

#### **ASX** Release

# RESULTS ANNOUNCEMENT FOR THE FINANCIAL YEAR ENDED 30 JUNE 2024

29 August 2024: Melbourne, Australia; Acrux Ltd (ASX:ACR)

In accordance with ASX Listing Rule 4.3A, please find attached the following for immediate release to the market:

- Appendix 4E; and
- Annual Report for the financial year ended 30 June 2024, including;
  - Operating and Financial Review;
  - Directors' Report including the Remuneration Report;
  - · Financial Reports; and
  - Independent Auditor's Report.

Approved for release by the Board of Directors of Acrux Ltd.

#### For more information, please contact:

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#### **About Acrux**

Acrux is a specialty pharma 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 licensees a number of products worldwide with emphasis on the United States. Acrux is formulating and developing a range of topical generic products by leveraging 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



# Appendix 4E -Preliminary Financial Report Results for announcement to the market

Name of Entity	Acrux Limited
ABN	72 082 001 152
Financial Year Ended	30 June 2024
Previous Corresponding Reporting Period	30 June 2023

				\$A'000
Total Revenue	Down	32%	to	8,098
(Loss) from ordinary activities after tax attributable to members	Up	92%	to	(5,800)
Net (loss) for the period attributable to members	Up	92%	to	(5,800)

Acrux is a specialty pharma 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 licensees a number of products worldwide with emphasis on the United States.

Acrux is formulating and developing a range of topical generic products by leveraging its skilled workforce, onsite laboratories, GMP manufacturing suite, technical, clinical and commercial experience to bring affordable products to market. Acrux continues to encourage collaboration, commercial partnering and product development opportunities.

No dividends have been declared or paid for the year ending 30 June 2024 or the prior corresponding period.

NTA Backing	Current period	Previous corresponding period
Net tangible asset backing per ordinary security	\$0.01	\$0.03

#### Other Information

There are no associates or joint ventures or other entities over which control has been gained or lost over the period.

Full financial details of the Group are reported in the attached audited financial report.





# Delivering on our promise

**ANNUAL REPORT 2024** 



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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. Download here:

www.investors.acrux.com.au/investor-centre



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

Drawing on 25 years of experience, Acrux is formulating and developing a portfolio of generic topical products using its highly skilled workforce and on-site laboratories. Through appointing overseas licensees Acrux has successfully marketed a number of products globally with primary emphasis on the United States.



# OUR BUSINESS MODEL



# OUR PEOPLE AND CULTURE

Acrux values the diversity of its workforce and provides an equitable and safe workplace. The team has the skills necessary for the development of topically applied pharmaceutical products.



#### OUR PORTFOLIO

We currently have 15 products in our pipeline including 3 which are currently marketed in the United States and 2 which are under review by the FDA.



#### OUR INFRASTRUCTURE

Particularly for product formulation, Acrux utilises its onsite laboratories and GMP suite.



#### OUR PARTNERSHIPS

Contract development and manufacturing organisations support the scale up of our products for commercial manufacture and to demonstrate bioequivalence with the brand name product. In-market specialists are contracted to launch and commercialise products after approval.



## **HIGHLIGHTS**

Sustained growth in Client Revenue **52% 5 year CAGR** 

Supported by products launched in FY23 and FY24

Launched FY23:

Prilocaine 2.5% and Lidocaine 2.5%, Cream

Launched FY24:

Dapsone 5%, Gel

1 dossier approved: **Dapsone 7.5%, Gel** 

2 dossiers under review:

Nitroglycerin 0.4%, Ointment Acyclovir 5%, Cream

Starting to realise vision – launches **ARE** driving sustainable revenue growth



#### PRODUCT DEVELOPMENT PIPELINE

Our key focus is progression of our product pipeline through the stages of formulation and development, to demonstrate bioequivalence. The dossiers are then submitted to regulatory agencies for review and the product is commercialised following approval.

#### **GENERIC DRUG**

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

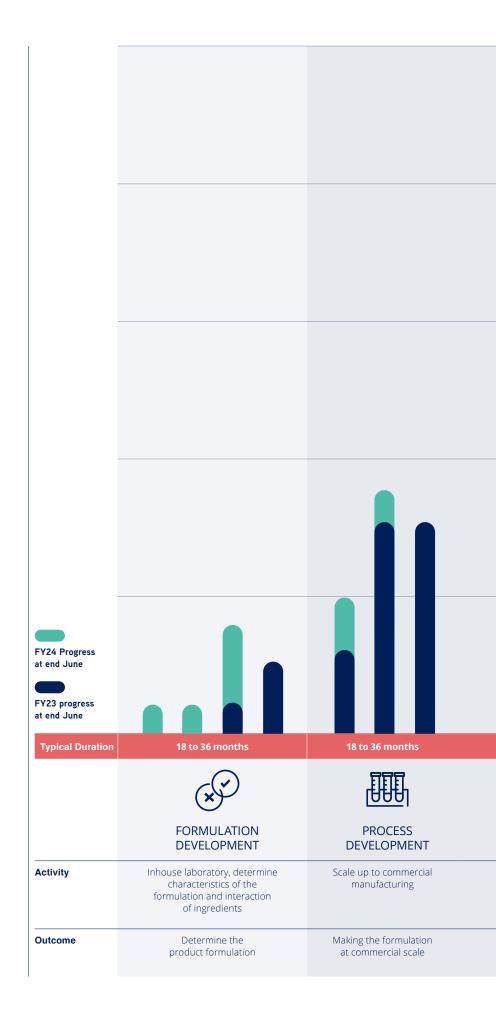
#### PRODUCT DEVELOPMENT PHASE

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

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

#### **TIMELINE FACTORS**

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





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#### REPORT OF THE CHAIRMAN & CEO

Acrux is a specialty pharmaceutical company with a team of specialised scientists focussed on developing a range of topically applied generic prescription pharmaceutical products which will be predominantly commercialised in the United States.

Acrux continues to execute our strategy of developing and commercialising topically applied pharmaceutical products with the launch of Dapsone 5%, Gel in April 2024 and approval of Dapsone 7.5%, Gel in August 2024

The Company has a successful track record of obtaining product approvals in the US which reflects our expertise in submitting dossiers that meet the US FDA's complex Product Specific Guidance<sup>1</sup> for ANDAs<sup>2</sup> to support future product launches and revenue growth. Our in-house expertise is complemented by our network of contract manufacturing and development organisations and commercial licensees.

This fundamental commercial strategy remains unchanged since Q4, 2017. The Company's objective is to create a diversified on-market portfolio of topically applied products generating sustainable revenues and to concurrently establish a broad development pipeline which generates regular regulatory submissions, approvals and future product launches.

The continuing execution of this strategy is reflected in the following milestones:

- Acrux submitted and had accepted for FDA review Nitroglycerin 0.4%, Ointment at the start of the financial year. This was the seventh regulatory dossier submitted by Acrux since 2017 and this product is now one of 2 which are progressing through the FDA's review processes. The product, when approved, will be used to treat moderate to severe pain associated with anal fissure.
- In April 2024 we launched Dapsone 5%, Gel into the United States market following its approval by the FDA. The product is approved for the treatment of acne vulgaris.
- In August 2024 we received FDA approval for Dapsone 7.5%, Gel. This product is approved for the treatment of acne vulgaris.
- We divested our Testosterone Topical Solution product in the United States because this ANDA no longer had any commercial value to Acrux due to a rapidly declining market characterised by low in-market pricing. The divestment was executed in the June quarter of 2024.



Analytical Development Scientist, Ebenezer



Formulation Scientist, Kayla

#### FINANCIAL PERFORMANCE

Acrux's reported revenue for FY24 totals \$8.098 million. Whilst this is a decline of \$3.830 million, the prior financial year included the onetime monetisation of the future Lenzetto® royalty stream of \$6.337 million. FY24 Revenue from client contracts totalled \$5.091 million and includes \$3.957 million of pass through revenues relating to raw materials purchased for the manufacture of commercialised products, now ceased as the raw materials are being purchased by our commercial partner. The 5 year Compound Annual Growth Rate ('CAGR') of client derived revenue is 52% and for total revenue the 5 year CAGR is 9%.

The outlook for product derived revenue growth in FY25 is encouraging as Dapsone 5%, Gel was launched in April 2024 and we have 2 further products planned for launch in FY25, dependent on the timely receipt of FDA approval.

On a year on year basis, external research and development expenses were lower because we have 2 products under evaluation at the FDA and 7 others in relatively early stage development. These beginning phases are typically less costly because they are predominantly conducted on our premises by our own staff and whilst the ANDA is under evaluation our product activities are focussed on responding to FDA queries. As our earlier stage projects progress to stages where we partner with contract development and manufacturing organisations, these expenses, along with the related Research and Development Tax Incentive offset, will increase.

Net loss before tax for the year was \$5.800 million, an increase over the prior year by \$5.036 million. However, excluding the impact of one time Lenzetto® monetisation and its associated asset impairment recorded in FY23, the underlying Net loss before tax was improved by \$1.929 million relative to the prior period.

Cash and cash equivalents on hand at year end totalled \$2.945 million and was \$3.287 million lower than the prior year end reflecting the value of FY24's Net loss before tax and offset by receipt of \$1.487 million of the FY24 research and development tax incentive rebate ('RDTI') claim which was financed and brought forward into FY24.

#### THE PRODUCT DEVELOPMENT PIPELINE

Acrux is advancing our product pipeline through the varying stages of development, both at Acrux and in conjunction with our contracted manufacturing partners. Our main priority is the progression of later stage products that will achieve commercialisation in the nearer term, while also continuing our work on earlier stage products to ensure breadth of our product pipeline and a continuous stream of product launches over coming years.

The Company has a portfolio of 15 products. The product development pipeline is illustrated in an infographic on pages 4 and 5. Currently 9 products are in active development, of which 2 are in late stages of review by the FDA. Four products are currently marketed with 2 products approved and not yet marketed. Over time, as ANDAs are approved, Acrux will add new projects in order to maintain a similar number of products in active development.

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.

With 1 product approved in August 2024 and 2 ANDAs currently under FDA review we plan to launch 2 products in FY25, subject to regulatory approval

FDA publishes product-specific guidances describing the agency's current thinking and expectations on how to develop generic drug products therapeutically equivalent to specific reference listed drugs.

Abbreviated New Drug Application (ANDA).

Acrux continues to progress its strategy of developing and commercialising a pipeline of topically applied pharmaceutical products. Dapsone 5%, Gel was launched in April 2024 and we are planning 2 further launches for FY25, including Dapsone 7.5%, Gel which was approved in August 2024 and one other product, subject to regulatory approval.





#### **STRATEGY**

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

Within our strategy there are three key priorities:

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

**Revenue realisation** is the transformation driver for the Company as we strive to be financially self-sustaining and consistently profitable.

The number of commercialised products will continue to expand following the recent launches of Prilocaine 2.5% and Lidocaine 2.5%, Cream and Dapsone 5%, Gel, approval of Dapsone 7.5%, Gel and 2 products which are under late stage review by the FDA of which we are hopeful that 1 will be approved in the near future. We plan to launch 2 products in FY25...

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

**Portfolio management** to maximise commercial returns based on strategic project selection of commercially attractive products which we have the technical capability to develop. A key component of successful portfolio management is the ongoing market 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.

#### **BOARD AND CORPORATE GOVERNANCE**

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

The Board has also reviewed the qualities that each Director brings to the Board to ensure the Board has the appropriate skills and experience to lead the company both now and in the future and to identify potential or emerging gaps in skill sets, any areas for improvement and to support succession planning.

The Directors consider that Acrux has complied with all applicable laws and regulations throughout the year ended 30 June 2024 and no issues have arisen between the end of the financial year and the date of this report.

Acrux is committed to sustainability and conducting business in a socially responsible manner. As we move towards mandatory climate related disclosure standards in Australia, we are actively contemplating how our business activities impact the environment and society to ensure we are prepared for changes in reporting standards to identify and implement initiatives to improve our performance and to ensure we are prepared for new and emerging stakeholder expectations. Our Environment, Social and Governance (ESG) Report can be found on page 10.

We would like to personally thank the Acrux team of employees and the Board for their valuable contributions, their sustained efforts to progress ANDAs through the FDA review process and the 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 progress into the revenue growth phase.

Ross Dobinson Chairman (L)

**Michael Kotsanis** Chief Executive Officer and Managing Director (R)

## **ENVIRONMENT, SOCIAL AND GOVERNANCE**

As we move towards mandatory climate related disclosure standards in Australia, Acrux is closely evaluating the way our business activities impact the environment and society, the associated risks and opportunities and seeks to put in place strategies to not only ensure we are well prepared for changes in mandatory reporting standards and frameworks but to also identify and implement initiatives which can improve our performance and fulfill new and emerging stakeholder expectations.

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

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

- Environmental Tenet includes the implementation of sustainability initiatives to measure and reduce Acrux's greenhouse gas emissions, to lower our carbon footprint and to preserve our natural environment,
- 2. **Social Tenet** considers Acrux's relationships with its employees, investors and the broader community including the way we conduct business, employee diversity, equity and inclusion programs as well as the safety and wellbeing of our employees and other stakeholders, and
- 3. **Governance Tenet** practising good corporate governance and conducting business ethical and socially accountable manner.

Through our Code of Conduct, corporate values and policies we prioritise activities and initiatives to achieve high standards in each of these tenets.

#### **Environmental Tenet**

Acrux is committed to conducting operations in an environmentally responsible manner, to manage its climate related risks and opportunities and to adopt practices to achieve sustainable outcomes through minimising waste, energy usage and emissions which are associated with our building operations, laboratory and office equipment.

Acrux occupies leased premises located at 103–113 Stanley Street, West Melbourne. These premises are 1,735 square meters, plus 365 square metres of open air car parking comprising spaces which are used as a laboratory, offices and warehousing. The building owner has not installed infrastructure to harness solar energy or to divert and recover rainwater. Our environmental strategies are focussed on the minimisation of energy usage and effective waste management through minimisation, recycling, and safe disposal.

We have identified and implemented a number of sustainability initiatives in order to reduce greenhouse gas emissions, including:

- Expanded company policies and standard operating procedures to include sustainability objectives;
- Introduced energy savings measures to reduce energy consumption and accelerate waste reduction;
- Considered climate-related risks and opportunities within in our broader risk management processes with each identified risk assessed for its impact, likelihood, detectability and the existence of mitigating factors;
- Identified and evaluated waste reduction initiatives in our laboratory and office following on site audits and workshops; and
- Digitised financial and operational records to minimise the use of paper records.

Strategies applied to minimise waste include avoiding single use products, purchasing more recycled, recyclable and biodegradeable materials, reusing office supplies and adopting digital document management and shareholder communication strategies to reduce our reliance on paper based products. We have successfully implemented digitisation projects including contract management and transactional finance processes, such as Accounts Payable and Payroll. We are progressively digitising our employee training records and are exploring enhancements which can be made in our Quality systems. This includes electronically signed documents and our Vendor Assurance program to ensure our suppliers also adopt sustainable practices in their manufacturing and sourcing cycles. Across our laboratory, office and staff kitchen recycling bins facilitate the recycling of waste which could otherwise become landfill.

#### **TENETS**



Environmental includes preservation of our natural environment



Social consideration of the safety and wellbeing of patients and our employees



Governance practising good corporate governance

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

The Directors consider Acrux has complied with all applicable environmental laws and regulations throughout the year ended 30 June 2024 and no issues have arisen since the end of the financial year to the date of this report.

#### **Social Tenet**

Acrux deeply values its highly skilled and specialised team and is committed to providing a stimulating, healthy and safe work environment for all employees, contractors and visitors. Our Code of Conduct documents our expected behaviours and ethical standards and guides and empowers our employees to make good decisions and act responsibly.

Health, safety and wellbeing is a key priority as is ensuring our employees have the skills and resources required to perform their roles to a high standard. Practicing safe systems of work is ingrained into Acrux's company culture and we have proactive and well developed processes to capture occupational health and safety data, including near misses. Should a near miss be reported it is thoroughly investigated and, if necessary, corrective measures are implemented. Our internal audit programme helps us assess health and safety standards in our laboratory, warehouse and offices at our West Melbourne site, including potential risks and hazards. Safety audits are conducted at regular intervals throughout the year by occupational health and safety team members who report their findings, including corrective action for any issues identified, to the Leadership Team. We have not recorded a Lost Time Injury since 2016.

Diversity and Inclusion supports our employees to be valued, respected and to experience fair treatment and merit based access to remuneration and employment opportunities. We prioritise our inclusive culture to ensure our workplace is safe for and attractive to a diverse range of people. Diversity is valued across gender, ethnicity, sexual orientation, disability, religious beliefs, family status and age. Diversity is embraced and celebrated as we believe this not only promotes wellbeing, productivity and safety but also enhances our ability to attract and retain skilled employees. We seek to attract and retain a workforce which is representative of our broader community and to remove unconscious biases from our behaviours, policies and processes.

Acrux is proud of its diverse workforce. Our team is comprised of more than 30 employees having family backgrounds from more than 20 different countries and we regularly share important cultural celebrations.

In our workplace Acrux achieves gender equality of participation and remuneration with slightly more female staff members than male and the average hourly remuneration of female employees is almost 1% higher than that of male employees. Our Leadership Team comprises five members, three of whom are female whilst our Board comprises five members, all of whom are male.

Acrux's Diversity and Inclusion Policy is integral to our talent management and recruitment strategies and can be viewed in the Investor Relations section of our website, <a href="https://investors.acrux.com.au/investor-centre">https://investors.acrux.com.au/investor-centre</a> and this policy.

Within our corporate and governance policy training programs regular online and compulsory training events are conducted for all staff to reinforce our policies and expectations on topics such as harassment, bullying, bribery, corruption, diversity, inclusion, whistleblowing and Code of Conduct.

#### ENVIRONMENT, SOCIAL AND GOVERNANCE (CONTINUED)

#### **Stakeholders**

Understanding the needs and expectations of our stakeholders is fundamental to the achievement of our Goals. We are committed to engaging with our stakeholders in Australia and internationally to improve our performance and to understand their priorities and objectives.

- Patients: With an increasing number of marketed products, the number of patients using our products has grown and will continue to do so with future product launches.
- Customers: Our licensees sell our products into more than 40 countries. We expect our licensees to uphold behaviours which are consistent with our Code of Conduct.
- People: Our employees are at the heart of Acrux. We engage regularly with our team, holding bi-monthly 'All Staff' meetings and frequent social activities embracing our diversity. We review employee performance at least a twice a year including written feedback and quantifiable performance measurement.
- Suppliers: We source materials from a large number of qualified global suppliers for the 15 products in our portfolio. We have eight contracted Contract Manufacturing Organisations ('CMO'), each of which is qualified to manufacture commercial products for the US market. We audit our CMOs to ensure they meet both our standards and the standards set by regulators for the country the product they manufacture is intended to be sold.
- **Investors**: We engage with current and potential investors in a number of ways. We regularly communicate through ASX announcements. We convene public webinars after each half year result is announced and attendees have the opportunity to ask questions. Webinar details are published in advance on the ASX platform and may be attended by any shareholder or interested party. We regularly meet individual shareholders outside closed reporting periods and presented at numerous investor forums including the MST Financial Hidden Gems in Life Sciences Forum, the 18th Bioshares Biotech Summit, Proactive Investors webinar, 3AW Money Talks program and others. New investor presentation decks are released around the time of results announcement and are updated for specific presentations at conferences or industry forums to keep shareholders abreast of our progress. We maintain an active LinkedIn account featuring occasional job openings and to highlight various events and news from the company.
- Government: We access funding through the Australian Federal Government's Research and Development Taxation Incentive program for which we are grateful. We are regulated by and licensed by the Australian Therapeutic Goods Administration allowing us to manufacture certain products in our laboratory to clinical trial stage. We had 94 separate engagements with the FDA during FY24 including Controlled Correspondence, teleconferences, video meeting and responses to questions on the products we have submitted for review.

 Environment: To ensure we prepared for changes in mandatory reporting standards and to implement initiatives to improve our performance and satisfy new and emerging stakeholder expectations.

#### **Governance Tenet**

Acrux is committed to good corporate governance, including ethical conduct, to ensure compliance with prevailing laws and regulations and to effectively manage risk. The Board is responsible for the effective leadership of Acrux and maintaining high standards of Governance. The Board leads by setting our strategy and values and oversees the implementation by management. Directors must act with integrity and promote the Acrux's culture and values. The Board also ensures there are appropriate processes in place to manage risk, including the Company's risk appetite and monitors financial and operational performance against objectives.

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

#### **GOVERNANCE STRUCTURE**

#### **Ethics and Values**

Acrux maintains high standards of corporate governance and employees are expected to act responsibly and with integrity at all times. Our corporate governance program is aligned with our strategy and purpose and is well established and mature. All Directors, employees and other parties representing the Company are required to follow the Company's principles, legal and ethical standards as consistent ethical behaviour promotes both inclusion and trust.

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

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

During the past 12 months compulsory on line training and quizzes have been delivered to all employees to reinforce Acrux's Code of Conduct and educate staff on Whistleblower rights and protections, equal employment opportunities, the benefits of diversity and inclusion and outlining expected conduct in order to avoid sexual harassment, work place bullying and bribery, corruption and fraud.

The Code of Conduct Policy, Whistleblower Policy, Security Trading Policy, Diversity and Inclusion Policy and Anti-Bribery, Corruption and Fraud Policy, are all reviewed annually by the Board of Directors and published on our public internet and staff intranet sites.

#### Structure of the Board and Board Committees

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

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

The Board Charter is central to Acrux's corporate governance framework as it lays out the responsibilities and duties of the Board of Directors and can be viewed in the Investor Relations section of our website, <a href="https://investors.acrux.com.au/investor-centre">https://investors.acrux.com.au/investor-centre</a>. Key responsibilities include overseeing management, providing strategic direction, capital planning, risk management, monitoring performance, human resource strategies and approval of budgets and business plans. Day-to-day management including implementation of approved strategies and business plans, is delegated to the CEO and Managing Director and the leadership team.

The Board maintains a breadth of skills in its membership, which considers individual experience and background in the pharmaceutical industry, leadership and strategy, international business, legal, finance and accounting, risk management, corporate governance, organisation and talent development as well as team fit and balance within the Board. Directors are required to demonstrate commitment to the Company's RIOS – Together Anything is Possible values.

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

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

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

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



# RISK MANAGEMENT

Managing risk is essential to operating and growing our business safely, effectively, and sustainably. We identify, assess and monitor risks through our Risk Management Framework with consideration of each risk's potential impact, probability, detectability and the existence of mitigating factors. The Board has ultimate oversight over risk management and the Audit and Risk Committee monitors the overall effectiveness of our risk management and internal controls framework.

implementation

of strategy

Our most material risks relate to potential delays to obtaining regulatory approval for new products which may be due to project timeline delays or extended review times of regulators due to dossier deficiency or new and emerging regulations, our capacity to financially support the progression of our pipeline and the ability of our commercial partners to achieve projected price and volumes following launch. Emerging risks associated with sustainability and environmental concerns as well as cyber and artificial intelligence have been identified and are also managed through the Risk Management Framework.

#### **ENVIRONMENT, SOCIAL AND GOVERNANCE (CONTINUED)**

#### **BOARD OF DIRECTORS AND SENIOR MANAGEMENT**

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

#### **Ross Dobinson**

Chairman, Non-executive Director

#### Michael Kotsanis

Managing Director and Chief Executive Officer

#### Geoffrey Brooke

Non-executive Director

#### Don Brumley

Non-executive Director

#### **Timothy Oldham**

Non-executive Director

There were five directors throughout the year, comprising four independent, Non-Executive directors and one Executive director. All Directors held office from the commencement of the financial year through to the date of this report.

# INFORMATION ON DIRECTORS AND COMPANY SECRETARY

The qualifications, experience and special responsibilities of each person who has been a Director of Acrux Limited since 1 July 2023 is provided below, together with details of the Company Secretary and other Senior Managers as at the year end.



**Ross Dobinson** Appointed March 1998

#### **Responsibilities** Chairman, Independent

Chairman, Independent Non-executive Director

**Qualifications**BBus (Acc)

#### Experience

Ross is a founder and former CEO of Acrux and has been a Director since 1998. He was first appointed as Chairman in January 2006 and additionally held the role of Executive Chairman from July 2012 to October 2014.

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



**Michael Kotsanis** Appointed November 2014

#### Responsibilities

Managing Director and Chief Executive Officer

#### Qualifications

BSc, Grad Dip Bus, MBus

#### **Experience**

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

Michael earned a Bachelor of Science from Monash University, Melbourne, a Graduate Diploma in Business from Edith Cowan University, Perth and a Master of Business from the University of Technology, Sydney. Michael is a former Non-executive Director of IDT Australia Limited (ASX: IDT).



**Geoff Brooke** Appointed June 2016

#### Responsibilities

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

**Qualifications** MBBS, MBA

#### **Experience**

Geoff founded GBS Venture Partners in 1996 and has more than 30 years of venture capital experience. In 2014, he sold his involvement in GBS and now concentrates on privately investing in a small number of companies. Geoff was formally President of Medvest, a US-based early-stage venture capital group he founded with Johnson & Johnson. Geoff's experience includes company formation and acquisitions, as well as public listings on the NYSE, NASDAQ and ASX exchanges. He commenced in 2017 as Chairman of Actinogen Medical Limited (ASX: ACW) and has been a founder, executive and director of private and public companies. In 2020 Geoff commenced as Chairman of Cynata Therapeutics Limited (ASX: CYP). From 2009 until 2015, he was an independent director of the Victoria WorkCover Authority.

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



**Don Brumley** Appointed June 2021

#### Responsibilities

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

**Qualifications** FCA, AICD

#### **Experience**

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

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



**Tim Oldham** Appointed October 2013

#### Responsibilities

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

#### Qualifications

BSc (Hons), LLB (Hons), PhD

#### **Experience**

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

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

#### ENVIRONMENT, SOCIAL AND GOVERNANCE (CONTINUED)

## INFORMATION ON SENIOR MANAGEMENT



**Joanna Johnson** Appointed as Company Secretary, June 2021

**Responsibilities**Chief Financial Officer and
Company Secretary

**Qualifications**CA, BEc, Grad Dip Management



**Felicia Colagrande** Appointed February 2015

**Responsibilities**Product Development and
Technical Affairs Director

**Qualifications**BSc (Hons), MBA



**Mark Hyman** Appointed July 2020

**Responsibilities**Project and Technical
Development Director

**Qualifications**BSc

#### **Experience**

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

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

Joanna earned a Bachelor of Economics from Adelaide University and a Graduate Diploma in Business Management from the University of South Australia.

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

Felicia has over 25 years of experience in the pharmaceutical/biotech industry and she joined Acrux in 2001. Felicia has previously held positions at Faulding Pharmaceuticals, the Department of Clinical Pharmacology and Therapeutics at the Austin Hospital, Silliker-Microtech Laboratories and was an Adjunct Appointee Lecturer with the Faculty of Pharmacy and Pharmaceutical Sciences at Monash University. Felicia has a Bachelor of Science degree (with Honours) from La Trobe University and an MBA from the Australian Institute of Business

#### **Experience**

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

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

Mark has a Bachelor of Science degree in Chemistry and Pharmacology from Monash University.

# DIRECTORS' REPORT (INCLUDING REMUNERATION REPORT) AND FINANCIAL STATEMENTS



#### **DIRECTORS' REPORT**

For the year ended 30 June 2024

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 2024. Complying with the provisions of the *Corporations Act 2001*, the Directors report as follows:

#### **DIRECTORS**

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

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

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

#### ATTENDANCE OF MEETINGS

	BOARD (	OF DIRECTORS		AND RISK		CAPITAL AND
	HELD	ATTENDED	HELD	ATTENDED	HELD	ATTENDED
Ross Dobinson	6	6	-	2*	-	2*
Geoffrey Brooke	6	6	2	2	2	2
Don Brumley	6	6	2	2	2	2
Timothy Oldham	6	6	2	2	2	2
Michael Kotsanis	6	6	-	2*	-	2*

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

#### **PRINCIPAL ACTIVITIES**

Acrux is a specialty pharma company with a successful track record of developing and commercialising a pipeline of topically applied pharmaceutical products which use dermal and transdermal drug delivery technology. There has been no significant change in the nature of these activities during the financial year.

#### **REVIEW OF OPERATIONS**

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

#### Operating review

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

#### Key portfolio progression milestones achieved include:

- In July 2023, Acrux's application for Nitroglycerin 0.4%, Ointment, a generic version of AbbVie's Rectiv 0.4%, Ointment, was accepted by the FDA for review. This product treats pain caused by chronic anal fissure and is Acrux's seventh ANDA application to be accepted for FDA review. IQVIA reports the addressable market for this product for the 12 months to June 2024 of US\$22.7 million;
- In April 2024, Dapsone 5%, Gel was launched in the United States by our partner TruPharma. IQVIA reports the addressable market for this product for the 12 months to June 2024 of US\$15.8 million;
- In August 2024, Dapsone 7.5%, Gel was approved by the FDA and is planned for launch in FY25. IQVIA reports the addressable market for this product of USD37.4 million for the 12 months to June 2024: and
- Following a portfolio review the testosterone ANDA was divested.

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

- Received \$2.869 million in relation to the Research and Development Tax Incentive ('RDTI') for FY23; and
- Accelerated receipt of RDTI applicable to FY24 with \$1.487 million received in June 2024 representing approximately 80% of our estimated claim to 30 April 2024.

#### Progression of Acrux's portfolio of products

	FY20	FY21	FY22	FY23	FY24
Commercialised (1)	2	2	3	4	4
Approved	2	4	5	6	6
Under review by FDA	5	2	3	3	2
Under development	8	11	8	7	7
Total products in portfolio	15	17	16	16	15

<sup>(1)</sup> Commercialised products are also included in the Approved category.

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

- Prilocaine 2.5% and Lidocaine 2.5%, Cream, which was launched in December 2022 and is a topical anaesthetic marketed by Padagis. IQVIA reports the addressable market for this product for the 12 months to June 2024 of US\$26.8 million,
- Estradiol Spray, which is used to treat symptoms associated with menopause and is marketed as Evamist® by Padagis, and
- Dapsone Gel, 5%, was launched in April 2024, is used to treat acne vulgaris and is marketed by TruPharma.

Furthermore, Dapsone 7.5%, Gel has been approved and is planned for launch in FY25 and Estradiol Spray is approved for sale and is marketed internationally as Lenzetto®. Whilst the Testosterone Topical Solution ANDA was divested during FY24 as this ANDA no longer had commercial value to Acrux.

Acrux's generic version of Jublia® (efinaconazole) 10%, Topical Solution used to treat fungal infections of toenails is approved by the FDA and will be commercialised in the future in accordance with the terms of the Settlement Agreement in relation to the Paragraph IV patent litigation.

The FDA has accepted and is currently reviewing the following 2 dossiers:

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

Acrux is hopeful that 1 of these products will be approved in the near future and launched in FY25.

The FDA's guidelines for the approval of generic products seeking to demonstrate their bioequivalence to the Reference Drug are evolving and this has been reflected in extended product approval timelines in some cases. Acrux believes our submissions provide the necessary evidence to support their approval and the products currently under review are expected to be approved once the FDA's assessments are complete.

Beyond approved and commercialised products, Acrux continues to advance its pipeline through projects which are in varying stages of development, both in our in house laboratory and with the support of our contracted development and manufacturing partners.

Acrux periodically reviews of its portfolio, including consideration of the technical and commercial feasibility of each product. As a consequence of this review during FY24 Testosterone Topical Solution was divested due to lack of ongoing value to the Company, 2 projects were discontinued and 2 projects were commenced.

The Company's key focus is on later stage projects that can be submitted for review in the nearer term, while continuing to identify new opportunities and progress development on earlier stage products to ensure the breadth of the product pipeline is maintained over time.

Overall, Acrux now has 15 products in its portfolio various stages of development and commercialisation.

#### DIRECTORS' REPORT (CONTINUED)

#### **Financial Performance**

Acrux's purpose is to develop and commercialise a pipeline of topically applied pharmaceutical products and as products are approved by the relevant regulatory authorities and commercially launched we will deliver on our objective of building a self sustaining and growing revenue stream to support our pipeline of development projects. We continue to progress towards this objective with the launch of Dapsone 5%, Gel late in FY24 and having 1 product approved in August 2024 and 2 products currently under review by the FDA we plan for further commercial launches and revenue growth in FY25.

Growth of higher quality client based profit share and royalty revenue is essential to fulfil Acrux's growth objectives. Acrux supported the launch phase of Prilocaine 2.5% and Lidocaine 2.5%, Cream by procuring API for commercial manufacture and this API was in turn was sold to our commercial partner. This practice supported the launch and early marketing of this product but did not deliver direct monetary value to Acrux and has been recently transitioned to our commercial partner. FY23's revenue included 6 months of Lenzetto® royalty income as well as the impact of the monetisation of the future royalty stream for EUR4.10 million. Excluding the impact of these one time and discontinued items, underling client based profit share and royalty revenue is up on a year on year basis from \$0.585 million to \$1.134 million.

With Dapsone 5%, Gel launched in April 2024 and with Dapsone 7.5%, Gel and 1 other product planned for launch in FY25 we expect client based profit share and royalty revenues to grow. However, with a number of pipeline projects moving into phases which require the manufacture and testing of exhibit and pilot batches at our contract development and manufacturing partners our direct project expenditure is also projected to increase.

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

#### Significant changes in the state of affairs

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

#### After balance date events

In August 2024, Acrux announced that the FDA had approved the Company's fifth ANDA, a generic version of Aczone® Gel, 7.5%. Dapsone 7.5%, Gel is a topical treatment for acne vulgaris and has an addressable market of USD37.4 million as measured by IQVIA as at June 2024.

No other matter or circumstance has arisen since 30 June 2024 that has significantly affected the Group's operations, results or state of affairs, or may do so in future years.

#### **Future Developments**

Acrux will continue to pursue and execute its strategy of developing a diversified, financially attractive portfolio of marketed generic topical prescription products. Acrux's future financial results will be materially influenced by the timing of receipt of regulatory approval from FDA for products in the development pipeline and the timing and commercial success of product launches, as well the progression of the pipeline including evaluation and selection of attractive new opportunities to be added to the development pipeline.

#### Indemnification and insurance of Directors, Officers and Auditors

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

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

#### REMUNERATION REPORT (AUDITED)

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

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

#### **Remuneration Policy**

The Human Capital and Nomination Committee is responsible for recommending the Group's remuneration framework to the Board, including structure of and participation in the Group's employee security and incentive plans. The key objectives of the Group's remuneration framework are to:

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

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

#### **Remuneration Structure**

Employee remuneration is structured in two parts:

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

#### **Short Term Incentive Plan**

Short term incentives reward employees for achievement of Corporate objectives which are established by the Board at the beginning of each year in consultation with senior management and, for some employees, personal objectives which are established at the beginning of the year in consultation with line management. Corporate objectives are linked to successful strategy execution and are selected because they create long term value for shareholders and include clearly defined and measurable outcomes. Achievement of company and personal objectives are assessed after the end of the financial year.

Short term incentives are subject to achievement of objectives and the Board's discretion. The Chief Executive Officer and Managing Director may receive an incentive up to 25% of his fixed remuneration. Senior management, other than the Chief Executive Officer and Managing Director, may receive an incentive up to 24% of fixed remuneration.

#### **Long Term Incentive Plan**

The long-term incentive plan is designed to align the interests of management with shareholders for the achievement of long term superior performance and is in accordance with the requirements of ASX Listing Rules and the *Pooled Development Funds Act 1992*.

The OEP governs the issue of securities to employees and Directors and was approved by shareholders at the 2023 Annual General Meeting ('AGM'). Subject to service criteria, permanent employees may be offered performance rights and/or ordinary shares.

#### DIRECTORS' REPORT (CONTINUED)

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

#### A. Chief Executive Officer and Managing Director ('CEO')

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

#### B. Senior management, including KMP

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

#### C. Employees, excluding KMP

At its discretion the Board may approve the annual issue of up to \$1000 value of tax exempt ordinary shares to employees who are not KMP at nil cost to the employee. There are no vesting conditions and shares are held in escrow for the lesser of 3 years or cessation of employment.

Further information about Share based payments is reported in Note 19 to the accounts.

The following table summarises the Group's earnings and other key performance indicators to 30 June 2024:

	2024	2023	2022	2021	2020
Revenue (\$000's)	8,098	11,928	5,103	5,156	3,945
Loss before tax (\$'000)	(5,800)	(212)	(9,582)	(12,432)	(9,385)
Dividends paid to shareholders	_	_	_	_	_
Share Price at end of the year (cents)	7.0	4.2	5.2	13.0	14.5
Basic earnings/(loss) per share (cents)	(2.00)	(0.27)	(3.46)	(5.75)	(5.65)
Number of Ordinary Shares on Issue	290,716,856	288,175,456	285,364,669	283,305,394	168,583,515
Market Capitalisation (\$ million)	20.35	12.10	14.84	36.83	24.44

#### **Remuneration of Directors**

The Human Capital and Nomination Committee determines the level of remuneration necessary to attract and retain Directors with the skills and experience required by the Group at its stage of development. The Committee makes recommendations to the Board.

The total value of Non-executive Director's remuneration was paid in equal proportions of cash and rights. No short term incentives or retirement allowances are paid to Directors nor is additional remuneration received for membership of Board Committees.

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

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

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

	Director Fee Payments \$	Post Employment Super- annuation \$	Share based Payments (Rights) \$	Total Remun- eration \$
2024				
Ross Dobinson (Chair)	37,079	29,121	64,914	131,114
Geoff Brooke	35,000	8,470	41,184	84,654
Don Brumley	35,000	8,470	40,542	84,012
Timothy Oldham	35,000	8,470	41,184	84,654
	142,079	54,531	187,824	384,434
2023				
Ross Dobinson (Chair)	45,098	13,902	41,322	100,322
Geoff Brooke	35,000	10,199	24,032	69,231
Don Brumley	35,000	8,827	32,993	76,820
Timothy Oldham	35,000	8,672	24,032	67,704
	150,098	41,600	122,379	314,077

#### Remuneration and termination entitlements of Senior Management

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

Names and positions of Senior management 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

#### DIRECTORS' REPORT (CONTINUED)

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

		PRIMARY		POST EMPLOY- MENT	LONG TERM BENEFIT	SHARE BASED PAYMENT			
	Salary \$	Movement Annual Leave Provision <sup>(2)</sup> \$	Short Term Incen- tive <sup>(3)</sup>	Super- annuation \$	Long Service Leave Accrued \$	Perfor- mance Rights <sup>(4)</sup> \$	Total Remun- eration \$	Equity as % Total %	Bonus as % Total %
2024									
Michael Kotsanis	480,143	27,221	35,068	27,399	13,739	118,389	701,959	17%	5%
Felicia Colagrande	241,688	(2,235)	10,634	26,586	4,668	14,630	295,971	5%	4%
Mark Hyman	233,517	(2,090)	10,275	25,687	5,896	11,824	285,109	4%	4%
Joanna Johnson	243,603	3,997	10,719	26,346	2,505	11,446	298,616	4%	4%
	1,198,951	26,893	66,696	106,018	26,808	156,289	1,581,655	10%	4%
2023									
Michael Kotsanis	462,729	(12,371)	30,501	25,292	11,707	192,380	710,238	27%	4%
Felicia Colagrande	233,444	1,594	9,019	24,512	6,977	20,808	296,354	7%	3%
Mark Hyman	225,552	6,497	8,715	23,683	8,960	13,243	286,650	5%	3%
Joanna Johnson	235,294	3,633	9,091	24,706	1,202	11,240	285,166	4%	3%
Charles O'Sullivan <sup>(1)</sup>	172,234	(2,008)	-	14,204	4,348	(40,271)	148,507		0%
	1,329,253	(2,655)	57,326	112,397	33,194	197,400	1,726,915	11%	3%

<sup>(1)</sup> Charles O'Sullivan retired on 30 March 2023. His reported salary includes \$36,956 for unused Annual and Long Service Leave accumulated over his employment and paid on retirement. In accordance with Australian Accounting Standards, the accounting value attributed to performance rights which were not vested at the time of his retirement was reversed to Profit or Loss.

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

<sup>(3)</sup> A short term incentive may be paid based on achievement of Corporate objectives established at the beginning of the financial year. For the year ended 30 June 2023, the Board assessed achievement of Corporate objectives at 25% with these balances paid in August 2023. For the year ended 30 June 2024, the Board has assessed achievement of Corporate objectives at 27.5%, paid in August 2024.

<sup>(4)</sup> Performance rights are issued to senior employees, with the accounting expense recognised over the vesting period. Accordingly, an employee with a longer tenure who has participated in more allocations will report a higher value of share based payments expense for a reporting period even if similar quantities of performance rights have been allocated in recent years.

#### **Equity instruments held by Key Management Personnel**

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

	Palana			
	Balance On	Market	Rights	Balance
	1 July 2023	Transactions	exercised	30 June 2024
Directors				
Ross Dobinson	4,355,174	_	894,071	5,249,245
Geoff Brooke (1)	1,413,927	_	276,374	1,690,301
Don Brumley	2,853,998	_	542,110	3,396,108
Tim Oldham (1)	1,105,058	_	414,561	1,519,619
Senior Management				
Michael Kotsanis	1,511,083	_	-	1,511,083
Felicia Colagrande	484,701	_	_	484,701
Mark Hyman	66,477	_	_	66,477
Joanna Johnson	_	_	_	-
	11,790,418	-	2,127,116	13,917,534

<sup>(1)</sup> 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

1,432,000 performance rights were issued to eligible employees on 14 February 2024, including but not limited to Senior managers. These performance rights may vest after one year provided the TSR over that period is equal to or is greater than 10% and employment is continuous. They expire after 7 years.

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

4,864,243 rights representing approximately half of the value of Non-executive Director remuneration for the next 12 months were issued to Non-executive Directors on 5 December 2023 after approval by shareholders at the 2023 Annual General Meeting. These rights vest quarterly and have no performance conditions other than continuous service.

The following table sets out the number of rights held by KMP.

	Balance at 1 July 2023	Granted as remun- eration	Exercised	Balance at 30 June 2024	Value of Rights Granted \$
Non-executive Directors					
Ross Dobinson	475,220	1,675,405	894,071	1,256,554	66,200
Geoff Brooke	276,374	1,062,946	276,374	1,062,946	42,000
Don Brumley	276,374	1,062,946	542,110	797,210	42,000
Tim Oldham	414,561	1,062,946	414,561	1,062,946	42,000
Senior Management					
Michael Kotsanis	6,000,000	-	-	6,000,000	-
Felicia Colagrande	585,000	320,000	-	905,000	14,400
Mark Hyman	585,000	320,000	-	905,000	14,400
Joanna Johnson	445,000	320,000	-	765,000	14,400
	9,057,529	5,824,243	2,127,116	12,754,656	235,400

#### DIRECTORS' REPORT (CONTINUED)

Rights which have been issued to Directors and employees but are neither exercised nor cancelled as at 30 June 2024, are as follows:

Date rights granted	Number rights	Value at grant date	Minimum Exercise price <sup>(5)</sup>	Rights expiry date
25 January 2018	7,000	\$0.17	\$0.1579 <sup>(2)</sup>	January 2025
4 February 2019	10,000	\$0.18	\$0.2081(2)	February 2026
4 February 2021	415,298	\$0.17	\$0.2706(2)	February 2028
30 November 2021	6,000,000	\$0.114	\$0.1258-\$0.1675(1)	December 2028
10 February 2022	928,949	\$0.103	\$0.1133(3)	February 2029
13 February 2023	1,072,000	\$0.072	\$0.0792(3)	February 2030
5 December 2023	4,179,656	\$0.040	_(4)	November 2024
14 February 2024	1,432,000	\$0.065	\$0.07127(3)	February 2031
	14,044,903			

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

This is the end of the audited remuneration report

#### Non-audit services

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

	2024 \$	2023 \$
Amount paid or payable to Pitcher Partners (Melbourne) for non-audit services	30,230	23,320

As non-audit services relate to the provision of corporate tax advice and completion of company tax returns Directors are satisfied that services provided are compatible with the general standard of auditors' independence 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 approved by the Audit and Risk Committee to ensure they do not impact on the integrity and objectivity of the auditor; and
- non-audit services do not undermine the general principles relating to auditor independence set out in APES 110 Code of Ethics for Professional Accountants (including independence standards) issued by the Accounting Professional & Ethical Standards Board, which includes reviewing or auditing the auditors' own work, acting in a management or decision making capacity for the Group, acting as an advocate for the Group or jointly sharing economic risks and rewards.

#### Auditor independence declaration

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

#### **Rounding of amounts**

The Company has applied ASIC Corporations (Rounding in Financial/Directors' Reports) Instrument 2016/191, dated 24 March 2016, whereby 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 28 August 2024 Don Brumley

Non-executive Director

Melbourne 28 August 2024

AUDITOR'S INDEPENDENCE DECLARATION

To the members 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 2024, to the best of my knowledge and belief there have been:

- No contraventions of the auditor independence requirements of the Corporations Act 2001; and
- (ii) no contraventions of the ethical requirements of the Accounting Professional and Ethical Standards Board's APES 110 Code of Ethics for Professional Accountants (including Independence Standards) in relation to the audit.

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

N R BULL Partner

28 August 2024

PITCHER PARTNERS Melbourne

Pitcher Partners. An independent Victorian Partnership ABN 27 975 255 196. Level 13, 664 Collins Street, Docklands, VIC 3008
Pitcher Partners is an association of independent firms. Liability limited by a scheme approved under Professional Standards Legislation.
Pitcher Partners is a member of the global network of Baker Tilly International Limited, the members of which are separate and independent legal entities

Adelaide Brisbane Melbourne Newcastle Sydney Perth

pitcher.com.au

# CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

For the year ended 30 June 2024

		CONSOI	LIDATED
	Note	2024 \$'000	2023 \$'000
Revenue from product agreements	4	5,091	8,429
Other revenue	4	3,007	3,499
Total revenue		8,098	11,928
Cost of goods sold		(3,957)	(558)
Employee benefits expense	5	(4,915)	(4,960)
Directors' fees		(197)	(192)
Securities based payment expense	19(a)	(381)	(370)
Depreciation and amortisation expenses	5	(510)	(595)
Impairment expense	13	_	(321)
Occupancy expenses		(281)	(244)
External research and development expenses		(2,418)	(3,812)
Professional fees		(358)	(340)
Other expenses		(649)	(748)
Total operating expenses		(9,709)	(11,582)
Profit/(loss) before income tax		(5,568)	(212)
Income tax expense	6	(232)	(552)
Net profit/(loss) for the year		(5,800)	(764)
Total comprehensive profit/(loss) for the year		(5,800)	(764)
Total comprehensive profit/(loss) attributable to:			
Members of the parent entity	20	(5,800)	(764)
Loss per share for loss attributable to the equity holders of the parent entity:			
Basic profit/(loss) per share	8	(2.00) cents	(0.27) cents
Diluted profit/(loss) per share	8	(2.00) cents	(0.27) cents

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

# CONSOLIDATED STATEMENT OF FINANCIAL POSITION

As at 30 June 2024

		CONSOLI	DATED
	Note	30 June 2024 \$'000	30 June 2023 \$'000
Current Assets			
Cash and cash equivalents	9	2,945	6,232
Receivables	10	2,889	3,306
Other current assets	11	147	353
Total Current Assets		5,981	9,891
Non-Current Assets			
Plant and equipment	12	597	559
Intangible assets	13	_	-
Deferred tax asset	6	572	803
Lease assets	14	1,813	2,032
Total Non-Current Assets		2,982	3,394
Total Assets		8,963	13,285
Current Liabilities			
Payables	15	1,074	1,372
Provisions	16	868	826
Borrowings	17	1,487	-
Lease liabilities	14	293	192
Total Current Liabilities		3,722	2,390
Non-Current Liabilities			
Provisions	16	41	38
Lease liabilities	14	1,924	2,161
Total Non-Current Liabilities		1,965	2,199
Total Liabilities		5,687	4,589
Net Assets		3,276	8,696
Equity			
Contributed equity	18	115,012	114,884
Reserves	20	8,551	8,299
Retained earnings/(losses)	20	(120,287)	(114,487)
Total Equity		3,276	8,696

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 2024

	Note	Contributed equity \$'000	Reserves \$'000	Retained earnings/ (losses) \$'000	Total equity \$'000
Balance as at 1 July 2023		114,884	8,299	(114,487)	8,696
Profit/(loss) for the year		-	-	(5,800)	(5,800)
Other comprehensive income/(loss) for the year		_	_	_	_
Total comprehensive income/(loss) for the year		-	-		
Transactions with owners in their capacity as owners					
Employee share scheme	19	26	252	-	278
Performance rights exercised	18(b)	102	_	-	102
Capital Raising	18(b)	_	_	_	_
Balance as at 30 June 2024		115,012	8,551	(120,287)	3,276

	Note	Contributed equity \$'000	Reserves \$'000	Retained earnings/ (losses) \$'000	Total equity \$'000
Balance as at 1 July 2022		114,563	8,250	(113,723)	9,090
Profit/(loss) for the year		_	_	(764)	(764)
Other comprehensive income/(loss) for the year		-	_	_	_
Total comprehensive income/(loss) for the year		-	-	(764)	(764)
Transactions with owners in their capacity as owners					
Employee share scheme	19	26	49	_	75
Performance rights exercised	18(b)	295	_	_	295
Capital Raising	18(b)	_	_	_	-
Balance as at 30 June 2023		114,884	8,299	(114,487)	8,696

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

# CONSOLIDATED STATEMENT OF CASHFLOWS

For the year ended 30 June 2024

		CONSOLI	DATED
	Note	30 June 2024 \$'000	30 June 2023 \$'000
Cashflows from operating activities			
Receipts from product agreements		5,604	8,534
Payments to suppliers and employees		(12,771)	(11,445)
Interest received		174	84
Finance costs		(179)	(201)
Research and development tax incentive rebate		2,869	3,731
Net cash generated/(used) in operating activities	21(a)	(4,303)	703
Cashflows from investing activities			
Payment for property, plant and equipment		(276)	(119)
Net cash used in investing activities		(276)	(119)
Cashflows from financing activities			
Net proceeds from/(used in) capital raising		_	-
Proceeds short term borrowings		1,487	-
Lease liability principal repayments		(195)	(183)
Net proceeds used in financing activities		1,292	(183)
Net increase/(decrease) in cash and cash equivalents		(3,287)	401
Cash and cash equivalents at beginning of year		6,232	5,831
Cash and cash equivalents at the end of the year	21(b)	2,945	6,232

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 2024

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

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

## 1. DISCLOSURE OF MATERIAL ACCOUNTING POLICIES

The material accounting policies adopted by the Group in the preparation and presentation of the financial report are described below or have been presented in the relevant note. Accounting policies have been consistently applied, unless otherwise stated.

## (a) Basis of preparation

This general purpose financial report is 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').

## Historical cost convention

The financial report has been prepared using the historical cost convention, except for certain instruments which are measured at fair value and as described in the accounting policies. Fair value is the price expected to be received to sell an asset or paid to settle a liability in an orderly transaction under current market conditions as at measurement date, regardless of whether the price is directly observable or estimated using another valuation technique.

When estimating the fair value of an asset or liability, valuation techniques are used as are appropriate in the circumstances and for which data is available to maximise the use of relevant observable inputs and minimise the use of unobservable inputs. Inputs to valuation techniques used to measure fair value are categorised into three levels according to the extent to which they are observable:

- Level 1 inputs are quoted prices in active markets for identical assets or liabilities accessible at measurement date
- Level 2 inputs are inputs other than Level 1 quoted prices 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 this financial report has required certain estimates and judgements in applying the Group's accounting policies. Estimates and judgements which are significant to the financial report are explained and disclosed in the Notes to the consolidated financial statements.

## (b) Going Concern Basis of Preparation

The financial report has been prepared on a going concern basis contemplating the continuity of normal business activities and realisation of assets and the settlement of liabilities in the ordinary course of business.

As reported in the financial statements, the Group incurred a loss after tax from ordinary activities of \$5.800 million for the year ended 30 June 2024 (30 June 2023: loss after tax from ordinary operations \$0.764 million) and as at balance date the Group had Total current assets of \$5.981 million (2023: \$9.891 million). The ability of the Group to continue as a going concern is dependent on its ability to generate future revenues which are sufficient to support progression of its development pipeline and its other operating activities.

The Group expects to receive more than \$2.7 million for RDTI for FY24, plus a further small balance should a new application for an Overseas Finding be successful. Of this balance \$1.487 million plus interest, accruing at a rate of 16% per annum, is repayable to Radium Capital in relation to the advance payment for RDTI calculated to 30 April which was received on 28 June 2024.

The Directors believe the Group can meet its financial obligations as an when they fall due based on cashflow projections which have been prepared for a period of twelve months beyond the date of approval of these financial statements and which incorporate the following key assumptions:

- Revenue growth of products currently on market;
- Obtaining FDA approval and launching pipeline products, including Dapsone Gel, 7.5% and Nitroglycerin 0.4%, Ointment in FY25;
- Continuing eligibility of product development expenditure for RDTI rebate; and
- The ability to execute other financial and funding transactions as and if required.

In order to progress the development of all of the products in our pipeline, these cashflow projections include increased external R&D expenditure for FY25 which is due to the timing of certain projects which have come to stages where we are working with contract manufacturers to and also due to new projects which were commenced earlier in 2024.

Directors closely monitor revenue and expenditure against projections and if cash inflows were to be materially lower than forecasted cash management strategies could be implemented include:

- Deferral of project development activities and associated expenditure;
- Management of operating and capital expenses;
- Monetisation of other assets or revenue streams:
- Execution of other financial and funding transactions.

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

Should the Group not achieve the assumptions detailed above and other initiatives were not implemented, there is a material uncertainty which would cast significant doubt as to whether the Group may be able to meet its debts as and when they fall due and therefore continue as a going concern. In that circumstance the Group may be required to realise assets and extinguish liabilities other than in the ordinary course of business and at amounts which differ to those stated in the financial statements.

Acrux Annual Report 2024

## DISCLOSURE OF MATERIAL ACCOUNTING POLICIES (CONTINUED)

#### (c) Principles of Consolidation

The consolidated financial statements comprise the financial statements of the parent entity and all controlled entities. The Group controls an entity when it is exposed to, or has rights over, variable returns from its involvement and can 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, using consistent accounting policies. Intercompany balances and transactions between Group companies are eliminated on consolidation.

A list of controlled entities is contained in Note 27 Controlled Entities.

## (d) Impairment of non-financial assets

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

## (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 the date that the Group commits itself to the purchase or sale of the asset (i.e. trade date accounting is adopted).

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

## Classification of financial assets

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

Financial assets not irrevocably designated on initial recognition at FVtOCI are classified and measured at amortised cost, FVtOCI or fair value through profit or loss ('FVtPL') on the basis of both the Group's business model for managing the financial assets and the contractual cash flow characteristics of the financial asset.

## Impairment of financial assets

Receivables from contracts with customers and contract assets are tested for impairment using the 'expected credit loss' impairment model. This 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.

# (f) Foreign currency translation and balances Functional and presentation currency

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

#### Transactions and balances

Foreign currency transactions are translated into functional currency at the exchange rate prevailing at transaction date. Foreign exchange gains and losses resulting from settlement of such transactions and translation of foreign currency denominated monetary assets and liabilities at period end exchange rates are recognised in profit or loss. Exchange differences arising on settlement or restatement are recognised as revenues or expenses in the financial year.

#### (g) Rounding amounts

The Company has applied ASIC Corporations (Rounding in Financial/Directors' Reports) Instrument 2016/191, dated 24 March 2016, relating to the "rounding off" of amounts in the financial statements. Amounts in the financial statements have been rounded in accordance with the Class Order to the nearest thousand dollars, or in certain cases, to the nearest dollar.

## (h) New and revised Accounting Standards effective as at 30 June 2024

All new and revised Australian Accounting Standards applicable to be adopted for the first time in the annual reporting period commencing 1 July 2023 have been applied with immaterial effect.

#### (i) Accounting Standards issued but not yet effective

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

# 2. SIGNIFICANT ACCOUNTING ESTIMATES AND JUDGEMENTS

Certain estimates and judgements that may affect the reported values of assets, liabilities, revenues and expenses have been made in the preparation of these financial statements requires. Management continually and critically evaluates such estimates and judgements based on historical experience and other factors considered to be reasonable under the circumstances, including expectations of future events.

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

## (a) Impairment testing

The Group prepares discounted cash flow models to ensure the carrying value of assets does not materially exceed their recoverable value. The following approach and assumptions have been applied:

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

## (b) Share based payments

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

## (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 and the timing of the payment.

## (d) Income tax

The recognition of deferred income tax benefits assumes that there are no adverse changes in income tax legislation and that the Group will derive sufficient future assessable income to enable the future benefit to be realised. Deferred tax assets have been recognised for deductible temporary differences where management considers it probable that future taxable income will be available to utilise those temporary differences.

#### 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. Material changes in interest rates could impact the value of discounted cashflows used for impairment testing to support asset valuations or the assessment of new product development opportunities.

Within the terms of the Pooled Development Fund Act, Acrux is prohibited from borrowing on a medium or long term basis and as a result the Group is not exposed to a material sensitivity from interest rate fluctuations from lending activities.

## (b) Currency risk

Currency risk is the risk that the fair value of a financial instrument will fluctuate due to changes in foreign exchange rates. The Group is exposed to currency risks due to revenues and certain expenses denominated in foreign currencies, predominantly US dollars. Currency risk management strategies are regularly reviewed and future foreign currency denominated cashflows from revenue are expected to largely offset expenditure, largely protecting Acrux from 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 to support the management of foreign exchange risk. As at 30 June 2024, Acrux held nil US dollar and Euro denominated cash reserves (2023: USD Denominated A\$0.005 million and Euro denominated A\$0.006 million).

The balance of foreign currency denominated receivables as at 30 June 2024 totals US\$0.090 million (2023: US\$0.357 million). The balance of foreign currency denominated payables totals US\$0.242 million (2023: US\$0.169 million) and EUR .001 million (2023 EUR 0.011 million).

A change in the exchange rates would therefore have immaterial impact on the consolidated net profit/(loss) and equity of the Group (2023: immaterial).

The Group does not enter forward exchange contracts.

## 3. FINANCIAL RISK MANAGEMENT (CONTINUED)

#### (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 value of receivable assets as disclosed in Consolidated Statement of Financial Position and notes to the Consolidated Financial Statements.

Credit risk is closely managed and procedures are in place to deal with credit worthy counterparties. Potential credit losses are regularly evaluated and a provision would be raised if there was evidence that a debt was unlikely to be collectible. There is no history of delayed or defaulted balances nor are there any presently overdue balances.

## (d) Liquidity risk

Liquidity risk is the risk that the Group will encounter difficulty in meeting the obligations associated with its financial liabilities that are settled by delivering cash or another financial asset. The Group's objective when managing liquidity is to ensure, as far as possible, that it will have sufficient liquidity to meet its liabilities when they are due.

The Group reports cash reserves of \$2.941 million (2022: \$6.232 million), which together with the initiatives outlined in Note 1(b) is, in the opinion of Directors, sufficient to settle existing liabilities and fund operating expenditure at planned levels for at least 15 months from the balance date based on current operating projections.

In June 2024 Acrux established a short term funding facility with Radium Capital to enable the timing of cashflows in relation to eligible R&D expenditure to be more closely matched with cash inflows associated with RDTI. In June 2024, the first advance of \$1.487 million was received under this facility, broadly representing 80% of the estimated balance receivable from the Australian Tax Office for RDTI for the 10 months to April 2024. This short term advance attracts interest at 16% per annum, is secured against the RDTI balance receivable and will be repaid later in the 2024 calendar year when the FY24 RDTI is received from the Australian Tax Office.

## Future cash outflows for the settlement of financial liabilities

	2024 \$'000	2023 \$'000
Lease Liabilities		
Not later than 1 year	386	374
Later than 1 year and not later than 5 years	1,171	1,557
Aggregate of lease payments contracted for at reporting date	1,557	1,931
Payables		
Not later than 1 year	1,074	1,372
Borrowings		
Not later than 1 year	1,487	_

## 4. REVENUE

	2024 \$'000	2023 \$'000
Revenue from contracts with customers		
Revenue from product agreements	5,091	8,429
Other revenue		
Interest	134	122
Grant revenue – RDTI	2,873	3,377
Total other revenue	3,007	3,499
Total revenue from continuing operations	8,098	11,928

## **Material Accounting Policies**

## *Revenue from contracts with customers*

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

## Other revenue

Other revenue is recognised as received or where it can be reliably estimated over the period to which it relates. The RDTI rebate is recognised at fair value as it is reasonably assured the grant will be received, it can be reliably measured and the Group complies with all conditions. Acrux has submitted an Overseas Finding ('OSF') to Ausindustry and, if successful, will support a minor additional claim for RDTI for FY24 not currently recognised in the Consolidated statement of profit or loss.

## 5. LOSS FROM CONTINUING OPERATIONS

	2024 \$'000	2023 \$'000
Loss from continuing operations before income tax has been determined after the following specific expenses:		
Employee benefits expense		
Wages and salaries	4,129	4,200
Superannuation costs	422	438
Other employee benefits expense	364	322
Total employee benefits expense	4,915	4,960
Depreciation of non-current assets		
Right of use asset	271	282
Plant and equipment	234	255
Total depreciation of non-current assets	505	537
Amortisation of non-current assets		
Leasehold improvements	5	5
Capitalised research and development	-	53
Total amortisation of non-current assets	5	58
Total depreciation and amortisation of non-current assets	510	595

#### 6. INCOME TAX

	2024 \$'000	2023 \$'000
(a) Income tax recognised in profit and loss		
Current tax	-	_
Deferred tax	232	552
Income tax (benefit)/expense attributable to profit and loss	232	552
(b) Reconciliation of income tax (benefit)/expense		
The prima facie tax payable on loss before income tax is reconciled to the income tax (benefit)/expense as follows:		
Profit/(loss) before tax from continuing operations	(5,568)	(212)
Prima facie income tax payable on loss before income tax	(1,392)	(174)
Add/(subtract) tax effect:		
Non-deductible expenses	97	111
Research and development tax incentive rebate	(718)	(1,013)
Tax losses not brought to account	2,245	1,382
Parent tax losses and temporary differences not brought to account	-	246
	1,624	726
Income tax (benefit)/expense attributable to loss	232	552
(c) Current tax		
Current tax (asset)/liability	_	_
(d) Deferred Tax		
Deferred tax assets is comprised:		
Accruals and provisions	250	317
Plant and equipment under lease	101	80
Plant and equipment and Intangible assets	1,004	1,019
Tax losses and research and development offset	208	401
	1,563	1,817
Deferred tax liabilities is comprised:		
Plant and Equipment and Intangible assets	(961)	(967)
Prepayments	(23)	(42)
Exchange differences	(7)	(5)
	(991)	(1,014)
Net deferred tax assets/(liabilities)	572	803
(e) Deferred tax assets not brought to account		
Temporary differences	5	4
Tax losses	20,934	21,895
	20,939	21,899

## Material accounting policies

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

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

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

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

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

## 7. DIVIDENDS

	2024 \$'000	2023 \$'000
(a) Dividends paid and declared		
Nil dividends were declared or paid during the financial year (2023: \$nil)		
(b) Franking account		
Balance of franking account at financial year end	43,835	43,835
8. LOSS PER SHARE		
	2024 \$'000	2023 \$'000
Loss from continuing operations	(5,800)	(764)
Loss used in calculating basic and diluted earnings per shares	(5,800)	(764)
	No. of shares	No. of shares
Weighted average number of ordinary shares used in calculating basic earnings per share	289,499,999	286,461,099
Effect of dilutive securities:	-	-
Adjusted weighted average number of ordinary shares used in calculating diluted earnings per share	289,499,999	286,461,099
Basic loss per share	2.00 cents	0.27 cents
Diluted loss per share	2.00 cents	0.27 cents
9. CASH AND CASH EQUIVALENTS		
	2024 \$'000	2023 \$'000
Cash on hand and at bank	2,945	3,232
Term deposits	-	3,000
	2,945	6,232
10. RECEIVABLES		
	2024 \$'000	2023 \$'000
Receivables from contracts with customers	4	385
Other receivables	2,885	2,921
	2,889	3,306

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## 10. RECEIVABLES (CONTINUED)

## Material accounting policies

The simplified approach under AASB 9 *Financial Instruments* has been used to measure the allowance for credit losses for receivables and from contracts with customers. Under this approach, the Group determines the allowance for credit losses on the basis of the lifetime expected credit losses of the financial asset being the expected credit losses from default events over the expected life of the financial asset. Expected credit losses are determined based on historical credit loss experience adjusted for factors specific to the financial asset as well as current and expected economic conditions. As there is no history of collection delays, defaulted balances or client dispute, no provision for expected credit losses is considered necessary at this time.

Other receivables reflect the estimated Research and development tax incentive rebate for the year ended 30 June 2024, recognised at fair value as there is reasonable assurance the grant will be received, it can be reliably measured and the Group complies with all conditions.

## 11. OTHER CURRENT ASSETS

	2024 \$'000	2023 \$'000
Prepayments	147	316
Other current assets	-	36
	147	352

## 12. PLANT AND EQUIPMENT

12. PLANT AND EQUIPMENT		
	2024 \$'000	2023 \$'000
Leasehold improvements		
At cost	49	47
Accumulated amortisation	(34)	(29)
Total leasehold improvements	15	18
Plant and equipment		
Capital Work in Progress	46	-
At cost	2,667	2,491
Accumulated depreciation	(2,131)	(1,950)
Total plant and equipment	582	541
	597	559
Reconciliations of the carrying amounts of plant and equipment at the beginning and end of the current financial year:		
Leasehold improvements		
Carrying amount at the start of the year	18	23
Additions	2	-
Amortisation expense	(5)	(5)
Carrying amount at the end of the year	15	18
Plant and equipment		
Carrying amount at the start of the year	541	659
Additions	274	119
Transfer from Leased assets	_	11
Depreciation expense	(233)	(248)
Carrying amount at the end of the year	582	541

## Material accounting policies

#### Cost and valuation

Each class of plant and equipment is carried at historical cost less applicable accumulated depreciation. Historical cost includes expenditure that is directly attributable to the items acquisition and installation. The carrying amount of each asset classification is reviewed to ensure it does not differ materially from its fair value at reporting date.

#### Depreciation

Depreciation expense is calculated on a straight line basis over the assets' estimated useful lives from the time the assets are held ready for use.

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

Useful lives	2024	2023
Leasehold improvements	5 to 20 years	5 to 20 years
Plant and equipment	1 to 16 years	1 to 16 years

#### **13. INTANGIBLE ASSETS**

	2024 \$'000	2023 \$'000
External development expenditure capitalised	1,071	1,071
Accumulated amortisation	(1,071)	(1,071)
Total intangible assets	-	-
Carrying amount of Estradiol at the start of the year	-	375
Additions	-	_
Amortisation	-	(54)
Impairment	-	(321)
Carrying amount of Estradiol at the end of the year	-	

#### Material accounting policies

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

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

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

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## 14. LEASE ASSETS AND LEASE LIABILITIES

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

	2024 \$'000	2023 \$'000
Carrying amount of lease assets, by class of underlying asset:		
Buildings under lease arrangements:		
At cost	2,919	2,867
Accumulated depreciation	(1,106)	(854)
	1,813	2,013
Plant and equipment under lease arrangements:		
At cost	89	89
Accumulated depreciation	(89)	(70)
	-	19
Total carrying amount of Leased assets	1,813	2,032
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	2,013	1,807
Depreciation	(252)	(252)
Restatement of Leased assets	52	458
Carrying amount at the end of the period	1,813	2,013
Plant and equipment under lease arrangements:		
Carrying amount at the beginning of the period	19	67
Depreciation	(19)	(30)
Leases paid out	_	(7)
Assets transferred to Plant and equipment	_	(11)
Carrying amount at the end of the period	-	19
Lease Liabilities		
Lease liabilities (current)	293	192
Lease liabilities (non-current)	1,924	2,161
Total carrying amount of lease liabilities	2,217	2,353
Lease expenses and cashflows		
Interest expense on lease liabilities	178	196
Depreciation expense on lease assets	271	282
Total cash outflow in relation to leases	384	379
Future commitments		
Future minimum lease payments to be made:		
Not later than 1 year	379	374
Later than 1 year and not later than 5 years	1,562	1,557
Aggregate of lease payments contracted for at reporting date	1,941	1,931

## Material accounting policies

A Leased asset is recognised at lease commencement, representing the right to use the underlying asset and a Lease liability represents the obligation to make future 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 lease commencement, less any lease incentives received, initial direct costs incurred by the Group and an estimate of costs required to dismantle and remove the underlying asset or restore the 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 availability 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.

Lease liabilities are initially recognised at the present value of the future lease payments, 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

	2024 \$'000	2023 \$'000
Current		
Trade payables	427	488
Sundry creditors and accruals	647	884
	1,074	1,372

## 16. PROVISIONS

	2024 \$'000	2023 \$'000
Current		
Employee entitlements	868	826
Non-current		
Employee entitlements	41	38
Aggregate employee entitlements	909	864

#### Material accounting policies

Provisions are recognised where there is a legal or constructive obligation with a probable future outflow of economic benefits which can be reliably measured. Provision is made for employee entitlements, including annual and long service leave. Liabilities expected to be settled within twelve months of the reporting date are measured based on remuneration rates expected to be paid when the liability is settled. Other employee benefit liabilities are measured at the present value of the estimated future cash outflows.

## 17. BORROWINGS

	2024 \$'000	2023 \$'000
Current		
Loan – RDTI advance	1,487	_

## Material accounting policies

In FY24 Acrux executed a short term funding facility with Radium Capital to provide access to funding of up to 80% of the estimated RDTI refund. On 28 June 2024 Acrux received a short term advance of \$1,487,144 based on eligible R&D expenditure incurred over the ten months to 30 April 2024. This short term advance attracts interest at 16% per annum, is secured against the RDTI receivable balance and will be repaid later in the 2024 calendar year at the time the FY24 RDTI is received from the Australian Tax Office.

## **18. CONTRIBUTED EQUITY**

	202	2024		2023	
	No. of shares	000's \$	No. of shares	000's \$	
(a) Issued and paid up capital					
Ordinary shares fully paid	290,716,856	115,012	288,175,456	114,884	
(b) Movements in ordinary shares on issue					
Beginning of the financial year	288,175,456	114,884	285,364,669	114,563	
Issued during the year:					
Conversion of rights under the OEP	2,140,116	102	2,463,662	296	
Shares issued under OEP	401,284	26	347,125	25	
Ordinary shares issued during the year	2,541,400	128	2,810,787	321	
Ordinary shares on issue at reporting date	290,716,856	115,012	288,175,456	114,884	

## (c) Rights

During the financial year 6,296,243 rights were issued under the OEP (2023: 3,883,684). Rights hold no participation rights, but shares issued on exercise of rights rank equally with existing ordinary shares. At 30 June 2024, 12,754,656 rights were held by KMP (2023: 9,057,529).

The closing market value of an ordinary Acrux Limited share on the Australian Securities Exchange at 28 June 2024 was 7.0 cents (2023: 4.2 cents).

	2024	2023
(i) Movement in the number of rights held under Omnibus Equity Plan are as follows:		
Opening balance	9,957,371	9,029,754
Granted during the year	6,296,243	3,884,684
Exercised during the year	(2,140,116)	(2,463,662)
Lapsed during the year	(68,595)	(493,405)
Closing balance	14,044,903	9,957,371
	2024 \$'000	2023 \$'000
(ii) Details of rights exercised under the OEP during the financial year:		
Rights exercised into shares, measured at Fair Value as at the issue date of the rights	129	296
	2024	2023
(iii) Details of the number of lapsed and cancelled rights		
Key management personnel	_	488,000
Other employees	68,595	5,405
Other employees		

## **19. SHARE BASED PAYMENTS**

## (a) Expenses recognised from share-based payment transactions under the OEP

	2024 \$′000	2023 \$'000
The expense recognised within securities based payments expense in the statement of comprehensive income was as follows:		
Rights issued	355	345
Issue of tax exempt ordinary shares to eligible employees	26	25
Total expenses recognised from securities based payment transactions	381	370

## 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. The Black Scholes pricing model is used to determine the fair value of Performance Rights during the period.

In addition to Performance Rights, employees who are not KMP, may be issued with tax exempt ordinary shares to a maximum value of \$1,000 per employee at the discretion of the Directors. Tax exempt ordinary shares are escrowed for 3 years from the date of issue.

## 19. SHARE BASED PAYMENTS (CONTINUED)

## (b) Omnibus Equity Plan

Details of movements in rights during the reporting period are provided below:

		Balance at beginning of				Balance at the end of	Exercisable as at
Grant date	Expiry date	the year	Granted	Exercised	Cancelled	the year	30 June 2024
Non-executive Direct	ors – rights issued as a o	component o	f remunerati	ion			
25 November 2022	25 November 2029	1,442,529	_	1,442,529	_	_	_
5 December 2023	5 December 2030	-	4,864,243	684,587	-	4,179,656	1,747,535
Performance Rights -	issued to CEO and othe	er manageme	nt				
25 January 2018	25 January 2025	15,000	_	8,000	_	7,000	7,000
4 February 2019	4 February 2026	15,000	-	5,000	_	10,000	10,000
4 February 2021	4 February 2028	429,893	_	_	14,595	415,298	-
30 November 2021	30 November 2028	6,000,000	_	_	_	6,000,000	-
10 February 2022	10 February 2029	958,949	_	_	30,000	928,949	-
13 February 2023	13 February 2030	1,096,000	_	_	24,000	1,072,000	-
14 February 2024	14 February 2031	-	1,432,000	_	_	1,432,000	
		9,957,371	6,296,243	2,140,116	68,595	14,044,903	1,764,535

The OEP was approved by shareholders on 29 November 2023.

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

On 5 December 2023, following resolution at the 2023 AGM, 4,864,243 rights were issued to Non-executive Directors representing approximately half of their remuneration for the next 12 months. These rights vest quarterly and have no performance conditions other than continuous service.

Other employees, including senior management, have been offered performance rights which vest subject to achievement of performance hurdles. On 14 February 2024, 1,432,000 performance rights were issued to employees including senior management. These rights may vest 12 months after issuance, subject to achievement of Total Shareholder Return of at least 10% per annum and include rollover provisions.

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

## Overview of Rights issued during the period:

Date of Issue	5 December 2023	14 February 2024
Type of Rights	Non executive Director's Remuneration	Employee Performance Rights
Number of Rights issued	4,864,243	1,432,000
Fair value Measure	Direct Value	Black Scholes
Weighted average share price at date of issue	3.95 cents	6.48 cents
Exercise price	n/a	7.13–9.49 cents
Volatility	n/a	73.25%
Dividend yield expectations	n/a	Nil
Term	7 years	7 years
Risk free interest rate	n/a	4.15%

## 20. RESERVES AND ACCUMULATED LOSSES

	2024 \$'000	2023 \$'000
Share based payment reserve	1,161	909
Profit reserve	7,390	7,390
Total Reserves	8,551	8,299
Accumulated losses	(120,287)	(114,487)
Share based payment reserve		
Nature and purpose of Share based payment reserve		
This reserve is used to record the value of equity benefit provided to employees and Directors as part of their remuneration.		
Movement in Share based payment reserve		
Balance at the beginning of year	909	860
Employee share scheme	252	49
Balance at end of year	1,161	909
Profit Reserve		
Nature and purpose of Profit reserve		
This reserve is used to record the profits which have been generated by the Group.		
Accumulated losses		
Movement in Accumulated losses		
Balance at the beginning of year	(114,487)	(113,723)
Net loss attributable to members of Acrux Limited	(5,800)	(764)
Balance at end of year	(120,287)	(114,487)

#### 21. CASHFLOW INFORMATION

	2024 \$'000	2023 \$'000
(a) Reconciliation of the cashflow from operations with loss after income tax:		
Loss from ordinary activities after income tax	(5,800)	(764)
Non-Cash Items		
Depreciation and amortisation	510	916
Share based payments expense	381	370
Changes in assets and liabilities		
(Increase)/decrease in trade and other receivables	417	459
(Increase)/decrease in other current assets	206	67
Increase/(decrease) in payables	(294)	(847)
Increase/(decrease) in employee entitlements	45	(50)
(Increase)/decrease in deferred tax assets	232	552
	606	181
Net cash (outflows)/inflows from operating activities	(4,303)	703
(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	2,945	3,232
At call and term deposits	_	3,000
Closing cash balance	2,945	6,232

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

The Group has credit card facilities with the ANZ Bank totalling \$120,000 (2023: \$120,000). At 30 June 2024 the Group had unused capacity on these facilities of \$116,763 (2022: \$115,607).

## 22. KEY MANAGEMENT PERSONNEL COMPENSATION

	2024 \$	2023 \$
KMP compensation is detailed in the Remuneration Report section of the Director's Report. A breakdown of the aggregate components is provided below:		
Short-term employment benefits	1,434,529	1,534,022
Post-employment benefits	187,357	187,191
Equity	342,379	319,779
Total KMP compensation	1,964,265	2,040,992

## 23. LOANS TO KEY MANAGEMENT PERSONNEL

No loans were made to KMP during the financial year.

## 24. RELATED PARTY DISCLOSURES

## Wholly owned Group transactions

Loans

Loans were made between Acrux Limited and its subsidiaries under normal terms and conditions. The aggregate amounts receivable from controlled entities by the parent entity at the end of the reporting period was \$28.733 million (2023: \$26.202 million).

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

Transactions with Directors and KMP concerning their remuneration and securities issued in accordance with the OEP are disclosed the Directors' Report and in Notes 18, 19 and 22. There were no other transactions or contracts between the Company, Directors and KMP in 2024 not in relation to remuneration (2023: nil).

## 25. AUDITOR REMUNERATION

	2024 \$'000	2023 \$'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	107	102
Taxation compliance and consulting	30	23
Other non-audit services	_	_
	137	125

## **26. SEGMENT REPORTING**

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

## Geographical segment information

	2024 \$'000	2023 \$'000
Australia	3,006	3,499
Europe and other countries	622	7,286
United States	4,470	1,143
	8,098	11,928

## Revenue by product group and services provided

	2024 \$'000	2023 \$'000
Revenue from product agreements	5,089	8,429
Research and development tax incentive rebate	2,875	3,377
Other, including other government support and interest received	134	122
	8,098	11,928

## **27. CONTROLLED ENTITIES**

	Country of Incorporation	2024	2023
Parent Entity			
Acrux Limited	Australia		
Subsidiaries of Acrux Limited			
Acrux DDS Pty Ltd	Australia	100%	100%
Acrux Pharma Pty Ltd	Australia	100%	100%
Acrux Commercial Pty Ltd	Australia	100%	100%
Subsidiary of Acrux Commercial Pty Ltd			
Fempharm Pty Ltd	Australia	100%	100%

## 28. PARENT ENTITY DETAILS

	PARENT I	PARENT ENTITY	
	2024 \$'000	2023 \$'000	
(a) Summarised statement of financial position of the parent entity, Acrux Limited			
Assets			
Current assets	40	3,258	
Non-current assets (1)	28,673	33,344	
Total assets	28,713	36,602	
Liabilities			
Current liabilities	487	249	
Non-current liabilities	_	7,142	
Total liabilities	487	7,391	
Net assets	28,226	29,211	
Equity			
Share capital	115,012	114,884	
Profit reserve	7,390	7,390	
Accumulated losses	(95,337)	(93,972)	
Share based payments reserve	1,161	909	
Total equity	28,226	29,211	
(b) Summarised statement of comprehensive income			
Loss for the financial year	(1,365)	(1,283)	
Other comprehensive income for the financial year	_		
Total comprehensive income for the financial year	(1,365)	(1,283)	

<sup>(1)</sup> Intercompany loans and 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.

#### 29. CONTINGENCIES

There were no contingencies at 30 June 2024 (2023: nil).

## **30. SUBSEQUENT EVENTS**

In August 2024, Acrux announced that the FDA had approved the Company's fifth ANDA, a generic version of Aczone® Gel, 7.5%. Dapsone 7.5%, Gel is a topical treatment for acne vulgaris and has an addressable market of USD37.4 million as measured by IOVIA as at June 2024.

No other matter or circumstance has arisen since 30 June 2024 that has significantly affected the Group's operations, results or state of affairs, or may do so in future years.

## 31. SIGNIFICANT CHANGES IN THE STATE OF AFFAIRS

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.

# CONSOLIDATED ENTITY DISCLOSURE STATEMENT

For the year ended 30 June 2024

Acrux Ltd is required by Australian Accounting Standards to prepare consolidated financial statements in relation to the Company and its controlled entities (the consolidated entity). In accordance with subsection 295(3A) of the *Corporations Act 2001*, this consolidated entity disclosure statement provides information about each entity that was part of the consolidated entity at the end of the financial year.

	Type of entity	Place incorporated	Share capital held (%)	Australian tax resident	Parent Company
Acrux Ltd	Body Corporate	Australia	n/a	Yes	n/a
Acrux Commercial Pty Ltd	Body Corporate	Australia	100%	Yes	Acrux Ltd
Fempharm Pty Ltd	Body Corporate	Australia	100%	Yes	Acrux Commercial Pty Ltd
Acrux DDS Pty Ltd	Body Corporate	Australia	100%	Yes	Acrux Ltd
Acrux Commercial Pty Ltd	Body Corporate	Australia	100%	Yes	Acrux Ltd

At the end of the financial year, no other entity within the consolidated entity was a trustee of a trust within the consolidated entity, a partner in a partnership within the consolidated entity or a participant in a joint venture within the consolidated entity.

## **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 29 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;
  - (c) giving a true and fair view of the financial position of the Group as at 30 June 2024 and of its performance for the year ended on that date; and
  - (d) the attached consolidated entity disclosure statement is true and correct.
- 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 2024.

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

Pometry

**Ross Dobinson** 

Non-executive Chairman

Melbourne 28 August 2024 **Don Brumley** 

Non-executive Director

Melbourne 28 August 2024

## 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 2024, 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 material accounting policy information, the consolidated entity disclosure statement and the directors' declaration.

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

- giving a true and fair view of the Group's financial position as at 30 June 2024 and of its financial performance for the year then ended; and
- (b) complying with Australian Accounting Standards and the Corporations Regulations 2001.

#### Basis for Opinion

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

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

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

## Material Uncertainty Related to Going Concern

We draw attention to Note 1(b) Going Concern in the financial report which discloses that the Group incurred a net loss for the year ended 30 June 2024 of \$5.800 million, and has current assets of \$5.981 million. As stated in Note 1(b), these conditions, along with other matters as set forth in Note 1(b), indicate that a material uncertainty exists which may cast significant doubt on the Group's ability to continue as a going concern and therefore, the Group may be unable to realise its assets and discharge its liabilities at the amounts stated in the financial statements in the normal course of business. Our opinion is not modified in respect of this matter.

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#### 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 Recoverability of Deferred Tax Assets

Note 2(d) on page 35 and note 6 on page 38.

The Group has \$572k (\$803k as at 30 June 2023) of deferred tax assets recognised as at 30 June 2024 relating to timing differences and Research and Development offset incurred by the subsidiary Acrux DDS Pty Ltd.

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

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

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

Our procedures included amongst others:

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

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#### INDEPENDENT AUDITOR'S REPORT TO THE MEMBERS OF 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 2024 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 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.

Responsibilities of the Directors for the Financial Report

The directors of the Company are responsible for the preparation of:

- a) the financial report (other than the consolidated entity disclosure statement) that gives a true and fair view in accordance with Australian Accounting Standards and the Corporations Act 2001; and
- the consolidated entity disclosure statement that is true and correct in accordance with the Corporations Act 2001; and for such internal control as the directors determine is necessary to enable the preparation of:
- (i) the financial report (other than the consolidated entity disclosure statement) that gives a true and fair view and is free from material misstatement, whether due to fraud or error; and
- (ii) the consolidated entity disclosure statement that is true and correct and is free of 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 have 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.

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:

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

- 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, actions taken to eliminate threats or safeguards applied.

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.

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

## Report on the Remuneration Report

Opinion on the Remuneration Report

We have audited the Remuneration Report included in pages 21 to 26 of the directors' report for the year ended 30 June 2024. In our opinion, the Remuneration Report of Acrux Limited and its controlled entities, for the year ended 30 June 2024, 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

28 August 2024

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# SHAREHOLDER INFORMATION

Additional information required by ASX Listing Rules and not disclosed elsewhere in this report, as at 12 August 2024.

#### **SHAREHOLDERS**

The Company has 290,716,856 ordinary fully paid shares on issue, held by 4,553 shareholders, and 14,044,903 rights held by 21 people. The Company has no other equity securities on issue. Holders of ordinary shares are entitled to receive dividends as declared and are entitled to one vote per share at shareholders' meetings. No voting rights or dividend entitlements attach to rights.

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

#### **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	930	467,732
1,001 to 5,000	1,271	3,684,996
5,001 to 10,000	600	4,858,795
10,001 to 100,000	1,302	46,886,155
100,001 and over	450	234,819,178
Total	4,553	290,716,856

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

## **SUBSTANTIAL HOLDERS**

Under the ASX Listing Rules "Substantial Holder" means, in general terms, a person who either alone or with their associates, has an interest in 5% or more of the voting shares of the Company. The following parties have declared a relevant interest in the number of ordinary shares under Part 6C.1 of the *Corporations Act 2001*.

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

## LARGEST HOLDERS OF FULLY PAID ORDINARY SHARES IN ACRUX LIMITED

		Number of Fully Paid Ordinary Shares	% Issued Capital
1	PHILLIP ASSET MANAGEMENT LIMITED	31,847,134	10.95
2	HISHENK PTY LTD	11,000,000	3.78
3	MR ROSS DOBINSON	5,249,245	1.81
4	DR THOMAS VUI CHUNG CHAI	4,951,985	1.70
5	WILLOUGHBY CAPITAL PTY LTD	4,500,000	1.55
6	CITICORP NOMINEES PTY LIMITED	4,149,492	1.43
7	MR CHRISTOPHER MURRAY ABBOTT	4,000,000	1.38
8	ASHWOOD RIVER PTY LTD	3,800,000	1.31
9	THE POOLE FAMILY SUPERANNUATION FUND PTY LTD	3,700,000	1.27
10	MR DONALD CHARLES BRUMLEY	3,396,108	1.17
11	NETWEALTH INVESTMENTS LIMITED	3,284,269	1.13
12	MR ALAN JEBB & MRS SANDRA JEBB	3,100,000	1.07
13	MNA FAMILY HOLDINGS PTY LTD	2,800,000	0.96
14	TSO PTY LTD	2,625,734	0.90
15	MR BIKASH KAJI BANIYA	2,339,711	0.80
16	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED	2,100,674	0.72
17	PACIFIC CUSTODIANS PTY LIMITED	2,048,427	0.70
18	MR IAN VICTOR LANCINI & MRS DEBRA ANN LANCINI	2,045,000	0.70
19	MR ZIRONG PU	2,023,000	0.70
20	ADAM JAMAL	1,905,719	0.66
21	MR MICHAEL JOHN KOTSANIS	1,511,083	0.52
22	MR ALLEN JAMES KIRBY	1,500,000	0.52
23	MR DAVID ANDREW SLOBOM & MRS LINDA JANE SLOBOM	1,409,596	0.48
24	NEWECONOMY COM AU NOMINEES PTY LIMITED	1,327,870	0.46
25	MRS NOLA KENDALL FLETCHER	1,300,000	0.45
	Top Shareholders	107,915,047	37.12%

#### SHAREHOLDER INFORMATION (CONTINUED)

#### POOLED DEVELOPMENT FUND

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

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

Shareholders of PDFs are entitled to concessionary tax treatment in Australia. Typically no capital gains tax is payable in relation to the sale of PDF shares and dividends are exempt from income tax. This means profits derived by shareholders from their investment are typically tax free and this concessionary tax treatment should be available to investors that hold their interests directly and indirectly through non-corporate trusts and partnerships.

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

- Where the gain on sale would be ordinary income of the investor, the gain will be treated as exempt income; and
- Where the gain on sale would be a capital gain, it is specifically excluded from the capital gains tax provisions of the *Income Tax Assessment Act 1997*.

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

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

Should the Company cease to be a PDF, each shareholder will be deemed to have sold their shares immediately before the Company ceased to be a PDF and to have acquired the shares at their market value immediately after the Company ceased to be a PDF. Any gain or loss realised on the sale after that time, calculated by reference to the deemed acquisition cost, will be subject to the general provisions of the *Income Tax Assessment Act 1997* and any such gain may be included in the shareholder's assessable income.

# **GLOSSARY**

Term	Abbreviation	Description
Abbreviated New Drug Application	ANDA	An ANDA is an application for a generic drug approval for an existing approved drug. It is evaluated by the FDA's Centre for Drug Evaluation and Research, Office of Generic Drugs. In order to achieve approval, applicants must demonstrate bioequivalence to the innovator drug. Once approved, an applicant may manufacture and market the generic drug product in the US as a safe, effective, low cost alternative. All approved products are listed in FDA's Orange Book.
Active Pharmaceutical Ingredient	API	Also known as active drug substance and is the therapeutically active component in a medicine's final formulation which is responsible for its physiological action.
Acyclovir 5%, Cream		Indicated in the United States for the topical treatment of cold sores.
Addressable market		Total market sales value and volume of a pharmaceutical product in a specific dosage form. This market data is purchased from IQVIA.
Australian Securities Exchange	ASX	The ASX, is the main securities exchange in Australia which operates as a marketplace where investors can buy and sell securities in publicly listed companies.
Australian Securities and Investment Commission	ASIC	ASIC is an independent commission of the Australian Government tasked to regulate company and financial services and enforce laws to protect Australian consumers, investors and creditors.
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 the drug substance becomes available at the site of drug action when administered at the same dose under similar conditions.
Compound Annual Growth Rate	CAGR	Measures the average annual rate of growth over time.
Contract Manufacturing Organisation	CMO or CDMO	A CMO provides services such as drug development services and commercial manufacturing on a contract basis.
Contract Research Organisation	CRO	A CRO supports the pharmaceutical, biotechnology, and medical device industries in the form of providing research services on a contract basis. CROs may be involved in all aspects of clinical development, from initial drug discovery through pre-clinical and clinical trials and regulatory approval.
Dapsone Gel		Indicated in the United States for the topical treatment of acne vulgaris.
Environment, Social and Governance	ESG	At the heart of Acrux's Environment, Social and Governance (ESG) framework is our commitment to economic and environmental sustainability and to conducting business in a responsible and ethical manner.
Estradiol		Estradiol is a form of estrogen a hormone produced by the ovaries and is used to treat menopause symptoms.
Evamist®		Brand name for Acrux's unique Estradiol Spray product in the United States. The Evamist® trademark is owned by Lumara Health and sublicensed to Padagis.
Food and Drug Administration	FDA	The FDA is the body that ensures safe and effective drugs are available to people in the US. It regulates and supervises prescription, over-the-counter pharmaceutical drugs, vaccines, biopharmaceuticals and veterinary products.

## GLOSSARY (CONTINUED)

Term	Abbreviation	Description	
Generic medicine		A generic medicine provides the same quality, safety and efficacy as the original brand name product and undergoes strict scrutiny before it is approved by national regulatory authorities.	
Good Manufacturing Practice	GMP or cGMP	GMP (also 'cGMP' or 'current Good Manufacturing Practice') is the aspect of quality assurance that ensures medicinal products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the product specification.	
In-vitro Permeation Testing	IVPT	IVPT 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.	
In-vitro Release Testing	IVRT	Measurement of drug release from dosage forms applied topically for the purpose of bioequivalence testing. IVRT allows for targeted and systematic drug development and guides the establishment of therapeutic equivalence. IVRT involves subjecting the drug formulation to conditions to induce drug release across a membrane and quantitating the amount released under those conditions.	
IQVIA		IQVIA Inc, is a US based multinational company which provides, on a subscription basis, pharmaceutical industry leading sales data.	
Lenzetto®		Brand name for Acrux's unique Estradiol Spray in the European Union and other countries excluding the United States. The Lenzetto® trademark is owned by Gedeon Richter.	
Nitroglycerin 0.4%, Ointment		Indicated in the United States for moderate to severe pain associated with chronic anal fissure.	
Omnibus Equity Plan	OEP	Approved at 2023 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. It identifies drug products approved by the FDA and related patent and exclusivity information.	
Overseas Finding	OSF	To be eligible for RDTI, expenditure on an R&D activity conducted overseas must:  1. Be covered by an advance Overseas Finding where the activities have been assessed as eligible R&D activities.	
		2. Have a significant scientific link to Australian core activities.	
		3. The overseas activity cannot be conducted in Australia.	
		4. Expenditure on the overseas activities is less than the expenditure on the related activities conducted in Australia.	
		A positive OSF gives assurance that registered R&D activities conducted overseas are eligible to be claimed under the RDTI. Overseas expenditure cannot be claimed without an OSF.	
Padagis		Padagis US LLC is a market leading pharmaceutical manufacturer in the US offering high quality generic and specialised pharmaceutical and OTC products. Padagis' line of topicals includes prescription creams, ointments, suspensions, gels, foams, sprays, patches, nasal, and suppositories.	
Pooled Development Fund	PDF	The <i>Pooled Development Fund Act 1992</i> was established by the Australian Federal Government to increase the supply of capital to small and medium-sized enterprises to support their growth and development, creating industry and jobs for Australia. A concessional tax regime applies to registered PDF companies.	
Prilocaine 2.5% and Lidocaine 2.5%, Cream		Indicated in the United States as a topical anesthetic for use on normal intact skin for local analgesia or genital mucous membranes for superficial minor surgery and a pretreatment for infiltration anesthesia.	

Term	Abbreviation	Description
Product-Specific Guidance	PSG	To facilitate generic drug product availability and identify the most appropriate methods for developing drugs and generating evidence to support ANDA approval, the FDA publishes product-specific guidance describing their current thinking and expectations on develop generic drug products which are therapeutically equivalent to specific reference listed drugs.
Reference Listed Drug	RLD	FDA approved drug product with established safety and effectiveness serving as basis for generic drug approval. A generic applicant must demonstrate it is the same as the RLD in terms of active ingredients, conditions of use, route of administration, dosage form, strength and labelling.
Research and Development Tax Incentive	RDTI	The Research and Development Tax Incentive (R&D Tax Incentive Rebate) is a tax offset for companies conducting eligible research and development (R&D) activities in Australia.
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.
TruPharma		TruPharma, LLC is a front-end pharma sales and marketing company focused on commercializing branded and generic prescription drugs for the U.S. Market. TruPharma has a diverse portfolio of products distributed across multiple channels. TruPharma is operated by a team of experienced executives focused on getting complex products FDA-approved and into the market.
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**

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

## **Company Secretary**

Joanna Johnson

## **Registered Office**

103–113 Stanley Street West Melbourne Victoria 3003

## **Principal Business Address**

103-113 Stanley Street West Melbourne Victoria 3003

Telephone: (03) 8379 0100 (within Australia) International telephone: +61 3 8379 0100

E: info@acrux.com.au www.acrux.com.au

## **Australian Business Number**

72 082 001 152

#### **Auditor**

Pitcher Partners Level 13, 664 Collins Street Docklands, Victoria 3008

## **Share Registry**

Link Market Services Level 13, Tower 4 727 Collins Street Docklands Victoria 3008

Australia Toll-free: 1300 554 474 (Australia only)

International: +61 1300 554 474

E: registrars@linkmarketservices.com.au www.linkmarketservices.com.au

## **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 ASX and the

Company website: Acrux.com.au



