



Invested in tomorrow

Annual Report 2022



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 through our licensees 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.

For further information on Acrux, visit www.acrux.com.au



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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 statements made in this report.

*Cover:
Senior formulation scientist,
Jean, visually inspecting
uniformity of blend of a cream.*

Operating and Financial Review

Revenue from licensing and customer contracts was up by 32% in FY22, predominantly due to Lenzetto which continues to gain market share in existing territories and is being launched into new territories.

In FY22 and we have worked to progress the pipeline through development and regulatory phases to have further products to launch in FY23 and beyond.

Highlights

1

Product launched

1

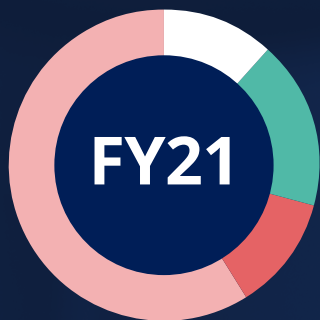
Product approved by the FDA

1

Dossier accepted for FDA review

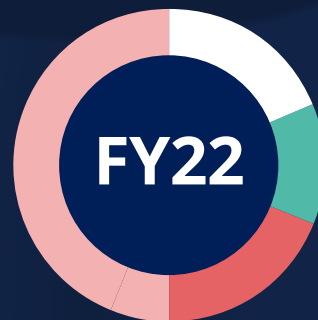
3

Dossiers under FDA review



- On market
- Approved for launch
- Under FDA review
- Under development

Portfolio progression



- On market
- Approved for launch
- Under FDA review
- Under development

Our key operational focus for the coming year is to achieve FDA approval for the 3 products currently under review and to have further products accepted.

The launch of these products will build a reliable and sustainable revenue stream to fund future portfolio development.

**The period to the end of 2023 is transformative.
The key objective is to build a sustainable and robust revenue stream.**

One product to launch 1HFY23

2 products to be accepted for FDA review in FY23

Pending FDA approval, 2 products to launch in 2023

Launching these products will drive sustainable revenues and generate cash for future profitability and provide funding for the product pipeline through operating cashflows.



*Analytical Development Team Leader,
Philippa, inspecting samples.*

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 our products.

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 the generic drug 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 and no difference when substituted for the brand name product.

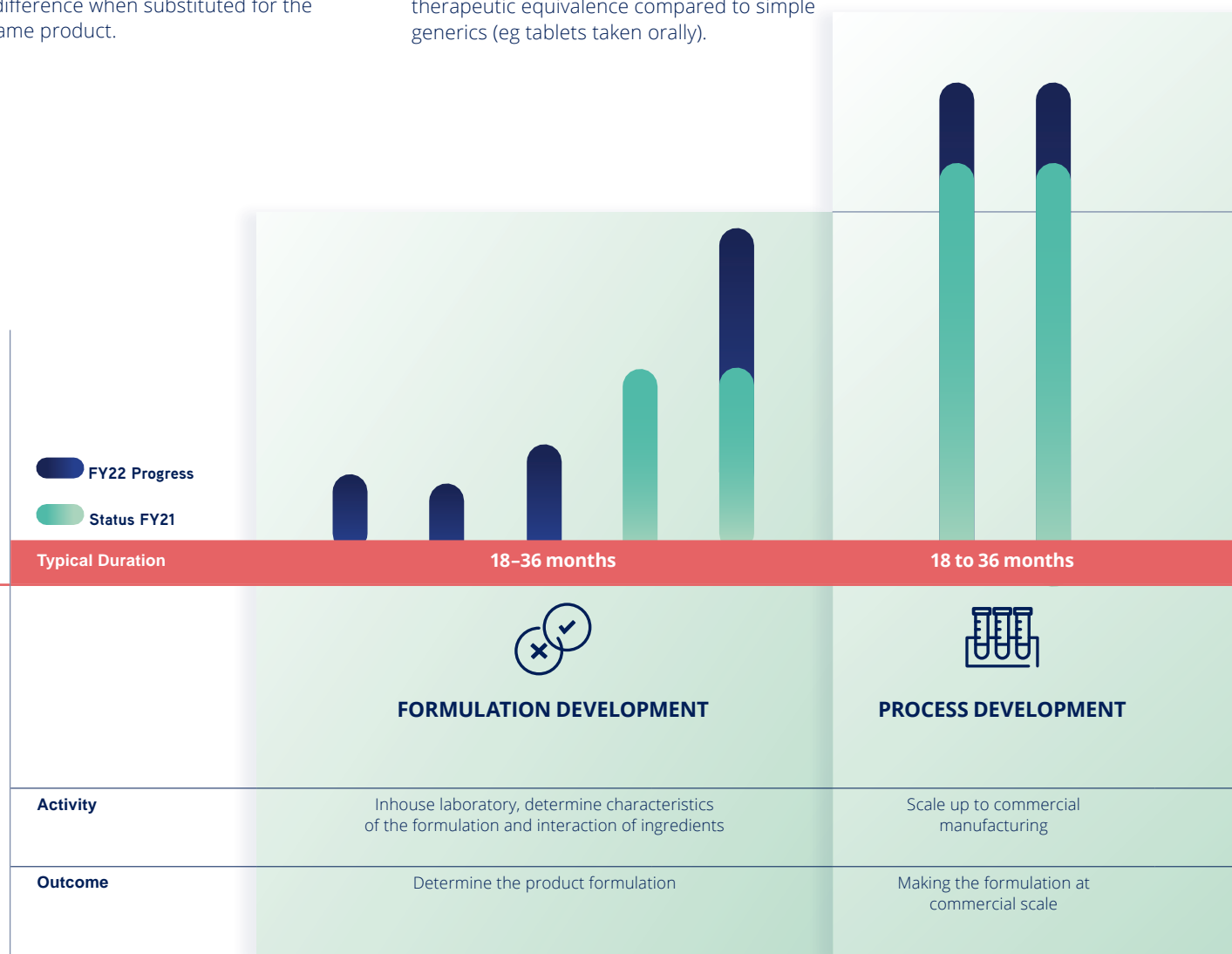
Product Development Phase

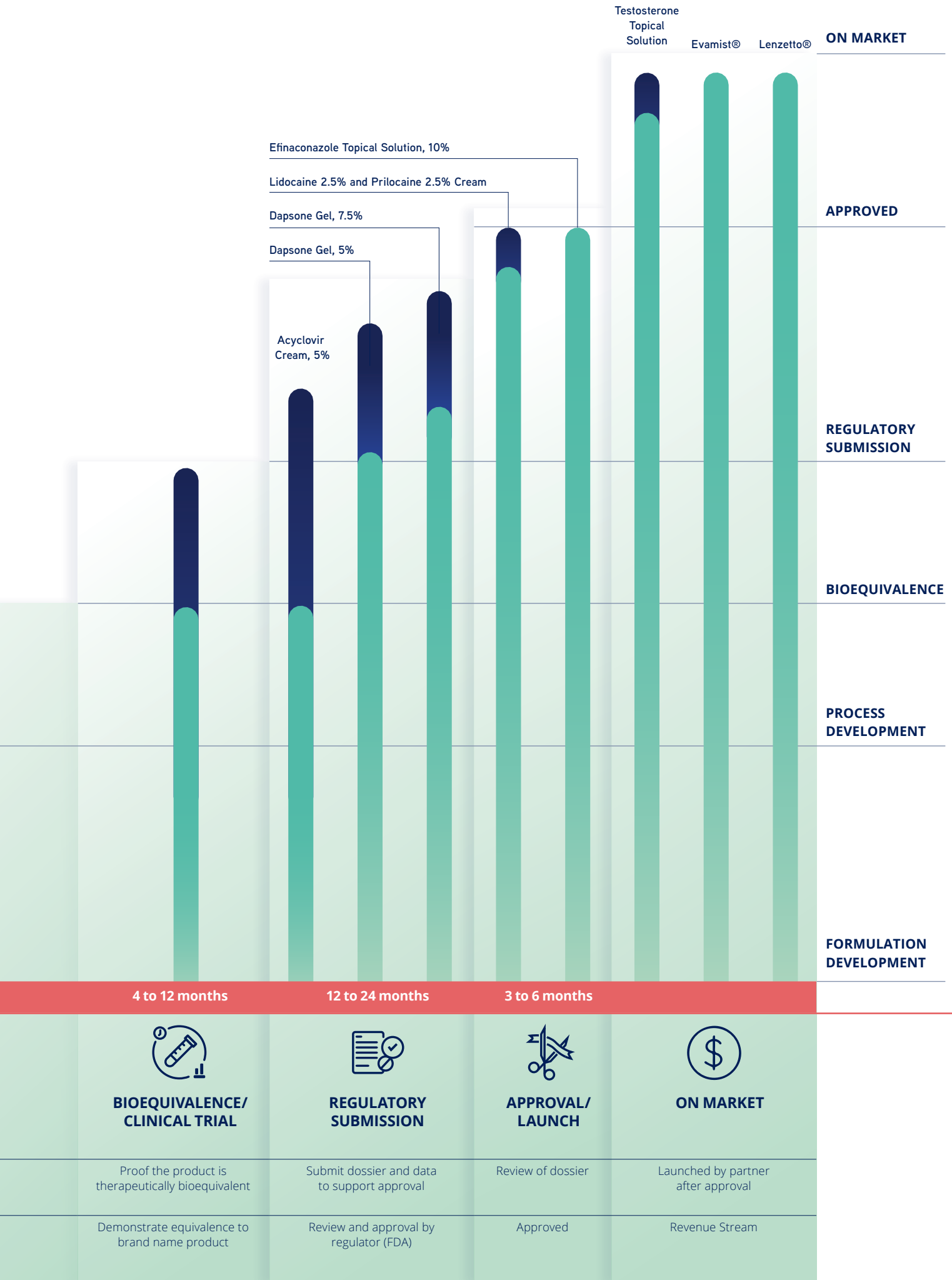
The timeline presented below is not strictly sequential and there is overlap between project phases, eg. elements of Formulation Development and Process Development can be performed concurrently rather than sequentially.

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).





Chairman & CEO Report

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

We enter our 25th year at a pivotal point in the Company's evolution

We enter our 25th year at a pivotal point in the Company's transformation as we progress our near-term product development candidates through the regulatory approval process and into commercialisation.

Acrux has several exciting product launches planned for the new financial year and two regulatory approvals are expected, which will lead to product launches.

THE PRODUCT DEVELOPMENT PIPELINE

Acrux has three commercialised products, two products nearing regulatory approval and an additional product that has recently been accepted for review by the FDA¹.

We are advancing our product pipeline through the varying stages of development, either at Acrux or with our contracted manufacturing partners. Our main priority is on later stage projects that will reach commercialisation in the short term, while continuing development of earlier-stage products to ensure breadth of our product pipeline.

The Company now has 16 products in its portfolio, including 5 approved products and 3 dossiers currently being reviewed by the FDA, and intends to maintain 10-12 products in development. Since the date of the last Directors' Report, we added 1 new development project to the pipeline and ceased development on 2 projects where it was considered that the estimated future commercial returns were unlikely to adequately cover development costs.

The Operating and Financial Review on pages 2 to 5 expands on the operational and pipeline progress made in FY22.

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.

STRATEGY

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

Our three key strategic priorities are:

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

Revenue realisation is the transformation driver for the Company. We have one product which has been approved with prelaunch activities in progress plus a further 2 products which are in late-stage review by the FDA. We continue to develop earlier-stage products to ensure the breadth of our pipeline.

Operational efficiency supported by resource and cost management to deliver a diversified portfolio of products to commercialisation with revenue generation over the next three years.

Portfolio management to maximise commercial returns based on strategic product selection. A key component of successful portfolio management is the ongoing intelligence gathering and assessment in a rapidly changing product and market landscape.

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

1. Refer ASX Announcement dated 8 August 2022 on the Company's website under the *Investor Centre* tab.

FINANCIAL PERFORMANCE

Acrux's total revenue was \$5.103 million for the financial year ended 30 June 2022 and which was consistent with the prior financial year. The net loss after tax was \$9.834 million, which was lower by 23% from the prior financial year, primarily driven by a reduction in external research and development expenditure.

Whilst the year on year external research and development expenditure was lower by \$2.557 million, progress on the product development pipeline has been maintained.

The value of research and development expenditure incurred in any period is dependent on the stage of projects, with late stage project costs associated with products at the FDA submission stage being materially lower than costs incurred at the process development or bioequivalence testing phases.

Through the period to the end of 2023 we plan:

- Continued revenue growth of the Estradiol product;
- Launching one product which has received FDA approval in 1HFY23;
- Obtaining FDA approval and launching 2 further products in 2023; and
- The continued eligibility of product development expenditure for the research and development tax incentive rebate.

Cash on hand reported at the end of June 2022 totalled \$5.831 million. Acrux's future cash requirements have been carefully considered and the timing and commercial success of product launches over the next 12 months are critical to these estimates. Due to the dependence on the timing of FDA approval for new products, additional capital management strategies which may include monetisation of receivable assets or the deferral of product development expenses can be implemented if required.

Six topical generic products are either approved or under FDA review and that number is expected to grow in the near term

Technical Affairs Manager, Visal, reviewing formulation blend.



*Formulation Scientist, Hemang,
mixing a test formulation.*





BOARD AND CORPORATE GOVERNANCE

In June 2021 Acrux was pleased to welcome Mr Don Brumley to the Board of Directors. Don was previously a Senior Partner at Ernst and Young. He brings significant, highly relevant financial skills and experience to the Board, particularly to his role as Chairman of the Company's Audit and Risk Committee. We refer you to page 16 for Don's biography alongside those of other members of our Board.

During the year, the Board has reviewed and updated all Corporate Governance policies as part of the routine review cycle. Our Corporate Governance policies are published on the Acrux website under the Corporate Governance tab.

The Board also reviewed the skills that each Director brings to the Board through the Board Skills Matrix. This is a necessary process to identify potential gaps in Board skill sets, areas for improvement and future skill requirements.

The Directors consider that Acrux has complied with all applicable environmental laws and regulations throughout the year ended 30 June 2022 and no related issues have arisen between the end of the financial year and the date of this report.

The Company promotes a supportive, equitable and inclusive culture where the need for diversity is recognised.

The Environment, Social and Governance (ESG) Report can be found on page 12.

INVESTED IN TOMORROW

Acrux has a number of exciting products in its pipeline. The majority of our pipeline products are already licensed for the US market with recognised commercial generic companies. We continue to receive enquiries from prospective licensees indicating the strong interest in our topical dosage product range, which is characterised by high development complexity relative to other generics. This results in lower commercial competition than is typical in the oral solid dose sector of the US market for generics.

FY23 OBJECTIVES

Our key objectives in FY23 are:

- One product is approved, licensed and ready for launch as soon as product batches have been manufactured and released for sale. An additional product is planned to be launched, following regulatory approval and manufacturing. Acrux will receive quarterly profit share payments for these products
- Receive approval for two products from the FDA to facilitate product launches in FY23 and FY24. Each product is licensed on the basis of a quarterly profit share payable to Acrux
- Submit two products for FDA review in FY23.

Revenue growth will accelerate in FY23 with several products progressing through regulatory review and into the commercialisation phase.

We would like to personally thank the Acrux team of employees and the Board for their valuable contributions, sustained efforts and focus on the company's revenue growth objectives.

Finally, we would like to thank you, our shareholders, for maintaining faith in Acrux which will be warranted as we enter the revenue growth phase.

Ross Dobinson
Chairman (L)

Michael Kotsanis
CEO & MD (R)

Our Strategy

Our three key strategic priorities are:

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

Revenue realisation is the transformation driver for the Company. We are in the commercialisation phase of several late-stage products. We will continue to develop earlier-stage products to ensure the breadth of our pipeline.

Operational efficiency supported by resource and cost management to deliver a diversified portfolio of products to commercialisation with revenue generation over the next three years.

Portfolio management to maximise future commercial returns based on strategic product selection. A key component of successful portfolio management is the ongoing intelligence gathering and assessment in a rapidly changing product and market landscape.

Our business model



1.

GENERIC DRUG IDENTIFICATION, OPPORTUNITY ASSESSMENT



2.

FORMULATION DEVELOPMENT



3.

PROCESS DEVELOPMENT AND TECHNOLOGY TRANSFER TO CONTRACT MANUFACTURERS



4.

BIOEQUIVALENCE - DEMONSTRATE THERAPEUTIC BIOEQUIVALENCE



5.

REGULATORY SUBMISSION AND REVIEW OF DOSSIER AND DATA



6.

PRODUCT APPROVAL AND LAUNCH



7.

ON-MARKET - PROFIT SHARE REVENUE FROM COMMERCIAL PARTNERS

Our Business

The success of Acrux's strategy and execution will be driven and measured by:

- commercial launch and cash flow generation from new topical generic drugs
- licensing and profit share agreements with generic pharmaceutical companies
- FDA approvals for new products
- ongoing screening and initiation of new products in development



Formulation Scientist, lasmin, reviewing samples.

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.



ENVIRONMENTAL TENET

Acrux strives to minimise its environmental impact by minimising the use of consumables such as paper, avoiding single use vessels and recycling materials where possible. We will continue to identify and implement initiatives in both the laboratory and office to minimise our environmental footprint.

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

- Laboratory Waste – 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 waste collection.
- Trade Water Waste – Acrux has an agreement with City West Water under the *Water Industry Act 1994* and *Water Industry Regulations 2006*, to ensure trade waste is managed effectively and responsibly.

The Directors consider Acrux has complied with all applicable environmental laws and regulations throughout the year ended 30 June 2022 and no related issues have arisen since the end of the financial year to the date of this report.

We seek to partner with organisations who share these environmental values.



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 well as ensuring our employees have the necessary skills and resources to perform their roles to a high standard. We promote a supportive, equitable and inclusive culture where diversity is embraced.

Acrux's diversity policy is integral to our talent management and recruitment strategies. Diversity is defined broadly to include gender, nationality, ethnicity, disability, sexual orientation, gender identity, age, socioeconomic status, family status, religious beliefs and language. Our diversity objectives support our employees to be valued and respected in the workplace (inclusion) and to experience fair treatment and access to opportunities (equity).

We seek to partner with organisations who share these social values.

COVID-19 impacts

The challenges Acrux continues to face with the pandemic are similar to those experienced by many companies. During government-imposed lockdowns our laboratory team continued their work from the company's laboratory and our administrative staff worked from home.

Acrux's diversity policy is integral to our talent management and recruitment strategies.

Project planning and execution had already become more complex in recent years with many contract manufacturers, raw material suppliers and commercial partners located outside Australia. The COVID pandemic has exacerbated that complexity and contributed to certain cost increases and time delays. Some service providers have been disrupted and were unable to provide a continuous service.

Acrux has proactively planned for contingencies including the assessment of alternate service providers and operational locations. The Acrux team has successfully progressed the development pipeline with minimal disruption while also dealing with the personal and professional challenges that COVID-19 has provided to the healthcare and general community in Australia and globally.

GOVERNANCE TENET

Acrux is committed to good corporate governance, including ethical conduct. Further to Acrux's corporate governance policies which are published on the Company's website, <https://www.acrux.com.au>, the Company's *RIOS – Together Anything is Possible* model articulates our Company values and the core behaviours are expected of all employees. These core Company values are: *Round the clock, Innovation, Openness and Standout*. Commitment to these 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

Acrux's corporate governance framework reflects the Company's values and culture and stands alongside legislative requirements in the *Corporations Act 2001* and guidance in the ASX Corporate Governance Council's Corporate Governance Principles and Recommendations (4th edition). Our Corporate Governance Statement has been considered and approved by the Board and can be viewed in the Investor Relations section of our website, <https://investors.acrux.com.au/investor-centre>.

The Board Charter is the central tenet 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>. The Board of Directors is responsible for overseeing management, providing strategic direction, capital planning, risk management, monitoring operational and financial 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, international business, finance and accounting, risk management, corporate governance, organisation and talent development as well as team fit.

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 reporting and audit. The Audit and Risk Committee is responsible for the evaluation of Acrux's risk profile and assessment of the risks and mitigation strategies which have been identified by management.

The Human Capital and Nominations Committee is in place ensure the Board is comprised of individuals who can best discharge the responsibilities of Directors and ensuring the Company recruits and retains employees of high quality and motivation to drive long term growth. Responsibilities include recruitment as well as the establishment of the short and long term remuneration framework and other people-related policies.

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

These committees each have Charters which formally outline their responsibilities and membership requirements and can be viewed in the Investor Relations section of our website, <https://investors.acrux.com.au/investor-centre>.

ETHICS AND VALUES

Our Code of Conduct provides the ethical framework for the way Acrux conducts business and relates to its stakeholders, including shareholders, employees, business partners, customers, suppliers, the community and the environment in which the Company operates.

We expect third parties with which we work to comply with the local laws and regulations of the countries in which they operate, and to also observe the principles outlined in our Code of Conduct. Acrux's Code of Conduct can be viewed in the Investor Relations section of our website, <https://investors.acrux.com.au/investor-centre>.



BOARD OF DIRECTORS

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

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

There were five directors throughout the year, comprising four independent, Non-Executive directors and one Executive director. All Directors have 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 2021 is provided below, together with details of the Company Secretary as at the year end.



Responsibilities

Non-executive Chairman

Qualifications

BBus (Acc)

Experience

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

Ross Dobinson
appointed
March 1998

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.



Responsibilities

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

Qualifications

BSc (Hons), LLB (Hons), PhD

Experience

Tim 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, an 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 Oldham
appointed
October 2013

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



Geoff Brooke
appointed
June 2016

Responsibilities

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



Don Brumley
appointed
June 2021

Responsibilities

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

Qualifications

FCA, AICD

Experience

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

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



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



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 Company Secretary and a member of the Institute of Chartered Accountants Australia and New Zealand. She has more than 25 years' experience in the pharmaceuticals industry, having held senior financial leadership positions at IDT Australia Ltd, Generic Health Pty Ltd, Hospira Inc, Mayne Pharma Ltd and FH Faulding Ltd.

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

INFORMATION ON SENIOR MANAGEMENT



Felicia Colagrande
Product Development
and Technical Affairs
Director since
February 2015

Qualifications

BSc (Hons), MBA

Experience

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

Felicia has 30 years' experience in the pharmaceutical/biotech industry, joining Acrux in 2001. Felicia has previously held positions at Faulding Pharmaceuticals, the Department of Clinical Pharmacology and Therapeutics at the Austin Hospital, Silliker-Microtech Laboratories and was an Adjunct Appointee Lecturer with the Faculty of Pharmacy and Pharmaceutical Sciences at Monash University. Felicia has a Bachelor of Science degree (with Honours) from La Trobe University and an MBA from the Australian Institute of Business.



Mark Hyman
Project and Technical
Development Director
since July 2020

Qualifications

BSc

Experience

Mark has a diverse background in the pharmaceutical and medical device industry. Following a pharmacokinetic research role with Melbourne University, Mark joined Acrux in 2015 and has more than 30 years' industry experience, previously holding leadership positions in Quality, Manufacturing, Logistics & Operations, Product Development, Project Management and Commercial Development.

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



Charles O'Sullivan
Portfolio Director
since July 2015

Qualifications

BPharm

Experience

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

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

Directors' Report (including Remuneration Report) and Financial Statements



*Formulation Scientist, Matthew,
testing a product formulation.*

Directors' Report

For the year ended 30 June 2022

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 2022. Complying with the provisions of the Corporations Act 2001, the Directors report as follows:

DIRECTORS

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

Ross Dobinson	Chairman
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 been in office from the commencement of the financial year to the date of this report. Additional details of the Board of Directors and the Company Secretary is set out in the Governance Section of this Annual Report. These details include the period they have held office, their qualifications, independence, experience, particular responsibilities and other directorships.

DIRECTORS ATTENDANCE OF MEETINGS

Attendance of Directors at Board and Board Committee meetings is set out in the table below:

	BOARD		AUDIT AND RISK		HUMAN CAPITAL AND NOMINATION	
	HELD ⁽¹⁾	ATTENDED	HELD ⁽¹⁾	ATTENDED	HELD ⁽¹⁾	ATTENDED
Ross Dobinson	6	6	–	2*	–	2*
Geoffrey Brooke	6	6	2	1	2	2
Don Brumley	6	6	2	2	2	2
Timothy Oldham	6	5	2	2	2	2
Michael Kotsanis	6	6	–	2*	–	2*

(1) The number of meetings held during the period and where the Director was a member of the Board or Committee. Directors who are not members of Committees 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 has continued to progress its product pipeline during the reporting period. Of the 5 currently approved products, 3 have been commercialised, one product has been approved and is planned for launch later in 2022 and launch plans for the fifth approved product Efinaconazole topical solution, 10% will progress within the terms of the confidential settlement agreement.

Within the development pipeline, 3 products are currently under review by the FDA. There are 8 products at various stages of active development.

Key milestones achieved in FY22 include:

- Lidocaine 2.5% and Prilocaine 2.5% Cream was approved by the FDA. This is Acrux's third Abbreviated New Drug Application ('ANDA') to receive approval and 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 reports annual sales of US\$29 million for the 12 months to December 2021 for this product;
- Testosterone Topical Solution USP, 30mg per actuation was launched through our partner Dash Pharmaceuticals. For the 12 months to December 2021 IQVIA reports an addressable market of US\$15 million per year for this product and there are 5 marketed generics;
- The generic equivalent to Aczone® (dapson) Gel, 5% was Acrux's fifth ANDA application to be accepted for review by the FDA in September 2021. IQVIA reports sales for the product for the 12 months to December 2021 of US\$25 million for this product. The product is used to treat acne;
- Patent litigation relating to the ANDA for a generic equivalent to Aczone® (dapson) Gel, 7.5% has been concluded in Acrux's favour. This product was accepted by the FDA for review in April 2021 and once regulatory review is complete and FDA approval received, Acrux will launch this product in conjunction with its commercial licensee. IQVIA reports sales for the 12 months to December 2021 of US\$124 million for this product; and
- In August 2022, Acrux's application for a generic version of cold sore treatment, Acyclovir Cream, 5% was accepted by the FDA for review following Acrux's regulatory ANDA submission to the FDA for the product in June 2022. This is the sixth ANDA application to be accepted for review by the FDA.

The Acrux portfolio of products is advancing

Acrux portfolio of topical prescription products	AUGUST 2020⁽²⁾	AUGUST 2021⁽²⁾	AUGUST 2022⁽²⁾
Commercialised ⁽¹⁾	2	2	3
Approved	2	4	5
Under review by FDA	3	2	3
Under development	10	11	8
Total products in portfolio	15	17	16

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

(2) Being the number of active projects reported as at the date of the Directors' Report.

At present, Acrux has 3 products commercialised with two of those in the United States. Acrux licensed its estradiol product in Europe and many other countries to Gedeon Richter who market the product as Lenzetto® in its broad territory. Acrux also has a licensing agreement with Padagis for its estradiol product in the United States which Padagis markets as Evamist®. Acrux has licensed its testosterone solution product to Dash who launched the product earlier in the FY22 financial year.

Acrux currently has 2 dapson gel products under FDA review. These products were accepted for review in April 2021 and September 2021 respectively. The Company believes it has satisfactorily addressed all questions received from the FDA in relation to both products. The Company also announced a patent challenge for dapson gel, 7.5% in June 2021 which was subsequently resolved to the satisfaction of Acrux in May 2022. ANDA approvals were received for efinaconazole solution in June 2021 and prilocaine/lidocaine cream in July 2021. Acyclovir Cream, 5% is the third product currently under review by the FDA having been accepted in August 2022.

As outlined in the timeline of the Acrux pipeline on page 4, Acrux is dependent on timely outcomes from its internal development activities, its technical transfer and support activities with its contracted manufacturing partners and also from the US regulator for review of its regulatory submissions. A number of products in the pipeline have taken longer than anticipated to progress through each phase of development. The Company remains dependent on timely outcomes from regulatory submissions for its near term outcomes.

Acrux also executed a licensing agreement with Padagis for a near term product launch of an already approved product. Further details will be disclosed at the time of the launch of this product.

Directors' Report (continued)

Financial Performance

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

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

The consolidated loss before tax totals \$9.582 million and this loss is 23% lower than the consolidated operating loss before tax for the prior corresponding period of \$12.432 million. This is due to a reduction of operating expenses relating to the timing of milestones within key product development projects resulting in a year on year reduction in costs incurred to progress the Group's generic pipeline \$2.557 million. Project activities remain on track and this timing of project expenses within projects does not reflect any adjustment to project timelines.

Revenue

Revenue and other income for the year was stable at \$5.103 million (2021: \$5.156 million).

Revenue from product licensing agreements is derived from partner sales of Estradiol and testosterone and totalled \$1.719 million, an increase of 29% over \$1.337 million reported in the prior period. This revenue growth is predominantly comprised of:

- Revenue share income of \$1.456 million (up by 33%) from licensee sales of Estradiol spray. This increase has been driven by continuing growth of sales of Lenzetto® by our partner, Gedeon Richter, for territories in Europe and other countries, contributing \$1.421 million, an increase of 39%;
- \$0.263 million for the sale of an active pharmaceutical ingredient to a commercial partner for use in commercial manufacture (2021: nil); and
- No contractual milestones were achieved in the current reporting period (2021: \$0.245 million).

Other Revenue predominantly reflects the research and development tax incentive rebate, including overseas finding, receivable from the Australian Taxation Office and has been estimated at \$3.050 million for the year ended 30 June 2022 bringing the income from the research and development tax incentive rebate reported for the current reporting period to \$3.366 million. This is consistent with \$3.421 million recorded in the prior reporting period.

In the prior reporting period \$0.364 million was received from the Australian Federal Government in the form of COVID-19 relief programs. No such government support was received in the current reporting period.

Further information about Revenue is reported in Note 4.

Expenses

Due to the timing of external development expenses associated with the progression of pipeline projects, such as bioequivalence studies and manufacturing scaleup, total operating expenditure for the year was lower than the prior corresponding period by \$2.903 million, 17%, declining to \$14.685 million. Employee benefits expense totaled \$5.245 million (2021: \$5.418 million).

Further information about Expenses is reported in Note 5.

Significant changes in the state of affairs

On 11th March 2020 the World Health Organisation declared the global outbreak of COVID-19 as a global pandemic. While the global economy has been impacted significantly, Acrux has experienced limited financial impact although at times has had difficulties with raw material supply and disrupted operations at contract research organisations (CROs) and contract manufacturing organisations ('CMOs') resulting in some minor delays to product development project timelines.

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 August the FDA accepted Acrux's sixth ANDA application for review for its generic version of cold sore treatment, Acyclovir Cream, 5%.

No other matter or circumstance has arisen since 30 June 2022 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 and commercial success of product launches, timely achievement of development milestones and receipt of regulatory approval from FDA for products in the development pipeline, as well the evaluation and selection of attractive new development 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 following Remuneration Report forming part of the Report of Directors, prepared in accordance with s300A of the *Corporations Act 2001*.

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

Remuneration Policy

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

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

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

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

Directors' Report (continued)

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; and
- variable remuneration, which may comprise a short term incentive in the form of a cash bonus and a long term incentive in the form of an equity instrument issued under the Omnibus Equity Plan.

The Group seeks to establish fixed remuneration at a level which is consistent with market rates for comparable jobs in the industry sector. Incentive plans are in place to reward superior performance and are awarded subject to achievement of objectives which are set and assessed by the Board.

Short Term Incentive Plan

The short term incentive plan is designed to reward the achievement of business and personal objectives as established at the beginning of each year by the Board and in consultation with senior management. Selected objectives create long term value for shareholders and include clearly defined outcomes for product development, regulatory approval and commercialisation. Achievement or non-achievement of objectives is objectively measured at the end of the financial year.

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

Long Term Incentive Plan

The long-term incentive plan is designed to align the interests of senior management with shareholders to achieve sustainable, long term superior performance. The long term incentive plan has been designed to comply with both the requirements of ASX Listing Rules and the *Pooled Development Funds Act 1992*.

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

Grants of securities under the OEP are as follows:

A. Chief Executive Officer ('CEO')

- At the 2021 AGM, 6 million performance rights over 4 tranches were approved. Each tranche vests after 12 months over 4 successive years, provided the total shareholder return ('TSR') over that period equals or is greater than 10% and employment is continuous;
- Unvested tranches may be "rolled over" into the next year but are subject to an additional 10% TSR hurdle for each year. Each tranche may be rolled over up to 3 times;
- Each performance right carries the right to one ordinary share in Acrux Ltd; and
- Performance rights expire 7 years after granting and are expensed over the life of the instrument.

B. Senior management, including KMP

- Directors may approve an annual grant of Performance Rights to management;
- Each grant of performance rights vests after one year, provided the TSR over that period equals or is greater than 10% and employment is continuous;
- Unvested tranches may be "rolled over" into following years, but are subject to an additional 10% TSR hurdle for each year. There will be no "roll-over" after the fourth year;
- Each performance right carries the right to one ordinary share in the Acrux Ltd; and
- Performance rights expire 7 years after granting and are expensed over the life of the instrument.

C. Directors

- At the 2018 AGM, shareholders approved the issue of rights equivalent to 10% of annual fees payable to Directors in lieu of an increase in cash fees. These rights are now fully vested;
- At the 2019 AGM, shareholders resolved that 50% of fees due to Directors would be paid in the form of rights. The final tranches of these rights vest in November 2022;
- Each right carries the right to one ordinary share in the Acrux Ltd;
- Rights vest quarterly, provided that the Director has been continuously engaged from the grant date to the vesting date; and
- Rights expire 7 years after grant.

D. Employees, other than KMP

- The Board may approve the issue of up to \$1000 value of tax exempt ordinary shares to employees, each year at nil cost;
- Each grant of tax exempt ordinary shares is held in escrow for 3 years;
- There are no vesting conditions; and
- If an employee ceases employment the shares are immediately released from escrow.

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

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.

The total value of remuneration payable to Non-executive Directors has been set at \$70,000 per annum plus superannuation and plus the annual value of rights which vest over a four year period to January 2022 which were granted in lieu of a fee increase of 10%, approved by shareholders at the 2018 AGM. The Non-executive Chairman, Ross Dobinson, received Director's fees inclusive of superannuation to a value of \$132,400 per annum, also payable in both cash and rights.

At the 2019 AGM shareholders resolved for Directors' remuneration to be paid in both cash and equity. Equity is issued to Directors in the form of rights which vest quarterly over a 3 year period, subject to service criteria. Rights which are unvested at the time of retirement of a Director are cancelled and rights are issued to newly appointed Directors after shareholder approval has been received at the AGM following their appointment.

The maximum aggregate value of Non-executive Directors' annual fees 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 Non-executive Directors do not receive additional remuneration for membership of Board Committees.

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

(1) Appointed Non-executive Director 4 June 2021.

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

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.

Directors' Report (continued)

Remuneration and termination entitlements of Key Management Personnel

Senior management do not have a fixed term of employment and employment contracts may be terminated by either party based on notice periods ranging between one and six months. Employment contracts contain no entitlement to termination benefits beyond statutory entitlements.

Names and positions held by 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

All KMP have been in office since the start of the financial year until the date of this report.

Details of the remuneration of the Group's KMP is provided in the following table:

	Primary			Post Employment	Long Term Benefit	Share Based Payments			Equity as % Total	Bonus as % Total
	Salary \$	Movement Annual Leave Provision ⁽⁴⁾ \$	Short Term Incentive ⁽⁵⁾ \$	Super-annuation \$	Long Service Leave Accrued \$	Other \$	Performance Rights \$	Total Remuneration \$		
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%
2021										
Michael Kotsanis	434,862	33,451	92,408	21,694	8,153	-	54,852	645,420	8%	14%
Deborah Ambrosini ⁽²⁾	251,667	19,089	-	27,088	(4,532)	62,044	5,306	360,662	1%	-
Felicia Colagrande	220,271	16,942	31,468	21,151	5,006	-	20,714	315,552	7%	10%
Mark Hyman	212,804	16,369	30,404	20,709	6,296	-	7,726	294,308	3%	10%
Joanna Johnson ⁽³⁾	9,659	-	-	966	-	-	-	10,625	-	-
Charles O'Sullivan	212,804	16,369	30,404	20,619	4,018	-	20,714	304,928	7%	10%
	1,342,067	102,220	184,684	112,227	18,941	62,044	109,312	1,931,495	6%	10%

(1) Effective 1 July 2021, Charles O'Sullivan's standard work hours reduced from 5 days per week to 4 days and his salary was adjusted accordingly.

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

(3) Chief Financial Officer and Company Secretary commenced 16 June 2021.

(4) 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.

(5) A short term incentive may be paid based on assessment of achievement of corporate objectives as established at the beginning of the financial year. For the financial year ended 30 June 2021, achievement of corporate objectives were assessed by the Board at 85% and the reported balances were accrued and then paid in August 2021. For the financial year ended 30 June 2022, achievement of corporate objectives were assessed by the Board at 55% and these reported balances were accrued and then paid in August 2022.

Equity instruments held by Key Management Personnel

Ordinary Shares

The number of ordinary shares held by Directors and KMP at financial year end is set out in the following table:

	Balance 1 July 2021	On Market Transactions	Rights exercised	Balance 30 June 2022
Directors				
Ross Dobinson	3,308,284	–	407,776	3,716,060
Geoff Brooke ⁽¹⁾	474,221	–	–	474,221
Don Brumley ⁽¹⁾	500,000	275,000	229,160	1,004,160
Tim Oldham ⁽¹⁾	223,539	–	646,110	869,649
Senior Management				
Michael Kotsanis	1,511,083	–	–	1,511,083
Felicia Colagrande	126,500	–	280,000	406,500
Mark Hyman	27,882	–	–	27,882
Joanna Johnson	–	–	–	–
Charles O'Sullivan	405,000	–	–	405,000
	6,576,509	275,000	1,563,046	8,414,555

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

Rights

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

6,000,000 performance rights were issued to the Chief Executive Officer, Mr Michael Kotsanis, following shareholder approval received at the 2021 Annual General Meeting. 3,000,000 unvested performance rights issued in November 2017 were cancelled because performance conditions were not achieved. Performance rights vest in 4 annual tranches, provided the total shareholder return (TSR) over that period is equal to or greater than 10% and continuous employment. Performance Rights expire after 7 years and are expensed over the life of the instrument.

1,136,039 performance rights were issued to eligible employees on 10 February 2022, including but not limited to KMP. Performance rights vest after one year, provided the total shareholder return (TSR) over that period equals or is greater than 10% and continuous employment. Performance Rights expire after 7 years and are expensed over the life of the instrument.

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

347,624 rights were granted to Mr Don Brumley after being approved by shareholders at the 2021 Annual General Meeting. Mr Brumley, who was appointed to the Board in June 2021, receives approximately half of his remuneration as equity in the form of rights vesting on a quarterly basis in arrears in accordance with service.

Directors' Report (continued)

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

	Balance at 1 July 2021	Granted as remuneration	Rights exercised	Cancelled	Balance at 30 June 2022	Value of Rights Granted \$(⁽¹⁾)
Directors						
Ross Dobinson	571,670	–	407,776	–	163,894	–
Geoff Brooke	663,332	–	–	–	663,332	–
Don Brumley	–	347,624	229,160	–	118,464	36,501
Tim Oldham	743,332	–	646,110	–	97,222	–
Senior Management						
Michael Kotsanis	3,000,000	6,000,000	–	3,000,000	6,000,000	436,930
Felicia Colagrande	420,000	210,000	280,000	–	350,000	13,020
Mark Hyman	178,595	210,000	–	–	388,595	13,020
Joanna Johnson	–	210,000	–	–	210,000	13,020
Charles O'Sullivan	140,000	168,000	–	–	308,000	10,416
	5,716,929	7,145,624	1,563,046	3,000,000	8,299,507	522,907

(1) Value of rights granted in current reporting period to be recognised over the life of the instrument.

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

Date rights granted	Number rights	Value at grant date	Minimum Exercise price ⁽⁵⁾	Rights expiry date
25 January 2018	64,000	\$0.17	\$0.1579 ⁽²⁾	January 2025
23 November 2018	80,000	\$0.19	– ⁽⁴⁾	January 2023
4 February 2019	138,000	\$0.18	\$0.2081 ⁽²⁾	February 2026
9 December 2019	844,448	\$0.185	– ⁽⁴⁾	November 2026
3 February 2020	82,595	\$0.185	\$0.1996 ⁽²⁾	February 2027
4 February 2021	575,298	\$0.17	\$0.2706 ⁽²⁾	February 2028
30 November 2021	6,000,000	\$0.114	\$0.1258 – \$0.1502 ⁽¹⁾	December 2028
30 November 2021	118,464	\$0.114	– ⁽⁴⁾	November 2026
10 February 2022	1,126,949	\$0.103	\$0.1128 ⁽³⁾	February 2029
	9,029,754			

(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 directors vest each quarter in arrears and are not subject to an exercise price.

(5) Minimum exercise price is the hurdle which must be achieved after 12 months for the Performance Rights to vest. If the original hurdle target is not achieved, additional uplift hurdles are applied each year for the right to vest over the life of the instrument.

Voting and comments made at the Company's 2021 Annual General Meeting (AGM)

Last year's Remuneration Report was supported at the 2021 AGM with 88% of votes cast in favour of acceptance. No questions relating to the Remuneration Report were received from shareholders.

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.

	2022 \$	2021 \$
Amount paid or payable to Pitcher Partners (Melbourne) for non-audit services	32,855	48,730
Amount paid or payable to network firms of Pitcher Partners for non-audit services	–	–
	32,855	48,730

Directors are satisfied that the provision of the non-audit services during the year by the auditors is compatible with the general standard of independence for auditors imposed by the *Corporations Act 2001* for the following reasons:

- all non-audit services were subject to the Group's corporate governance procedures and have been reviewed and approved by the Audit and Risk Committee to ensure they do not impact on the integrity and objectivity of the auditor; and
- the non-audit services 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 *Corporation Act 2001* in relation to the audit for the financial year is included after this report.

Rounding of amounts

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

Directors Resolution

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



Ross Dobinson
Non-executive Chairman
Melbourne
25 August 2022



Don Brumley
Non-executive Director
Melbourne
25 August 2022

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 2022, to the best of my knowledge and belief there have been:

- (i) No contraventions of the auditor independence requirements of the *Corporations Act 2001*; and
- (ii) No contraventions of APES 110 *Code of Ethics for Professional Accountants (including Independence Standards)*.

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

A handwritten signature in black ink, appearing to be 'N R Bull'.

N R BULL
Partner

25 August 2022

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

PITCHER PARTNERS
Melbourne

Pitcher Partners. An independent Victorian Partnership ABN 27 975 255 196. Level 13, 664 Collins Street, Docklands, VIC 3008
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Consolidated Statement of Profit or Loss and Other Comprehensive Income

For the year ended 30 June 2022

	Note	Consolidated	
		2022 \$'000	2021 \$'000
Revenue from licensing agreements	4	1,719	1,337
Other revenue	4	3,384	3,819
Total revenue		5,103	5,156
Employee benefits expense	5	(5,245)	(5,418)
Directors' fees		(185)	(184)
Securities based payment expense	18(a)	(450)	(507)
Depreciation and amortisation expenses	5	(660)	(665)
Occupancy expenses		(201)	(247)
External research and development expenses		(6,371)	(8,928)
Professional fees		(454)	(644)
Other expenses		(1,119)	(995)
Total expenses		(14,685)	(17,588)
Loss before income tax		(9,582)	(12,432)
Income tax expense	6	(252)	(197)
Net loss for the year		(9,834)	(12,629)
Total comprehensive loss for the year		(9,834)	(12,629)
Total comprehensive loss attributable to:			
Members of the parent entity	19	(9,834)	(12,629)
Loss per share for loss attributable to the equity holders of the parent entity:			
Basic loss per share	8	(3.46) cents	(5.75) cents
Diluted loss per share	8	(3.46) cents	(5.75) cents

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

Consolidated Statement of Financial Position

As at 30 June 2022

	Note	Consolidated	
		30 June 2022 \$'000	30 June 2021 \$'000
Current Assets			
Cash and cash equivalents	9	5,831	15,270
Receivables	10	3,765	3,159
Other current assets	11	420	165
Total Current Assets		10,016	18,594
Non-Current Assets			
Plant and equipment	12	682	538
Intangible assets	13	375	482
Deferred tax asset	6	1,355	1,607
Lease assets	14	1,874	2,106
Total Non-Current Assets		4,286	4,733
Total Assets		14,302	23,327
Current Liabilities			
Payables	15	2,219	1,780
Provisions	16	875	801
Lease liabilities	14	224	185
Total Current Liabilities		3,318	2,766
Non-Current Liabilities			
Provisions	16	40	41
Lease liabilities	14	1,854	2,049
Total Non-Current Liabilities		1,894	2,090
Total Liabilities		5,212	4,856
Net Assets		9,090	18,471
Equity			
Contributed equity	17	114,563	114,213
Reserves	19	8,250	8,147
Retained earnings/(losses)	19	(113,723)	(103,889)
Total Equity		9,090	18,471

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 2022

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

	Note	Contributed equity \$'000	Reserves \$'000	Retained earnings/ (losses) \$'000	Total equity \$'000
Balance as at 1 July 2021		114,213	8,147	(103,889)	18,471
Total comprehensive 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 2022

	Note	Consolidated	
		30 June 2022 \$'000	30 June 2021 \$'000
Cashflows from operating activities			
Receipts from product agreements		1,357	1,228
Payments to suppliers and employees		(13,144)	(15,785)
Interest received		26	40
Finance costs		(172)	(185)
Research and development tax incentive rebate		3,114	2,924
Government support received		-	364
Net cash used in operating activities	20(a)	(8,819)	(11,414)
Cashflows from investing activities			
Payment for property, plant and equipment		(465)	(102)
Net cash used in investing activities		(465)	(102)
Cashflows from financing activities			
Proceeds from capital raising		-	17,747
Lease liability principal repayments		(155)	(167)
Net proceeds from/(used in) financing activities		(155)	17,580
Net increase/(decrease) in cash and cash equivalents		(9,439)	6,064
Cash and cash equivalents at beginning of year		15,270	9,206
Cash at the end of the year	20(b)	5,831	15,270

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

Notes to the Consolidated Financial Statements

For the year ended 30 June 2022

This financial report covers Acrux Limited and controlled entities as a Group. Acrux Limited is a for-profit entity, incorporated and domiciled in Australia. It is a company limited by shares publicly traded on the Australian Securities Exchange. The address of Acrux Limited's registered office and 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 fair value, as described in the accounting policies. Fair value is the price that would be received to sell an asset, or paid to transfer a liability, in an orderly transaction between market participants (under current market conditions) at measurement date, regardless of whether that price is directly observable or has been 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 are available to measure fair value, maximising the use of relevant observable inputs and minimising the use of unobservable inputs.

Inputs to valuation techniques used to measure fair value are categorised into three levels according to the extent to which 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 significant to the financial report are disclosed in the Notes to the consolidated financial statements.

(b) Going Concern Basis of Preparation

The financial report has been prepared on a going concern basis which contemplates 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 \$9,834 million during the year ended 30 June 2022 (30 June 2021: loss after tax from ordinary operations \$12.629 million) and produced a negative cash flow from operating activities for the year ended 30 June 2022 of \$8,819 million (30 June 2021: negative cash flow from operating activities \$11.414 million). The ability of the Group to continue as a going concern is dependent on its ability to generate future revenues which will support improved cash flows from 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 twelve months beyond the date of approval of these financial statements, which incorporate the following factors:

- Continued revenue growth of the Estradiol product;
- Launching one product which has received FDA approval;
- Obtaining FDA approval and launching further products, which are currently undergoing the FDA review process; and,
- The continued eligibility of product development expenditure for the research and development tax incentive rebate.

Additionally, the Directors continue to monitor expenditure against budget and are exploring other options should the cashflows be materially different to those forecast. In the event of a product launch which may be delayed, the Company could implement cash management strategies which could include:

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

On this basis no adjustments have been made to the financial report 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. Accordingly, the financial report has been prepared on a going concern basis.

Should the Group be unsuccessful with the initiatives detailed above then, there is 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 different from those shown in the financial statements.

Notes to the Consolidated Financial Statements (continued)

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, including unrealised profits or losses, between Group companies are eliminated on consolidation. A list of controlled entities is contained in Note 26.

(d) Impairment of non-financial assets

In accordance with *AASB 136 Impairment of assets*, assets subject to annual depreciation or amortisation are reviewed for impairment at least annually or whenever events or circumstances arise that indicate the carrying amount may be impaired. An impairment loss is recognised where the carrying amount of the asset exceeds its estimated recoverable amount. The estimated recoverable amount is the higher of its fair value less costs to dispose and its value in use. An impairment loss is disclosed as a separate line item on the Consolidated Statement of Comprehensive Income.

(e) Financial instruments

Initial recognition and measurement

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

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

Classification of financial assets

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

Financial assets not irrevocably designated on initial recognition at FVtOCI are classified and measured at amortised cost, FVtOCI or fair value through profit or loss ('FVtPL') on the basis of both 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 that entity operates ('the functional currency'). Consolidated financial statements are presented in Australian dollars, which is the functional and presentation currency of the Group and 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 re-statement 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, except if 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.

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

(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 off 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 at 30 June 2022

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

2. SIGNIFICANT ACCOUNTING ESTIMATES AND JUDGEMENTS

Preparation of these financial statements requires the Group to make estimates and judgements that may affect the reported values of assets, liabilities, revenues and expenses. Management continually evaluates such estimates and judgements based on historical experience and other factors it believes 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 and have the most significant effect on amounts recognised in the Group's financial statements:

(a) Income tax

Income tax benefits are recognised based on assumptions that no adverse change will occur in income tax legislation, that the Group will derive sufficient future assessable income to enable the benefit to be realised and it will comply with the conditions of deductibility imposed by the law. Deferred tax assets are recognised for deductible temporary differences where management considers that 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 evaluate and determine that capitalised product development costs and other assets are not carried at a value that materially exceeds the recoverable value. Future cash flows are estimated and are discounted for risks specific to the assets as well as for the time value of money. The following approach and assumptions have been applied:

- product revenue is estimated using current market data and projections of future market volumes, product pricing trends and market share, adjusted for the impact of potential competitors entering the market and the market impact of those competitors;
- cash flow forecasts are over 10 years; and
- cash flows have been 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, calculated based on assessment of trends relating to retention of staff, future remuneration levels 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 Consolidated Statement of Profit or Loss and Other Comprehensive Income in the period(s) the benefit is earned over the life of the instrument. The total value of the share or right is calculated at the time of issue and performance rights are valued using Monte Carlo or Black and Scholes pricing models which require input of 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 past 12 months. The risk free interest rate is the Reserve Bank of Australia's cash rate as at the instrument's grant date.

Notes to the Consolidated Financial Statements (continued)

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 or future cash flows of a financial instrument will fluctuate due to changes in foreign exchange rates. The Group is exposed to currency risks due to certain revenues and expenses being denominated in a foreign currency, typically US dollars and Euro. Currency risk management strategies are regularly reviewed and the Company expects to have future foreign currency denominated cashflows in place from future revenues and to offset expenditure and protect against the impact of short term currency fluctuations.

Bank accounts denominated in US dollars and Euro are maintained to facilitate foreign currency receipts and payments and manage foreign exchange risk. As at 30 June 2022, US dollar denominated cash reserves totalled A\$0.008 million (2021: A\$0.032 million) and Euro denominated cash reserves totalled A\$0.369 million (2021: A\$0.263 million).

The balance of receivables as at 30 June 2022 includes US\$0.181 million (2021: US\$0.01 million) and EUR 0.392 million (2021: EUR 0.182 million). The balance of payables includes US\$0.161 million (2021: US\$0.153 million) and EUR nil (2021: EUR 0.001 million). A change in the AUD/USD and AUD/EUR exchange rates would therefore have little financial impact on the consolidated net profit/(loss) and equity of the Group (2021: 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. Credit worthiness is reviewed and exposure to any one party is monitored. Potential credit loss is regularly assessed and a provision would be raised if there was evidence that a debt was no longer collectible. The Company does not have a history of defaulted balances nor 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 \$5.831 million (2021: \$15.270 million), which as outlined in Note 1(b) above 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 cashflow projections.

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

4. REVENUE

	2022 \$'000	2021 \$'000
Revenue from contracts with customers		
Revenue from licensing agreements	1,719	1,337
Other revenues		
Interest	18	34
Grant revenue – R&D tax incentive rebate	3,366	3,421
Grant revenue – Other	–	364
Total other revenue	3,384	3,819
Total revenue from continuing operations	5,103	5,156

Key Accounting Policies

Revenue from contracts with customers

Revenue is derived from licensing agreements with customers in the form of revenue and profit share receipts, sale of active pharmaceutical ingredients and also contractual milestones. Revenue is recognised in the period in which product sales occur. Revenue from contractual milestones is recognised at completion of the milestone.

Other revenues

Other revenue is recognised as it has been received or, if it can be reliably estimated, over the period to which it relates. Grants from the Government are recognised at fair value where there is reasonable assurance that the grant will be received, it can be reliably measured and the Group will comply with all conditions. As the Group can reliably estimate its R&D tax incentive rebate an accrual has been recognised. In the prior reporting period \$0.364 million other grant revenue was received from the Australian Federal Government in the form of COVID-19 relief programs, including the JobKeeper allowance.

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

5. LOSS FROM CONTINUING OPERATIONS

	2022 \$'000	2021 \$'000
Loss from continuing operations before income tax has been determined after the following specific expenses:		
Employee benefits expense		
Wages and salaries	4,448	4,574
Superannuation costs	418	400
Other employee benefits expense	379	444
Total employee benefits expense	5,245	5,418
Depreciation of non-current assets		
Right of use asset	200	233
Plant and equipment	344	322
Total depreciation of non-current assets	544	555
Amortisation of non-current assets		
Leasehold improvements	9	3
Capitalised research and development	107	107
Total amortisation of non-current assets	116	110
Total depreciation and amortisation of non-current assets	660	665

Notes to the Consolidated Financial Statements (continued)

6. INCOME TAX

	2022 \$'000	2021 \$'000
(a) Income tax recognised in profit and loss		
Current tax	–	–
Deferred tax	252	197
Over/under provision in prior years	–	–
Income tax (benefit)/expense attributable to profit and loss	252	197
(b) Reconciliation of income tax (benefit)/expense		
The prima facie tax payable on loss before income tax is reconciled to the income tax (benefit)/expense as follows:		
Loss before tax from continuing operations	(9,582)	(12,432)
Prima facie income tax payable on loss before income tax	(2,919)	(3,232)
Add/(subtract) tax effect:		
Non-deductible expenses	140	132
Research and development tax incentive rebate	(1,010)	(890)
Non-assessable income	–	(13)
Impact of change in tax rate on Deferred tax asset	28	38
Tax losses not brought to account	3,824	4,106
Parent entity net rate adjustment and tax losses and temporary differences not brought to account	189	56
	3,171	3,429
Income tax (benefit)/expense attributable to loss	252	197
(c) Current tax		
Current tax (asset)/liability	–	–
(d) Deferred Tax		
<i>Deferred tax assets is comprised:</i>		
Accruals and provisions	318	197
Leasehold improvements and Plant and equipment	–	108
Plant and equipment under lease	51	33
Intangible Assets	1,023	1,068
Exchange differences	2	–
Tax losses and research and development offset	932	1,076
	2,326	2,482
<i>Deferred tax liabilities is comprised:</i>		
Plant and Equipment and Intangible assets	(942)	(844)
Prepayments	(29)	(26)
Exchange differences	–	(5)
	(971)	(875)
Net deferred tax assets/(liabilities)	1,355	1,607
(e) Deferred tax assets not brought to account		
Temporary differences	(106)	(123)
Tax losses	22,784	19,385
	22,678	19,262

Key accounting policies

Current income tax expense/benefit is the tax payable on the current period's taxable income at the applicable income tax rate adjusted by changes in deferred tax assets and liabilities attributable to temporary differences and to unused tax losses.

Deferred tax assets and liabilities are recognised as temporary differences at the applicable tax rate when the assets are expected to be recovered or liabilities to be settled. No deferred tax asset or liability is recognised in relation to temporary differences if they arose in a transaction, other than a business combination, that at the time of the transaction did not affect either accounting profit or taxable profit or loss. Deferred tax assets are recognised for deductible temporary differences and unused tax losses only when it is probable that future taxable amounts will be available to utilise those temporary differences and losses.

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

	2022 \$'000	2021 \$'000
(a) Dividends paid and declared		
Nil dividends were declared or paid during the financial year (2021: \$nil)	–	–
(b) Franking account		
Balance of franking account at financial year end, adjusted for franking credits arising from payment of income tax, franking debits from payment of dividends and any credits that may be prevented from distribution in subsequent years.	43,835	43,835

8. LOSS PER SHARE

	2022 \$'000	2021 \$'000
Loss from continuing operations	(9,834)	(12,629)
Loss used in calculating basic and diluted earnings per shares	(9,834)	(12,629)

	No. of shares	No. of shares
Weighted average number of ordinary shares used in calculating basic earnings per share	283,881,613	219,726,077
Effect of dilutive securities:	–	–
Adjusted weighted average number of ordinary shares used in calculating diluted earnings per share	283,881,613	219,726,077
Basic loss per share (cents)	3.46	5.75
Diluted loss per share (cents)	3.46	5.75

9. CASH AND CASH EQUIVALENTS

	2022 \$'000	2021 \$'000
Cash on hand and at bank	2,831	7,270
Term Deposits	3,000	8,000
	5,831	15,270

Key accounting policies

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

Notes to the Consolidated Financial Statements (continued)

10. RECEIVABLES

	2022 \$'000	2021 \$'000
Receivables from contracts with customers	262	288
Other receivables	3,503	2,871
	3,765	3,159

Key accounting policies

Trade and other 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 simplified approach, the Group determines losses based on the expected life of the instrument. After initial measurement, the collectability of receivable balances is reviewed on an ongoing basis and a provision raised if collection in full is not considered probable. Debts which are known to be uncollectable are written off. The Company does not have a history of collection delays, defaulted balances or client dispute and does not consider a provision for expected credit losses is necessary at this time.

11. OTHER CURRENT ASSETS

	2022 \$'000	2021 \$'000
Prepayments	420	165

12. PLANT AND EQUIPMENT

	2022 \$'000	2021 \$'000
<i>Leasehold improvements</i>		
At cost	47	47
Accumulated amortisation	(24)	(15)
Total leasehold improvements	23	32
<i>Plant and equipment</i>		
At cost	2,319	1,916
Accumulated depreciation	(1,660)	(1,410)
Total plant and equipment	659	506
	682	538
Reconciliations of the carrying amounts of plant and equipment at the beginning and end of the current financial year:		
<i>Leasehold improvements</i>		
Carrying amount at the start of the year	32	24
Additions	–	11
Amortisation expense	(9)	(3)
Carrying amount at the end of the year	23	32
<i>Plant and equipment</i>		
Carrying amount at the start of the year	506	737
Additions	465	91
Depreciation expense	(312)	(322)
Carrying amount at the end of the year	659	506

Key accounting policies

Cost and valuation

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

Depreciation

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

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

The useful lives for each class of assets are:

	2022	2021
Leasehold improvements	5 to 20 years	5 to 20 years
Plant and equipment	1 to 16 years	1 to 16 years

13. INTANGIBLE ASSETS

	2022 \$'000	2021 \$'000
External development expenditure capitalised	1,071	1,071
Accumulated amortisation	(696)	(589)
Total intangible assets	375	482
Carrying amount of Estradiol at the start of the year	482	589
Additions	–	–
Amortisation	(107)	(107)
Carrying amount of Estradiol at the end of the year	375	482

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 technical, financial and other resources to complete development of the product, 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 amortised on a systematic basis from the time the product becomes available for use until the earlier of the date that the asset is classified as held for sale (or included in a disposal group that is classified as held for sale) in accordance with *AASB 5 Non-current assets held for sale and discontinued operations* and the date that the asset is derecognised.

The remaining estimated useful life and total economic benefit for each asset is reviewed at least annually.

Notes to the Consolidated Financial Statements (continued)

14. LEASE ASSETS AND LEASE LIABILITIES

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

	2022 \$'000	2021 \$'000
Leased assets		
Carrying amount of lease assets, by class of underlying asset:		
Buildings under lease arrangements		
At cost	2,409	2,409
Accumulated depreciation	(602)	(402)
	1,807	2,007
Plant and equipment under lease arrangements		
At cost	142	142
Accumulated depreciation	(75)	(43)
	67	99
Total carrying amount of Leased assets	1,874	2,106
Reconciliation of carrying amount of Leased assets at the beginning and end of the financial year:		
Buildings under lease arrangements		
Carrying amount at the beginning of the period	2,007	2,208
Depreciation	(200)	(201)
Carrying amount at the end of the period	1,807	2,007
Plant and equipment under lease arrangements		
Carrying amount at the beginning of the period	99	131
Depreciation	(32)	(32)
Carrying amount at the end of the period	67	99
Lease Liabilities		
Lease liabilities (current)	224	185
Lease liabilities (non-current)	1,854	2,049
Total carrying amount of lease liabilities	2,078	2,234
Lease expenses and cashflows		
Interest expense on lease liabilities	172	185
Depreciation expense on lease assets	201	233
Total cash outflow in relation to leases	327	352
Future commitments		
Future minimum lease payments to be made:		
— Not later than 1 year	335	344
— Later than 1 year and not later than 5 years	1,295	1,317
Aggregate of lease payments contracted for at reporting date	1,630	1,661

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 the date of lease commencement. These lease payments are discounted at the interest rate implicit in the lease.

Subsequent to initial recognition, Lease liabilities are measured at the present value of the remaining lease payments 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

	2022 \$'000	2021 \$'000
Current		
Trade payables	789	312
Sundry creditors and accruals	1,430	1,468
	2,219	1,780

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 usually paid within 30 days of recognition. Payables are presented as current liabilities if payment is within 12 months of the reporting period.

16. PROVISIONS

	2022 \$'000	2021 \$'000
Current		
Employee entitlements	875	801
Non-current		
Employee entitlements	40	41
Aggregate employee entitlements	915	842

Key accounting policies

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

Provision is made for employee entitlements arising from employees rendering services up to the reporting date, including annual leave and long service leave. Liabilities 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 and are presented as current employee entitlements on the balance sheet. All other employee benefit liabilities are measured at the present value of the estimated future cash outflows in respect of services provided up to the reporting date and presented as a non-current liability on the balance sheet.

Notes to the Consolidated Financial Statements (continued)

17. CONTRIBUTED EQUITY

	2022		2021	
	No. of shares	000's \$	No. of shares	000's \$
(a) Issued and paid up capital				
Ordinary shares fully paid	285,364,669	114,563	283,305,394	114,213
(b) Movements in ordinary shares on issue				
Beginning of the financial year	283,305,394	114,213	168,583,515	96,137
Issued during the year:				
Issue of shares – two tranche placements	–	–	49,777,982	7,815
Issue of shares – Share Purchase Plan	–	–	63,298,095	9,932
Conversion of rights under the Omnibus Equity Plan	1,776,641	322	1,498,438	301
Share issues under Omnibus Equity Plan	282,634	28	147,364	28
Ordinary shares issued during the year	2,059,275	350	114,721,879	18,076
Ordinary shares on issue at reporting date	285,364,669	114,563	283,305,394	114,213

(c) Rights

During the financial year 7,483,663 rights were issued under the OEP (2021: 1,451,418). Rights hold no participation rights, but shares issued on exercise of rights rank equally with existing shares. At 30 June 2022, 8,299,507 rights were held by key management personnel (2021: 5,716,929).

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

	2022	2021
(i) Movement in the number of rights held under Omnibus Equity Plan are as follows:		
Opening balance	6,353,348	6,943,556
Granted during the year	7,483,663	1,451,418
Exercised during the year	(1,776,641)	(1,498,438)
Lapsed during the financial year	(3,030,616)	(543,188)
Closing balance	9,029,754	6,353,348

	2022 \$'000	2021 \$'000
(ii) Details of rights exercised during the financial year:		
Fair value as at issue date of shares issued during the financial year	322	301
(iii) Details of lapsed and cancelled rights		
Key management personnel	3,000,000	489,998
Other employees	30,616	53,190
Total rights lapsed or cancelled during the year	3,030,616	543,188

18. SHARE BASED PAYMENTS

	2022 \$'000	2021 \$'000
(a) Expenses recognised from share-based payment transactions		
The expense recognised within securities based payments expense in the statement of comprehensive income was as follows:		
Rights under the OEP	422	479
Issue of tax exempt ordinary shares to eligible employees	28	28
Total expenses recognised from securities based payment transactions	450	507

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, with both the Black Scholes option-pricing model and the Monte Carlo Simulation option-pricing model utilised.

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 a period of 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 or forfeited	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	320,000	–	(240,000)	–	80,000	80,000
9 December 2019	28 November 2026	1,658,334	–	(813,886)	–	844,448	665,276
30 November 2021	30 November 2028	–	347,624	(229,160)	–	118,464	–
Performance Rights – issued to CEO, KMP and other senior management							
14 November 2017	14 November 2024	3,000,000	–	–	(3,000,000)	–	–
25 January 2018	25 January 2025	97,000	–	(33,000)	–	64,000	64,000
4 February 2019	4 February 2026	381,000	–	(243,000)	–	138,000	138,000
3 February 2020	3 February 2027	300,190	–	(217,595)	–	82,595	82,595
4 February 2021	4 February 2028	596,824	–	–	(21,526)	575,298	–
30 November 2021	30 November 2028	–	6,000,000	–	–	6,000,000	–
10 February 2022	10 February 2029	–	1,136,039	–	(9,090)	1,126,949	–
		6,353,348	7,483,663	(1,776,641)	(3,030,616)	9,029,754	1,031,813

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 were issued to Directors in 2019 to comprise approximately 50% of the value of their remuneration. These rights have no performance conditions, vest on a quarterly basis and will be fully vested in November 2022. Following his appointment in June 2021 and after the following AGM, 347,237 rights were approved and issued to Don Brumley in December 2021. Assuming his continued service these rights vest on a quarterly basis until November 2022.

On 26 November 2021, 6,000,000 performance rights were issued to the Managing Director and CEO, Michael Kotsanis. These performance rights vest in 4 annual tranches subject to achievement of Total Shareholder Return of at least 10% per annum and including roll over provisions. 3,000,000 performance rights issued to him in 2017 did not vest and were cancelled.

Other senior employees, including KMP are offered performance rights which vest subject to achievement of performance hurdles. On 10 February 2022, 1,136,039 performance rights were issued to senior 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 on exercise of rights rank equally with existing ordinary shares.

Notes to the Consolidated Financial Statements (continued)

18. SHARE BASED PAYMENTS CONTINUED

Overview of Rights issued during the period:

Date of Issue	30 November 2021	30 November 2021	10 February 2022
Type of Rights	Non executive Directors Remuneration	CEO Performance Rights	Employee Performance Rights
Number of Rights issued	347,624	6,000,000	1,136,039
Fair value Measure	Direct Value	Black Scholes	Black Scholes
Weighted average share price at date of issue	11.4 cents	11.4 cents	10.3 cents
Exercise price	n/a	12.58–16.75 cents	11.33–12.46 cents
Volatility	n/a	67.75%	64.57%
Dividend yield expectations	n/a	Nil	Nil
Term	7 years	7 years	7 years
Risk free interest rate	n/a	1.14%	1.14%

19. RESERVES AND ACCUMULATED LOSSES

	2022 \$'000	2021 \$'000
Share based payment reserve	860	757
Profit reserve	7,390	7,390
Total Reserves	8,250	8,147
Accumulated losses	(113,723)	(103,889)
Share based payment reserve		
<i>(i) Nature and purpose of Share based payment reserve</i>		
This reserve is used to record the value of equity benefit provided to employees and Directors as part of their remuneration.		
<i>(ii) Movement in Share based payment reserve</i>		
Balance at the beginning of year	757	582
Employee performance rights expense for the year	103	175
Balance at end of year	860	757
Profit Reserve		
<i>Nature and purpose of Profit reserve</i>		
This reserve is used to record the profits which have been generated by the Group.		
Accumulated losses		
<i>Movement in Accumulated losses</i>		
Balance at the beginning of year	(103,889)	(91,260)
Net loss attributable to members of Acrux Limited	(9,834)	(12,629)
Balance at end of year	(113,723)	(103,889)

20. CASHFLOW INFORMATION

	2022 \$'000	2021 \$'000
(a) Reconciliation of the cashflow from operations with loss after income tax:		
Loss from ordinary activities after income tax	(9,834)	(12,629)
Non-Cash Items		
Depreciation and amortisation	660	664
Share based payments expense	450	507
Changes in assets and liabilities		
(Increase)/decrease in trade and other receivables	(606)	(600)
(Increase)/decrease in other current assets	(255)	415
Increase/(decrease) in payables	441	(103)
Increase/(decrease) in employee entitlements	73	135
Increase/(decrease) in deferred tax assets	252	197
	1,015	1,215
Net cash (outflows)/inflows from operating activities	(8,819)	(11,414)
(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	2,831	7,270
At call deposits with financial institutions	3,000	8,000
Closing cash balance	5,831	15,270

(c) Credit stand-by arrangement and loan facilities

The Group has credit card facilities with financial institutions available to the extent of \$120,000 (2021: \$120,000). At 30 June 2022 the Group had unused facilities of \$109,009 (2021: \$101,311).

21. KEY MANAGEMENT PERSONNEL COMPENSATION

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

	\$	\$
Short-term employment benefits	1,578,787	1,793,151
Post-employment benefits	158,917	213,196
Equity	397,797	332,715
Total KMP compensation	2,135,501	2,339,062

22. LOANS TO KEY MANAGEMENT PERSONNEL

No loans were made to Key Management Personnel 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 \$18.188 million (2021: \$13.399 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 (2021: \$0.366 million).

Other transactions with Key Management Personnel and their personally related entities

Transactions of Directors and Key Management Personnel concerning shares in accordance with the OEP are disclosed the Directors' Report and in Notes 17 and 18. There were no other transactions or contracts between the Company and Directors and Key Management Personnel in 2022 (2021: nil).

Notes to the Consolidated Financial Statements (continued)

24. AUDITOR REMUNERATION

	2022 \$'000	2021 \$'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	88	78
Taxation compliance and consulting	33	49
Other non-audit services	–	–
	121	127

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.

	2022 \$'000	2021 \$'000
Geographical segment information		
Australia	3,383	3,819
Europe and other countries	1,421	1,025
United States	299	312
	5,103	5,156
Revenue by product group and services provided		
Revenue from licensing agreements	1,719	1,092
Contractual milestones received in relation to development products	–	245
R&D Tax Incentive rebate	3,366	3,421
Other, including other government support and interest received	18	398
	5,103	3,945

26. CONTROLLED ENTITIES

	COUNTRY OF INCORPORATION	2022	2021
Parent Entity			
Acrux Limited	Australia		
Subsidiaries of Acrux Limited			
Acrux DDS Pty Ltd	Australia	100%	100%
Acrux Pharma Pty Ltd	Australia	100%	100%
Acrux Commercial Pty Ltd	Australia	100%	100%
Subsidiaries of Acrux Commercial Pty Ltd			
Fempharm Pty Ltd	Australia	100%	100%

27. PARENT ENTITY DETAILS

	PARENT ENTITY	
	2022 \$'000	2021 \$'000
(a) Summarised statement of financial position of the parent entity, Acrux Limited		
Assets		
Current assets	5,139	10,946
Non-current assets ⁽¹⁾	25,299	20,510
Total assets	30,438	31,456
Liabilities		
Current liabilities	314	381
Non-current liabilities	-	-
Total liabilities	314	381
Net assets	30,124	31,075
Equity		
Share capital	114,563	114,213
Profit reserve	7,390	7,390
Accumulated losses	(92,689)	(91,285)
Share based payments reserve	860	757
Total equity	30,124	31,075
(b) Summarised statement of comprehensive income		
Loss for the financial year	(1,404)	(875)
Other comprehensive income for the financial year	-	-
Total comprehensive income for the financial year	(1,404)	(875)

(1) Investment in subsidiaries are 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.

28. CONTINGENCIES

There were no contingencies at 30 June 2022 (2021: nil).

29. SUBSEQUENT EVENTS

In August the FDA accepted Acrux's sixth ANDA application for review for its generic version of cold sore treatment, Acyclovir Cream, 5%.

No other matter or circumstance has arisen since 30 June 2022 that has significantly affected the Group's operations, results or state of affairs, or may do so in future years.

30. SIGNIFICANT CHANGES IN THE STATE OF AFFAIRS

On 11th March 2020 the World Health Organisation declared the global outbreak of COVID-19 as a global pandemic. While the global economy has been impacted significantly, Acrux has experienced limited financial impact although at times has had difficulties with raw material supply and disrupted operations at contract research organisations (CROs) and contract manufacturing organisations (CMOs) resulting in some minor delays to product development project timelines.

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 51, 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 2022 and of its performance for the year ended on that date.
2. In the Directors' opinion there are reasonable grounds to believe that Acrux Limited will be able to pay its debts as and when they become due and payable.

This declaration has been made after receiving the declarations required to be made by the Chief Executive Officer and Chief Financial Officer to the Directors in accordance with section 295A of the *Corporations Act 2001* for the financial year ending 30 June 2021.

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



Ross Dobinson
Non-executive Chairman
Melbourne
25 August 2022



Don Brumley
Non-executive Director
Melbourne
25 August 2022

Independent Auditor's Report

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 2022, 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 2022 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.

Material Uncertainty Related to Going Concern

We draw attention to Note 1(b) in the financial report, which indicates that the Group incurred a net loss of \$9.834m during the year ended 30 June 2022 (2021: \$12.629m loss) and has produced a negative cash flow from operating activities for the year ended 30 June 2022 of \$8.822m (2021 negative cash flow: \$11.414m). As stated in Note 1(b), these events or conditions, along with other matters as set forth in Note 1(b), indicate that a material uncertainty exists that may cast significant doubt on the Group's ability to continue as a going concern. Our opinion is not modified in respect of this matter.

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

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

Key Audit 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
Assessment of impairment of Intangible Assets	
Refer to page 32 consolidated statement of financial position, note 2(b) on page 37 and note 13 on page 43.	
The Group has \$0.37 million (\$0.48 million as at 30 June 2021) of capitalised development costs as at 30 June 2022 after accumulated amortisation and impairment loss. We view intangible assets in relation to capitalised development costs to be a Key Audit Matter due to the management judgement required in making Discounted Cash Flow (DCF) model key assumptions such as discount rate, growth rate, foreign exchange rate and forecast cashflows.	Our procedures included amongst others: <ul style="list-style-type: none">• Critically evaluating management's DCF model methodology and their key assumptions utilised;• Testing the mathematical accuracy of the DCF model and assessing forecast cash flows to external data;• Performing sensitivity analysis around the discount rate, growth rates and foreign exchange rate used in the DCF model;• Understanding and evaluating the design and implementation of management's processes and controls around the impairment of intangible assets; and,• Assessing the appropriateness of the disclosures included in Notes 2 and 13 to the financial report in respect of impairment testing and sensitivity analysis.

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

Key Audit Matter	How our audit addressed the key audit matter
<p>Recoverability of Deferred Tax Assets</p> <p>Refer to note 1(d) on page 36, note 2(a) on page 37 and note 6 on page 40.</p> <p>The Group has \$1.356 million (\$1.607 million as at 30 June 2021) of deferred tax assets recognised as at 30 June 2022 relating to timing differences and Research and Development offset incurred by the subsidiary Acrux DDS Pty Ltd.</p> <p>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.</p> <p>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:</p> <ul style="list-style-type: none"> • 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. 	<p>Our procedures included amongst others:</p> <ul style="list-style-type: none"> • Tax expert review of the deferred tax calculation; • 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
ACRUX LIMITED**

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 2022 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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**ACRUX LIMITED
AND CONTROLLED ENTITIES
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**INDEPENDENT AUDITOR'S REPORT
TO THE MEMBERS OF
ACRUX LIMITED**

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

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

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 23 to 28 of the directors' report for the year ended 30 June 2022. In our opinion, the Remuneration Report of Acrux Limited and its controlled entities, for the year ended 30 June 2022, complies with section 300A of the *Corporations Act 2001*.

Responsibilities

The directors of the Company are responsible for the preparation and presentation of the Remuneration Report in accordance with section 300A of the *Corporations Act 2001*. Our responsibility is to express an opinion on the Remuneration Report, based on our audit conducted in accordance with Australian Auditing Standards.



N R BULL
Partner



PITCHER PARTNERS
Melbourne

25 August 2022

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Shareholder Information

Additional information required by Australian Securities Exchange Listing Rules and not disclosed elsewhere in this report, as at 8 August 2022.

SHAREHOLDERS

The Company has 285,364,669 ordinary fully paid shares on issue, held by 5,078 shareholders, and 9,029,754 rights held by 30 people. The Company has no other equity securities on issue. Holders of ordinary shares are entitled to receive dividends as declared from time to time and are entitled to one vote per share at shareholders' meetings. No voting rights attach to rights.

All fully paid ordinary shares are quoted on the Australian Securities Exchange. No other equity securities of the Company are quoted on the Australian Securities Exchange.

DISTRIBUTION SCHEDULE

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

Category	Number of Shareholders	Securities
1 to 1,000	1,016	514,121
1,001 to 5,000	1,457	4,254,158
5,001 to 10,000	651	5,266,311
10,001 to 100,000	1,467	52,209,523
100,001 and Over	463	11,120,556
Total	5,054	285,364,669

2,869 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

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

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

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

Shareholder Information (continued)

TWENTY LARGEST HOLDERS OF FULLY PAID ORDINARY SHARES IN ACRUX LIMITED

		Number of fully paid ordinary shares	Percentage of issued capital
1	PHILLIP ASSET MANAGEMENT LIMITED	31,847,134	11.16
2	DDH GRAHAM LIMITED	10,950,000	3.84
3	HISHENK PTY LTD	4,500,000	1.58
4	DR THOMAS VUI CHUNG CHAI	4,460,560	1.56
5	CITICORP NOMINEES PTY LIMITED	4,101,513	1.44
6	ASHWOOD RIVER PTY LTD	3,800,000	1.33
7	MR ROSS DOBINSON	3,716,060	1.30
8	MR PAUL COZZI	3,159,121	1.11
9	MR CHRISTOPHER MURRAY ABBOTT	3,000,000	1.05
10	PACIFIC CUSTODIANS PTY LIMITED	2,384,901	0.84
11	TSO PTY LTD	2,325,734	0.82
12	ALMIKE PTY LIMITED	2,162,456	0.76
13	MR IAN VICTOR LANCINI & MRS DEBRA ANN LANCINI	2,045,000	0.72
14	DURBIN SUPERANNUATION PTY LTD	2,035,000	0.71
15	ADAM JAMAL	1,905,719	0.67
16	ASIA UNION INVESTMENTS PTY LIMITED	1,691,083	0.59
17	MR ALAN JEBB & MRS SANDRA JEBB	1,514,041	0.53
18	MR MICHAEL JOHN KOTSANIS	1,511,083	0.53
19	NEWECONOMY COM AU NOMINEES PTY LIMITED	1,481,634	0.52
20	MR BIKASH KAJI BANIIYA	1,475,773	0.52
Total of Top 20 shareholders		90,066,812	31.56

POOLED DEVELOPMENT FUND

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

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

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

Gains realised by an investor from disposal of shares in the Group will not be included in the investor's assessable income in Australia because:

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

Equally, an investor will not be entitled to any deduction or capital loss on the sale of the Company's shares. Shares held in a PDF cannot be held as trading stock. Accordingly, share traders cannot treat PDF shares as trading stock.

Unfranked dividends received by an Australian resident shareholder from the Company will be exempt from tax in the hands of the shareholder. Franked dividends will also be exempt from tax unless the shareholder elects to treat the franked dividend as taxable.

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

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

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

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

Glossary

Term	Abbreviation	Description
Abbreviated New Drug Application	ANDA	ANDAs are termed “abbreviated” because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and effectiveness of a generic drug product. Instead, applicants must scientifically demonstrate bioequivalence to the innovator drug. Once approved, an applicant may manufacture and market the generic drug product as a safe, effective, low cost alternative. All approved products, both innovator and generic, are listed in FDA’s Orange Book.
Active Pharmaceutical Ingredient	API	Also known as drug substance. A substance used in a finished pharmaceutical product, intended to furnish pharmacological activity.
Addressable market		Total market sales value of a pharmaceutical product and dosage form. The data is purchased from IQVIA for products for which an Acrux product will directly compete when approved.
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	A CMO is a company that serves other companies in the pharmaceutical industry on a contract basis to provide services that include commercial manufacturing.
Contract Research Organisation	CRO	A CRO is a company that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis.
Estradiol		Estradiol is a form of estrogen, a female sex hormone produced by the ovaries. Estrogen is necessary for many processes in the body.
Evamist®		Brand name for Acrux’s unique Estradiol spray product in the United States. The Evamist® trademark is owned by Lumara Health and sublicensed to Padagis.
Food and Drug Administration	FDA	The FDA is responsible for protecting and promoting public health through the regulation and supervision of prescription, over-the-counter pharmaceutical drugs (medications), vaccines, biopharmaceuticals and veterinary products in the United States.
Gedeon Richter		Gedeon Richter Plc. is Acrux’s licensee for Lenzetto® and is a major pharmaceutical company headquartered in Hungary. Consolidated sales for 2021 exceeded EUR 1.75 billion and market capitalisation exceeds EUR 4.4 billion. Richter is a significant global player in female healthcare.
Generic medicine		A generic medicine provides the same quality, safety and efficacy as the original brand name product and undergoes strict scrutiny before it is licensed and given market approval by national regulatory authorities.

Term	Abbreviation	Description
Good Manufacturing Practice	GMP	Set of manufacturing principles and procedures that when followed helps ensure therapeutic goods are of high quality.
In-vitro Permeation Testing	IVPT	In-vitro permeation testing studies across biological membranes for formulations that are applied to the skin are vital to guide product development and establish product bioequivalence. IVPT is a critical tool for understanding drug delivery into the various layers of skin and can aid in formulation selection.
In-vitro Release Testing	IVRT	Measurement of drug release from complex dosage forms applied topically for the purpose of drug product bioequivalence testing. IVRT allows for targeted and systematic drug development and guides the establishment of therapeutic equivalence. IVRT involves subjecting the drug formulation to conditions that will induce drug release across a membrane and quantitating the amount of drug released under those conditions. In development, it is an essential test in assessing differences between formulations, predicting the timeframe of API release and modelling in vivo behaviour.
IQVIA		IQVIA, formerly Quintiles and IMS Health, Inc., is a US based multinational company which provides, on a subscription basis, pharmaceutical industry-leading sales data from over 90 countries.
Lenzetto®		Brand name for Acrux's unique Estradiol spray in the European Union. The Lenzetto® trademark is owned by Gedeon Richter.
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.
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, 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. Examples include Axiron®, Evamist® and Lenzetto®.
Topical		Topical is a route of administration wherein active pharmaceutical ingredients are applied to or affect a localised area of the body.

Corporate Directory

COMPANY INFORMATION

Directors

R Dobinson – Non-executive Director and Chairman

G Brooke – Non-executive Director

D Brumley – Non-executive Director

T Oldham – Non-executive Director

M Kotsanis – CEO and Managing Director

Company Secretary

Joanna Johnson

Registered Office

103–113 Stanley Street

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Victoria 3003

Principal Business Address

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Victoria 3003

Telephone: (03) 8379 0100

Website: www.acrux.com.au

Australian Business Number

72 082 001 152

Auditor

Pitcher Partners

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Docklands,

Victoria 3008

Share Registry

Link Market Services

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Australian Securities Exchange Listing

Australian Securities Exchange Limited

(Home Exchange: Melbourne, Victoria)

ASX Code: ACR

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

