Annual Report 2023

A Pivotal Year

ACRUX

Acrux (ASX:ACR) is a specialty pharmaceutical company with a successful track record of developing and commercialising a pipeline of topically applied pharmaceutical products.

Drawing on 25 years of experience, Acrux has successfully marketed a number of products worldwide, with an emphasis on the United States.

Acrux is formulating and developing a range of topical generic products through leverage of its highly skilled workforce, on-site laboratories, GMP manufacturing suite, technical, clinical and commercial experience to bring affordable products to market.

Acrux encourages collaboration and is well positioned to discuss commercial partnering and product development opportunities.

Acrux Formulation Scientist, Kayla.

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Acrux Cover: Formulation Scientist, Kara.

ABOUT THIS REPORT

This Annual Report combines Acrux's financial and non-financial performance into a single document which links strategic priorities to our operational results. 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 future actual results, performance or achievements of Acrux to differ from state-ments made in this report. Download here: www.acrux.com.au/annualreport

Operating and Financial Review

FY23 has been a pivotal year for Acrux which saw:

- **Prilocaine 2.5% and Lidocaine 2.5%, Cream launched with superior market share achieved**
- **Dapsone 5%, Gel approved by the FDA, to be launched in FY24**
- **Nitroglycerin 0.4%, Ointment submitted for FDA review**
- **Acyclovir 5%, Cream submitted for FDA review**
- **Executed royalty buyout of Lenzetto® to release working capital to fund portfolio progression**

With 5 year CAGR of revenue of almost 30% and with 3 products currently under FDA evaluation including 1 planned for launch in FY24, Acrux is achieving sustainable revenue growth which is capable of funding future portfolio development.

FY23 PORTFOLIO PROGRESSION

Launched
Prilocaine 2.5% and Lidocaine 2.5%, Cream

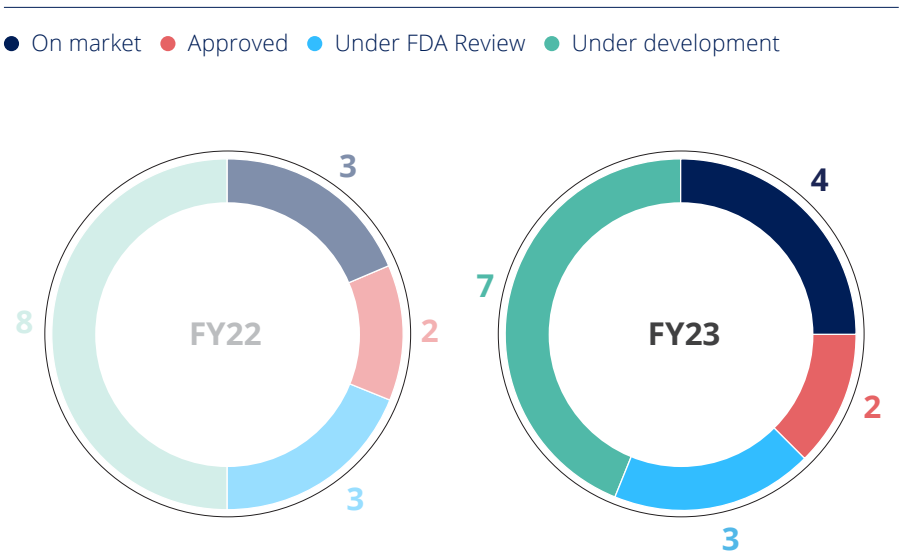
Approved
Dapsone 5%, Gel

Accepted by FDA for review
Nitroglycerin 0.4%, Ointment

Accepted by FDA for review
Acyclovir 5%, Cream

3 dossiers currently under FDA review

PORTFOLIO PROGRESSION FY22–FY23



CASE STUDY

Prilocaine 2.5% and Lidocaine 2.5%, Cream was launched in the US in December 2022 by our partner Padagis. This product is a generic version of EMLA® Cream, indicated as a topical anaesthetic for use on normal intact skin for local analgesia, genital mucous membranes for superficial minor surgery and as a pre-treatment for infiltration anaesthesia. IQVIA reported annual sales of this product of US$37.9 million for the 12 months to April 2023.

Early in 2023 a key competitor filed for bankruptcy and withdrew from the market. Since then Padagis has achieved superior market share and Prilocaine 2.5% and Lidocaine 2.5%, Cream is exceeding expectations.

Acrux Senior Formulation Scientist, Jean.

Product Development Pipeline

Our key focus is to progress our products through the stages of formulation and development, to demonstrate bioequivalence, to be reviewed and approved by the regulatory agency and to commercialise.

GENERIC DRUG, FDA DEFINITION

A generic drug is identical to the brand name drug in dosage, safety, strength, how it is taken, quality, performance, and intended use. Before approving a generic drug product, the FDA requires many rigorous tests and procedures to be conducted to assure it can be safely substituted for the brand name drug. The FDA bases their evaluations of substitutability, or "therapeutic equivalence," of generic drugs on scientific evaluations. By law, a generic drug product must contain the identical amounts of the same active ingredient(s) as the brand name product. Drug products evaluated as "therapeutically equivalent" can be expected to have equal effect when substituted for the brand name product.

PRODUCT DEVELOPMENT PHASE

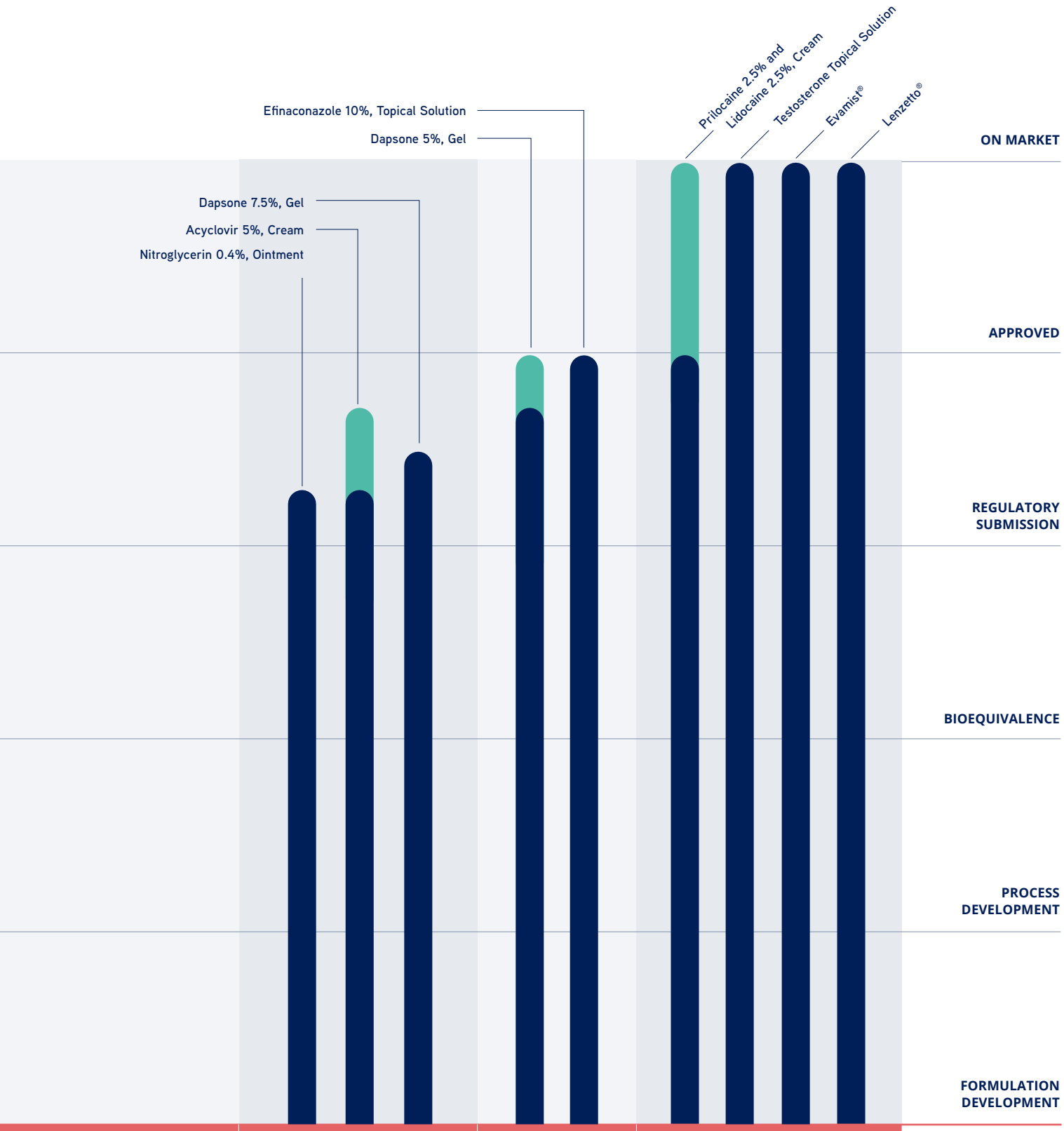
The timeline presented on this page is not strictly sequential and there is overlap between project phases, eg. elements of Formulation Development and Process Development can be performed concurrently rather than sequentially.

An average product development timeline is 4 to 5 years with 3 years being the perfect scenario for a simple formulation.

TIMELINE FACTORS

Complex generics such as topical, otic, and ophthalmic products which Acrux develops have a more challenging pathway to demonstrate therapeutic equivalence compared to simple generics (eg tablets taken orally).

	FORMULATION DEVELOPMENT	PROCESS DEVELOPMENT
Typical Duration	18 to 36 months	18 to 36 months
Activity	Inhouse laboratory, determine characteristics of the formulation and interaction of ingredients	Scale up to commercial manufacturing
Outcome	Determine the product formulation	Making the formulation at commercial scale



4 to 12 months	12 to 24 months	3 to 6 months	
BIOEQUIVALENCE	REGULATORY SUBMISSION	APPROVAL/ LAUNCH	ON MARKET
Proof the product is therapeutically bioequivalent	Submit dossier and data to support approval	Review of dossier	Launched by partner after approval
Demonstrate equivalence to brand name product	Review and approval by regulator (FDA)	Approved	Revenue Stream

Product launches, approvals and ANDA submissions drive strengthening of Acrux's portfolio.

Since 2017, Acrux has been pursuing a strategy of developing a product portfolio capable of generating broadly based and sustainable revenue.

Our long term objective is to create a diversified portfolio capable of generating a consistent stream of regulatory submissions for pharmaceutical product approvals and launches. The Company's strategy is beginning to bear fruit, with the recent regulatory submission of our seventh product to the FDA since 2017. Three of those products are currently under FDA review and our portfolio of products on market is continuing to grow following approvals granted by the FDA

Prilocaine 2.5% and Lidocaine 2.5%, Cream was launched late in 2022. This product is indicated for use as a local anaesthetic and it is directly substitutable into an existing market for a widely used product. Over 230,000 tubes of this product are currently used on patients each month in the United States, based on twelve months of IQVIA data. Following our product's commercial launch, the major supplier for that market announced in February 2023 that they were immediately ceasing operations due to their unfortunate bankruptcy. As a result, Acrux together with its commercial, manufacturing and raw materials partners have been focussed on procurement, manufacturing and supply of this product to the United States market. The increased product demand and supply generated following these developments are considerably above Acrux's expectations when the product was initially launched.

Early in 2023 Acrux monetised its royalty stream for Lenzetto®, its Estradiol Spray product that is sold in Europe and a number of countries outside Europe. That transaction optimised this product's value to Acrux and provided Working Capital to be invested into product development and regulatory activities supporting the progression of the commercialisation of several products for the United States market.

In June 2023, the FDA's approval of the Company's generic Dapsone 5%, Gel product for the treatment of acne was announced and launch preparations are well underway for this product.

In early July 2023, Acrux announced that its seventh Abbreviated New Drug Application (ANDA) was accepted for review by the FDA. The product is a generic of Nitroglycerin 0.4%, Ointment which is used for moderate to severe pain as a result of chronic anal fissure.

The Company relaunched Testosterone Topical Solution, 30mg/1.5mL as a generic in August 2021, with modest expectations at the time, as the market had been significantly eroded by generic competition which began in July 2017 when the first generic of Axiron® (Testosterone Topical Solution) was launched and which lead to withdrawal of the product by Acrux's licensee. The US market for testosterone replacement therapies has been in decline on a year on year basis since 2014 and with significant levels of generic competition evident for Testosterone Solution and other transdermal versions of testosterone the commercial viability of this market is diminished.

FINANCIAL PERFORMANCE

Acrux's reported revenue totalled $11.928 million which was up by $6.825 million or 134%, over the prior financial year. Monetisation of the Lenzetto® royalty stream added $6.337 million. After excluding this transaction, the underlying annual growth of Acrux's total revenue was 10%. The 5 year Compound Annual Growth Rate (CAGR) of revenue from licensing arrangements for the period FY18 to FY23 is 26% and for total revenue the 5 year CAGR is 28%.

With the strong opportunity for Prilocaine 2.5% and Lidocaine 2.5%, Cream and with launch plans well under way for Dapsone 5%, Gel we expect revenue from licensing arrangements to continue to grow through FY24.

Strong revenue growth achieved in FY23 was the key driver behind the material reduction of Acrux's reported Loss after tax. The Net loss for the year for FY23 totalled $0.764 million, which represents an improvement of $9.070 million over the prior financial year.

Cash and cash equivalents on hand at year end totalled $6.232 million, representing an increase of $0.401 million over the prior year end, without needing to draw on either external debt or equity funding.

	Annual FY22	6 months to December 2022	6 months to June 2023	Annual FY23
Revenue	5,103	3,249	8,679	11,928
Profit/(loss) before tax	(9,582)	(3,083)	2,871	(212)
Cash reserves	5,831	4,350	6,232	6,232
Increase/(Decrease) in Cash reserves	(8,819)	(1,481)	1,882	401

Seven topical generic products have been submitted to the FDA for review since 2017.

A comparison of the annual and half year operating financials shows Acrux's achievement of strong progress and growth particularly in the second half of FY23 with significantly higher revenue resulting in a profitable second half which in turn supported the generation of positive cashflows for the 6 month period as well as increased cash on hand for the year ended 30 June 2023.

THE PRODUCT DEVELOPMENT PIPELINE

Acrux has three products currently under FDA review and an additional two products which have been approved but which have not yet launched.

Our product pipeline is progressing through varying stages of development, both at Acrux and with our contract manufacturing partners. We are working on both later-stage products that are expected to reach commercialisation in the short term and are progressing the development of earlier-stage products to ensure breadth of our product pipeline.

The Company continues to have 16 products in its portfolio. This includes 6 approved products and 3 dossiers which are currently being reviewed by the FDA and over time intends to maintain 10–12 products in development.

The product development pipeline is shown in an infographic on pages 4 and 5, and FY23 progress is expanded on in the Operating and Financial Review on pages 2 to 3.

Our corporate strategy is reflected in our operational structure and the processes in place to deal efficiently and effectively to meet our revenue generation objectives.

Acrux Analytical Development Scientist, Ebenezer.

The Company has invested to secure and maintain the necessary blend of skills, knowledge and experience to deliver on our strategic priorities.

Acrux Analytical Development Scientist, Amal.

STRATEGY

Acrux's strategy focuses on the development and commercialisation of topically applied pharmaceutical products

Within our strategy there are three key priorities:

1. Revenue realisation
2. Operational effectiveness
3. Optimal portfolio management

Revenue realisation is the transformation driver for the Company to be self-funding and consistently profitable. In FY23 we reported a 134% increase in total revenue, which is reflected an increase on cash and cash equivalents of $0.401 million.

The number of commercialised products will continue to expand following the launch of Prilocaine 2.5% and Lidocaine 2.5%, Cream, with Dapsone 5%, Gel launch activities underway following its approval in June 2023 and ANDAs of a further 3 products currently being reviewed by the FDA.

Operational effectiveness is supported by project management, resource and cost management to enabling Acrux to continue to submit ANDA's for FDA review and commercialise our diversified portfolio of topically applied pharmaceutical products.

Portfolio management to maximise commercial returns based on strategic product selection of commercially attractive products and for which we have the technical capability to develop. Ongoing market intelligence gathering and assessment in a rapidly changing product and market landscape is a key component of successful portfolio management.

The Company has invested to secure and maintain the necessary blend of skills, knowledge and experience to deliver on our strategic priorities.

Through FY24 we plan:

- Continued revenue growth of Prilocaine 2.5% and Lidocaine 2.5%, Cream
- To launch Dapsone 5%, Gel
- To obtain FDA approval to support the future launches of products which are currently progressing through the FDA review process; specifically
  - Dapsone 7.5%, Gel
  - Acyclovir 5%, Cream and
  - Nitroglycerin 0.4%, Ointment
- To continue eligibility of product development expenditure for the research and development tax incentive rebate.

BOARD AND CORPORATE GOVERNANCE

During the year, the Board has reviewed and where necessary updated all Corporate Governance policies as part of the routine review cycle. Current Corporate Governance policies can be viewed on the Acrux website under the Corporate Governance tab. The Board has also reviewed the skills that each Director brings to the Board through the Board Skills Matrix in order to ensure Directors with appropriate skills and experience are in place to lead the Company and to identify potential gaps in skill sets, areas for improvement and to plan for future skill requirements.

The Directors consider that Acrux has complied with all applicable laws and regulations throughout the year ended 30 June 2023 and no related issues have arisen between the end of the financial year and the date of this report.

The detailed Environment, Social and Governance (ESG) Report can be found on page 10.

FY23 OBJECTIVES

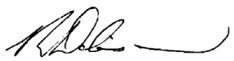
Our key objectives in FY23 were:

- Launch two additional topical generic products.
  - Acrux launched one product in December 2022. Approval for the second product was achieved in June 2023 and launch preparations are now well underway.
- Receive approval from the FDA for two products to facilitate product launches in FY23 and FY24. Each product is already licensed on the basis of a quarterly profit share to Acrux.
  - Acrux received regulatory approval for one product (Dapsone 5%, Gel) in June 2023 and currently has three further products under evaluation by the FDA.
- Submit one further product for FDA approval in the second half of FY23.
  - Acrux submitted its ANDA for Nitroglycerin 0.4%, Ointment in June 2023 and this dossier was formally accepted for review by the FDA in July 2023.

We would like to personally thank the Acrux team and the Board for their valuable contributions through FY23 with the progression of ANDAs through the FDA review process to commercialisation and focus on the Company's revenue growth objectives.

We believe the 2023 financial year was a pivotal period for Acrux and we would like to thank our shareholders for maintaining faith in our progress. This is an exciting time for Acrux. We thank you for your support.

$6.232m
Cash on hand
Increased by
$0.401m



Ross Dobinson
Chairman (l)

Michael Kotsanis
CEO & MD (r)

Environment, Social and Governance

Acrux is developing a range of topically applied generic medicines that improve affordability for patients and which conform with the highest possible product safety and regulatory requirements. The Company is committed to operating in a socially responsible manner, which we consider in three key operational tenets:

TENETS

Environmental Tenet – includes preservation of our natural environment.

Social Tenet – consideration of the safety and wellbeing of patients and our employees.

Governance Tenet – practising good corporate governance.

We are responsible to the communities in which we operate as well as our stakeholders.

TENETS

At the heart of Acrux's Environment, Social and Governance (ESG) framework is our commitment to long term economic and environmental sustainability and to conducting business in a responsible and ethical manner. We consider this commitment to be important to the way we develop and commercialise our range of topically applied generic medicines which are both affordable and meet the highest possible product safety and regulatory standards. Our purpose is closely aligned with our culture, values, behaviours and strategy.

This report outlines Acrux's ongoing commitment to ESG objectives and to the enhancement of the economic, social and environmental wellbeing in and of our community.

Acrux's commitment to operating in a socially responsible manner is considered through three key operational tenets:

1. **Environmental Tenet** – includes preservation of our natural environment through minimising the use of energy and the discharge of waste,
2. **Social Tenet** – includes consideration of Acrux's relationships in its community such as employee diversity, equity, equality and inclusion priorities and care for the safety and wellbeing of our employees and other stakeholders, and
3. **Governance Tenet** – practising good corporate governance and conducting business in an ethical and socially accountable manner.

Through our Code of Conduct, corporate values and policies our ESG framework is embedded throughout our operations and we prioritise activities and initiatives to achieve high standards in each of these tenets.

Environmental Tenet

Acrux is committed to conducting operations in an environmentally responsible manner and we adopt practices to guide our actions to lead to sustainable outcomes through the minimisation of energy usage and reduction of emissions which are associated with our building operations, laboratory and office equipment.

Acrux applies strategies to minimise general office waste such as the use of consumables, avoiding single use vessels, reusing office supplies where practical and maximising the use of digital document management and shareholder communication strategies to reduce our use of paper based products. Across our laboratory, office and staff kitchen recycling bins collect common recyclables to facilitate the recycling of waste which could otherwise become landfill.

Acrux's employees are trained in standard operating procedures to manage the types of laboratory waste which are generated in our laboratory and we have documented procedures to ensure all hazardous, controlled and non-hazardous waste is disposed of strictly in accordance with relevant environmental regulations, standards and codes. Acrux holds licences to store and use hazardous and controlled substances and an agreement is in place with City West Water under the *Water Industry Act 1994* and *Water Industry Regulations 2006*, to ensure our trade water waste is managed effectively and responsibly. All waste, including laboratory waste, is safely collected, transported and disposed of and is recycled where possible. To ensure compliance with the *Environment Protection Act 1970* an external waste management consultant with ISO 14001:2015 Certification for Environmental Management is used and an EPA Transport Certificate is issued for each hazardous or controlled waste collection.

The Directors consider Acrux has complied with all applicable environmental laws and regulations throughout the year ended 30 June 2023 and no issues have arisen since the end of the financial year to the date of this report.

Social Tenet

Acrux deeply values its highly skilled team and is committed to providing a healthy and safe work environment for all employees as well as our contractors and visitors. Health, safety and wellbeing is a key priority as is ensuring our employees have the necessary skills and resources to perform their roles to a high standard.

Together with practicing safer systems of work, occupational health and safety is deeply ingrained into Acrux's company culture and we have proactive and well developed processes of capturing safety data, including near misses. In the event that a near miss incident is reported it is thoroughly investigated and corrective measures are put in place where necessary. We have not recorded a Lost Time Injury since 2016.

Our culture is supportive, equitable and inclusive. Diversity is embraced and celebrated as we believe this not only promotes safety, productivity and wellbeing but also enhances our ability to attract and retain skilled employees. We seek to attract and retain a workforce that represents our broader community and to remove unconscious biases from all of our behaviours, policies and processes.

Acrux's Diversity and Inclusion Policy can be viewed in the Investor Relations section of our website, https://investors.acrux.com.au/investor-centre and this policy is integral to our talent management and recruitment strategies. Diversity is broadly defined to include gender, nationality, ethnicity, disability, sexual orientation, gender identity, age, socioeconomic status, family status, religious beliefs and language.

Our Diversity and Inclusion objectives support our employees to be valued and respected in the workplace and to experience fair treatment and merit based access to opportunities. Our Diversity and Inclusion priorities include fostering an inclusive culture as well as building the skills and confidence of our leaders to manage diverse teams to improve diversity amongst our leadership and to ensure our workplace is safe for and attractive to a diverse range of people.

Governance Tenet

Acrux is committed to good corporate governance, including ethical conduct.

Acrux's corporate governance policies are published on the Company's website, https://www.acrux.com.au and the Company's *RIOS – Together Anything is Possible* model articulates our Company Values and the core behaviours expected of all employees. These core Company Values are: *Round the clock, Innovation, Openness* and *Standout*. Commitment to these Company Values underpins how our employees work together to solve problems and make decisions and must be demonstrated in order for an employee to be invited to participate in short and long term incentive programs.

GOVERNANCE STRUCTURE

Ethics and Values

Acrux has a well established governance program. All Directors, employees and other parties representing the Company are required to follow the Company's principles, moral, legal and ethical standards as consistent ethical behaviour promotes both inclusion and trust.

Our Code of Conduct documents and communicates the framework for the way Acrux conducts business and relates to its stakeholders, including shareholders, employees, business partners, customers and suppliers as well as the wider community and the environment in which the Company operates. We expect third parties with which we work to comply with the principles outlined in our Code of Conduct which can be viewed in the Investor Relations section of our website, https://investors.acrux.com.au/investor-centre.

It is important that Acrux's employees and other stakeholders feel safe and empowered to report concerns about behaviour which may appear to be inconsistent with our Code of Conduct or other corporate policies. Our Whistleblower Policy ensures such reports can be made in good faith and with the confidence they will be investigated fairly and confidentially whilst the person who made the report is protected. Our Whistleblower Policy can be viewed in the Investor Relations section of our website, https://investors.acrux.com.au/investor-centre.

No breaches of the Code of Conduct, Whistleblower or the Antibribery, Corruption and Fraud Policies have been reported.

Structure of the Board and Board Committees

Acrux's corporate governance and risk and compliance framework reflects and supports the Company's values and culture and stands alongside the legislative requirements of the *Corporations Act 2001* and the guidance in the ASX Corporate Governance Council's Corporate Governance Principles and Recommendations (4th edition).

All governance practices as recommended by the ASX have been implemented by Acrux, unless otherwise stated in the Corporate Governance Statement. Our Corporate Governance Statement is considered and approved by the Board annually and it can be viewed in the Investor Relations section of our website, https://investors.acrux.com.au/investor-centre.

The Board Charter is central to Acrux's corporate governance framework as it lays out the principles under which the Board of Directors operates and this document can be viewed in the Investor Relations section of our website, https://investors.acrux.com.au/investor-centre. In summary, the Board of Directors is responsible for overseeing management, providing strategic direction, capital planning, risk management, monitoring performance, strategic human resource matters and approval of budgets and business plans. Day-to-day management as well as the implementation of approved strategies and business plans, is delegated to the CEO and Managing Director as well as the leadership team.

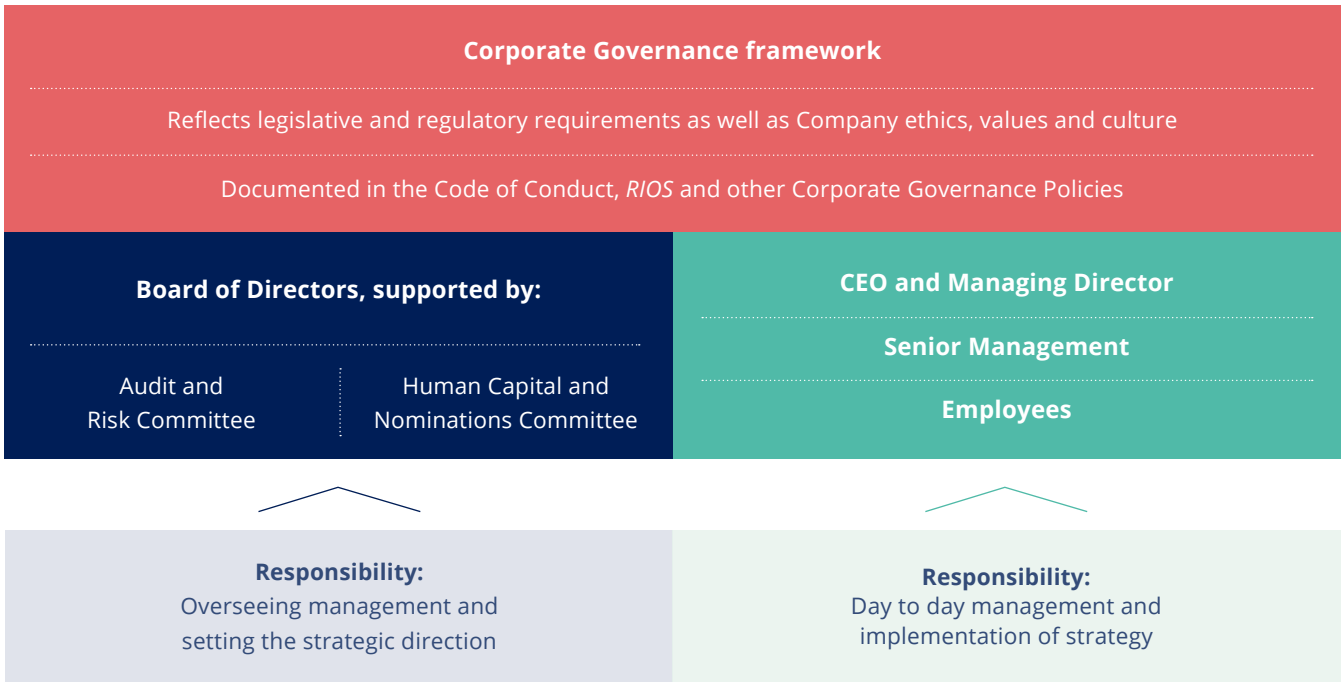
To ensure it can perform its responsibilities, the Board maintains an appropriate mix of skills in its membership, including individual experience and background in the pharmaceutical industry, leadership and strategy, international business, legal, finance and accounting, risk management, corporate governance, organisation and talent development as well as team fit and balance within the Board. Directors are required to demonstrate commitment to the Company's *RIOS – Together Anything is Possible* values.

Details of the members of the Board, their experience and personal qualifications are stated in this Annual Report.

The Board has established an Audit and Risk Committee to assist the Board fulfil its corporate governance and oversight responsibilities relating to financial accounting practices, internal control systems, risk management, external financial reporting and audit. The Audit and Risk Committee is responsible for the evaluation of Acrux's risk profile and the assessment of risks and mitigation strategies which have been identified and implemented by management. The Audit and Risk Committee Charter can be viewed in the Investor Relations section of our website, https://investors.acrux.com.au/investor-centre.

The Human Capital and Nominations Committee has been established by the Board to ensure the Board is comprised of individuals who can best discharge the responsibilities of Directors and to ensure the Company recruits and retains employees of high quality and motivation to drive long term growth. Responsibilities of the Human Capital and Nomination Committee include recruitment as well as the establishment of the short and long term remuneration framework and other people-related policies. The Human Capital and Nominations Committee Charter can be viewed in the Investor Relations section of our website, https://investors.acrux.com.au/investor-centre.

Where appropriate, these Board Committees make recommendations for consideration by the Board.



BOARD OF DIRECTORS AND SENIOR MANAGEMENT

The following persons were Directors of Acrux during and since the end of the financial year:

Ross Dobinson
Chairman, Non-executive Director

Michael Kotsanis
Managing Director and Chief Executive Officer

Geoffrey Brooke
Non-executive Director

Don Brumley
Non-executive Director

Timothy Oldham
Non-executive Director

There were five directors throughout the year, comprising four independent, Non-Executive directors and one Executive director. All Directors held office from the commencement of the financial year through 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 since 1 July 2022 is provided below, together with details of the Company Secretary as at the year end.

Ross Dobinson
Appointed March 1998

Responsibilities
Chairman, Independent Non-executive Director

Qualifications
BBus (Acc)

Experience
Ross has been a Director since 1998, was first appointed as 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 a founding Director of Starpharma Holdings Limited (ASX: SPL), Executive Director 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.

Michael Kotsanis
Appointed November 2014

Responsibilities
Managing Director and Chief Executive Officer

Qualifications
BSc, Grad Dip Bus, MBus

Experience
Michael has more than 30 years of experience in the global pharmaceutical industry including significant senior leadership experience. 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. He has 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 led the commercial activities 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 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 a former Non-executive Director of IDT Australia Limited (ASX: IDT).

Geoff Brooke
Appointed June 2016

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

Qualifications
MBBS, MBA

Experience
Geoff founded GBS Venture Partners in 1996 and has more than 30 years of venture capital experience. In 2014, he reduced his involvement in GBS and is now special adviser to the firm and its funds. Geoff was formally President of Medvest, 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 2017 as Chairman of Actinogen Medical Limited (ASX: ACW) and has been a founder, executive and director of private and public companies. In 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 Australia and his post-graduate work was in anaesthetics and intensive care. He earned his Bachelor of Medicine/Surgery from the University of Melbourne and a Master of Business Administration from IMEDE (now IMD) in Lausanne, Switzerland.

Don Brumley
Appointed June 2021

Responsibilities
Independent 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 Chairman and non-executive director of Bio-Gene Technology Ltd (ASX: BGT).

Tim Oldham
Appointed October 2013

Responsibilities
Independent 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 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), a clinical stage biotech company developing an innovative range of new antibody-like drugs. Prior to this, he led Tijan Ventures, a life sciences advisory business focussed on strategic advisory and leadership services and acquiring cell and gene therapy assets. He was 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 which encompassed the development and commercialisation of generic pharmaceuticals, devices, biologics and cellular therapies. Tim began his career as an engagement manager with McKinsey & Company.

Tim is a Non-executive Director of BioMelbourne Network Inc and has chaired the European Generic Medicines Association Biosimilars and Biotechnology Committee and been a Non-executive Director of the Alliance for Regenerative Medicine and Non-executive Director of the Generic Medicines Industry Association.

INFORMATION ON SENIOR MANAGEMENT

Joanna Johnson
Appointed as Company Secretary, June 2021

Responsibilities
Chief Financial Officer and Company Secretary

Qualifications
CA, BEc, Grad Dip Management

Experience
Joanna is an experienced Chief Financial Officer and Company Secretary and is a member of the Institute of Chartered Accountants Australia and New Zealand. She has more than 25 years of 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, risk management, corporate compliance and investor relations.

Felicia Colagrande
Appointed February 2015

Responsibilities
Product Development and Technical Affairs Director

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 bioequivalence, with a focus on generic topical product development and exploiting the company's drug delivery technology.

Felicia has over 25 years of experience in the pharmaceutical/biotech industry and she joined 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
Appointed July 2020

Responsibilities
Project and Technical Development Director

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 and has held 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.

Directors' Report (including Remuneration Report) and Financial Statements

Acrux Formulation Scientist, Steven.

Directors' Report

For the year ended 30 June 2023

The Board of Directors of the consolidated entity consisting of Acrux Limited ('Acrux') and its controlled entities (collectively the 'Group') has pleasure in presenting this report for the financial year ended 30 June 2023. Complying with the provisions of the *Corporations Act 2001*, the Directors report as follows:

DIRECTORS

The following persons were Directors of Acrux during and since the end of the financial year:

Ross Dobinson	Chairman, Non-executive Director
Geoffrey Brooke	Non-executive Director
Don Brumley	Non-executive Director
Timothy Oldham	Non-executive Director
Michael Kotsanis	Managing Director and Chief Executive Officer

All Directors have held office from the commencement of the financial year to the date of this report. Biographical details of each of the Directors and the Company Secretary are provided in the Governance Section of this Annual Report, including their period of office, qualifications, independence, experience, particular responsibilities and other directorships.

ATTENDANCE OF MEETINGS

	BOARD OF DIRECTORS		AUDIT AND RISK COMMITTEE		HUMAN CAPITAL AND NOMINATION COMMITTEE	
	HELD	ATTENDED	HELD	ATTENDED	HELD	ATTENDED
Ross Dobinson	6	6	–	2*	–	2*
Geoffrey Brooke	6	5	2	2	2	2
Don Brumley	6	6	2	2	2	2
Timothy Oldham	6	5	2	2	2	2
Michael Kotsanis	6	6	–	2*	–	2*

Directors who are not Committee members are invited to attend Committee meetings. Where a Director has attended a Committee Meeting of which they are not a member their attendance is denoted with an asterix (*).

PRINCIPAL ACTIVITIES

Acrux is a specialty pharma company with a successful track record of developing and commercialising a pipeline of topically applied 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:

Operating review

Acrux continues to work towards its objective of developing a pipeline of topically applied generic pharmaceutical products for commercialisation through licensees and with an emphasis on the US market. Progression of product development projects within this pipeline towards submission, regulatory approval and commercial launch is fundamental to Acrux's strategic success.

Key portfolio progression milestones achieved this year include:

- Prilocaine 2.5% and Lidocaine 2.5%, Cream was launched in the US in December 2022 by our partner Padagis. This product is a generic version of EMLA® Cream which is indicated as a topical anaesthetic for use on normal intact skin for local analgesia, genital mucous membranes for superficial minor surgery and as a pre-treatment for infiltration anaesthesia. IQVIA reports annual sales of this product totalling US$37.9 million for the 12 months to April 2023.

  Early in 2023 a key competitor announced the immediate withdrawal of its product after filing for bankruptcy creating greater opportunity for our product. To capitalise on this opportunity Acrux and its partners have focused on materials sourcing and manufacturing capacity in order to support product demand which is now anticipated to considerably exceed Acrux's expectations when the product was initially launched;
- In June 2023, Dapsone Gel 5%, was approved by the FDA. Dapsone Gel, 5% is the generic equivalent of Aczone® Gel, 5% which is used to treat acne vulgaris. IQVIA reports sales for the product for the 12 months to April 2023 of US$17.6 million. A commercial partner has been licensed for this product and process validation batches are being manufactured to support launch in FY24;
- In July 2023, Acrux's application for a generic version of AbbVie's Rectiv 0.4%, Ointment, Nitroglycerin 0.4%, Ointment, was accepted by the FDA for review. This product treats pain caused by chronic anal fissure and is Acrux's seventh ANDA application to be accepted for FDA review. IQVIA reports sales for the product for the 12 months to April 2023 of US$19.9 million;
- In August 2022, Acrux's application for a generic treatment for cold sores located on the lips and face, Acyclovir 5%, Cream was accepted by the FDA for review. This was the Acrux's sixth ANDA application to be accepted by the FDA and IQVIA reports product sales for the 12 months to April 2023 of US$15.5 million; and
- In January 2022 the FDA conducted a Remote Regulatory Assessment (RRA) of Acrux's laboratory and did not identify any objectionable conditions nor did they make any adverse observations. The FDA conducts RRA's to support their regulatory decisions and they are performed in lieu of a physical inspection.

In support of these key milestones and the progression of the pipeline portfolio, two important funding events were achieved:

- Gedeon Richter Plc's advance buy out of the Lenzetto®'s future royalty stream for their contracted territories, which was due to conclude at the beginning of 2025, for EUR4.1 million; and
- Receipt of $3.731 million in relation to the Research and Development Tax Incentive for FY22, including Overseas Findings, of $0.455 million.

Consequently, Acrux has achieved an increase of Cash Reserves for FY23 totalling $0.401 million without drawing on debt or raising equity funding.

Progression of Acrux's portfolio of products

	FY20	FY21	FY22	FY23
Commercialised[1]	2	2	3	4
Approved	2	4	5	6
Under review by FDA	5	2	3	3
Under development	8	11	8	7
Total products in portfolio	**15**	**17**	**16**	**16**

(1) Commercialised products are also included in the Approved category.

Acrux currently has three products which have received FDA approval and are currently marketed in the US:

- Prilocaine 2.5%, and Lidocaine 2.5% Cream, which was launched in December 2022 and is a topical anaesthetic marketed by Padagis,
- Estradiol Spray, which is used to treat symptoms associated with menopause and is marketed as Evamist® by Padagis, and
- Testosterone Topical Solution, 30mg/1.5ML, which is used to treat conditions in males caused by a lack of testosterone and is marketed by Dash Pharmaceuticals.

Furthermore, internationally Estradiol Spray is approved for sale and is marketed as Lenzetto®.

Two further products have been approved by the FDA but are yet to be launched:

- Dapsone 5%, Gel was approved in June 2023 and is a treatment for acne vulgaris. This product is planned for launch in FY24 and launch plans are progressing with our commercial partner and manufacturer, and
- A generic of Jublia® (efinaconazole) 10%, Topical Solution, which is used to treat fungal infections of toenails. Acrux will commercialise this product in the future in accordance with the terms of the Settlement Agreement of the Paragraph IV patent litigation.

The FDA has accepted and is currently reviewing the following dossiers:

- Nitroglycerin 0.4%, Ointment, which is a treatment for pain caused by chronic anal fissure,
- Acyclovir 5%, Cream, which is a treatment for cold sores, and
- Dapsone 7.5%, Gel, which is a treatment for acne vulgaris.

The FDA's guidelines for the approval of products which seek to demonstrate their bioequivalence through IVPT and IVRT techniques are evolving and this is being reflected in product approval timelines in some cases. The Company believes it has provided the necessary evidence to support approval and the three products currently under review are expected to be approved once the FDA's assessments are complete.

Beyond these approved and commercialised products, Acrux continues to advance its pipeline of products through projects which are in varying stages of development, both in our in house laboratory and with our contracted development and manufacturing partners. The Company's key focus is on later stage projects that can be submitted for review in the nearer term, while continuing to identify new opportunities and to progress development on earlier stage products to ensure the breadth of the product pipeline is maintained over time.

Overall, Acrux now has 16 products in its portfolio various stages of development and commercialisation.

Financial Performance

Acrux reports a materially improved consolidated loss before tax totalling $0.212 million which is $9.370 million lower than the consolidated operating loss before tax for the prior corresponding period (2022: $9,582 million). This turn around is due to both an increase in reported revenue and a reduction of operating expenses.

Acrux's cash reserves have increased by $0.401 million to $6.232 million, with this increase achieved without drawing on any external debt or equity funding. Significant funding events achieved through the year include Gedeon Richter Plc.'s advance buy out of the future Lenzetto® royalty stream, which was due to conclude early in 2025 in the contracted territories, for EUR4.10 million. This advance royalty buy out and the receipt of $3.731 million in relation to the Research and Development Tax Incentive (RDTI) for FY22 have supported Acrux's capacity to provide the necessary working capital to fund the progression of the product pipeline whilst also adding to Acrux's total available cash reserves through the current reporting period.

Further information about the consolidated loss before tax is reported in the Consolidated Statement of Profit or Loss and Other Comprehensive Income and Notes 4, 5 and 6.

Revenue

At $11.928 million, Revenue and other income for the year was $6.825 million higher than the prior corresponding period (2022: $5.103 million).

The most important individual revenue transaction for FY23 was the buy out of the future Lenzetto® royalties which were due to conclude at the beginning of 2025 for a contracted sum of EUR4.1 million in January 2023. The future royalties received as a settlement sum received totalled $6.337 million plus $0.949 million for Lenzetto® royalties received for the period up to the buyout date.

Prilocaine 2.5%, and Lidocaine 2.5%, Cream was launched at the end of December 2022. Due to a key competitor exiting this market in February 2023, Padagis has successfully scaled up manufacture and won key new accounts resulting in strong market share gains and Acrux's profit share revenue to the end of June totalling $0.573 million. Furthermore, Acrux is currently responsible for the procurement of ingredients required for the manufacture of Prilocaine 2.5% and Lidocaine 2.5%, Cream and the consequent sale of these ingredients to our commercial partner totalled $0.532 million (2022: $0.263 million).

Dapsone 5%, Gel received FDA approval in June 2023 and plans are underway to launch this product in FY24.

Other Revenue predominantly reflects the RDTI, including overseas finding, which is receivable from the Australian Taxation Office and is estimated at $2.722 million for the year ended 30 June 2023. During September and October 2022, $3.731 million was received in relation to the FY22 RDTI claim, which was $0.654 million higher than had been estimated in the financial statements of the prior reporting period.

Further information about Revenue is reported in the Consolidated Statement of Profit or Loss and Other Comprehensive Income and Note 4.

Expenses

Expenses for the year totalled $12.140 million and were 17% lower than $14.685 million reported in relation to the prior corresponding period. This reduction was achieved despite recognition of the one time impairment of Estradiol® ($0.321 million) following the Lenzetto® royalty buyout and purchases relating to the sale of ingredients required for the manufacture of Prilocaine 2.5% and Lidocaine 2.5%, Cream, ($0.558 million). Externally incurred product Research and Development expenses totalled $3.812 million and were $2.599 million lower than the prior corresponding period. This is due to the timing of external development expenses associated with the progression of pipeline projects, such as bioequivalence studies and manufacturing scaleup.

Employee benefits expense totaled $4.960 million (2021: $5.245 million).

Further information about Expenses is reported in the Consolidated Statement of Profit or Loss and Other Comprehensive Income and Note 5.

Significant changes in the state of affairs
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
In July 2023, Acrux's application for a generic version of AbbVie's Reactiv 0.4%, Ointment, Nitroglycerin 0.4%, Ointment was accepted by the FDA for review. This product treats pain caused by chronic anal fissures and is Acrux's seventh ANDA application to be accepted for the FDA review.

No other matter or circumstance has arisen since 30 June 2023 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 marketed generic topical prescription products. Acrux's future financial results will be materially influenced by the timing of receipt of regulatory approval from FDA for products in the development pipeline and the timing and commercial success of product launches, as well the progression of the pipeline including evaluation and selection of attractive new opportunities.

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 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.

The company has not otherwise, during or since the end of the financial year, except to the extent permitted by law, indemnified or agreed to indemnify an officer or auditor of the consolidated entity against a liability incurred as such an officer or auditor.

REMUNERATION REPORT (AUDITED)
The Directors of the Group are pleased to present the 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 sets out remuneration information for the Group's Key Management Personnel ('KMP'), including any Director, who have authority and responsibility for planning, directing and controlling the Group's activities, either directly or indirectly and explains the remuneration policies and philosophy adopted by the Board. It has been audited as required by s308 (3C) of the *Corporations Act 2001*.

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

The key objectives of the Group's remuneration policy are to:

— remunerate at levels to attract, retain and motivate employees and to reward good performance;
— structure incentives to reward superior performance and increasing long term shareholder value; and
— formally link remuneration to the achievement of business objectives.

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

Remuneration Structure
Employee remuneration is structured in two parts:

— fixed remuneration, comprising salary, superannuation and other benefits which may be provided in lieu of salary, which is benchmarked against remuneration for comparable jobs in the industry sector; and
— variable remuneration which is paid at the discretion of the Board and may comprise a short term incentive paid as a cash bonus and a long term incentive granted in the form of an equity instrument issued under the company's Omnibus Equity Plan.

Short Term Incentive
The short term incentive plan rewards achievement of Company objectives which are established by the Board in consultation with senior management at the beginning of each year and, for some employees, personal objectives which are also established in consultation with line management at the beginning of the year. Company objectives are selected because they create long term value for shareholders and include clearly defined outcomes, such as a product launch, dossier submission or approval or achievement of a key development milestone. Achievement of company and personal objectives are assessed after the end of the financial year.

Subject to assessed achievement of objectives, senior management, other than the Chief Executive Officer, may receive a cash incentive of up to 24% of their fixed remuneration. The Chief Executive Officer may receive a cash incentive up to 25% of his fixed remuneration, and this percentage can be varied at the Board's discretion.

Long Term Incentive
The long-term incentive plan has been designed to align the interests of senior management with shareholders for the achievement of sustainable, long term superior performance and is compliant with the requirements of ASX Listing Rules and the *Pooled Development Funds Act 1992*.

The Omnibus Equity Plan ('OEP') governs the issue of Company securities to employees and Directors and was approved by shareholders at the 2020 Annual General Meeting ('AGM').

Grants of securities to employees under the OEP are summarised as follows:

A. Chief Executive Officer ('CEO')
- At the 2021 AGM the issue of 6 million performance rights was approved. Equal tranches vest annually over 4 successive years, provided the total shareholder return ('TSR') over that period equals is at least 10% and employment is continuous;
- Unvested tranches may be 'rolled over' to following years but are subject to an additional 10% TSR hurdle for each additional year. Each tranche may be rolled over up to 3 times; and
- Subject to achievement of vesting conditions, each performance right carries the right to one ordinary share in Acrux Ltd, expires 7 years after granting and is expensed over the life of the instrument.

B. Senior management, including KMP
- Directors may grant performance rights to senior management, including KMP;
- Grants of performance rights are typically made on an annual basis, subject to the Board's discretion;
- Each grant of performance rights vests after one year, provided the TSR over that period equals is at least 10% and employment is continuous;
- Unvested tranches may be "rolled over" to following years but are subject to an additional 10% TSR hurdle for each additional year. Each tranche may be rolled over up to 3 times; and
- Subject to achievement of vesting conditions, each performance right carries the right to one ordinary share in Acrux Ltd Ltd, expires 7 years after granting and is expensed over the life of the instrument.

C. Employees, excluding KMP
- The Board at its discretion may approve the issue of up to $1000 value of tax exempt ordinary shares to employees who are not KMP each year at nil cost to the employee;
- There are no vesting conditions; and
- Shares are held in escrow for the lesser of 3 years or cessation of employment.

Further information about Share based payments is reported in Note 18 to the accounts.

The following table summarises the Group's earnings and other key performance indicators to 30 June 2023:

	2023	2022	2021	2020	2019	2018
Revenue ($000's)	11,928	5,103	5,156	3,945	5,286	3,432
Loss before tax ($'000)	(212)	(9,582)	(12,432)	(9,385)	(8,335)	(16,125)
Dividends paid to shareholders	–	–	–	–	–	–
Share Price at end of the year (cents)	4.2	5.2	13.0	14.5	18.0	14.5
Basic earnings/(loss) per share (cents)	(0.27)	(3.46)	(5.75)	(5.65)	(5.00)	(8.52)
Number of Ordinary Shares on Issue	288,175,456	285,364,669	283,305,394	168,583,515	166,577,711	166,521,711
Market Capitalisation ($ million)	12.10	14.84	36.83	24.44	29.98	24.15

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.

Remuneration of Non-executive Directors is currently $77,000 per annum plus superannuation, which is paid in equal proportions of cash and rights. The Non-executive Chairman, receives Director's fees inclusive of superannuation of $132,400 per annum, which is also paid in equal proportions of cash and rights.

The maximum aggregate value of Non-executive Directors' annual remuneration is $450,000, as approved at the 2004 Annual General Meeting.

Non-executive Directors are entitled to be reimbursed for reasonable expenses incurred on Group business. No short term incentives or retirement allowances are paid and Directors do not receive additional remuneration for membership of Board Committees.

Michael Kotsanis has served as CEO and Managing Director since November 2014. As an Executive Director his remuneration details are disclosed in the senior management remuneration table.

Remuneration of each person who held the position of Non-executive Director at any time during the financial year is outlined below:

	Director Fee Payments $	Post Employment Super-annuation $	Share based Payments (Rights)[1] $	Total Remun-eration $
2023				
Ross Dobinson (Chair)	45,098	13,902	41,322	100,322
Geoff Brooke	35,000	10,199	24,032	69,231
Don Brumley	35,000	8,827	32,993	76,820
Timothy Oldham	35,000	8,672	24,032	67,704
	150,098	**41,600**	**122,379**	**314,077**
2022				
Ross Dobinson (Chair)	57,212	1,788	65,631	124,631
Geoff Brooke	35,000	7,000	35,997	77,997
Don Brumley	35,000	7,000	24,334	66,334
Timothy Oldham	35,000	7,000	35,997	77,997
	162,212	**22,788**	**161,959**	**346,959**

(1) The accounting treatment of share based payments can differ to the way the remuneration arrangements are described above. This difference is mainly associated with the rights which were issued in 2019 for which the accounting expense was heavily weighted and recorded at the beginning of the period of the instruments meaning that the expense recorded over the final vesting periods to November 2022 was comparatively low. For the purposes of calculating the remuneration value of the rights issued to Mr Brumley in 2022 a valuation of 18cents per share was used but for the purpose of recording the accounting expense the prevailing VWAP at the time the rights were issued was applied as this was the true value of the benefit received.

Remuneration and termination entitlements of Key Management Personnel

Senior management do not have fixed terms of employment. Employment contracts may be terminated by either party based on notice periods which range between one and six months. There is no entitlement to termination benefits beyond statutory entitlements.

Names and positions of KMP of the Group in office during the financial year are:

Michael Kotsanis	Chief Executive Officer and Managing Director
Felicia Colagrande	Product Development and Technical Affairs Director
Mark Hyman	Project and Technical Development Director
Joanna Johnson	Chief Financial Officer & Company Secretary
Charles O'Sullivan	Portfolio Director (retired 30 March 2023)

All KMP held office from the start of the financial year to the date of this report, other than Charles O'Sullivan.

Remuneration of the Group's KMP is detailed in the following table:

	PRIMARY			POST EMPLOY-MENT	LONG TERM BENEFIT	SHARE BASED PAYMENTS			
	Salary $	Movement Annual Leave Provision[2] $	Short Term Incentive[3] $	Super-annuation $	Long Service Leave Accrued $	Perfor-mance Rights[4] $	Total Remun-eration $	Equity as % Total %	Bonus as % Total %
2023									
Michael Kotsanis	462,729	(12,371)	30,501	25,292	11,707	192,380	710,238	27%	4%
Felicia Colagrande	233,444	1,594	9,019	24,512	6,977	20,808	296,354	7%	3%
Mark Hyman	225,552	6,497	8,715	23,683	8,960	13,243	286,650	5%	3%
Joanna Johnson	235,294	3,633	9,091	24,706	1,202	11,240	285,166	4%	3%
Charles O'Sullivan[1]	172,234	(2,008)	–	14,204	4,348	(40,271)	148,507		0%
	1,329,253	**(2,655)**	**57,326**	**112,397**	**33,194**	**197,400**	**1,726,915**	**11%**	**3%**
2022									
Michael Kotsanis	445,683	(28,459)	64,522	23,568	5,874	158,618	669,806	24%	10%
Felicia Colagrande	225,485	(533)	19,843	22,549	5,623	26,974	299,941	9%	7%
Mark Hyman	217,863	6,247	19,172	21,786	10,457	19,781	295,306	7%	6%
Joanna Johnson	227,229	9,003	20,000	23,689	687	4,363	284,971	2%	7%
Charles O'Sullivan[1]	174,222	966	15,332	17,422	4,474	26,102	238,518	11%	6%
	1,290,482	**(12,776)**	**138,869**	**109,014**	**27,115**	**235,838**	**1,788,542**	**13%**	**8%**

(1) Charles O'Sullivan's standard work hours were 4 days per week until his retirement on 30 March 2023. His reported salary includes payment of $36,956 for unused Annual and Long Service Leave which had been accumulated over the term of his employment and was paid to him following his retirement. In accordance with Australian Accounting Standards, the accounting value which has been attributed to performance rights which were not vested at the time of his retirement has been reversed to Profit or Loss.

(2) Employees do not accumulate excessive Annual Leave balances. An expense is recorded where a KMP has used less than their full Annual Leave entitlement in a given year.

(3) A short term incentive may be paid to a KMP based on achievement of Corporate objectives which were established at the beginning of the year. For the financial year ended 30 June 2022, Corporate objectives achievement was assessed by the Board at 55% and these reported short term incentive balances were paid in August 2022. For the financial year ended 30 June 2023, Corporate objectives achievement was assessed by the Board at 25% and these short term incentive balances were paid in August 2023.

(4) Performance rights have been issued to senior employees, including KMP, annually since 2019 with the accounting expense for this share based payment recognised over the life of the instrument. Accordingly, an employee with a longer tenure who has participated in more allocations will report a relatively higher share based payments expense for the reporting period even if similar quantities of performance rights have been allocated in recent years.

Equity instruments held by Key Management Personnel

Ordinary Shares

Ordinary shares held by Directors and KMP at financial year end is detailed in the following table:

	Balance 1 July 2022	On Market Transactions	Rights exercised	Balance 30 June 2023
Directors				
Ross Dobinson	3,716,060	–	639,114	4,355,174
Geoff Brooke[1]	474,221	–	939,706	1,413,927
Don Brumley[1]	1,004,160	1,455,000	394,838	2,853,998
Tim Oldham[1]	869,649	–	235,409	1,105,058
Senior Management				
Michael Kotsanis	1,511,083	–	–	1,511,083
Felicia Colagrande	406,500	–	–	406,500
Mark Hyman	27,882	–	38,595	66,477
Joanna Johnson	–	–	–	–
Charles O'Sullivan[2]	405,000	–	–	n/a
	8,414,555	**1,455,000**	**2,247,662**	**11,712,217**

(1) Includes relevant interests under the control of the KMP, these ordinary shares are held both directly and through controlled entities.
(2) Charles O'Sullivan's equity instruments are reported to the date of his retirement in March 2023 when he ceased to be a KMP.

Rights

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

1,276,000 performance rights were issued to eligible employees on 13 February 2023, including but not limited to KMP. These performance rights vest after one year, provided the TSR over that period is equal to or is greater than 10% and employment is continuous. They expire after 7 years and are expensed over the life of the instrument.

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

2,608,684 rights representing approximately half of Non-executive Director remuneration for the next 12 months were issued to Non-executive Directors on 25 November 2022 after approval by shareholders at the 2022 Annual General Meeting. These rights have no performance conditions other than continuous service and they vest quarterly.

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

	Balance at 1 July 2022	Granted as remun-eration	Rights exercised	Cancelled	Balance at 30 June 2023	Value of Rights Granted[1] $
Directors						
Ross Dobinson	163,894	950,440	639,114	–	475,220	66,200
Geoff Brooke	663,332	552,748	939,706	–	276,374	38,500
Don Brumley	118,464	552,748	394,838	–	276,374	38,500
Tim Oldham	97,222	552,748	235,409	–	414,561	38,500
Senior Management						
Michael Kotsanis	6,000,000	–	–	–	6,000,000	–
Felicia Colagrande	350,000	235,000	–	–	585,000	11,280
Mark Hyman	388,595	235,000	38,595	–	585,000	11,280
Joanna Johnson	210,000	235,000	–	–	445,000	11,280
Charles O'Sullivan[2]	308,000	180,000	–	488,000	–	8,640
	8,299,507	**3,493,684**	**2,247,662**	**488,000**	**9,057,529**	**224,180**

(1) Value of rights granted in current reporting period is recognised over the life of the instrument.
(2) Charles O'Sullivan's equity instruments are reported to the date of his retirement in March 2023 when he ceased to be a KMP. In accordance with the provisions of the OEP, performance rights which were not exercised at the time of his retirement have been cancelled.

Rights which have been issued but are neither exercised nor cancelled as at 30 June 2023, are as follows:

Date rights granted	Number rights	Value at grant date	Minimum Exercise price[5]	Rights expiry date
25 January 2018	15,000	$0.17	$0.1579[2]	January 2025
4 February 2019	15,000	$0.18	$0.2081[2]	February 2026
4 February 2021	429,893	$0.17	$0.2706[2]	February 2028
30 November 2021	6,000,000	$0.114	$0.1258–$0.1675[1]	December 2028
10 February 2022	958,949	$0.103	$0.1133[3]	February 2029
25 November 2022	1,442,529	$0.069	–[4]	November 2023
13 February 2023	1,096,000	$0.072	$0.0792[3]	February 2030
	9,957,371			

(1) Exercise price is subject to a 10% performance hurdle applied each year for 4 equal annual tranches.
(2) Exercise price is subject to a 12% performance hurdle over a volume weighted price for the 30 days prior to the rights issue.
(3) Exercise price is subject to a 10% performance hurdle over a volume weighted price for the 30 days prior to the rights issue.
(4) Rights issued to Non-executive Directors comprise approximately half of their remuneration. Rights vest quarterly in arrears and are not subject to an exercise price or performance hurdle.
(5) Minimum exercise price is the hurdle which must be achieved for the Performance Rights to vest. If the original hurdle target is not achieved, additional uplift hurdles are applied each subsequent year for up to seven years for the right to vest.

Voting and comments made at the Company's 2022 Annual General Meeting (AGM)

At the 2022 AGM the Remuneration Report for the year ended 30 June 2022 received 74.22% of votes cast in favour of acceptance which is less that the 75% threshold required to avoid a 'First Strike'. In the case that fewer than 75% votes are cast in favour of accepting the Remuneration Report for the year ended 30 June 2023 as is included in this Annual Report at the 2023 AGM a 'Second Strike' would be recorded and shareholders would then be asked to vote to determine whether the Non-executive Directors would be required to stand for re-election.

After receiving this 'First Strike' at the 2022 AGM the Company has discussed the company's strategy and key elements of the Remuneration Report with numerous shareholders including the way remuneration of Directors, KMP and other company employees is linked to company performance.

As detailed earlier in this Remuneration Report, remuneration is linked to company performance through three key elements:

1. Approximately 50% of the value of Non-executive Director remuneration is granted in the form of Rights. This practice commenced in 2018 in response to shareholder feedback which requested improved alignment of the perspective of Non-executive Directors with shareholders through increased share ownership and additionally as a strategy to preserve the company's cash reserves.

   Rights are issued to Non-executive Directors after they have been approved by shareholders at the relevant AGM. The value of the Right is detailed in the Notice of Meeting and is established at the prevailing VWAP at the time of shareholder approval. As the Rights issued to Non-executive Directors vest on a quarterly basis in accordance with completion of service, the value of the security in the Director's hands is highly sensitive to subsequent increases or decreases in the Company's share price.
2. Subject to Board approval and the conditions of the OEP, KMP and other senior managers may receive an allocation of Performance Rights. These Performance Rights do not vest unless the Company's share price increases and the TSR threshold is achieved. Performance Rights which were issued to KMP and other senior managers in 2020, 2021 and 2022 are currently unvested because the TSR threshold has not been achieved.
3. KMP and other employees may be eligible to receive an annual cash bonus depending on Directors' assessment of achievement of Corporate objectives which are established at the beginning of the year and selected based on expected contribution to shareholder value. Corporate objectives are always tied to material pipeline progression and achievement of key development milestones which could include product approval by the FDA, commercial launch of a product, acceptance of a dossier by the FDA for review, successful completion of a bioequivalence study or manufacture of a pilot batch. In FY22 this percentage was assessed by the Board at 55% and for FY23 25% has been assessed as achieved.

The total value of Remuneration of Directors, KMP and other company employees, which includes cash payments, rights and bonus potential, is benchmarked against comparable industry roles to ensure it is competitive and is sufficient to attract and retain well qualified and high calibre individuals.

This is the end of the audited remuneration report

Non-audit services
Non-audit services are recommended by the Audit and Risk Committee and approval is resolved by the Board of Directors. Non-audit services provided by the auditor, Pitcher Partners (Melbourne) and their network firms are detailed below.

	2023 $	2022 $
Amount paid or payable to Pitcher Partners (Melbourne) for non-audit services	23,320	32,855
Amount paid or payable to network firms of Pitcher Partners for non-audit services	–	–
	23,320	**32,855**

Non-audit services relate to the provision of corporate tax advice and completion of company tax returns and as such Directors are satisfied that non-audit services provided during the year 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 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.

Auditor independence declaration
A copy of the Auditor's Independence Declaration as required under section 307C of the *Corporations Act 2001* in relation to the audit for the financial year is 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
24 August 2023

Don Brumley
Non-executive Director

Melbourne
24 August 2023

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 2023, 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.

N R BULL
Partner

24 August 2023

PITCHER PARTNERS
Melbourne

Consolidated Statement of Profit or Loss and Other Comprehensive Income

For the year ended 30 June 2023

	Note	CONSOLIDATED 2023 $'000	CONSOLIDATED 2022 $'000
Revenue from licensing agreements	4	8,429	1,719
Other revenue	4	3,499	3,384
Total revenue		**11,928**	**5,103**
Cost of goods sold		(558)	–
Employee benefits expense	5	(4,960)	(5,245)
Directors' fees		(192)	(185)
Securities based payment expense	18(a)	(370)	(450)
Depreciation and amortisation expenses	5	(595)	(660)
Impairment expense	13	(321)	–
Occupancy expenses		(244)	(201)
External research and development expenses		(3,812)	(6,371)
Professional fees		(340)	(454)
Other expenses		(748)	(1,119)
Total operating expenses		**(11,582)**	**(14,685)**
Profit/(loss) before income tax		(212)	(9,582)
Income tax expense	6	(552)	(252)
Net profit/(loss) for the year		**(764)**	**(9,834)**
Total comprehensive profit/(loss) for the year		**(764)**	**(9,834)**
Total comprehensive profit/(loss) attributable to:			
Members of the parent entity	19	(764)	(9,834)
Loss per share for loss attributable to the equity holders of the parent entity:			
Basic profit/(loss) per share	8	(0.27) cents	(3.46) cents
Diluted profit/(loss) per share	8	(0.27) cents	(3.46) cents

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

Consolidated Statement of Financial Position

As at 30 June 2023

	Note	CONSOLIDATED 30 June 2023 $'000	CONSOLIDATED 30 June 2022 $'000
Current Assets			
Cash and cash equivalents	9	6,232	5,831
Receivables	10	3,306	3,765
Other current assets	11	353	420
Total Current Assets		**9,891**	**10,016**
Non-Current Assets			
Plant and equipment	12	559	682
Intangible assets	13	–	375
Deferred tax asset	6	803	1,355
Lease assets	14	2,032	1,874
Total Non-Current Assets		**3,394**	**4,286**
Total Assets		**13,285**	**14,302**
Current Liabilities			
Payables	15	1,372	2,219
Provisions	16	826	875
Lease liabilities	14	192	224
Total Current Liabilities		**2,390**	**3,318**
Non-Current Liabilities			
Provisions	16	38	40
Lease liabilities	14	2,161	1,854
Total Non-Current Liabilities		**2,199**	**1,894**
Total Liabilities		**4,589**	**5,212**
Net Assets		**8,696**	**9,090**
Equity			
Contributed equity	17	114,884	114,563
Reserves	19	8,299	8,250
Retained earnings/(losses)	19	(114,487)	(113,723)
Total Equity		**8,696**	**9,090**

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 2023

	Note	Contributed equity $'000	Reserves $'000	Retained earnings/ (losses) $'000	Total equity $'000
Balance as at 1 July 2022		**114,563**	**8,250**	**(113,723)**	**9,090**
Profit/(loss) for the year		–	–	(764)	(764)
Other comprehensive income/(loss) for the year		–	–	–	–
Total comprehensive income/(loss) for the year		–	–	(764)	(764)
Transactions with owners in their capacity as owners					
Employee share scheme	19	25	49	–	74
Performance rights exercised	17(b)	296	–	–	296
Capital Raising	17(b)	–	–	–	–
Balance as at 30 June 2023		**114,884**	**8,299**	**(114,487)**	**8,696**
Balance as at 1 July 2021		**114,213**	**8,147**	**(103,889)**	**18,471**
Profit/(loss) for the year				(9,834)	(9,834)
Other comprehensive income/(loss) for the year		–	–	–	–
Total comprehensive income/(loss) for the year		–	–	(9,834)	(9,834)
Transactions with owners in their capacity as owners					
Employee share scheme	19	28	103	–	131
Performance rights exercised	17(b)	322	–	–	322
Capital Raising	17(b)	–	–	–	–
Balance as at 30 June 2022		**114,563**	**8,250**	**(113,723)**	**9,090**

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

Consolidated Statement of Cashflows

For the year ended 30 June 2023

	Note	CONSOLIDATED 30 June 2023 $'000	CONSOLIDATED 30 June 2022 $'000
Cashflows from operating activities			
Receipts from product agreements		8,534	1,357
Payments to suppliers and employees		(11,445)	(13,144)
Interest received		84	26
Finance costs		(201)	(172)
Research and development tax incentive rebate		3,731	3,114
Net cash generated/(used) in operating activities	**20(a)**	**703**	**(8,819)**
Cashflows from investing activities			
Payment for property, plant and equipment		(119)	(465)
Net cash used in investing activities		**(119)**	**(465)**
Cashflows from financing activities			
Proceeds from capital raising		–	–
Lease liability principal repayments		(183)	(155)
Net proceeds used in financing activities		**(183)**	**(155)**
Net increase/(decrease) in cash and cash equivalents		**401**	**(9,439)**
Cash and cash equivalents at beginning of year		5,831	15,270
Cash and cash equivalents at the end of the year	**20(b)**	**6,232**	**5,831**

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

This financial report covers Acrux Limited and its controlled entities as a Group. Acrux Limited is a for profit entity which is incorporated and domiciled in Australia. It is a company limited by shares which are publicly traded on the Australian Securities Exchange. The address of Acrux Limited's registered office and its principal place of business is 103–113 Stanley Street, West Melbourne, Victoria, 3003.

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

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. Accounting policies have been consistently applied, unless otherwise stated.

(a) Basis of preparation

This general purpose financial report has been prepared in accordance with *Corporations Act 2001*, Australian Accounting Standards, Interpretations and other applicable authoritative pronouncements of the Australian Accounting Standards Board ('AASB'), International Accounting Standards Board ('IASB') and International Financial Reporting Standards ('IFRS'). Material accounting policies adopted in the preparation of this financial report are presented below.

Historical cost convention

The financial report has been prepared under the historical cost convention, except for certain instruments which have been measured at their fair value, and which have been described in the accounting policies. Fair value is the price that would be expected to be received to sell an asset or paid to transfer a liability, in an orderly transaction between market participants (under current market conditions) at 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 as are appropriate in the circumstances and for which sufficient data is available to maximise the use of relevant observable inputs and minimise 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 inputs are observable:

- Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities that can be accessed at measurement date.
- Level 2 inputs are inputs other than quoted prices 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. Estimates and judgements which are significant to the financial report are explained and 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 which contemplates the continuity of normal business activities and the realisation of assets and the settlement of liabilities in the ordinary course of business.

The Group incurred a loss after tax from ordinary activities of $0.764 million during the year ended 30 June 2023 (30 June 2022: loss after tax from ordinary operations $9.834 million) and produced a positive cash flow from operating activities for the year ended 30 June 2023 of $0.703 million (30 June 2022: negative cash flow from operating activities totalled $8.819 million). The ability of the Group to continue as a going concern is dependent on its ability to generate future revenues which will support operating activities and the management of cash reserves.

The Directors are of the opinion the Group is a going concern based on the cashflow projections prepared for a period of twelve months beyond the date of approval of these financial statements, and which incorporate the following factors:

- Continued revenue growth of products currently on market, particularly Prilocaine 2.5% and Lidocaine 2.5%, Cream which was launched in December 2022;
- Obtaining FDA approval and launching pipeline products, including Dapsone Gel, 5% which was approved in June 2023 and,
- The continued eligibility of product development expenditure for the research and development tax incentive rebate.

Directors closely monitor revenue and expenditure against budget and have identified several options which could be implemented should revenues be materially lower than forecasted. Cash management strategies could include:

- Deferral of project development activities and expenditure;
- Management of operating and capital expenses; or
- Monetisation of assets, such as actioning advance receipt of research and development tax incentive rebate or other revenue streams.

On this basis the financial report has been prepared on a going concern basis and no adjustments have been made relating to the recoverability and classification of the carrying amount of assets or the amount and classification of liabilities that might be necessary should the Group not continue as a going concern.

Should the Group's revenues be materially lower than modelled and the initiatives detailed above could not be implemented, there could be a material uncertainty as to whether the Group may be able to continue as a going concern and may therefore be required to realise assets and extinguish liabilities other than in the ordinary course of business with the amount realised being potentially different from those shown in the financial statements.

1. STATEMENT OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

(c) Principles of Consolidation

The consolidated financial statements are those of the Group, comprising the financial statements of the parent entity and all entities controlled by the parent entity. 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 entity's activities. 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 between Group companies are eliminated on consolidation.

A list of controlled entities is contained in Note 26 Controlled Entities.

(d) Impairment of non-financial assets

In accordance with AASB 136 *Impairment of assets*, assets which are subject to depreciation are reviewed for impairment at least annually or when events or circumstances arise that could indicate the carrying amount may be impaired. An impairment loss is recognised where the carrying amount of the asset exceeds its estimated recoverable amount at the higher of its fair value less costs to dispose and its value in use.

Following the buy out of Lenzetto® royalties by Gedeon Richter Plc., it was considered that the future revenue from Estradiol spray is reasonably expected to be insufficient to support the remaining carrying value of the Intangible Asset. Accordingly, an Impairment loss for this item has been recorded in the current financial period and disclosed as a separate line item on the Consolidated Statement of Profit or Loss and Other Comprehensive Income and in Note 13 Intangible Assets.

(e) 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 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 the Group's business model for managing the financial assets and 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 based on the lifetime expected credit losses of the financial asset which represent the credit losses 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 they have been billed to the Group. Trade liabilities are usually settled within 30 days of period end.

(f) Foreign currency translation and balances

Functional and presentation currency

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

Transactions and balances

Transactions in foreign currencies 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 foreign currency denominated monetary assets and liabilities at period end exchange rates are recognised in profit or loss. All resulting exchange differences arising on settlement or restatement are recognised as revenues or expenses for the financial year.

(g) Goods and services tax (GST)

Revenues, expenses and assets are recognised net of GST, unless 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.

(h) 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 in accordance with the Class Order to the nearest thousand dollars, or in certain cases, to the nearest dollar.

(i) New and revised Accounting Standards effective as at 30 June 2023

All new and revised Australian Accounting Standards applicable to be adopted for the first time in the annual reporting period commencing 1 July 2022 have been applied with immaterial effect.

(j) Accounting Standards issued but not yet effective

Certain new standards and interpretations have been issued but as they are not yet mandatory they 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 certain estimates and judgements that may affect the reported values of assets, liabilities, revenues and expenses. Management continually and critically evaluates such 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 financially impact the entity.

The following critical judgements have been made in application of the Group's accounting policies having the most significant effect on amounts recognised in the Group's financial statements.

(a) Income tax

Income tax benefits are recognised based on the assumption of no adverse change in income tax legislation and also that the Group will derive sufficient future assessable income to enable the benefit to be realised. Deferred tax assets are recognised for deductible temporary differences where management considers it is probable that future tax profits will be available to utilise those temporary differences.

(b) Impairment testing

The Group prepares discounted cash flow models to ensure assets are not carried at a value that materially exceeds their recoverable value. Future cash flows are discounted for risks specific to the assets and for the time value of money. The following approach and assumptions have been applied:

- Product revenue is estimated using current market data and projected future sales volumes, product pricing, market share, the potential market impact of new competitors and anticipated launch dates for new products;
- Expenses are estimated based on projected product development activities and a CPI uplift factor has been applied to operating overheads and salaries; and
- Cash flow forecasts are prepared over 10 years and are discounted using an after tax rate of 12%.

(c) Employee benefits

Long term employment benefits are valued at the present value of estimated future cash outflows which are calculated based on assessment of trends relating to retention of staff, future remuneration and the timing of the settlement of the benefits.

(d) Share based payments

The OEP is the legal framework for issuing securities to Directors and employees. The value of securities issued is recognised as an expense in the period(s) the benefit is earned over the life of the instrument. The total value of the instrument is calculated at the time of issue and performance rights are valued using the Black and Scholes pricing models which considers a number of variables including estimated future volatility and a risk free interest rate. Volatility is estimated based on the movements in Acrux Limited's share price on the Australian Securities Exchange over the prior 12 months. The risk free interest rate is the Reserve Bank of Australia's cash rate prevailing at the instrument's grant date.

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 has overall responsibility for identifying and managing operational and financial risks. Sensitivity analysis and other methods are used to measure financial risks and to determine whether further mitigation strategies are required to protect the Group's financial security.

(a) Interest rate risk

Interest rate risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate due to changes in market interest rates. As forecasted cashflows do not project the use of bank debt facilities the Group is not exposed to a material sensitivity from interest rate fluctuations.

(b) Currency risk

Currency risk is the risk that the fair value of a financial instrument will fluctuate due to changes in foreign exchange rates. The Group is exposed to currency risks due to revenues and certain expenses being denominated in foreign currencies, predominantly US dollars. Currency risk management strategies are regularly reviewed and the Company expects future foreign currency denominated cashflows from revenues will be largely offset by expenditure, protecting Acrux from the impact of short term currency fluctuations.

3. FINANCIAL RISK MANAGEMENT (CONTINUED)

Bank accounts denominated in US dollars and Euro are maintained to facilitate foreign currency receipts and payments and to assist in the management of foreign exchange risk. As at 30 June 2023, US dollar denominated cash reserves totalled A$0.005 million (2022: A$0.008 million) and Euro denominated cash reserves totalled A$0.006 million (2022: A$0.369 million).

The balance of foreign currency denominated receivables as at 30 June 2023 totals US$0.357 million (2022: US$0.181 million) and EUR nil (2022: EUR 0.392 million). The balance of payables totals US$0.169 million (2022: US$0.161 million) and EUR 0.011 (2022 EUR nil).

A change in the exchange rates would therefore have immaterial impact on the consolidated net profit/(loss) and equity of the Group (2022: immaterial).

The Group does not enter forward exchange contracts.

(c) Credit risk

Credit risk refers to the risk a counterparty defaults on its obligations, resulting in a financial loss to the Group. The maximum exposure to credit risk at balance date is the carrying amount of receivable 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 procedures are in place to deal with credit worthy counterparties. Potential credit losses are regularly evaluated and a provision would be raised if there was evidence that a debt was unlikely to be collectible. The Company does not have a history of defaulted balances nor are there any presently 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 and other operating cashflow requirements.

The Group reports cash reserves of $6.232 million (2022: $5.831 million), which as outlined in Note 1(b) is, in the opinion of Directors, sufficient to settle existing liabilities and fund operating expenditure at planned levels for at least 15 months from the balance date based on current operating projections.

Funds are held in high interest bearing accounts and term deposits which are managed to ensure liquidity is available to settle liabilities as and when they fall due. The Group does not maintain an overdraft or loan facility.

Future cash outflows for the settlement of financial liabilities	2023 $'000	2022 $'000
Lease Liabilities		
Not later than 1 year	374	335
Later than 1 year and not later than 5 years	1,557	1,295
Aggregate of lease payments contracted for at reporting date	1,931	1,630
Payables		
Not later than 1 year	1,372	2,219

4. REVENUE

	2023 $'000	2022 $'000
Revenue from contracts with customers		
Revenue from licensing agreements	8,429	1,719
Other revenue		
Interest	122	18
Grant revenue – research and development tax incentive rebate	3,377	3,366
Total other revenue	**3,499**	**3,384**
Total revenue from continuing operations	**11,928**	**5,103**

Key Accounting Policies

Revenue from contracts with customers

Revenue is derived from licensing agreements with customers in the form of royalty and profit share income as well as the sale of active pharmaceutical ingredients. Revenue is recognised in the period in which product sales occur or when it can be reliably estimated.

Other revenue

Other revenue is recognised as it is received or where it can be reliably estimated over the period to which it relates. The Research and development tax incentive rebate is recognised at fair value as it is reasonably assured the grant will be received, it can be reliably measured and the Group complies with all conditions.

All revenue is reported net of any applicable of goods and services tax (GST).

5. LOSS FROM CONTINUING OPERATIONS

	2023 $'000	2022 $'000
Loss from continuing operations before income tax has been determined after the following specific expenses:		
Employee benefits expense		
Wages and salaries	4,200	4,448
Superannuation costs	438	418
Other employee benefits expense	322	379
Total employee benefits expense	**4,960**	**5,245**
Depreciation of non-current assets		
Right of use asset	282	200
Plant and equipment	255	344
Total depreciation of non-current assets	**537**	**544**
Amortisation of non-current assets		
Leasehold improvements	5	9
Capitalised research and development	53	107
Total amortisation of non-current assets	**58**	**116**
Total depreciation and amortisation of non-current assets	**595**	**660**

6. INCOME TAX

	2023 $'000	2022 $'000
(a) Income tax recognised in profit and loss		
Current tax	–	–
Deferred tax	552	252
Income tax (benefit)/expense attributable to profit and loss	552	252
(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:		
Profit/(loss) before tax from continuing operations	(212)	(9,582)
Prima facie income tax payable on loss before income tax	(174)	(2,919)
Add/(subtract) tax effect:		
Non-deductible expenses	111	140
Research and development tax incentive rebate	(1,013)	(1,010)
Impact of change in tax rate on Deferred tax asset	–	28
Tax losses not brought to account	1,382	3,824
Parent tax losses and temporary differences not brought to account	246	189
	726	3,171
Income tax (benefit)/expense attributable to loss	552	252
(c) Current tax		
Current tax (asset)/liability	–	–
(d) Deferred Tax		
Deferred tax assets is comprised:		
Accruals and provisions	317	318
Plant and equipment under lease	80	51
Intangible Assets	1,019	1,023
Exchange differences	–	2
Tax losses and research and development offset	401	932
	1,817	2,326
Deferred tax liabilities is comprised:		
Plant and Equipment and Intangible assets	(967)	(942)
Prepayments	(42)	(29)
Exchange differences	(5)	–
	(1,014)	(971)
Net deferred tax assets/(liabilities)	803	1,355
(e) Deferred tax assets not brought to account		
Temporary differences	4	(106)
Tax losses	21,895	22,784
	21,899	22,678

Key accounting policies

Current income tax expense/(benefit) is the tax payable on current period taxable income at the applicable income tax rate adjusted by changes in deferred tax assets and liabilities attributable to temporary differences and 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 for temporary differences arising in a transaction, other than a business combination, if the transaction did not affect either accounting profit or taxable profit or loss. Deferred tax assets are recognised for deductible temporary differences when it is probable that future taxable amounts will be available to utilise those temporary differences and losses.

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.

Subsidiary companies of Acrux Limited are subject to the general company tax rate.

7. DIVIDENDS

	2023 $'000	2022 $'000
(a) Dividends paid and declared		
Nil dividends were declared or paid during the financial year (2022: $nil)		
(b) Franking account		
Balance of franking account at financial year end.	43,835	43,835

8. LOSS PER SHARE

	2023 $'000	2022 $'000
Loss from continuing operations	(764)	(9,834)
Loss used in calculating basic and diluted earnings per shares	(764)	(9,834)

	No. of shares	No. of shares
Weighted average number of ordinary shares used in calculating basic earnings per share	286,461,099	283,881,613
Effect of dilutive securities:	–	–
Adjusted weighted average number of ordinary shares used in calculating diluted earnings per share	286,461,099	283,881,613
Basic loss per share (cents)	0.27 cents	3.46 cents
Diluted loss per share (cents)	0.27 cents	3.46 cents

9. CASH AND CASH EQUIVALENTS

	2023 $'000	2022 $'000
Cash on hand and at bank	3,232	2,831
Term deposits	3,000	3,000
	6,232	**5,831**

Key accounting policies
Cash and cash equivalents include bank term deposits and high interest bearing accounts which are readily convertible to cash on hand and used in the day-to-day cash management function.

10. RECEIVABLES

	2023 $'000	2022 $'000
Receivables from contracts with customers	385	262
Other receivables	2,921	3,503
	3,306	**3,765**

Key accounting policies
Trade receivables arise from the transactions with customers and are normally settled on terms of 45 days from the date of invoice.

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 other assets. Under this approach, the Group determines the allowance for credit losses for receivables on the basis of the lifetime expected credit losses of the financial asset. Lifetime expected credit losses represent the expected credit losses that are expected to result from default events over the expected life of the financial asset.

Expected credit losses are determined based on the Group's historical credit loss experience adjusted for factors specific to the financial asset as well as relevant current and expected economic conditions. There has been no change in the estimation techniques or significant assumptions made during the reporting period. As there is no history of collection delays, defaulted balances or client dispute no provision for expected credit losses is considered necessary at this time.

Other receivables reflects the estimated Research and development tax incentive rebate for the year ended 30 June 2023, recognised at fair value as there is reasonable assurance the grant will be received, it can be reliably measured and the Group complies with all conditions.

11. OTHER CURRENT ASSETS

	2023 $'000	2022 $'000
Prepayments	316	420
Other current assets	36	–
	352	**420**

12. PLANT AND EQUIPMENT

	2023 $'000	2022 $'000
Leasehold improvements		
At cost	47	47
Accumulated amortisation	(29)	(24)
Total leasehold improvements	18	23
Plant and equipment		
At cost	2,491	2,319
Accumulated depreciation	(1,950)	(1,660)
Total plant and equipment	541	659
	559	682
Reconciliations of the carrying amounts of plant and equipment at the beginning and end of the current financial year:		
Leasehold improvements		
Carrying amount at the start of the year	23	32
Additions	–	–
Amortisation expense	(5)	(9)
Carrying amount at the end of the year	18	23
Plant and equipment		
Carrying amount at the start of the year	659	506
Additions	119	465
Transfer from Leased assets	11	–
Depreciation expense	(248)	(312)
Carrying amount at the end of the year	**541**	**659**

Key accounting policies

Cost and valuation

Each class of plant and equipment is carried at historical cost less applicable accumulated depreciation and impairment losses. Historical cost includes expenditure that is directly attributable to the acquisition and installation 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

Depreciation expense is calculated on a straight line basis over the assets' estimated useful lives 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.

Useful lives	2023	2022
Leasehold improvements	5 to 20 years	5 to 20 years
Plant and equipment	1 to 16 years	1 to 16 years

13. INTANGIBLE ASSETS

	2023 $'000	2022 $'000
External development expenditure capitalised	1,071	1,071
Accumulated amortisation	(1,071)	(696)
Total intangible assets	–	375
Carrying amount of Estradiol at the start of the year	375	482
Additions	–	–
Amortisation	(54)	(107)
Impairment	(321)	–
Carrying amount of Estradiol at the end of the year	**–**	**375**

Key accounting policies

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

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

Capitalised development costs have a finite life and are systematically amortised from the time the product becomes available for use.

On 23 January 2023 Acrux executed an agreement with Gedeon Richter Plc. to buy out the future royalties of Estradiol for EUR4.1million, which is sold as Lenzetto® in most markets other than US. As the royalties from Gedeon Richter Plc for Lenzetto® represent the majority of Acrux's income in relation to Estradiol, the Intangible Asset was impaired in full as at the time of the buyout.

14. LEASE ASSETS AND LEASE LIABILITIES

The Group leases its office, laboratory and warehouse facilities. The lease was renewed by Acrux DDS Pty Limited for an initial period of 4 years from 1 June 2018 and the first of three options to extend for further three year periods was exercised from the effective date of 1 June 2022. Acrux has two remaining options to extend for periods of three years. There is no option to purchase at the end of the lease period.

	2023 $'000	2022 $'000
Leased assets		
Carrying amount of lease assets, by class of underlying asset:		
Buildings under lease arrangements		
At cost	2,867	2,409
Accumulated depreciation	(854)	(602)
	2,013	1,807
Plant and equipment under lease arrangements		
At cost	89	142
Accumulated depreciation	(70)	(75)
	19	67
Total carrying amount of Leased assets	**2,032**	**1,874**
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	1,807	2,007
Depreciation	(252)	(200)
Restatement of Leased assets following lease extension	458	–
Carrying amount at the end of the period	2,013	1,807
Plant and equipment under lease arrangements		
Carrying amount at the beginning of the period	67	99
Depreciation	(30)	(32)
Leases paid out	(7)	–
Assets transfered to Plant and equipment	(11)	–
Carrying amount at the end of the period	19	67
Lease Liabilities		
Lease liabilities (current)	192	224
Lease liabilities (non-current)	2,161	1,854
Total carrying amount of lease liabilities	**2,353**	**2,078**
Lease expenses and cashflows		
Interest expense on lease liabilities	196	172
Depreciation expense on lease assets	282	232
Total cash outflow in relation to leases	379	327
Future commitments		
Future minimum lease payments to be made:		
– Not later than 1 year	374	335
– Later than 1 year and not later than 5 years	1,557	1,295
Aggregate of lease payments contracted for at reporting date	**1,931**	**1,630**

14. LEASE ASSETS AND LEASE LIABILITIES (CONTINUED)

Key accounting policies

The Group recognises a Leased asset at the date of lease commencement, 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 impairment loss.

Lease liabilities are initially recognised at the present value of the future lease payments which are unpaid at 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 which 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.

15. PAYABLES

	2023 $'000	2022 $'000
Current		
Trade payables	488	789
Sundry creditors and accruals	884	1,430
	1,372	**2,219**

Key accounting policies

These amounts represent liabilities for goods and services provided to the Group prior to the end of the financial year and which are unpaid. Balances are unsecured and are typically paid within 30 days of being incurred. Payables are presented as current liabilities where settlement is required within 12 months of the reporting period.

16. PROVISIONS

	2023 $'000	2022 $'000
Current		
Employee entitlements	826	875
Non-current		
Employee entitlements	38	40
Aggregate employee entitlements	**864**	**915**

Key accounting policies

Provisions are recognised when the Group has a legal or constructive obligation 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 arising from employees rendering services to the reporting date, including annual leave and long service leave. Liabilities which are 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.

Other employee benefit liabilities are measured at the present value of the estimated future cash outflows.

17. CONTRIBUTED EQUITY

	2023		2022	
	No. of shares	000's $	No. of shares	000's $
(a) Issued and paid up capital				
Ordinary shares fully paid	288,175,456	114,884	285,364,669	114,563
(b) Movements in ordinary shares on issue				
Beginning of the financial year	285,364,669	114,563	283,305,394	114,213
Issued during the year:				
Conversion of rights under the OEP	2,463,662	296	1,776,641	322
Shares issued under OEP	347,125	25	282,634	28
Ordinary shares issued during the year	2,810,787	321	2,059,275	350
Ordinary shares on issue at reporting date	**288,175,456**	**114,884**	**285,364,669**	**114,563**

17. CONTRIBUTED EQUITY (CONTINUED)

(c) Rights

During the financial year 3,884,684 rights were issued under the OEP (2022: 7,483,663). Rights hold no participation rights, but shares issued on exercise of rights rank equally with existing ordinary shares. At 30 June 2023, 9,057,529 rights were held by KMP (2022: 8,299,507).

The closing market value of an ordinary Acrux Limited share on the Australian Securities Exchange at 30 June 2023 was 4.2 cents (2022: 5.2 cents).

	2023	2022
(i) Movement in the number of rights held under Omnibus Equity Plan are as follows:		
Opening balance	9,029,754	6,353,348
Granted during the year	3,884,684	7,483,663
Exercised during the year	(2,463,662)	(1,776,641)
Lapsed during the year	(493,405)	(3,030,616)
Closing balance	**9,957,371**	**9,029,754**

	2023 $'000	2022 $'000
(ii) Details of rights exercised under the OEP during the financial year:		
Rights exercised into shares, measured at Fair Value as at the issue date of the rights	296	322

	2023	2022
(iii) Details of the number of lapsed rights		
Key management personnel	488,000	3,000,000
Other employees	5,405	30,616
Total rights lapsed during the year	**493,405**	**3,030,616**

18. SHARE BASED PAYMENTS

(a) Expenses recognised from share-based payment transactions

	2023 $'000	2022 $'000
The expense recognised within securities based payments expense in the statement of comprehensive income was as follows:		
Rights issued under the OEP	345	422
Issue of tax exempt ordinary shares to eligible employee under the OEPs	25	28
Total expenses recognised from securities based payment transactions	**370**	**450**

Share-based payments
The fair value of rights is recognised as an employee benefit expense in the Consolidated Statement of Profit or Loss and Other Comprehensive Income in the period(s) over which the benefit to the employee or Director is accrued over the life of the instrument. Fair value is determined using an appropriate pricing model to value Performance Rights during the period depending on the exercise conditions using the Black Scholes option pricing model.

In addition to rights, and within the provisions of the OEP, employees who are neither Directors nor KMP, may be issued with tax exempt ordinary shares to a maximum value of $1,000 per employee at the discretion of the Directors. Exempt ordinary shares are escrowed for 3 years from the date of issue.

(b) Omnibus Equity Plan
Details of movements in rights during the reporting period are provided below:

Grant date	Expiry date	Balance at beginning of the year	Granted	Exercised	Cancelled	Balance at the end of the year	Exercisable at the end of the year
Non-executive Directors – rights issued as a component of remuneration							
23 November 2018	1 January 2023	80,000	–	80,000	–	–	–
9 December 2019	28 November 2026	844,448	–	844,448	–	–	–
30 November 2021	30 November 2028	118,464	–	118,464	–	–	–
25 November 2022	25 November 2029	–	2,608,684	1,166,155	–	1,442,529	138,187
Performance Rights – issued to CEO, KMP and other senior management							
25 January 2018	25 January 2025	64,000	–	49,000	–	15,000	15,000
4 February 2019	4 February 2026	138,000	–	123,000	–	15,000	15,000
3 February 2020	3 February 2027	82,595	–	82,595	–	–	–
4 February 2021	4 February 2028	575,298	–	–	145,405	429,893	–
30 November 2021	30 November 2028	6,000,000	–	–	–	6,000,000	–
10 February 2022	10 February 2029	1,126,949	–	–	168,000	958,949	–
13 February 2023	23 February 2030		1,276,000	–	180,000	1,096,000	–
		9,029,754	**3,884,684**	**2,463,662**	**493,405**	**9,957,371**	**168,187**

The Group operates an OEP which was approved by shareholders on 12 November 2020.

Within the terms of the OEP and as approved by shareholders, rights have been issued to Non-executive Directors since 2019 to comprise approximately 50% of the total value of their remuneration. These rights have no performance conditions other than continuous service and they vest on a quarterly basis in arrears.

On 26 November 2021 and as approved by shareholders, 6,000,000 performance rights were issued to the Managing Director and CEO, Michael Kotsanis. These rights vest in 4 equal annual tranches subject to achievement of Total Shareholder Return of at least 10% per annum and include roll over provisions.

Other employees, including KMP, are offered performance rights which vest subject to achievement of performance hurdles. On 13 February 2023, 1,276,000 performance rights were issued to employees, including KMP. These rights vest 12 months after issuance, subject to achievement of Total Shareholder Return of at least 10% per annum and include rollover provisions.

Ordinary shares issued following the exercise of rights rank equally with existing ordinary shares.

18. SHARE BASED PAYMENTS (CONTINUED)

Overview of Rights issued during the period:

Date of Issue	25 November 2022	13 February 2023
Type of Rights	Non executive Directors Remuneration	Employee Performance Rights
Number of Rights issued	2,608,684	1,276,000
Fair value Measure	Direct Value	Black Scholes
Weighted average share price at date of issue	6.96 cents	7.20 cents
Exercise price	n/a	7.92–10.54 cents
Volatility	n/a	67.69%
Dividend yield expectations	n/a	Nil
Term	7 years	7 years
Risk free interest rate	n/a	3.77%

19. RESERVES AND ACCUMULATED LOSSES

	2023 $'000	2022 $'000
Share based payment reserve	909	860
Profit reserve	7,390	7,390
Total Reserves	8,299	8,250
Accumulated losses	(114,487)	(113,723)
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	860	757
Employee performance rights expense for the year	49	103
Balance at end of year	**909**	**860**
Profit Reserve		
Nature and purpose of Profit reserve		
This reserve is used to record the profits which have been generated by the Group.		
Accumulated losses		
Movement in Accumulated losses		
Balance at the beginning of year	(113,723)	(103,889)
Net loss attributable to members of Acrux Limited	(764)	(9,834)
Balance at end of year	**(114,487)**	**(113,723)**

20. CASHFLOW INFORMATION

	2023 $'000	2022 $'000
(a) Reconciliation of the cashflow from operations with loss after income tax:		
Loss from ordinary activities after income tax	(764)	(9,834)
Non-Cash Items		
Depreciation and amortisation	916	660
Share based payments expense	370	450
Changes in assets and liabilities		
(Increase)/decrease in trade and other receivables	459	(606)
(Increase)/decrease in other current assets	67	(255)
Increase/(decrease) in payables	(847)	441
Increase/(decrease) in employee entitlements	(50)	73
Increase/(decrease) in deferred tax assets	552	252
	1,467	1,015
Net cash (outflows)/inflows from operating activities	703	(8,819)
(b) Reconciliation of cash		
Cash at the end of the financial year as shown in the Statement of Cashflows and the Statement of Financial Position is as follows:		
Cash at bank	3,232	2,831
At call and term deposits	3,000	3,000
Closing cash balance	**6,232**	**5,831**

(c) Credit stand-by arrangement and loan facilities

The Group has credit card facilities with financial institutions totalling $120,000 (2022: $120,000). At 30 June 2023 the Group had unused capacity on these facilities of $115,607 (2022: $109,009).

21. KEY MANAGEMENT PERSONNEL COMPENSATION

	2023 $	2022 $
KMP compensation is detailed in the Remuneration Report section of the Director's Report. A breakdown of the aggregate components is provided below:		
Short-term employment benefits	1,534,022	1,578,787
Post-employment benefits	187,191	158,917
Equity	319,779	397,797
Total KMP compensation	**2,040,992**	**2,135,501**

22. LOANS TO KEY MANAGEMENT PERSONNEL

No loans were made to KMP during the financial year.

23. 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 $26.202 million (2022: $18.188 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 $0.866 million (2022: $0.866 million).

Other transactions with Key Management Personnel and their personally related entities

Transactions with Directors and KMP concerning securities made in accordance with the OEP are disclosed the Directors' Report and in Notes 17 and 18. There were no other transactions or contracts between the Company, Directors and KMP in 2023 (2022: nil).

24. AUDITOR REMUNERATION

	2023 $'000	2022 $'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	102	88
Taxation compliance and consulting	23	33
Other non-audit services	–	–
	125	**121**

25. 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.

	2023 $'000	2022 $'000
Geographical segment information		
Australia	3,499	3,383
Europe and other countries	7,286	1,421
United States	1,143	299
	11,928	**5,103**
Revenue by product group and services provided		
Revenue from licensing agreements	8,429	1,719
Research and development tax incentive rebate	3,377	3,366
Other, including other government support and interest received	122	18
	11,928	**5,103**

26. CONTROLLED ENTITIES

	COUNTRY OF INCORPORATION	2023	2022
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%
Subsidiary of Acrux Commercial Pty Ltd			
Fempharm Pty Ltd	Australia	100%	100%

27. PARENT ENTITY DETAILS

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

	PARENT ENTITY	
	2023 $'000	2022 $'000
Assets		
Current assets	3,258	5,139
Non-current assets[1]	33,344	25,299
Total assets	**36,602**	**30,438**
Liabilities		
Current liabilities	249	314
Non-current liabilities	7,142	–
Total liabilities	**7,391**	**314**
Net assets	**29,211**	**30,124**
Equity		
Share capital	114,884	114,563
Profit reserve	7,390	7,390
Accumulated losses	(93,972)	(92,689)
Share based payments reserve	909	860
Total equity	**29,211**	**30,124**

(1) Investment in subsidiaries re initially recognised at cost and 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

	PARENT ENTITY	
	2023 $'000	2022 $'000
Loss for the financial year	(1,283)	(1,404)
Other comprehensive income for the financial year		–
Total comprehensive income for the financial year	**(1,283)**	**(1,404)**

28. CONTINGENCIES

There were no contingencies at 30 June 2023 (2022: nil).

29. SUBSEQUENT EVENTS

In July 2023, Acrux's application for a generic version of AbbVie's Rectiv 0.4%, Ointment, Nitroglycerin 0.4%, Ointment was accepted by the FDA for review. This product treats pain caused by chronic anal fissure and is Acrux's seventh ANDA application to be accepted for FDA review.

No other matter or circumstance has arisen since 30 June 2023 that has significantly affected the group's operations, results or state of affairs, or may do so in the future years.

30. SIGNIFICANT CHANGES IN THE STATE OF AFFAIRS

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.

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 31 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 2023 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 2023.

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
24 August 2023

Don Brumley
Non-executive Director

Melbourne
24 August 2023

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 2023, the consolidated statement of profit and 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 Company's financial position as at 30 June 2023 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 a Financial Report* section of our report. We are independent of the Company 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.

ACRUX LIMITED
AND CONTROLLED ENTITIES
ABN 72 082 001 152

INDEPENDENT AUDITOR'S REPORT
TO THE MEMBERS OF
ACRUX LIMITED

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.

Key Audit Matter	How our audit addressed the key audit matter
Recoverability of Deferred Tax Assets Refer to note 1(b) on page 35, note 2(a) on page 37 and note 6 on page 40.	
The Group has $803k ($1.356 million as at 30 June 2022) of deferred tax assets recognised as at 30 June 2023 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 key management assumptions required in forecasting future taxable profit. Management's key 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; • Understanding and evaluating the design and implementation of 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.

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INDEPENDENT AUDITOR'S REPORT
TO THE MEMBERS OF
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Other Information

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 2023 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, 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.

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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 22 to 28 of the directors' report for the year ended 30 June 2023. In our opinion, the Remuneration Report of Acrux Limited and its controlled entities, for the year ended 30 June 2023, 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

24 August 2023

Shareholder Information

Additional information required by Australian Securities Exchange Listing Rules and not disclosed elsewhere in this report, as at 17 August 2023.

SHAREHOLDERS

The Company has 288,188,456 ordinary fully paid shares on issue, held by 4,797 shareholders, and 9,944,371 rights held by 25 people. The Company has no other equity securities on issue. Holders of ordinary shares are entitled to receive dividends as declared and are entitled to one vote per share at shareholders' meetings. No voting rights or dividend entitlements 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	990	493,167
1,001 to 5,000	1,376	4,012,839
5,001 to 10,000	604	4,882,535
10,001 to 100,000	1,351	48,222,515
100,001 and over	476	230,577,400
Total	**4,797**	**288,188,456**

2,978 shareholders hold less than a marketable parcel of fully paid ordinary shares, based on the market price at the date set out above.

SUBSTANTIAL HOLDERS

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. 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

TWENTY-FIVE LARGEST HOLDERS OF FULLY PAID ORDINARY SHARES IN ACRUX LTD

		Number of Fully Paid Ordinary Shares	Percentage of issued Capital
1	PHILLIP ASSET MANAGEMENT LIMITED	31,847,134	11.05
2	CITICORP NOMINEES PTY LIMITED	4,831,059	1.68
3	HISHENK PTY LTD	4,500,000	1.56
4	DR THOMAS VUI CHUNG CHAI	4,460,560	1.55
5	MR ROSS DOBINSON	4,355,174	1.51
6	PACIFIC CUSTODIANS PTY LIMITED	3,849,912	1.34
7	ASHWOOD RIVER PTY LTD	3,800,000	1.32
8	DDH GRAHAM LIMITED	3,682,818	1.28
9	MR PAUL COZZI	3,259,121	1.13
10	THE POOLE FAMILY SUPERANNUATION FUND PTY LTD	3,000,000	1.04
10	MR CHRISTOPHER MURRAY ABBOTT	3,000,000	1.04
11	MR DONALD CHARLES BRUMLEY	2,853,998	0.99
12	TSO PTY LTD	2,625,734	0.91
13	MR ALAN JEBB & MRS SANDRA JEBB	2,430,707	0.84
14	WILLOUGHBY CAPITAL PTY LTD	2,300,000	0.80
15	MR IAN VICTOR LANCINI & MRS DEBRA ANN LANCINI	2,045,000	0.71
16	MR BIKASH KAJI BANIYA	2,012,119	0.70
17	ADAM JAMAL	1,905,719	0.66
18	DURBIN SUPERANNUATION PTY LTD	1,727,640	0.60
19	ASIA UNION INVESTMENTS PTY LIMITED	1,691,083	0.59
20	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED	1,657,801	0.58
21	NEWECONOMY COM AU NOMINEES PTY LIMITED	1,511,799	0.52
22	MR MICHAEL JOHN KOTSANIS	1,511,083	0.52
23	MR DAVID ANDREW SLOBOM & MRS LINDA JANE SLOBOM	1,409,596	0.49
24	MR STEPHEN EDWARD MAHNKEN & MRS DIOR LEONE MAHNKEN	1,319,986	0.46
25	MORGAN STANLEY AUSTRALIA SECURITIES (NOMINEE) PTY LIMITED	1,306,852	0.45
Total Top 25 shareholders		**98,894,895**	**34.32**

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 of PDFs are entitled to concessionary tax treatment in Australia. Typically no capital gains tax is payable in relation to the sale of PDF shares and dividends are exempt from income tax. This means profits derived by shareholders from their investment are typically tax free and this 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 *Income Tax Assessment Act 1997*.

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

Australian resident shareholders can elect to treat dividends as exempt from tax. Unfranked PDF distributions and the unfranked part of a franked distribution are exempt from tax and a franked portion of a PDF distribution is also exempt from income tax unless the shareholder elects to be taxed on it.

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 *Income Tax Assessment Act 1997* and any such gain may be included in the shareholder's assessable income.

Glossary

Term	Abbreviation	Description
Abbreviated New Drug Application	ANDA	An ANDA is an application for a generic drug approval for an existing approved drug. The ANDA is submitted for review to the FDA's Centre for Drug Evaluation and Research, Office of Generic Drugs. Once approved, an applicant may manufacture and market the generic drug product to provide a safe, effective, low cost alternative to the American public. All approved products are listed in FDA's Orange Book. In order to achieve approval, applicants must demonstrate bioequivalence to the innovator drug.
Active Pharmaceutical Ingredient	API	Also known as active drug substance and is the therapeutically active component in a medicine's final formulation which is responsible for its physiological action.
Acyclovir 5%, Cream		Indicated in the United States for the topical treatment of coldsores.
Addressable market		Total market sales value and volume of a pharmaceutical product in a specific dosage form. This market data is purchased from IQVIA.
Bioequivalence/ Bioavailability		Bioequivalence studies compare the bioavailability of the proposed drug product with the Reference Listed Drug (RLD) containing the same active ingredient. Bioequivalence is the absence of a significant difference in the rate and extent to which the drug substance becomes available at the site of drug action when administered at the same dose under similar conditions.
Contract Manufacturing Organisation	CMO or CDMO	A CMO serves other companies in the pharmaceutical industry on a contract basis to provide services that may range from drug development services and commercial manufacturing.
Contract Research Organisation	CRO	A CRO provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis. CROs may be involved in all aspects of the clinical development process, from initial drug discovery through pre-clinical and clinical trials and regulatory approval.
Dapsone Gel		Indicated in the United States for the topical treatment of acne vulgaris.
Estradiol		Estradiol is a form of estrogen, a female sex hormone produced by the ovaries and is used to treat symptoms of menopause.
Evamist®		Brand name for Acrux's unique Estradiol Spray product in the United States. The Evamist® trademark is owned by Lumara Health and sublicensed to Padagis.
Food and Drug Administration	FDA	The FDA is the government body that ensures safe and effective drugs are available to improve the health of people in the United States. It regulates and supervises prescription, over-the-counter pharmaceutical drugs (medications), vaccines, biopharmaceuticals and veterinary products.
Gedeon Richter		Gedeon Richter Plc. is Axrux's licensee for Lenzetto® and is a major international pharmaceutical company headquartered in Hungary.
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 approved by national regulatory authorities.
Good Manufacturing Practice	GMP or cGMP	Good Manufacturing Practices (GMP, also referred to as 'cGMP' or 'current Good Manufacturing Practice') is the aspect of quality assurance that ensures medicinal products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the product specification.
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.

Term	Abbreviation	Description
In-vitro Release Testing	IVRT	Measurement of drug release from dosage forms applied topically for the purpose of 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.
IQVIA		IQVIA Inc, is a US based multinational company which provides, on a subscription basis, pharmaceutical industry-leading sales data.
Lenzetto®		Brand name for Acrux's unique Estradiol Spray in the European Union and other countries. The Lenzetto® trademark is owned by Gedeon Richter.
Nitroglycerin 0.4%, Ointment		Indicated in the United States for moderate to severe pain associated with chronic anal fissure.
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) and related patent and exclusivity information.
Padagis		Padagis US LLC is a pharmaceutical manufacturer that offers high quality generic and specialised pharmaceutical and OTC products that meet strict standards of quality and safety. Padagis' line of extended topicals includes prescription creams, ointments, suspensions, gels, foams, sprays, patches, nasal, and suppositories and is a market leader in that segment in the United States.
Pooled Development Fund	PDF	The *Pooled Development Fund Act 1992* was established by the Federal Government to increase the supply of capital to Australian small and medium-sized enterprises to enable those businesses to grow and develop their own markets, creating industry and jobs for Australia. To incentivise investors, a concessional tax regime was established for those companies that were registered as Pooled Development Funds (PDFs).
Prilocaine 2.5% and Lidocaine 2.5%, Cream		Indicated in the United States topical anesthetic for use on normal intact skin for local analgesia or genital mucous membranes for superficial minor surgery and as pretreatment for infiltration anesthesia.
Product-Specific Guidance	PSG	To facilitate generic drug product availability and identify the most appropriate methodology for developing drugs and generating evidence to support ANDA approval, the FDA publishes product-specific guidance describing their current thinking and expectations on how to develop generic drug products therapeutically equivalent to specific reference listed drugs.
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.
Topical		Topical is a route of administration wherein active pharmaceutical ingredients are applied to or affect a localised area of the body.
Volume Weighted Average Price	VWAP	Being a commonly used abbreviation for the Volume Weighted Average Share Price.

Corporate Directory

COMPANY INFORMATION

Directors
Ross Dobinson – Non-executive Director and Chairman
Geoff Brooke – Non-executive Director
Don Brumley – Non-executive Director
Tim Oldham – Non-executive Director
Michael Kotsanis – CEO and Managing Director

Company Secretary
Joanna Johnson

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Link Market Services
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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

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