaluating management's DCF model methodology and their key assumptions utilised;
- Testing the mathematical accuracy of the DCF model and assessing forecast cash flows to external data;
- Performing sensitivity analysis around the discount rate, growth rates and foreign exchange rate used in the DCF model;
- Understanding and evaluating management's processes and controls around the impairment of intangible assets; and,
- Assessing the appropriateness of the disclosures included in Notes 2 and 13 to the financial report in respect of impairment testing and sensitivity analysis.

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INDEPENDENT AUDITOR'S REPORT
TO THE MEMBERS OF
ACRUX LIMITED

Key Audit Matter	How our audit addressed the key audit matter
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Recoverability of Deferred Tax Assets

Refer to note 2(a) on page 34 and
note 6 on page 37.

The Group has \$1.61 million (\$1.80 million as at 30 June 2020) of deferred tax assets recognised as at 30 June 2021 relating to timing differences and Research and Development offset incurred by the subsidiary Acrux DDS Pty Ltd.

The ability to recognise the deferred tax assets is dependent upon the probable generation of sufficient future taxable profit in order for the benefits of the deferred tax assets to be realised, in accordance with AASB 112. These benefits are realised by reducing tax payable on future taxable profits.

We view the deferred tax assets as a Key Audit Matter due to the management judgement required in forecasting future taxable profit. Management's assumptions include but are not restricted to:

- Ongoing profitable contract research and development activities;
 - Successful commercialisation of generics; and
 - The number of competitors in the market, market share and profit sharing rates with commercial partners.
-

Our procedures included amongst others:

- Reviewing and assessing management's key assumptions relating to the forecasts of future taxable profit and evaluating the reasonableness of these assumptions;
- Undertaking sensitivity analysis around the forecast cashflows in order to challenge management's assumptions;
- Understanding and evaluating management's processes and controls around the recognition of deferred tax assets; and
- Assessing the appropriateness of the disclosures included in Note 6 in respect of current and deferred tax balances.

**ACRUX LIMITED
AND CONTROLLED ENTITIES
ABN 72 082 001 152**



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

Other Information – The annual report is not complete at the date of the audit report.

The directors are responsible for the other information. The other information comprises the Directors Report which was obtained as at the date of our audit report, and any additional other information included in the Company's annual report for the year ended 30 June 2021 but does not include the financial report and our auditor's report thereon.

Our opinion on the financial report does not cover the other information and accordingly we do not express any form of assurance conclusion thereon.

In connection with our audit of the financial report, our responsibility is to read the other information identified above and, in doing so, consider whether the other information is materially inconsistent with the financial report or our knowledge obtained in the audit or otherwise appears to be materially misstated. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

When we read the other information not yet received as identified above, if we conclude that there is a material misstatement therein, we are required to communicate the matter to the directors and use our professional judgment to determine the appropriate action to take.

Responsibilities of the Directors 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 preparing the financial report, the directors are responsible for assessing the ability of the Group to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the directors either intend to liquidate the Group or to cease operations, or has no realistic alternative but to do so.

Auditor's Responsibilities for the Audit of the Financial Report

Our objectives are to obtain reasonable assurance about whether the financial report as a whole is free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance but is not a guarantee that an audit conducted in accordance with the Australian Auditing Standards will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if,

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**ACRUX LIMITED
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**INDEPENDENT AUDITOR'S REPORT
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ACRUX LIMITED**

individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of this financial report.

As part of an audit in accordance with the Australian Auditing Standards, we exercise professional judgement and maintain professional scepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the financial report, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion.
- The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of internal control relevant to the audit 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 Group's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the directors.
- Conclude on the appropriateness of the directors' use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the financial report or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the Group to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the financial report, including the disclosures, and whether the financial report represents the underlying transactions and events in a manner that achieves fair presentation.
- Obtain sufficient appropriate audit evidence regarding the financial information of the entities or business activities within the Group to express an opinion on the financial report. We are responsible for the direction, supervision and performance of the Group audit. We remain solely responsible for our audit opinion.

We communicate with the directors regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

We also provide the directors with a statement that we have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, related safeguards.

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From the matters communicated with the directors, we determine those matters that were of most significance in the audit of the financial report of the current period and are therefore the key audit matters. We describe these matters in our auditor's report unless law or regulation precludes public disclosure about the matter or when, in extremely rare circumstances, we determine that a matter should not be communicated in our report because the adverse consequences of doing so would reasonably be expected to outweigh the public interest benefits of such communication.

Report on the Remuneration Report

Opinion on the Remuneration Report

We have audited the Remuneration Report included in pages 18 to 24 of the directors' report for the year ended 30 June 2021. In our opinion, the Remuneration Report of Acrux Limited and its controlled entities, for the year ended 30 June 2021, complies with section 300A of the *Corporations Act 2001*.

Responsibilities

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.



N R BULL
Partner



PITCHER PARTNERS
Melbourne

25 August 2021

SHAREHOLDER INFORMATION

Additional information required by Australian Securities Exchange Listing Rules and not disclosed elsewhere in this report, as at 16 August 2021.

SHAREHOLDERS

The Company has 283,305,394 ordinary fully paid shares on issue, held by 5,429 shareholders, and 6,637,237 rights held by 37 people. The Company has no other equity securities on issue. 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 rights.

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.

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	Securities
1 to 1,000	1,064	545,683
1,001 to 5,000	1,603	4,689,043
5,001 to 10,000	720	5,793,717
10,001 to 50,000	1,262	31,502,383
50,001 to 100,000	329	24,632,933
100,001 and Over	451	216,141,635
Total	5,429	283,305,394

2,125 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

The following parties have declared a relevant interest in the number of ordinary shares under Part 6C.1 of the *Corporations Act 2001*.

Name	Number of fully paid ordinary shares
Phillip Asset Management Ltd atf BioScience Managers Translation Fund I	31,847,134

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

		Number of fully paid ordinary shares	Percentage of issued capital
1	PHILLIP ASSET MANAGEMENT LIMITED	31,847,134	11.24
2	DDH GRAHAM LIMITED	10,950,000	3.87
3	J P MORGAN NOMINEES AUSTRALIA PTY LIMITED	10,425,182	3.68
4	DR THOMAS VUI CHUNG CHAI	4,310,561	1.52
5	HISHENK PTY LTD	4,200,000	1.48
6	CITICORP NOMINEES PTY LIMITED	3,816,023	1.35
7	ASHWOOD RIVER PTY LTD	3,800,000	1.34
8	MR ROSS DOBINSON	3,308,284	1.17
9	MR CHRISTOPHER MURRAY ABBOTT	3,000,000	1.06
10	MR IAN VICTOR LANCINI & MRS DEBRA ANN LANCINI	2,045,000	0.72
11	DURBIN SUPERANNUATION PTY LTD	2,035,000	0.72
12	ASIA UNION INVESTMENTS PTY LIMITED	1,691,083	0.60
13	BNP PARIBAS NOMINEES PTY LTD	1,580,072	0.56
14	MR MICHAEL JOHN KOTSANIS	1,511,083	0.53
15	NEWECONOMY COM AU NOMINEES PTY LIMITED	1,481,634	0.52
16	TSO PTY LTD	1,475,734	0.52
17	MR DAVID ANDREW SLOBOM & MRS LINDA JANE SLOBOM	1,409,596	0.50
18	PACIFIC CUSTODIANS PTY LIMITED	1,390,657	0.49
19	WILLOUGHBY CAPITAL PTY LTD	1,300,000	0.46
20	ADAM JAMAL	1,218,727	0.43
Total Top 20 Shareholders		92,795,770	32.75

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 general summary.

Acrux Limited is a Pooled Development Fund (PDF) 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 which is registered and regulated by the PDF Registration Board in accordance with the PDF Act.

Shareholders in the Company are 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 from disposal of shares in the Group will not be included in the investor's assessable income in Australia 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	Abbreviated New Drug Applications (ANDAs) are termed “abbreviated” because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and effectiveness of a generic drug product. Instead, generic applicants must scientifically demonstrate bioequivalence to the innovator drug. Once approved, an applicant may manufacture and market the generic drug product to provide a safe, effective, low cost alternative. All approved products, both innovator and generic, are listed in FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book).
Active Pharmaceutical Ingredient	API	Also known as drug substance. A substance used in a finished pharmaceutical product, intended to furnish pharmacological activity or to otherwise have direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease, or to have direct effect in restoring, correcting or modifying physiological functions in human beings.
Addressable market		Sales value for a pharmaceutical product and dosage form. The data is obtained from IQVIA for products for which an Acrux product will directly compete when approved.
Axiron®		Brand name for Acrux’s testosterone replacement therapy solution product that was formerly licensed globally to Lilly. The Axiron® trademark is owned by Eli Lilly.
Bioequivalence/ Bioavailability		Bioequivalence studies compare the bioavailability of the proposed drug product with the Reference Listed Drug (RLD) product containing the same active ingredient. Bioequivalence is defined as the absence of a significant difference in the rate and extent to which the drug (active ingredient) becomes available at the site of drug action when administered at the same dose under similar conditions.
Competitive Generic Therapies	CGT	The FDA Reauthorization Act of 2017 (FDARA) created a new pathway by which FDA may, at the request of the applicant, designate a drug with “inadequate generic competition” as a competitive generic therapy (CGT). At the applicant’s request, FDA may expedite the development and review of an abbreviated new drug application (ANDA) for a drug designated as a CGT. FDARA created a new type of 180-day exclusivity, different from 180-day patent challenge exclusivity, for the first approved applicant of a drug with a CGT designation for which there were no unexpired patents or exclusivities listed in the Orange Book at the time of original submission of the ANDA.
Contract Manufacturing Organisation	CMO	A CMO is a company that serves other companies in the pharmaceutical industry on a contract basis to provide services that include product scale and commercial drug manufacturing.
Contract Research Organisation	CRO	A CRO is a company that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis.
Estradiol		Estradiol is a form of estrogen, a female sex hormone produced by the ovaries. Estrogen is necessary for many processes in the body.
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 Hungary, is a major pharmaceutical company in Central Eastern Europe, with an expanding direct presence in Western Europe. Consolidated sales for 2020 exceeded EUR 1.6 billion, and market capitalisation was in excess of EUR 3.8billion. Richter’s product portfolio covers a range of therapeutic areas, including gynaecology, central nervous system and cardiovascular. Richter is a significant player in the female healthcare field worldwide.
Generic medicine		A generic medicine provides the same quality, safety and efficacy as the original brand name product and undergoes strict scrutiny before it is licensed and given market approval by national regulatory authorities.
Good Manufacturing Practice	GMP	Set of manufacturing principles and procedures that when followed helps ensure therapeutic goods are of high quality.

Term	Abbreviation	Description
In-vitro Permeation Testing	IVPT	In-vitro permeation testing studies across biological membranes for formulations that are applied to the skin are vital to guide product development and establish product bioequivalence. IVPT is a critical tool for understanding drug delivery into the various layers of skin and can aid in formulation selection.
In-vitro Release Testing	IVRT	Measurement of drug release from complex dosage forms intended for topical application is important for some drug product bioequivalence testing. IVRT allows for targeted and systematic drug development and guides the establishment of therapeutic equivalence. IVRT involves subjecting the drug formulation to conditions that will induce drug release across a membrane and quantitating the amount of drug released under those conditions. In development, it is an essential test in assessing differences between formulations, predicting the timeframe of API release and modelling in vivo behaviour.
IQVIA (formerly IMS)		IQVIA, formerly Quintiles and IMS Health, Inc., is a US based multinational company which provides, on a subscription basis, pharmaceutical industry-leading sales data from over 90 countries.
Lenzetto®		Brand name for Acrux's unique Estradiol spray in the European Union. The Lenzetto® trademark is owned by Gedeon Richter.
New Drug Application	NDA	When the sponsor of a new drug believes that enough evidence on the drug's safety and effectiveness has been obtained to meet FDA (or other national health regulator) requirements for marketing approval, the sponsor submits to the regulator a new drug application (NDA). The application must contain technical data for review, including chemistry, pharmacology, medical, biopharmaceutics, and statistics. If the NDA is approved, the product may be marketed in the in that country.
Omnibus Equity Plan	OEP	Approved at 2020 AGM to govern the issue of securities to employees and Directors.
Orange Book		The publication Approved Drug Products with Therapeutic Equivalence Evaluations is commonly known as the Orange Book and identifies drug products approved on the basis of safety and effectiveness by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act and related patent and exclusivity information.
Paragraph IV filing or Paragraph 4 filing	PIV	A type of ANDA submitted during the patent term of the originator product. The filing asserts that either the patents supporting the originator product are invalid or that they are not applicable ("not infringed") to the product that is the subject of the ANDA.
Pharmacokinetic	PK	Pharmacokinetics is defined as the study of the time course of drug absorption, distribution, metabolism, and excretion.
Pooled Development Fund	PDF	Refer to separate section in the Annual Report for an overview of PDF or the following website www.business.gov.au/assistance/pooled-development-funds .
Product-Specific Guidance	PSG	To facilitate generic drug product availability and assist the generic pharmaceutical industry identify the most appropriate methodology for developing drugs and generating evidence to support ANDA approval, FDA publishes product-specific guidance describing the FDA's current thinking and expectations on how to develop generic drug products therapeutically equivalent to specific reference listed drugs.
Reference Listed Drug	RLD	An RLD is an approved drug product to which new generic versions are compared to show that they are bioequivalent.
Testosterone		Testosterone is a naturally occurring sex hormone that is produced in a man's testicles.
Total Shareholder Returns	TSR	Total Shareholder Returns, measured by the annual share price increase.
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.
Topical		Topical is a route of administration wherein active pharmaceutical ingredients are applied to, or affect a localised area of the body.

CORPORATE DIRECTORY

COMPANY INFORMATION

Directors

R Dobinson – Non-executive Chairman

G Brooke – Non-executive Director

D Brumley – Non-executive Director

T Oldham – Non-executive Director

M Kotsanis – CEO and Managing Director

Company Secretary

Joanna Johnson

Registered Office

103-113 Stanley Street
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Victoria 3003

Principal Business Address

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Australian Business Number

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Auditor

Pitcher Partners

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Share Registry

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Australian Securities Exchange Listing

Australian Securities Exchange Limited
(Home Exchange: Melbourne, Victoria)

ASX Code: ACR

For further information about Acrux and its operations, refer to Company Announcements of the Australian Securities Exchange and to the Company website: Acrux.com.au

