ADVANCING DEVELOPMENT

Annual Report 2019

ACRUX
DRUG DELIVERY SOLUTIONS

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Risk and uncertainty

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

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

Who we are

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

Financial Outcomes

Cash reserves remain healthy at $18.2 million and will provide the platform to support our growth and diversification strategy. 2019 financial performance was impacted by the termination of the Axiron® licensing agreement in the prior year resulting in nil royalty revenue from Axiron®.

Cash Reserves

$18.2m

down $10.3 million p.c.p

Revenue

$5.3m

up $1.9 million p.c.p, including R&D Tax Incentive rebate accrual of $2.0 million

R&D Investment

$10.9m

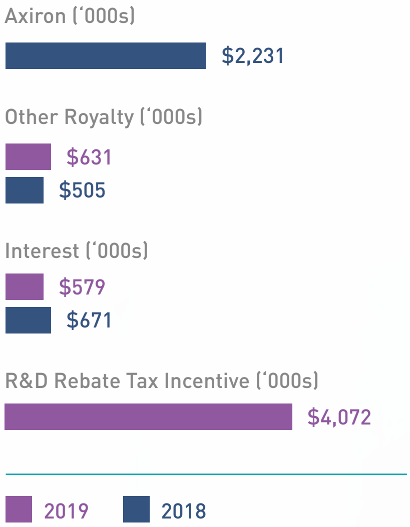
up $0.3 million p.c.p

Operating Loss Before Tax

$8.3m

down $7.8 million p.c.p

Revenue 2019

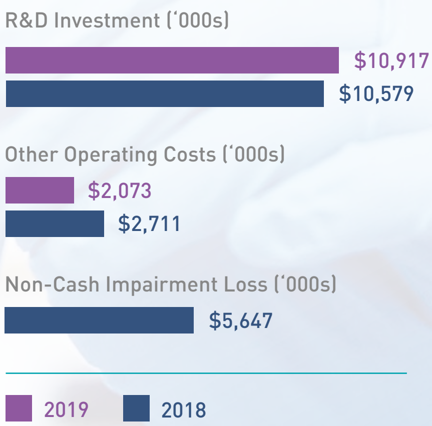


Royalty revenue from Lenzetto® was $0.581 million (2018: $0.327 million) which is an increase of 77.6% on prior year and interest on cash deposits were $0.579 million (2018: $0.671 million).

Royalty revenue from Axiron® decreased to nil in the current year (2018: $2.231 million) reflecting the termination of the Axiron licensing agreement during the 2017 calendar year.

The Group received $2.057 million (2018:nil) in relation to an R&D Tax Incentive Rebate from the Australian Taxation office for the 2017/2018 financial year. A further $2.015 million was accrued in the 2019 financial year and is expected to be received in the 2019 calendar year.

Other Financial Outcomes



R&D investment increased to $10.9 million up 3% on prior financial year due to the progression and increase in research and development projects and higher utilisation of external suppliers for contract manufacture engagement, API procurement and clinical research activities.

Increases in external R&D costs of $1.096 million for contract manufacture engagement, API procurement for the manufacture of exhibit batches and clinical research organisation engagement was offset by a significant reduction in non-recurring legal fees associated with the Axiron patent appeal litigation in the prior year and lower depreciation and amortisation expense of $0.426 million (2018: $0.618 million).

Business Achievements

Acrux is advancing its strategy with continued execution of the development and progression of our pipeline.

R&D Investment

$10.9m

up $0.3 million from the prior year

2019 milestones

- Acrux received confirmation that the submitted ANDA to the FDA for a generic version of Jublia® (efinaconazole) had been accepted for review.
- Acrux submitted its second ANDA application to the FDA for its generic version of a testosterone topical solution, which was subsequently accepted for review.
- Acrux submitted its third ANDA application to the FDA for its generic version of EMLA® (lidocaine 2.5% and prilocaine 2.5% cream) in June 2019.
- Lenzetto® continues to be launched in additional countries within the European Union, Latin America and CIS countries by our licensee Gedeon Richter.
- Acrux successfully engaged additional CMOs that manufacture and supply FDA approved products, providing the infrastructure to begin scale up of 6 projects from the Acrux laboratory to exhibit batch manufacturing.
- Acrux received an R&D Tax Incentive Rebate from the Australian Taxation Office of $2.057 million.
- Acrux settled the Hatch Waxman patent litigation relating to Acrux's first to file of ANDA for the generic equivalent Jublia.

Future milestones

- An additional 4 ANDA dossiers to be accepted for review by the FDA during calendar year 2020.
- Execute licensing deals for products in our pipeline.
- Initial revenue from generic pipeline expected during calendar year 2019.
- Add further products to our topical generic pipeline.

Market and Business Opportunities

Generic portfolio

Created a diversified portfolio of marketed products to generate its future income streams.

Avoid commoditised market segments with significant pricing pressure.

Generic product pipeline has attractive projected internal rates of return, with a collectively lower risk profile and faster pathway to approval than specialty products:

I. $3–4 million to develop each generic

II. Efficacy of drug has already been demonstrated

III. Attractive market and licensee terms

IV. Future revenue derived from milestones and royalties

	Total market	Oral drugs	Acrux focus Topical drugs
Definition of market	Total US prescription pharma market	Drugs that are ingested orally	Drugs that are applied topically (including directly to the skin, eyes, ears and nose)
Market size[1]	>US$460bn	~US$200bn	~US$20bn[2]
Generic market share	~90%[3]	~91%[3]	47%[4]
Typical generic development complexity		Low	Greater complexity than oral generic drug development
Generic competition	**Variable**	**High levels of generic competition from a significant number of drug manufacturers**	**Limited generic competition given niche market size and development complexity**

Source:

1. US market by dosage form, IQVIA Q1, 2019 MAT, US market sales (US$)
2. Market size for topically applied drugs IQVIA Q1, 2019 MAT (US$)
3. IQVIA Global Generic and Biosimilars Trends and Insights – 2018
4. IQVIA, National Sales Perspectives, January 2019 – Unbranded generic share of dermatology, MAT

Acrux generic pipeline addressable market value[1,2]

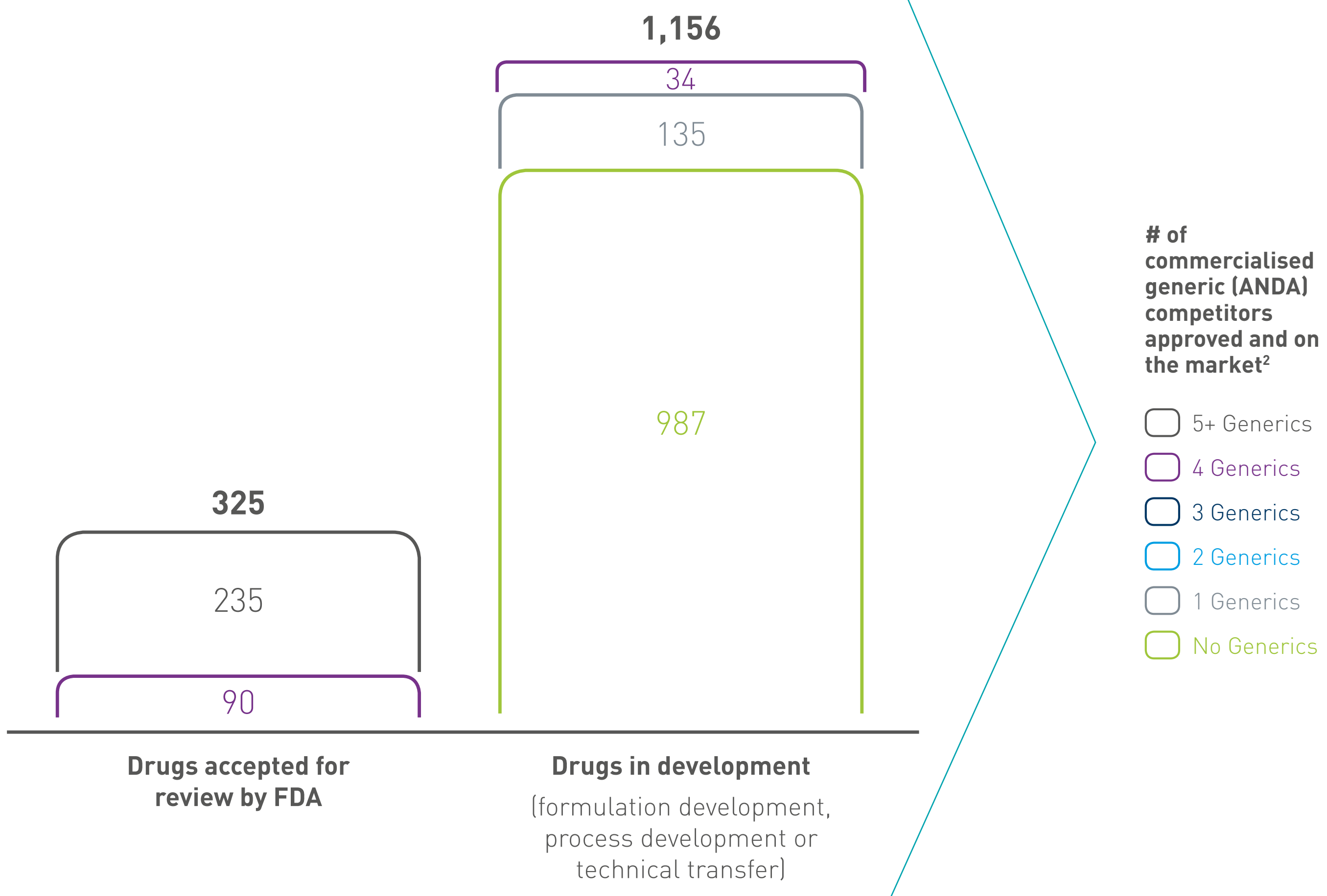
- Focus on the topical sector of the pharmaceutical market in the United States.

Acrux is targeting a large addressable market

- Addressable market of US$1.5 billion based on 14 products currently in the Acrux topical generic pipeline.

Fewer generic competitors in our targeted market segments creates favourable economics for Acrux

- For markets with lower levels of competition, Acrux expects to capture relatively higher market share.
- Currently, over half of the portfolio's addressable market does not have any generic competitors.
- FDA Priority Review is given to ANDA applications with three or fewer approved generics.



1. August 2019 pipeline addressable market based on twelve months sales to end March 2019 derived from IQVIA (Quintiles and IMS Health) sales data.
2. As at August 2019. Note that there are currently 10+ dossiers submitted to the FDA and neither approved nor commercialised for a generic version of Jublia® and 4 commercialised generics of EMLA® cream.

Generic Product Portfolio and Pipeline

- 14 products in generic topical portfolio
- 2 products accepted for review by the FDA during FY19

Progress as at FY18

Progress during FY19

1. Based on FDA Guidance, a number of products in the Acrux generic pipeline do not require a clinical study for product approval.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Chairman's Address

At last year's Annual General Meeting I referenced the macro factors assessed in determining our corporate strategy and material developments since initiating that strategy in 2015. Over the past year there have been several developments that will influence our strategy moving forward and Michael will address these in more detail in his CEO and Managing Director report, so I will only reference the broader issues in my introduction.

The Company's routine activity includes maintaining consistent monitoring of topical drug markets, the competitive landscape and FDA guidance documents which could impact Acrux's position. This includes changes to the FDA Product Specific Guidances (PSG), which presents both opportunities and risks. Acrux has a very clear focus on Competitive Generic Therapies (CGT) products, which have no generic competition and receive priority review from the FDA. As noted in previous guidance to shareholders, a key objective in generics development is introducing the product early to market to market in order to gain commercial advantages over competitors. For some generic products which are first to market, exclusivity is received for the first six months of that product's commercial life.

The knowhow developed by the Company over the last twenty years of operations does provide competitive advantages. Acrux has unique capabilities in product development and for in-vitro drug development including IVRT (*in-vitro* release testing) and IVPT (*in-vitro* permeation testing). For some products, the FDA has recently included *in vitro* testing as an alternative development approach to expensive clinical endpoint studies to demonstrate bioequivalence for topical generics. This enables Acrux to utilise its capabilities to develop eligible drugs more efficiently than our competitors.

Commercial discussions with prospective licensees have commenced for some of the products the Company has been developing. Our product pipeline will be covered in more detail in Michael's CEO and Managing Director report and we are confident that we have the capacity to maintain a consistent number of products in development in our pipeline as earlier projects are completed and licensed out. To optimise shareholder value, our pipeline will be expanded gradually after initial licensing activity validates our business model.

I would like to extend my personal thanks to the Board for their input over the last year, which has been a productive one. I would also like to extend the Board's appreciation to Michael and his team for their work over the last year. The Acrux team has faced one of the heaviest workloads since the Company's inception, but there is a great *esprit de corps* within the Company and genuine enthusiasm and excitement for the coming year's activity.

Ross Dobinson
Chairman

CEO & Managing Director's Report

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

Acrux strategic focus

Acrux is creating a diversified portfolio of products to generate its future income streams. In August 2015, the company began development of its pipeline of topical generic products. The first three of these products have now been submitted as Abbreviated New Drug Applications (ANDAs) to the FDA.

Throughout FY19, we focussed our activity on the progression of our pipeline of topical generic products, which now includes fourteen separate generic products. The number of active development projects is consistent with our goal to expand the number of generic products in our portfolio which we believe will lead to commercially relevant and valued products for the company in the future.

The focus within Acrux has, since 2015, been on the execution of a strategy to capitalise on the existing skill sets with the Acrux development team and to apply those skills to the development of a broad range of topical generic products for the United States market. This focus is a transformational change to the depth and breadth of our pipeline.

Each of these projects has been selected based on a range of criteria that include the size of the addressable market, the patent landscape of the reference listed drug (RLD), the formulation of the RLD and the cost and degree of complexity involved in the development of a generic product.

All the products in the development pipeline are applied topically, which is consistent with our strategy to leverage our existing capabilities.

The Acrux generic pipeline

Acrux has now submitted three ANDAs to the FDA for review and has an additional eleven products in various stages of formulation development or technical transfer to a contract manufacturer. The development of the Acrux generic pipeline is based upon the selection of generic product candidates from within the topical sector of the pharmaceutical market in the US. The generic product pipeline of the Company can be characterised by its collectively lower risk profile and faster pathway to approval than could be achieved with product development of specialty products or new chemical entities.

The topical generic market is generally less competitive than the much larger oral generic market and it features many products that are considered by regulators to be more complex to develop than products in the oral generic market.

Each of the topical generic products in the Acrux pipeline has been assessed for its commercial prospects specifically in the US market. The addressable annual market in the US for the fourteen generic products in our pipeline is approximately US$1.5 billion based on IQVIA data for twelve months to the end of March 2019.

Acrux filed a Paragraph IV Abbreviated New Drug Application (ANDA) with the U.S. Food and Drug Administration (FDA) for a generic version of Jublia® (efinaconazole) topical solution, 10%. Subsequent patent litigation on this product was settled in April 2019.

CEO & Managing Director's Report continued

Acrux also submitted an ANDA of testosterone solution in August 2018 which was accepted for review in October 2018. Acrux submitted its third ANDA of a generic of lidocaine 2.5% and prilocaine 2.5% cream for review by the FDA in June 2019 which was accepted for review in August 2019.

A major focus for the Company during the 2019 financial year was and continues to be the technical transfer of products to our Contract Manufacturing Organisations (CMOs). During the financial year 6 additional technical transfers were initiated. The process is underway for each product to transfer our product formulation and subsequently manufacture the exhibit batches required for review and subsequent approval by the FDA. This is a vital step. This involves the technical transfer of the Acrux developed formulations of generic products and the associated methods of manufacture to a CMO that will scale up manufacturing to commercial batch sizes for both regulatory submission and commercial purposes. That requires a significant internal focus with a range of CMOs.

During the 2020 financial year we intend to add additional products to our pipeline. This is important for our momentum and to sustain a diversified and commercially viable portfolio of products. We continue to actively review and identify additional product candidates, all of which are applied topically, for development and will add additional products to our pipeline over course of the year.

Estradiol spray

Estradiol spray was the first product to be developed by Acrux.

Lenzetto® is the trade name given to the estradiol product by our licensee Gedeon Richter. Lenzetto® was launched during the second half of the 2016 financial year in Europe. Gedeon Richter launched the product in 21 European countries and during 2018 the product was also launched in a number of smaller Latin American, European and CIS markets. As of June 2019, the product has been launched in 33 countries in total.

Axiron®

Since 2014, a number of product liability lawsuits have been filed against Acrux and Eli Lilly in the United States District Court for the Northern District of Illinois, including claims that assert injury caused by testosterone replacement therapy.

The conduct of the lawsuits will not have a material impact on Acrux's operating expenditure.

Financial performance

Cash reserves decreased over the prior financial year by 36.1% to $18.2 million. This reflects the ongoing expenditure on our development pipeline. Cash reserves are in line with our expectations.

Looking forward

The Acrux team has continued to invest tremendous energy into the progression of our pipeline. The company has now submitted three ANDAs that have been accepted for review by the FDA. Our pipeline continues to grow, and the progress of our projects is a direct reflection of the collective efforts of the team throughout the 2019 financial year.

The team responsible for our growth should be proud of their achievements during the year and I thank them for their efforts. I firmly believe we are positioning the Company to take advantage of the commercial opportunities that we have identified in the topical generic market in the United States with our goal to create a growth-oriented company with a diversified on-market portfolio and a broad pipeline of financially attractive products.

Michael Kotsanis
CEO and Managing Director

Corporate Governance Statement

The Board of Directors is responsible for the overall corporate governance of Acrux Limited ("Company"). The Board monitors the operational and financial position and performance of the Company and oversees its business strategy, including approving strategic objectives, plans and budgets of the Company. The Board is committed to optimising performance and building sustainable value for shareholders. In conducting business with these objectives, the Board seeks to ensure that the Company is appropriately managed to protect and enhance shareholder interests and that the Company, its Directors, officers and personnel operate in an appropriate environment of corporate governance. Accordingly, the Board has created a framework for managing the Company, including adopting relevant internal controls, risk management processes and corporate governance policies and practices that it believes are appropriate for the Company's business and that are designed to promote responsible management and conduct of the Company.

The Australian Securities Exchange ("ASX") Corporate Governance Council has developed and released its Corporate Governance Principles and Recommendations 3rd edition ("ASX Principles") for entities listed on the ASX in order to promote investor confidence and to assist companies to meet stakeholder expectations. This Corporate Governance Statement outlines the key aspects of the Company's governance framework and governance practices which are consistent with the ASX Principles unless stated otherwise.

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

- Statement of Corporate Governance Principles
- Code of Conduct
- Board Charter
- Audit and Risk Committee Charter
- Human Capital and Nomination Committee Charter
- Continuous Disclosure and Shareholder Reporting Policy
- Share Trading Policy
- Whistle-blower Policy
- Diversity Policy

This statement has been approved by the Board of Acrux Limited and is current at 22 August 2019.

1. The Board of Directors

1.1 Board role and charter

The Board Charter sets out details of the Board's composition, its role and responsibilities, the expected relationship and interaction between the Board and management, details of the responsibilities and functions expressly reserved to the Board and those authorities which are delegated by the Board to management and Board Committees. A copy of the charter can be viewed on the Company's website.

The Board is responsible for the management, oversight and performance of the Company, including but not limited to the following matters:

Strategic and financial objectives

a) evaluating, approving and monitoring the strategic and financial plans and performance objectives for the Company;

b) evaluating, approving and monitoring the annual budgets and business plans;

c) evaluating, approving and monitoring major capital expenditure, capital management and all major corporate transactions including the issue of any securities of the Company;

d) evaluating and approving the annual and half year financial reports and associated announcements and disclosures;

e) monitoring other material reporting and external communications by the Company including financial projections and or statements as to future financial performance; and

f) appointing external auditors.

Board and senior management

g) nomination and remuneration of Directors;

h) appointment of the Chair;

i) evaluation of Board and individual Director performance;

j) appointing, removing and managing the performance of, and the succession planning for, the Chief Executive Officer;

k) overseeing and ratifying the terms of appointment and, where appropriate, removal, of Senior Management (being those persons reporting directly to the Chief Executive Officer), including their remuneration;

l) monitoring Senior Management performance and their implementation of strategy and ensuring appropriate resources are available;

m) control of membership and Charters of Board Committees; and

n) corporate governance matters relating to the Board and Senior Management and matters of principle regarding corporate governance.

Corporate Governance Statement continued

Risk and compliance management

o) monitoring the Company's performance in relation to best practice principles of corporate governance;

p) approving and monitoring the Company's risk management strategy and internal controls and accountability systems and their effectiveness;

q) approving and monitoring compliance with the Company's Code of Conduct and other policies; and

r) monitoring and reviewing the Company's operations in relation to, and compliance with, legal and regulatory requirements.

Secretarial and other

s) convening of shareholder meetings;

t) issuing shares, equity instruments or other securities;

u) disclosure of Directors' interests;

v) major litigation;

w) continuous disclosure and shareholder communications;

x) related party transactions;

y) insider trading; and

z) design of any short or long-term incentive plans to employees of the Company including, but not limited to employee share and option plans;

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

a) developing business plans, budgets and company strategies for consideration by the Board and, to the extent approved by the Board, implementing those plans, budgets and strategies;

b) operating the business of the Company within the parameters determined by the Board and keeping the Board promptly informed of all developments material to the Company and its business;

c) where proposed transactions, commitments or arrangements to be undertaken by Senior Management exceed limits authorised by the Board, referring the matter to the Board for consideration and approval;

d) identifying and managing operational risks and formulating strategies for managing those risks for consideration by the Board;

e) managing the Company's financial and other reporting mechanisms and control and monitoring systems to ensure that they capture all relevant material information on a timely basis and are functioning effectively;

f) ensuring that the Board is provided with sufficient information on a timely basis in relation to the Company's business and, in particular, in relation to the Company's performance, financial condition, operating results, risks and prospects to enable the Board to discharge its duties; and

g) implementing the policies, processes and codes of conduct approved by the Board.

1.2 Board composition

The Board seeks to achieve a mix of skills and diversity that enables it to most effectively carry out the functions and responsibilities set out in the Board Charter. The Board uses a skills matrix that it has established when considering the appointment of Directors.
This includes:

Skills or experience required by all Directors:

a) Knowledge of corporate governance requirements and practices and risk management is important because we are a publicly listed company and must ensure our integrity, values and the way in which we assess and manage risk are set from the top.

b) Significant leadership and strategy experience over extended periods is important because it helps identify these qualities in the management team and brings a practical understanding of organisations and how to drive change and growth.

c) Fit and balance within board is important to ensure that the board can build effective team work.

d) Demonstrates Company values is important because the values drive standards, behaviour and how we should interact. The Company values are "Round the clock","Innovation", "Openness", "Standout."

Skills or experience required to be represented on the board in light of Acrux's current and expected future business needs:

a) Financial management is important because it assists understanding and oversight of financial reporting and controls, because our corporate structures are complex.

b) Investor/investment management and capital markets experience is important to ensure strong alignment with our investors and to review distribution of, or raising of capital.

c) Technology or project selection experience is important because we are choosing to invest in new projects which require allocation of capital, assessment of risk and financial returns.

d) Pharmaceutical industry experience is important in understanding and reviewing our strategy and investment decisions and managing our risks.

e) Legal or contract or IP experience relevant to industry is important in understanding strategy related to intellectual property and reviewing and managing alliances governed through contractual relationships.

f) Sectoral experience relevant to corporate strategy is important because our competitive advantage is based on know-how and our pipeline is dependent on making good product selections.

g) Clinical development experience is important as our projects will usually involve the coordination of clinical and non clinical trials which are pivotal to regulatory assessment and approval of products that Acrux develops.

h) International experience is important because the products Acrux develops will have a greater market potential outside the local Australian market and potential partners will most likely be based outside Australia.

i) Alliance management or partner management experience is important because all of our development projects and commercialised products are intended for marketing through partnerships making alliance management a critical success factor for Acrux.

j) Talent management or organisational development or change management experience is important because we are a highly skilled organisation making talent acquisition, development and retention a critical success factor.

The Board adopts and regularly reviews a skills matrix that defines a set of skills appropriate for the Board to discharge its duties having regard to the current and future strategies and operational priorities of the Company.

The current Board is made up of a Chairman (Ross Dobinson), three non-executive Directors (Timothy Oldham, Simon Green and Geoffrey Brooke) and an Executive Director (Michael Kotsanis). The names of the Directors, the dates of their appointments, their non-executive, executive or independent status and whether they will seek election at the 2019 Annual General Meeting are set out in the table below.

The details of their background, skills and experience are set out on pages 25-27 of the financial report.

Name	Appointed/resigned	Non-Executive	Executive	Independent	Seeking election at 2019 AGM
Ross Dobinson	Appointed 1998	Yes	No	Yes	No[1]
Timothy Oldham	Appointed 1 October 2013	Yes	No	Yes	No[2]
Michael Kotsanis	Appointed 1 November 2014	No	Yes	No	No[3]
Simon Green	Appointed 1 June 2016	Yes	No	Yes	Yes
Geoff Brooke	Appointed 1 June 2016	Yes	No	Yes	Yes

1. Mr Dobinson was re-elected on 26 October 2017.
2. Timothy Oldham was re-elected on 1 November 2018.
3. Michael Kotsanis is the Managing Director.

Corporate Governance Statement continued

1.3 Director independence

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

The Board comprises a majority of independent Directors. A Director is considered to be independent where he/she is independent of management and is free of any business or other relationship with could materially interfere with, or could reasonably be perceived to interfere with, the exercise of their unfettered and independent judgement. The Board Charter sets out guidelines to assist in considering the independence of Director. The Board considers that each of Ross Dobinson, Tim Oldham, Simon Green and Geoff Brooke are independent for the purposes of the ASX Principles.

In accordance with the recommendation of ASX Principle 2.5 the roles of Chair and Chief Executive Officer are not exercised by the same individual. The Chair is responsible for the leadership of the Board, for ensuring that the Board functions effectively and, where appropriate, communicating the views of the Board to the public. The Chair sets the agendas for Board meetings and manages the conduct of meetings by facilitating open discussion between Board members, between the Board and Senior Management and with the public.

1.4 Terms of director appointment

The Chairman, Non-executive Directors and Managing Director have formal letters of appointment. Remuneration of the non-executive Directors, Managing Director and the terms of appointment of the Chairman are disclosed in the Remuneration Report.

Non-executive Directors should be willing to serve for not less than that period of time determined by the Board at the time of the non-executive Director's appointment before retiring from the Board. Each non-executive Director will resign pursuant to ASX guidelines unless the other Directors unanimously request that Director to continue in office. In that case the non-executive Director will continue as a Director until he or she resigns or does not stand for re-election or another Director does not approve of him or her standing for re-election.

1.5 Access to information and independent advice

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

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

1.6 Human capital and nomination committee

The current members of the Human Capital and Nomination Committee of the Board are Timothy Oldham (Chair), Geoff Brooke and Simon Green. During the financial year, the Committee met on 6 December 2018 and 20 June 2019 with only one absence at one meeting by members.

Members of the Committee are chosen having regard to their skills and experience in relation to the matters for which the Committee is responsible. Members of the Committee have unrestricted access to company records, Senior Management, advisers and the external auditors.

The objective and purpose of the Committee is to support and advise the Board in fulfilling its responsibilities to shareholders in ensuring that the Board is comprised of individuals who are best able to discharge the responsibilities of Directors and ensuring that the Company obtains and retains Senior Management and employees of high quality and motivation to drive the long term growth of the Company.

The Committee's duties and responsibilities, which are set out in its Charter, in general terms is to:

a) establish a formal and transparent procedure for the selection and appointment of new Directors to the Board;

b) identify suitable candidates to fill Board vacancies as and when they arise and nominating candidates for the approval of the Board;

c) consider processes for the orientation and education of new Directors and developing ongoing policies to facilitate continuing education and development of Directors;

d) periodically assess the skills required for each Director to discharge competently the Director's duties;

e) regularly review the structure, size and composition of the Board and the effectiveness of the Board as a whole;

f) establish and conduct an appropriate evaluation of the Board's process and of existing Directors, including an evaluation of whether each Director is contributing the time required of him or her for Board duties;

g) recommend to the Board a policy and framework for Senior Management's remuneration;

h) review and monitor the implementation of the human resources plan of the Company and succession planning for Senior Management; and

i) review and recommend to the Board the total individual remuneration package of each member of Senior Management, including any bonuses, incentive payments, and participation in any share or share option plans in accordance with the policy and framework for Senior Management's remuneration.

In accordance with the recommendations of ASX Principle 2.4, the Committee's Charter further provides that, where practical, a majority of the Committee must be independent non-executive Directors and the Chair must be a non-executive Director who is not the Chair of the Company. Executive Directors may not be members of the Committee. A further recommendation of ASX Principle 2.1 is that the Committee have at least 3 members.

The Company's Code of Conduct, which has been in place since 2005, contains a principle of equal opportunity to be applied in all human resource decisions and in the workplace environment. The Committee has supplemented the Code of Conduct principle by adopting a formal diversity policy. However, the Committee has not yet set measurable objectives for gender diversity.

The workforce at Acrux is small and the majority of positions require specialist qualifications and experience. The Committee believes specific diversity objectives are impractical at this time. At the date of this report, 61% of Acrux's workforce were female. The Senior Management team consists of two female members and one male member, while the five current Board members are male. The Committee and the Board will review the potential need for formal diversity objectives in the future as the Company evolves.

1.7 Audit and risk committee

The current members of the Audit and Risk Committee are Geoff Brooke (Chair), Timothy Oldham and Ross Dobinson. During the financial year, the Committee met on 16 August 2018 and 21 February 2019.

Members are chosen having regard to their skills and experience in relation to the matters for which the Committee is responsible. Members of the Committee have unrestricted access to company records, Senior Management, advisers and the external auditors.

The objective and purpose of the committee is to assist the Board in fulfilling its corporate governance and oversight responsibilities relating to the Company's financial accounting practices, internal control systems, risk management procedures, external reporting and the external audit function.

The Committee's duties and responsibilities, which are set out in its Charter, in general terms is:

Corporate Governance Statement continued

1. overseeing the Company's system of financial reporting for the purpose of safeguarding its integrity, including viewing all regular financial reports and other formal announcements relating to the Company's financial performance prepared for release to the ASX, regulators and the public before making appropriate recommendations to the Board;
2. determining the extent of internal audit activities required and monitor the effectiveness of those activities (note that the Committee has determined that the Company, due to its size, does not presently warrant establishing a separate internal audit function);
3. monitoring the performance and activities of the external auditor including:
   - overseeing the process for the appointment, reappointment and removal of the external auditors (including audit engagement letters), overseeing the rotation of the principal audit partner and reviewing the level of the external auditors' fees;
   - assessing the performance and independence of the external auditors and the quality of the audit work performed;
   - requiring, reviewing and monitoring compliance with the audit plan of the external auditors, including the scope of the plan and the levels of financial statement materiality;
   - reviewing reports from the external auditors and meeting with the external auditors at least once annually in the absence of Senior Management and also meeting with the external auditors as requested by the Board, the Committee or the external auditors; and
   - receiving, reviewing, developing and implementing policy on the engaging of the external auditors to supply non-audit services.
4. overseeing and reviewing the Company's financial and risk management compliance and internal control framework including:
   - overseeing the creation, implementation and maintenance of the risk management system of the Company and its controlled entities and their internal control framework, including information systems;
   - reviewing the effectiveness of the Company's implementation of its risk management systems and internal controls on an ongoing basis and reviewing the outcome of any non-financial audits;
   - requiring Senior Management to report to the Board at least annually on whether the Company's material business risks are being managed effectively;
   - developing an understanding of the overall business environment, relevant laws and codes of importance to the Company and the programs that the Company has in place to provide reasonable assurance of compliance;
   - reviewing the Company's occupational health and safety policies and ensuring regular reporting to the Committee on issues related to occupational health and safety;
   - reviewing insurance coverage and claims trends;
   - ensuring that the Chief Executive Officer and the Chief Financial Officer state in writing to the Board annually that:
     i. the Company's financial reports present a true and fair view, in all material respects, of the Company's financial condition and operational results and are in accordance with the relevant accounting standards;
     ii. the statement in (i) above is founded on a sound system of risk management and control which implements the policies adopted by the Board; and
     iii. the Company's risk management and internal compliance and control systems are operating efficiently and effectively in all material respects. The Board has received the report from Senior Management referred to above, advising whether the Company's material business risks are being managed effectively.

The Board received the statement in writing referred to above from the Chief Executive Officer and the Chief Financial Officer on 22 August 2019.

In accordance with the recommendations of ASX Principle 4.1, the Committee's Charter provides that the Committee have at least three members, Executive Directors may not be members of the Committee, a majority of the Committee must be independent Directors and the Chair must not be the Chair of the Company.

1.8 Director and senior management remuneration and performance

The remuneration structure for Senior Management and Directors and the amounts paid to each during the year are set out in the Remuneration Report section of the Directors' Report on pages 32–36. Non-executive Directors are remunerated by way of fees. They are also eligible to participate in the Company's Omnibus Equity Plan.

At the end of each financial year, the performance of Senior Executives against the company and their personal goals is assessed. At the same time personal goals and development plans for the next financial year are set, to be aligned with the Company's objectives.

The review of Senior Management team members is carried out by the Chief Executive Officer and the results are subject to further review and approval by the Chair of the Human Capital and Nomination Committee.

The review of the Chief Executive Officer's performance is carried out by the Human Capital and Nomination Committee and the Committee's remuneration recommendations are then approved by the Board. A performance evaluation in accordance with this process was undertaken in respect of the year ended 30 June 2019.

A review of the performance of the Board and its Committees was undertaken and discussed at the Human Capital and Nomination Committee on 22 June 2019. No areas of under-performance requiring immediate remedial action were identified.

The Board remains focussed on continuous improvement and monitors the following areas:

a) Board skills, experience and diversity;

b) Role of the board vis-a-vis management; and

c) Board process and dynamics.

2. Disclosure and communication

2.1 Continuous disclosure

The Board has adopted a Continuous Disclosure Policy to ensure compliance with the ASX Listing Rules continuous disclosure requirements. The Policy sets out procedures aimed at ensuring the Company fulfils its obligations in relation to the timely disclosure of material price-sensitive information. The Company has an obligation to keep the market fully informed of any information it becomes aware of concerning the Company which may have a material effect on the price or value of the Company's securities, subject to certain exceptions.

A copy of the Continuous Disclosure Policy is available on the Company's website.

This policy:

a) gives guidance as to the information that may need to be disclosed;

b) gives guidance for dealing with market analysts and the media;

c) establishes regular reminders to Directors and Senior Management to actively consider whether there is any price sensitive information which needs disclosure;

d) allocates responsibility for approving public disclosures and shareholder communications.

Corporate Governance Statement continued

2.2 Communications with shareholders

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

a) annual and half-yearly reports;

b) media releases, public announcements and investor briefings; and

c) annual general meetings.

All the above communications are posted on the Company's website (www.acrux.com.au). Shareholders are encouraged to receive shareholder materials electronically and can do so by visiting our investor centre, located on the Company's website. In addition, the Company is committed to using general meetings of the Company to effectively communicate with shareholders and to allow reasonable opportunities for informed shareholder participation at these meetings.

Where possible the Company will comply with the ASX Best Practice Guidelines for the content of notices of meeting. Further, the external auditor is requested to attend the annual general meeting and be available to answer shareholder questions about the conduct of the audit of the Company

and the preparation and content of the auditor's report. The Company is committed to further developing its communications strategies to optimise shareholder communication.

3. Share trading

Under the Company's share trading policy, the Directors, Senior Executives and all other employees of the Company (and their collective designated persons) are prohibited from trading in the Company's shares if they are in possession of inside information.

In addition, the Directors, Senior Executives and all other employees (and their collective designated persons) are prohibited from trading in the Company's shares during the periods starting at the end of either the financial year or the half year and ending when the financial results related to these periods are released to the market.

The Directors, Senior Executives and all other employees of the Company (and their collective designated persons) may not trade in the Company's shares without the approval of the Company Secretary (who must obtain approval from the Chair) and only if they have provided a statement that they are not in possession of material non-public information. Such approval expires after five business days. If the Chair wishes to trade in the Company's shares, proper approval must be obtained from the Chair of the Audit and Risk Committee or the Company Secretary.

4. Conduct and ethics

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

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

The Board have set the following general principles which are covered by the Code of Conduct:

a) values

b) compliance with laws

c) fair dealing

d) confidentiality and protection of Company assets

e) conflicts of interest

f) shareholders and the financial community

g) trading in Company securities

h) equal opportunity

i) health, safety and environment

j) reporting non-compliance and grievances

k) compliance with taxation laws

l) bribes and financial inducements

m) political donations

As part of the Company's commitment to observing high standards of ethics and behaviour in all of its activities, the Company has adopted a Whistle-blower Policy. The Company is also committed to maintaining a culture where all staff are encouraged to raise concerns about poor or unacceptable practice and misconduct and can do so safely. A whistleblowing program is an important aspect of detecting poor or unacceptable practice and misconduct in an organisation.

The purpose of this policy is to encourage the reporting of conduct by employees of the Company and other persons with whom the Company deals closely where the interests of others, including the public, or of the Company itself are at risk.

The conduct covered by the policy is conduct that is:

a) illegal, dishonest, fraudulent or corrupt;

b) in breach of Commonwealth or state legislation or local authority by-laws;

c) in breach of applicable industry practices, such as Good Laboratory Practice, Good Clinical Practice or Good Manufacturing Practice;

d) unethical (being either a breach of the Company's Code of Conduct or generally);

e) gross mismanagement;

f) a serious or substantial waste of resources;

g) an unsafe work practice;

h) failure to comply with the Company's Code of Conduct;

i) failure to comply with agreements with the Company's commercial partners;

j) a breach of proper environmental practice;

k) discriminatory, bullying or harassing;

l) other serious improper conduct; and

m) any other conduct that may cause financial or non-financial loss to the Company or otherwise be detrimental to the interests of the Company.

Directors' Report

The Directors present their report, together with the Financial Report of the consolidated entity consisting of Acrux Limited (the Company) and its controlled entities (the Group), for the financial year ended 30 June 2019 and independent review report thereon. This Financial Report has been prepared in accordance with Australian Accounting Standards.

Directors

The names of directors in office at any time during or since the end of the year are:

Name		Appointed/resigned
Ross Dobinson	Chairman	Appointed 19 March 1998
Timothy Oldham	Non-Executive Director	Appointed 1 October 2013
Michael Kotsanis	Managing Director & Chief Executive Officer	Appointed 3 November 2014
Simon Green	Non-Executive Director	Appointed 1 June 2016
Geoffrey Brooke	Non-Executive Director	Appointed 1 June 2016

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

Directors' meetings

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

			Committee Meetings			
	Board		Audit and Risk		Human Capital and Nominations	
	Held[1]	Attended	Held[1]	Attended	Held[1]	Attended
Ross Dobinson	7	7	2	2	2	2
Timothy Oldham	7	7	2	2	2	2
Michael Kotsanis	7	7	2	2	2	2
Simon Green	7	7	2	2	2	2
Geoffrey Brooke	7	7	2	2	2	1

1. The number of meetings held during the period the Director was a member of the Board or Committee.

All Directors who are not members of Committees are invited to attend Committee meetings.

Principal activities

The principal activities of the consolidated entity during the financial year were the development and commercialisation of pharmaceutical products. There has been no significant change in the nature of these activities during the financial year.

Operating results

	2019 $'000	2018 $'000
Revenue	5,286	3,432
Net loss after tax	(8,325)	(14,182)
Loss per share	(5.00) cents	(8.52) cents
Cash on hand	18,152	28,470

The consolidated loss after income tax attributable to the members of Acrux Limited was $8.325 million (2018 loss: $14.182 million). Loss per share was 5.00 cents (2018: loss per share 8.52 cents).

Review of operations

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

Mission

Acrux is a pharmaceutical company dedicated to developing and commercialising generic and specialty topical pharmaceuticals.

Business Strategy

Acrux is developing a range of topically applied products with an expanding pipeline of products under active development. Acrux uses its internal development capabilities and know-how to develop generics which target a substantial portion of the US topical market. The development time required for generic products is substantially shorter and less costly than the length of time required for a new drug development.

Topical generic portfolio

At the date of this report, Acrux has 14 generic topical products in various stages of development, including 3 that have been submitted for review to the FDA. The addressable market value for the pipeline of 14 products is approximately US$1.5 billion based on IQVIA reported annual sales data at March 2019. Over half the value of the pipeline and over half the number of products in development currently have no marketed generic alternatives in the United States.

Acrux believes that a number of its products in development will qualify for the recently introduced Competitive Generic Therapies (CGT) incentives provided by the U.S Food and Drug Administration (FDA) for the development of products with inadequate generic competition, meaning there is not more than one approved drug in the active section of the FDA Orange Book, protecting the reference product from potential generic competition. FDA incentives for CGT products include a potentially faster FDA review process than other Abbreviated New Drug Application (ANDA) submissions and a granting of 180 day market exclusivity for the first approved generic alternative.

Acrux has now engaged with 6 contract manufacturing organisations (CMOs) to manufacture different products from its portfolio of generic topical products. All CMOs are FDA approved. During the 2019 financial year, Acrux also engaged with contract manufacturing organisations for an additional 6 products for the technical transfer, upscaling and subsequent exhibit batch manufacturing formulations of topical generic products that have been developed by Acrux in its GMP laboratories in Melbourne, Australia. These products will form the next wave of ANDA submissions to the FDA.

Acrux Regulatory Submissions

Acrux submitted its first generic product to the FDA during the 2018 financial year. In August 2018, the FDA informed Acrux that its dossier had been accepted for review. This filing was a Paragraph IV ANDA for a generic version of Jublia® (efinaconazole) topical solution, 10%. The subsequent patent litigation was settled in April 2019.

Acrux submitted its second generic product to the FDA in August 2018 and this was accepted for review by the FDA in October 2018. The product filed was an ANDA for testosterone solution 30mg/1.5mL.

During the 2019 financial year, Acrux submitted its third generic product to the FDA. The Company filed an ANDA for lidocaine 2.5% and prilocaine 2.5% cream in June 2019 and the FDA accepted this product for review in August 2019. All three ANDAs are under review by the FDA.

Marketed topical portfolio

The Group's commercialised products include Estradiol spray branded as Evamist® and Lenzetto®. Evamist® is marketed by Perrigo in the US and Lenzetto® is marketed by Gedeon Richter in Europe.

The marketing of Lenzetto® commenced in Q1 2016 and has since been launched in countries across the European Union and other markets. Sales of Lenzetto® grew 77.6% year on year and are expected to continue to grow as the product captures market share in existing countries and is progressively launched into new countries.

Evamist® sales declined compared to the prior year as a result of sales returns and adjustments incurred by the Group's commercial licensee.

Directors' Report continued

Key Events During Year

The following were key events for the Group during the year:

- Acrux received confirmation that the submitted ANDA to the FDA for a generic version of Jublia® had been accepted for review.
- Acrux submitted its second ANDA application to the FDA for its generic version of a testosterone topical solution, which was subsequently accepted for review.
- Acrux submitted its third ANDA application to the FDA for its generic version of lidocaine 2.5% and prilocaine 2.5% cream in June 2019, which was subsequently accepted for review.
- Lenzetto® continues to be launched progressively in additional countries within the European Union by our licensee (Gedeon Richter).
- Acrux successfully engaged additional CMOs that manufacture and supply FDA approved products, providing the infrastructure to begin scale up of 6 projects from the Acrux laboratory to exhibit batch manufacturing.
- Acrux received an R&D Tax Incentive Rebate from the Australian Taxation Office of $2.057 million.
- Acrux settled the Paragraph IV patent litigation relating to Acrux's first to file ANDA for the generic equivalent of Jublia. As at August 2019, there are currently 10+ dossiers submitted to the FDA that are neither approved nor commercialised for a generic version of Jublia.

Operating Results

The consolidated loss before tax was $8.335 million (2018: loss $16.125 million). The reduced loss is primarily attributable to the prior period write down of intangible assets associated with Axiron. The consolidated loss after tax was $8.325 million (2018 loss: $14.182 million).

Revenue

Revenue for the financial year increased by $1.854 million (54.0%) to $5.286 million (2018: $3.432 million). Royalty revenue from Axiron® decreased to nil (2018: $2.231 million) reflecting the termination of the Axiron licensing agreement during the 2017 calendar year. Royalty revenue from Lenzetto® was $0.581 million (2018: $0.327 million) which is an increase of 77.6% on prior year and interest on cash deposits were $0.579 million (2018: $0.671 million).

The Group received $2.057 million (2018: nil) in relation to an R&D Tax Incentive Rebate from the Australian Taxation Office for the 2017/2018 financial year. A further $2.015 million was accrued for the 2019 financial year and is expected to be received in the 2019 calendar year.

Expenses

Total expenses for the financial year were $13.621 million (2018: $19.557 million). The reduction from the prior year is due to non-recurrence of: a) non-cash (pre-tax) loss of $5.647 million in relation to the impairment of Axiron® capitalised development costs, which were fully written down as at 31 December 2017 and b) legal fees of $0.729 million associated with the Axiron® patent appeal litigation.

Total operating expenditure for the financial year decreased by 2.1% to $13.621 million (2018: $13.910 million).

Employee benefits expense totalled $5.044 million (2018: $4.720 million) increasing $0.324 million or 6.9% year on year, reflecting the increased resources required while developing the pipeline.

Increases in external R&D costs of $1.096 million for contract manufacture engagement, API procurement for the manufacture of exhibit batches and clinical research organisation engagement was offset by a significant reduction in non-recurring legal fees for the Axiron patent appeal litigation and lower depreciation and amortisation expense of $0.426 million (2018: $0.618 million).

Income Tax

Income tax benefit of $0.010 million (2018: benefit $1.943 million) was recorded for the financial year. The change from the prior financial year is mainly attributable to the higher operating loss and the reversal of the deferred tax liability associated with the amortisation and impairment of Axiron® capitalised development costs. Further details of the income tax expense are provided at Note 1(k) of the financial report.

Cash flow

Cash received from licensing agreements for the financial year was $0.576 million (2018: $7.872 million). Royalties received from Axiron® were nil (2018: $7.307 million) reflecting the termination of the of the Axiron licensing agreement during the prior year. The Group paid $13.233 million to suppliers and employees (2018: $12.731 million) as a consequence of increased investment in the R&D pipeline. Income tax payments decreased to $0.051 million from $1.033 million in the prior financial year driven by lower operating results across the Group. The Group received $2.057 million (2018: nil) in relation to an R&D Tax Incentive Rebate from the Australian Taxation Office for the 2017/2018 financial year.

Capital expenditure was $0.380 million, up 28.4% on the prior financial year reflecting the timing of expenditure as the Group carries out upgrades of existing equipment to improve our internal analytical and testing capabilities.

Cash reserves at the end of the period were $18.152 million (2018: $28.470 million).

Contributed Equity

During the year ended 30 June 2019 there were 56,000 (2018: nil) ordinary shares issued on the exercise of employee performance rights.

The number of outstanding employee share options on issue at the date of this report was nil (30 June 2018: 2,000,000). The number of outstanding employee performance rights on issue at the date of this report was 6,235,000 (30 June 2018: 4,836,000), representing 3.7% of the Company's issued share capital.

Further details of share based payments are provided in Note 17 of the Financial Report which follows the Directors' Report.

Significant changes in the state of affairs

There have been no significant changes in the Group's state of affairs during and since the end of the financial year that have not been disclosed elsewhere in this report.

Dividends

The Directors have not declared a dividend for the 2019 financial year.

After balance date events

Other than disclosed at Note 30 there have been no matters or circumstances that have arisen since the end of the financial year that have significantly affected or may significantly affect the operations of the Group, the results of those operations, or the state of affairs of the Group in future financial years.

Likely developments

For the foreseeable future, the Group will continue to pursue and execute its strategy of developing a diversified, on-market, financially attractive portfolio of topical generic products.

The Group's financial results will be materially influenced by its ability to commercialise the initial product suite of its development pipeline, and the efficient evaluation and selection of additional generic products.

Environmental regulation

The Group's operations are subject to certain environmental regulations under the laws of the Commonwealth and of the State of Victoria. Details of the Group's performance in relation to such environmental regulations are as follows:

Laboratory Waste

To ensure compliance with the Environment Protection Act 1970, the Group engages an external waste management consultant. This consultant has ISO 14001:2004 Certification for Environmental Management to comply with the legislative requirements, and issues an EPA Transport Certificate at every collection of waste to ensure safe collection, transport, delivery and disposal/ recycling procedures.

Directors' Report continued

Trade Water Waste

An agreement exists with City West Water to ensure compliance under the *Water Industry Act 1994* and *Water Industry Regulations 1995*. This agreement ensures that the acceptance of trade waste into the sewage network is managed effectively and that City West Water is aware of the type and quantities of waste disposed of by the Group.

The Directors are not aware of any breaches during the period covered by this report.

Share options

The number of outstanding employee share options on issue at the date of this report was nil (30 June 2018: 2,000,000).

Shares issued on exercise of options

There were no shares issued during the financial year as a result of the exercise of share options.

Performance rights

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

Date performance rights granted	Number of unissued ordinary shares under performance rights	Value at grant date	Exercise price	Expiry date of the performance rights
14 November 2017	4,000,000	$0.09	$0.00	November 2024
25 January 2018	668,000	$0.11	$0.00	January 2025
23 November 2018	800,000	$0.19	$0.00	January 2023
4 February 2019	767,000	$0.08	$0.00	February 2026
	6,235,000			

No performance right holder has the right to participate in any other share issue of the Company.

Shares issued on exercise of performance rights

There were 56,000 (2018: Nil) shares issued during the financial year as a result of the exercise of performance rights.

Information on Directors and Company Secretary

The qualifications, experience and special responsibilities of each person who has been a Director of Acrux Limited at any time during or since 1 July 2018 is provided below, together with details of the company secretary as at the year end. The Directors have been in office since the start of the financial year to the date of this report unless otherwise stated.

Ross Dobinson

Director since March 1998)

Responsibilities

From November 2014, Non-Executive Chairman; 1 July 2012 to November 2014, Executive Chairman; prior to 1 July 2012, Non-Executive Chairman. Member of the Audit and Risk Committee.

Qualifications

BBus Acc

Experience

Ross has been a Director since 1998 and was appointed Chairman in January 2006 and then Executive Chairman from 1 July 2012 to October 2014. He is a founder and former CEO of Acrux. Ross has a background in investment banking and stockbroking. He is currently Managing Director of TSL Group Ltd, a corporate advisory company specialising in establishing and advising life sciences companies. He is a Director of Reliance Worldwide Corporation (ASX: RWC). He was previously a founding Director of Starpharma Holdings Limited (ASX: SPL), Executive Chairman of Hexima Limited (ASX: HXL), Chairman of TPI Enterprises Limited (Now Palla Pharma Ltd. ASX: TPE), Director of Roc Oil Company Limited (ASX: ROC) and a Director of Racing Victoria Limited.

Tim Oldham

Director since October 2013

Responsibilities

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

Qualifications

BSc (Hons), LLB (Hons), PhD

Experience

Tim joined the Board in October 2013. He has more than 15 years of life sciences business development, alliance management and sales and marketing experience in Europe, Asia and Australia. Tim is the Executive Leader of Tijan Ventures, an advisory business focussed on growing life sciences companies through strategic advisory and interim CEO, executive and non-executive leadership services, with a particular focus on cell and gene therapies. He was CEO and Managing Director of Cell Therapies Pty Ltd, a leading contract manufacturer and distributor cellular therapies in Asia Pacific. Tim was President of Asia Pacific for Hospira, Inc., having held a variety of senior management roles with Mayne Pharma Ltd prior to its acquisition by Hospira. These roles encompassed the development and commercialisation of pharmaceuticals, devices, biologics and cellular therapies. Prior to this, Tim was an engagement manager with McKinsey & Co. Tim has been chairman of the European Generic Medicines Association Biosimilars and Biotechnology Committee, a Director of the Alliance for Regenerative Medicine, a Director of the Generic Medicines Industry Association and a member of the Pharmaceutical Industry Strategy Group. He has also been a Director of Respiri Ltd (ASX: RSH) and is a current member of AusBiotech's Regenerative Medicine Advisory Group.

Directors' Report continued

Geoff Brooke

Director since June 2016

Responsibilities

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

Qualifications

MBBS, MBA

Experience

Geoff joined the Board in June 2016. He founded GBS Venture Partners Pty Ltd in 1996 and has more than 20 years' venture capital experience. In January 2014, he reduced his involvement in GBS and is now special adviser to the firm and its funds. Geoff was formally President of Medvest Inc., a US-based early-stage venture capital group he founded with Johnson & Johnson. Geoff's experience includes company formation and acquisitions, as well as public listings on the NYSE, NASDAQ and ASX exchanges. He commenced in March 2017 as Chairman of Actinogen Medical Limited (ASX: ACW) and has been a founder, executive and director of private and public companies. From 2009 until 2015, he was an independent director of the Victoria WorkCover Authority. Geoff is licensed in clinical medicine by the Medical Board of Victoria, Australia and his post-graduate work was in anaesthetics and intensive care. He earned his Bachelor of Medicine/Surgery from the University of Melbourne, Australia and a Master of Business Administration from IMEDE (now IMD) in Lausanne, Switzerland.

Simon Green

Director since June 2016

Responsibilities

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

Qualifications

BSc (Hons), PhD

Experience

Simon joined the Board in June 2016. He is an experienced biotechnology professional with expertise in drug development, having worked at Genentech and Novartis in San Francisco before joining CSL Limited in 1998. At CSL, Simon held several roles in project and portfolio management before being promoted to Senior Vice President of Global Research and Development for CSL Behring. He also held roles as General Manager of CSL Behring's plasma products manufacturing operations in Germany and Australia. Simon left CSL in November 2015 to start up a biotech company, Immunosis Pty Ltd, focused on improved diagnostic outcomes for patients with immune deficiencies. He also founded a consultancy service providing advice to companies in the plasma products field. Simon graduated from Monash University and completed his PhD in the field of immunology at Melbourne University in 1992. He is a graduate of the Australian Institute of Company Directors and previously held Board governance roles for several CSL subsidiary companies in Australia and Germany and for the European Plasma Protein Therapeutics Association. Simon has provided strategic advice to Government through his membership of the Victorian Biotechnology Advisory Council and Northern Innovation and Investment Fund.

Michael Kotsanis

Managing Director since November 2014

Responsibilities

Managing Director and Chief Executive Officer

Qualifications

BSc, MBus

Experience

Michael has over 30 years of experience in the pharmaceutical industry and has significant senior leadership experience across the global pharmaceutical markets. Michael was formally the Chief Commercial Officer for Synthon Holding BV, an international pharmaceutical company and a leader in the field of generic medicines, with revenue over EUR250 million, and was based in the Netherlands, a position he held for four years. Prior to Synthon, he served as President, Europe, Middle East and Africa, for Hospira, 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 served as President Asia Pacific from 2002. He joined Mayne following their acquisition of Faulding Pharmaceuticals in 2001, where he held responsibility for commercial activities in Australia and New Zealand. Prior to Faulding, Michael held a variety of sales and marketing positions with Boehringer Ingelheim, a German multinational pharmaceutical company over an 11 year period. Michael earned a Bachelor of Science from Monash University, and a Master of Business from the University of Technology, Sydney.

Deborah Ambrosini

Company Secretary since June 2019

Responsibilities

Chief Financial Officer and Company Secretary

Qualifications

BCom (Acc & Business Law), CA, GIA (Cert)

Experience

Deborah commenced at Acrux as Chief Financial Officer and Company Secretary in June 2019. She is a fellow of Chartered Accountants Australia and New Zealand with over 20 years experience in leading financial strategies to facilitate growth plans. Her experience spans the biotechnology, mining, IT communications and financial services sectors. Deborah possesses extensive experience in debt and equity capital raising activities, regulatory compliance, process improvement, investor relations, large contract management and leading all aspects of accounting, budgeting, forecasting and financial analysis. She also has significant experience both nationally and internationally in financial and business planning, compliance and taxation. Deborah has held Director roles in both listed and unlisted entities. Deborah has been a state finalist in the Telstra Business Woman Awards. She was also named as one of the Top 40 pre-eminent business leaders in the highly prestigious WA Business News 40 under 40 awards.

Felicia Colagrande

Product Development and Technical Affairs Director since February 2015

Responsibilities

Product Development and Technical Affairs Director

Qualifications

BSc (Hons), MBA

Experience

Felicia was appointed Product Development and Technical Affairs Director in February 2015. Felicia has a broad background in pharmaceutical operations, dermal drug development, analytical development and production. Felicia leads and facilitates all technical aspects of pharmaceutical product development including R&D, analytical development, project management and CMC development, with a focus on exploiting and optimising the company's drug delivery technology. Felicia has 25 years' experience in the pharmaceutical/biotech industry and 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.

Directors' Report continued

Charles O'Sullivan

Portfolio Director since July 2015

Responsibilities

Portfolio Director

Qualifications

BPharm

Experience

Charles commenced at Acrux as Portfolio Director in July 2015. He is an experienced healthcare executive with senior and international leadership roles in scientific affairs, medical affairs, health economics and government affairs. Prior to Acrux, Charles was Asia Pacific Director of Medical and Government Affairs for Hospira (now Pfizer). Other pharmaceutical industry roles were at Mayne Pharma (Pricing and Reimbursement Manager), GSK and Zeneca Pharmaceuticals. Additional external roles included being a Director of the Generic Medicines Industry Association of Australia (now the Generic and Biosimilar Association) and membership of a number of industry and government working parties. As a qualified pharmacist, Charles has senior experience in the public hospital sector including pharmacy management and key committee membership including Bio-Ethics Committees, and Drug and Therapeutics Committees. Charles has a Bachelor of Pharmacy degree from Monash University and a Graduate Diploma of Epidemiology and Biostatistics from Melbourne University.

Directors' and Executives' interests in equity instruments

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

	Total No. of shares	Total No. of options	Total No. of performance rights
Directors			
Ross Dobinson	1,372,593	–	320,000
Tim Oldham[1]	96,150	–	160,000
Geoff Brooke	75,750	–	160,000
Simon Green	130,435	–	160,000
Michael Kotsanis	–	–	4,000,000
Executives			
Deborah Ambrosini	–	–	–
Charles O'Sullivan	–	–	265,000
Felicia Colagrande	1,500	–	265,000
Total	**1,676,428**	**–**	**5,330,000**

1. Related party interests of Tim Oldham hold 400 shares of Acrux Limited.

Directors' interests in contracts

Directors' interests in contracts are disclosed in Note 24 to the financial statements.

Indemnification and insurance of Directors, officers and auditors

During the financial year, the consolidated entity has paid premiums in respect of an insurance contract to indemnify officers against liabilities that may arise from their positions as officers of the Group. Officers indemnified include the company secretary, all Directors and all executive officers participating in the management of the Group.

Consistent with section 300(9) of the Corporations Act 2001 further policy details are not disclosed.

Court proceedings

Since 2014, a number of product liability lawsuits have been filed against Acrux and Eli Lilly in the United States District Court for the Northern District of Illinois, including claims that assert injury caused by testosterone replacement therapy. The conduct of the lawsuits will not have a material impact on Acrux's operating expenditure.

Remuneration report (audited)

The Directors present the Group's 2019 remuneration report which details the remuneration information for Acrux Limited's Non-Executive Chairman, Non-Executive Directors and other key management personnel.

Human Capital and Nomination Committee

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

(a) recommending to the Board a policy and framework for senior employees' remuneration which aims to set remuneration which:

 (i) is competitive, fair and designed to attract employees of high quality, skill and experience;

 (ii) motivates senior employees to achieve challenging goals that are linked to the creation of sustainable shareholder returns within the appropriate control framework; and

 (iii) establishes a clear relationship between the performance of senior management and their remuneration;

(b) reviewing and recommending to the Board the total individual remuneration package of each member of senior management, including any bonuses, incentive payments, and participation (including the level of participation) in any share or share option plans in accordance with the policy and framework for senior employees' remuneration;

(c) reviewing benchmarks against which salary reviews are made;

(d) reviewing and recommending the establishment and terms of any employee share or share option plan or other incentive plan and recommending any changes to the Board;

(e) reviewing and making recommendations on the superannuation arrangements of the Group; and

(f) ensuring that equity-based senior management remuneration is made in accordance with thresholds set in plans approved by shareholders.

Remuneration policy

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

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

Remuneration structure

The remuneration of employees is structured in two parts:

- FIXED REMUNERATION, which comprises salary, superannuation and other benefits in lieu of salary; and
- VARIABLE REMUNERATION, which may comprise a short term incentive in the form of cash and a long term incentive in the form of equity instrument under the omnibus equity plan (OEP), the Chief Executive Officer's (CEO) share option plan (CSOP) or the employee share option plan (ESOP). All permanent staff (including the CEO) are eligible to participate in the short term incentive plan and the OEP. Only the CEO participates in the CSOP and the employees participate in the ESOP. The level of participation varies according to both the level of seniority of the employee and the employee's ability to influence the performance of the business.

The Group aims to set the level of fixed remuneration based on market rates for comparable jobs in the Group's industry sector. The Group aims to set the short and long term incentives to provide for superior achievement to merit higher levels of remuneration, subject to achievement of goals set by the Board.

The aim of both the short term and long term incentive plans is to drive performance to successfully implement annual business plans and to increase shareholder value.

Remuneration report (audited) continued

Short term incentive plan

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

The business objectives are clearly defined outcomes for product development and commercialisation. The achievement or non-achievement of the business objectives are objectively measured at the end of the financial year.

Each objective is expected to either create value for shareholders or represent material progress towards enhancing shareholder value.

Under the short term incentive plan senior executives (other than the Chief Executive Officer) are able to achieve annual cash incentives of up to 24% of their fixed remuneration. The Chief Executive Officer is able to achieve annual cash incentives of 25% of his fixed remuneration, which can be varied by Board discretion.

The key principles of the plan are:

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

Long term incentive plans

The purpose of the long term incentive plan is to align the interests of senior executives and other employees more closely with those of the shareholders in terms of sustainable, long term superior performance. Long term incentive plans are designed to comply with both the requirements of ASX Listing Rules and the *Pooled Development Funds Act 1992*. At the time of signing there are two long term incentive plans, providing incentives through options and rights to acquire ordinary shares.

The first plan, the Omnibus Equity Plan, is for all employees including the Chief Executive Officer and it was approved by shareholders at the 2017 Annual General Meeting. Grants made to date under the OEP are subject to the following terms:

A. Chief Executive Officer ('CEO')

- Shareholders approved the issue of 4 million performance rights for nil cash consideration and each performance right carries the right to acquire one ordinary share in the Company;
- The 4 million performance rights will vest in 4 equal tranches, with each successive tranche vesting at the end of each of the 4 years after grant, provided that the CEO is still employed and that the total return to shareholders (TSR) over the year preceding the vesting of each tranche is equal to or greater than 12%.
- Tranches that do not vest in any year of the cycle may be "rolled over" into the next year of the cycle and will be subject to an additional 12% TSR hurdle. There will be no "roll-over" after the fourth year; and
- The rights will expire 7 years after grant.

B. Employees

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

C. Directors

- Shareholders approved the issue of performance rights to Directors that are granted on the basis of a four-year cycle at nil cost;
- Each performance right carries the right to acquire one ordinary share in the Company;
- Each grant of performance rights will vest annually, provided that the Director has been continuously engaged by a Company in the Group from the grant date to vesting date.
- The rights will expire 4.08 years after grant.

For further details refer to Note 17 to the accounts.

The second plan is the Chief Executive Officer Share Option Plan and grants made under this plan are subject to the following terms:

- The options vest on grant and expire three years after grant;
- The options lapse on termination of employment, other than through death or redundancy; and
- The exercise price is set at a 25% premium to the volume weighted average market price of the Company's shares 5 days prior to grant and comprise 3 tranches.
  - Tranche 1 was granted on 3 February 2015 and expired on 3 February 2018 with options not being exercised;
  - Tranche 2 was granted on 22 July 2015 and expired on 22 July 2018 with options not being exercised; and
  - Tranche 3 was granted on 22 July 2016 and expired on 22 July 2019 with options not being exercised.

In prior years, equity based long term incentives were awarded to employees under an Employee Share Option Plan (ESOP). The plan was approved by shareholders at 2015 Annual General Meeting. In the ordinary course of reviewing the appropriateness of employee remuneration, the Board and Human Capital and Nomination Committee (HCNC) has determined that the grant of options under the ESOP no longer provides incentives and since 2017 have been replaced with performance right awards under the OEP.

The Board continues to re-evaluate the effectiveness of long term incentive plans as the business environment changes.

Group performance

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

	2019	2018	2017	2016	2015
Revenue ($'000)	5,286	3,432	23,934	28,557	25,368
% increase in revenue	54%	-86%	-16%	13%	-53%
(Loss)/profit before tax ($'000)	(8,335)	(16,125)	(94)	18,092	16,806
% increase in loss before tax	-48%	17054%	-101%	8%	-62%
Change in share price (%)	28%	-34%	-69%	-15%	-16%
Dividend paid to shareholders ($'000)	–	–	–	9,991,303	13,321,737
Total remuneration of Key Management	1,829,372	2,021,723	2,032,539	1,909,941	2,114,293
Total performance based remuneration	83,415	269,328	198,179	209,110	176,603

Remuneration report (audited) continued

Remuneration and termination entitlements of Senior Management

Senior executives have no fixed term of employment and either party to management employment contracts may terminate the contract on periods of written notice ranging between one and six months. The employment contracts contain no other entitlement to termination benefits beyond statutory entitlements.

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

Executive		
Michael Kotsanis	Chief Executive Officer	Commenced 3 November 2014
Deborah Ambrosini	Chief Financial Officer & Company Secretary	Commenced 3 June 2019
Felicia Colagrande	Product Development and Technical Affairs Director	Commenced 15 February 2015
Charles O'Sullivan	Portfolio Director	Commenced 1 July 2015
Tim Bateman	Chief Financial Officer & Company Secretary	Commenced 3 October 2016, last day of employment 14 June 2019
Nina Webster	Commercial Director	Commenced 1 July 2013, last day of employment 22 November 2018

Share options

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

No options over ordinary shares were granted during or since the end of the financial year.

(b) Shares issued on exercise of options

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

Performance rights

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

A total of 4,000,000 performance rights were issued by Acrux Limited to the Chief Executive Officer, Mr. Kotsanis, on 14 November 2017 under the Omnibus Equity Plan, approved by shareholders at the 2017 Annual General Meeting. Performance rights issued to Mr. Kotsanis vest upon the Group achieving performance metrics approved by the Board and his continued employment.

A total of 836,000 performance rights were issued by Acrux Limited to eligible employees on 25 January 2018 under the Omnibus Equity Plan. Performance rights issued to eligible employees vest upon the Group achieving performance metrics approved by the Board and their continued employment.

A total of 804,000 performance rights were issued by Acrux Limited to eligible employees on 4 February 2019 under the Omnibus Equity Plan. Performance rights issued to eligible employees vest upon the Group achieving performance metrics approved by the Board and their continued employment.

(b) Shares issued on exercise of performance rights

No ordinary shares were issued to Executives on the exercise of performance rights held by those parties during or since the end of the financial year.

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

	Primary				Share Based Payments				
2019	Salary $	Bonus* $	Post-employment super $	Termination Benefits $	Options $	Performance Rights	Total $	Equity as a % of total %	Bonus as a % of total %
Michael Kotsanis[1]	451,046	49,476	20,531	–	–	–	521,053	0%	9%
Deborah Ambrosini[2]	22,624	–	1,979	–	–	–	24,603	0%	0%
Felicia Colagrande[3]	211,888	17,033	19,574	–	–	11,155	259,650	4%	7%
Charles O'Sullivan[4]	196,197	16,906	18,770	–	–	11,155	243,028	5%	7%
Tim Bateman[5]	218,456	–	20,531	–	–	–	238,987	0%	0%
Nina Webster[6]	27,828	–	6,636	7,637	–	–	42,101	0%	0%
	1,128,039	83,415	88,021	7,637	–	22,310	1,329,422	2%	6%
2018									
Michael Kotsanis[1]	406,332	129,877	20,048	–	–	133,618	689,875	19%	19%
Felicia Colagrande[3]	185,821	34,667	18,252	–	6,620	5,669	251,029	5%	14%
Charles O'Sullivan[4]	185,821	34,667	18,252	–	6,620	5,669	251,029	5%	14%
Tim Bateman[5]	234,702	49,593	20,048	–	6,987	7,029	318,359	4%	16%
Nina Webster[6]	122,036	20,524	13,248	–	4,045	3,628	163,481	5%	13%
	1,134,712	**269,328**	**89,848**	**–**	**24,272**	**155,613**	**1,673,773**	**11%**	**16%**

* Bonus relates to achievement of objectives for the financial year ended 30 June 2019.
1. Appointed Chief Executive Officer and Managing Director 3 November 2014.
2. Appointed Chief Financial Officer and Company Secretary 3 June 2019.
3. Appointed Product Development and Technical Affairs Director 15 February 2015.
4. Appointed Portfolio Director 1 July 2015.
5. Appointed Chief Financial Officer and Company Secretary 10 October 2016 and last day of employment was 14 June 2019.
6. Appointed Commercial Director 1 July 2013 and last day of employment was 22 November 2018

Remuneration report (audited) continued

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, which subsequently puts those recommendations for approval by the shareholders at the next Annual General Meeting.

The director services of the Non-Executive Chairman Ross Dobinson are provided by Espasia Pty Ltd. The contract for services can be terminated by either party giving three months' notice in writing. For the 2018/19 financial year the contract provided for fees of $118,000 per annum in respect of director services. For the 2018/19 financial year Non-Executive Directors' fees were $70,000 per annum, plus superannuation, for each Non-Executive Director. At the 2004 Annual General Meeting shareholders set the maximum cash aggregate amount of Non-Executive Directors' fees at $450,000. In addition, Non-Executive Directors are entitled to reimbursement of reasonable expenses incurred by them on Group business.

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

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

	Primary							
2019	Fees $	Bonus $	Post-employment super $	Termination Benefits $	Share Based Payments $	Total $	Equity as a % of total %	Bonus as a % of total %
Ross Dobinson[1]	118,000	–	–	–	60,800	178,800	–	–
Timothy Oldham[2]	70,000	–	6,650	–	30,400	107,050	–	–
Geoff Brooke[3]	70,000	–	6,650	–	30,400	107,050	–	–
Simon Green[3]	70,000	–	6,650	–	30,400	107,050	–	–
	328,000	–	19,950	–	152,000	499,950	–	–

A review of Non-executive Directors' remuneration was conducted by Egan Associates in the prior year. The Non-executive Directors' remuneration has not been adjusted since 2014. The Company believes that issuing rights to Non-executive Directors in lieu of increasing cash remuneration is a prudent approach and aligns with the Company's continual approach to implementing cash-saving measures. The granting of the rights was approved by shareholders at the 2018 Annual General Meeting. Performance rights issued to Directors will vest equally over a 4 year period with the final tranche vesting on 1 January 2022. Each tranche is expensed uniformly between the grant date and the vesting date over the 4 year period. Any additional persons (who require approval under ASX Listing Rule 10.14) who become entitled to participate in the OEP will not participate until approval is obtained under ASX Listing Rule 10.14. The issue will align the interests of the Non-executive Directors with those of shareholders towards long term sustained superior growth. No ordinary shares were issued to Directors on the exercise of performance rights held by those parties during or since year end.

	Primary							
2018	Fees $	Bonus $	Post-employment super $	Termination Benefits $	Share Based Payments $	Total $	Equity as a % of total %	Bonus as a % of total %
Ross Dobinson[1]	118,000	–	–	–	–	118,000	–	–
Timothy Oldham[2]	70,000	–	6,650	–	–	76,650	–	–
Geoff Brook[3]	70,000	–	6,650	–	–	76,650	–	–
Simon Green[3]	70,000	–	6,650	–	–	76,650	–	–
	328,000	–	19,950	–	–	347,950	–	–

1. Appointed Non-Executive Chairman post appointment of the Chief Executive Officer, November 2014.
2. Appointed Non-Executive Director 1 October 2013.
3. Appointed Non-Executive Director 1 June 2016.

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

Equity instruments held by Key Management Personnel

Ordinary shares

The number of ordinary shares held by key management personnel at financial year end is set out in the following table:

Directors and Executives	Balance 1/07/18	Granted as remuneration	Options exercised	Net change other	Balance 30/06/19
Directors					
Ross Dobinson[1]	1,372,593	–	–	–	1,372,593
Timothy Oldham[2]	16,150	–	–	80,000	96,150
Geoff Brooke[3]	75,750	–	–	–	75,750
Simon Green[3]	60,600	–	–	69,835	130,435
Executives					
Felicia Colagrande[4]	1,500	–	–	–	1,500
Total	**1,526,593**	**–**	**–**	**149,835**	**1,676,428**

1. Appointed Non-Executive Chairman post appointment of the Chief Executive Officer, November 2014.
2. Appointed Non-Executive Director 1 October 2013.
3. Appointed Non-Executive Director 1 June 2016.
4. Appointed Product Development and Technical Affairs Director 15 February 2015.

Share options

The number of employee share options held by key management personnel at financial year end is set out in the following table:

Executives	Balance 1/07/18	Granted as remuneration	Options exercised	Net change other	Balance 30/06/19	Value of options granted during the year at grant date	Value of options expensed in 30/06/2019
Executives							
Michael Kotsanis[1]	2,000,000	–	–	(1,000,000)	1,000,000	–	–
Deborah Ambrosini[2]	–	–	–	–	–	–	–
Felicia Colagrande[3]	–	–	–	–	–	–	–
Charles O'Sullivan[4]	–	–	–	–	–	–	–
Total	**2,000,000**	**–**	**–**	**(1,000,000)**	**1,000,000**	**–**	**–**

1. Appointed Chief Executive Officer and Managing Director 3 November 2014.
2. Appointed Chief Financial Officer and Company Secretary 3 June 2019.
3. Appointed Product Development and Technical Affairs Director 15 February 2015.
4. Appointed Portfolio Director 1 July 2015.

Remuneration report (audited) continued

Performance rights

The number of employee performance rights held by key management personnel at financial year end is set out in the following table:

Directors and Executives	Balance 1/07/18	Granted as remuneration	Rights exercised	Lapsed	Balance 30/06/19	Value of performance rights at grant date	Value of performance rights expensed at 30/06/2019
Directors							
Ross Dobinson[1]	–	320,000	–	–	320,000	60,800	30,696
Timothy Oldham[2]	–	160,000	–	–	160,000	30,400	15,348
Geoff Brooke[3]	–	160,000	–	–	160,000	30,400	15,348
Simon Green[3]	–	160,000	–	–	160,000	30,400	15,348
Executives							
Michael Kotsanis[4]	4,000,000	–	–	–	4,000,000	370,296	134,465
Deborah Ambrosini[5]	–	–	–	–	–	–	–
Felicia Colagrande[6]	125,000	140,000	–	–	265,000	24,418	12,057
Charles O'Sullivan[7]	125,000	140,000	–	–	265,000	24,418	12,057
Tim Bateman[8]	155,000	–	–	–	155,000	24,418	12,723
Nina Webster[9]	80,000	–	–	80,000	–	–	–
Total	**4,485,000**	**1,080,000**	**–**	**80,000**	**5,485,000**	**595,550**	**248,042**

1. Appointed Non-Executive Chairman post appointment of the Chief Executive Officer, November 2014.
2. Appointed Non-Executive Director 1 October 2013.
3. Appointed Non-Executive Director 1 June 2016.
4. Appointed Chief Executive Officer and Managing Director 3 November 2014.
5. Appointed Chief Financial Officer and Company Secretary 3 June 2019.
6. Appointed Product Development and Technical Affairs Director 15 February 2015.
7. Appointed Portfolio Director 1 July 2015.
8. Appointed Chief Financial Officer and Company Secretary 10 October 2016 and last day of employment was 14 June 2019.
9. Appointed Commercial Director 1 July 2013 and last day of employment was 22 November 2018.

A total of 804,000 additional performance rights were issued by Acrux Limited to eligible employees on 4 February 2019 under the Omnibus Equity Plan, approved by shareholders at the 2017 Annual General Meeting. Performance rights issued to eligible employees vest upon the Group achieving performance metrics approved by the Board and their continued employment.

A total of 800,000 performance rights were issued by Acrux Limited to the Directors on 23 November 2018 under the Omnibus Equity Plan, approved by shareholders at the 2017 Annual General Meeting. The granting of the rights was approved by shareholders at the 2018 Annual General Meeting. Performance rights issued to Directors will vest equally over a 4 year period with the final tranche vesting on 1 January 2022. Each tranche is expensed uniformly between the grant date and the vesting date with the largest expense being incurred in the first year of amortisation.

Voting and comments made at the company's 2018 Annual General Meeting (AGM)

At the Company's 2018 Annual General Meeting (AGM), a resolution to adopt the prior year's Remuneration Report was put to the vote and less than 25% of the votes cast on the resolution to adopt the 2018 Remuneration Report were cast against the resolution. No comments were made at the AGM by shareholders in relation to the Remuneration Report.

This is the end of the audited remuneration report.

Directors' Report continued

Non-audit services

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

- all non-audit services were subject to the corporate governance procedures adopted by the Group and have been reviewed and approved by the Audit Committee to ensure they do not impact on the integrity and objectivity of the auditor; and
- the non-audit services provided do not undermine the general principles relating to auditor independence as set out in APES 110 Code of Ethics for Professional Accountants, as they did not involve reviewing or auditing the auditors' own work, acting in a management or decision making capacity for the Group or any of its related entities, acting as an advocate for the Group or any of its related entities, or jointly sharing risks and rewards in relation to the operations or activities of the Group or any of its related entities.

	2019 $	2018 $
Amounts paid or payable to Pitcher Partners (Melbourne) for non-audit services	58	32,255
Amounts paid or payable to network firms of Pitcher Partners for non-audit services	–	27,297
Total auditors' remuneration for non-audit services	**58**	**59,552**

Auditor's Independence Declaration

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

Rounding of amounts

In accordance with *ASIC Corporations (Rounding in Financial/Directors' Reports) Instrument 2016/191* the amounts in the Directors' Report have been rounded to the nearest one million dollars and in the Financial Report have been rounded to the nearest one thousand dollars, or in certain cases, to the nearest dollar (where indicated).

Signed in accordance with a resolution of the Directors:

Ross Dobinson
Non-Executive Chairman

Melbourne
Dated this 23rd day of August 2019

Geoff Brooke
Non-Executive Director

Melbourne
Dated this 23rd day of August 2019

Auditor's independence declaration to the Directors of Acrux limited

ACRUX LIMITED
AND CONTROLLED ENTITIES
ABN 72 082 001 152

INDEPENDENT AUDITOR'S REPORT
TO THE MEMBERS OF
ACRUX LIMITED

Report on the Audit of the Financial Report

Opinion

We have audited the financial report of Acrux Limited "the Company" and its controlled entities "the Group", which comprises the consolidated statement of financial position as at 30 June 2019, the consolidated statement of profit or loss and other comprehensive income, the consolidated statement of changes in equity and the consolidated statement of cash flows for the year then ended, and notes to the financial statements, including a summary of significant accounting policies, and the directors' declaration.

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

(a) giving a true and fair view of the Group's financial position as at 30 June 2019 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* "the Code" that are relevant to our audit of the financial report in Australia. We have also fulfilled our other ethical responsibilities in accordance with the Code.

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

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

Key Audit Matters

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

Consolidated Statement of Profit or Loss and other Comprehensive Income

For the year ended 30 June 2019

	Notes	2019 $'000	2018 $'000
Revenue	4	5,286	3,432
Employee benefits expense	5	(5,044)	(4,720)
Directors' fees		(346)	(348)
Share options expense		(284)	(228)
Depreciation and amortisation expenses	5	(426)	(618)
Impairment losses	5	–	(5,647)
Occupancy expenses		(536)	(498)
External research and development expenses		(5,123)	(4,027)
Professional fees		(749)	(2,683)
Royalty expense		–	(50)
Foreign exchange loss	5	–	(192)
Other expenses		(1,113)	(546)
Total expenses		(13,621)	(19,557)
Loss before income tax		(8,335)	(16,125)
Income tax benefit/(expense)	6	10	1,943
Net loss for the year		(8,325)	(14,182)
Total comprehensive (loss)/income for the year		(8,325)	(14,182)
Total comprehensive (loss)/income attributable to:			
Members of the parent entity	18(b)	(8,325)	(14,182)
Non-controlling interest	20	–	–
		(8,325)	(14,182)
Loss per share for profit attributable to the equity holders of the parent entity:			
Basic loss per share	8	(5.00) cents	(8.52) cents
Diluted loss per share	8	(5.00) cents	(8.52) cents

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

Consolidated Statement of Financial Position

As at 30 June 2019

	Notes	2019 $'000	2018 $'000
Current assets			
Cash and cash equivalents	9	18,152	28,470
Receivables	10	2,301	261
Current tax asset	6	–	51
Other current assets	11	487	179
Total current assets		20,940	28,961
Non-current assets			
Plant and equipment	12	906	845
Intangible assets	13	696	803
Deferred tax asset	6	1,891	1,881
Total non-current assets		3,493	3,529
Total assets		24,433	32,490
Current liabilities			
Payables	14	1,869	1,966
Provisions	15	547	518
Total current liabilities		2,416	2,484
Non-current liabilities			
Provisions	15	81	35
Total non-current liabilities		81	35
Total liabilities		2,497	2,519
Net assets		21,936	29,971
Equity			
Contributed capital	16	95,879	95,873
Reserves	18(a)	639	581
Retained earnings	18(b)	(74,582)	(66,483)
Equity attributable to equity holders of the Parent		21,936	29,971
Non-controlling interests	20	–	–
Total equity		21,936	29,971

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 2019

	Notes	Contributed equity $'000	Reserves $'000	Retained earnings $'000	Total equity $'000
Balance as at 1 July 2017		95,873	1,215	(53,163)	43,925
Loss for the period		–	–	(14,182)	(14,182)
Total comprehensive income for the year		–	–	(14,182)	(14,182)
Transactions with owners in their capacity as owners:					
Employee share scheme	18(a)	–	228	–	228
Employee share options that lapsed during period	18(a)	–	(862)	862	–
Balance as at 30 June 2018		95,873	581	(66,483)	29,971
Balance as at 1 July 2018		**95,873**	**581**	**(66,483)**	**29,971**
Loss for the period		**–**	**–**	**(8,325)**	**(8,325)**
Total comprehensive income for the year		**–**	**–**	**(8,325)**	**(8,325)**
Transactions with owners in their capacity as owners:					
Employee share scheme	18(a)	**–**	**284**	**–**	**284**
Performance rights exercised	16(v)	**6**	**–**	**–**	**6**
Employee share options that lapsed during period	18(a)	**–**	**(226)**	**226**	**–**
Balance as at 30 June 2019		**95,879**	**639**	**(74,582)**	**21,936**

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

Consolidated Statement of Cashflows

For the year ended 30 June 2019

	Notes	2019 $'000	2018 $'000
Cash flow from operating activities			
Receipts from product agreements		576	7,872
Payments to suppliers and employees		(13,233)	(12,731)
Interest received		611	610
Research and development tax incentive		2,057	–
Income tax received/(paid)		51	(1,033)
Net cash (used in)/provided by operating activities	19(a)	(9,938)	(5,282)
Cash flow from investing activities			
Payment for property, plant and equipment		(380)	(296)
Net cash used in investing activities		(380)	(296)
Net (decrease)/increase in cash and cash equivalents		(10,318)	(5,578)
Cash and cash equivalents at beginning of year		28,470	33,974
Foreign exchange differences on cash holdings		–	74
Cash and cash equivalents at end of the year	19(b)	18,152	28,470

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 2019

1. Statement of significant accounting policies

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

(a) Basis of preparation

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

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

The financial report covers Acrux Limited and its controlled entities as a Group. Acrux Limited is a company limited by shares, incorporated and domiciled in Australia. The address of Acrux Limited's registered office and principal place of business is 103-113 Stanley Street, West Melbourne, Vic, 3003, Australia. Acrux Limited is a for-profit entity for the purpose of preparing the financial report. The financial report was approved by the Directors as at the date of the Directors' Report.

Compliance with IFRS

The financial report also complies with the International Financial Reporting Standards (IFRS) issued by the International Accounting Standards Board (IASB).

Historical cost convention

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

Significant accounting estimates and judgements

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

(b) Going concern

The financial report has been prepared on a going concern basis. During the year ended 30 June 2019 the Group reported an operating loss after tax of $8.325 million (2018: loss $14.182 million) and at the reporting date total assets exceeded total liabilities by $21.936 million (2018: $29.971 million).

(c) Principles of consolidation

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

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

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

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

Notes to the Consolidated Financial Statements continued

For the financial year ended 30 June 2019

(d) Revenue from Contracts with Customers

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

(e) Other revenues

Revenue from the R&D Tax Incentive

As a result of a change in processes the Company is now able to obtain a reliable estimate of its R&D tax incentive in the year that it is incurred allowing the Company to record an accrual in that year under Australian Accounting Standards. Revenue will be accrued at a rate 43.5% of the approved R&D expenditure.

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

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

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

(f) Cash and cash equivalents

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

(g) Plant and equipment

Cost and valuation

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

Depreciation

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

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

The useful lives for each class of assets are:

	2019	2018
Leasehold improvements	5 to 20 years	5 to 20 years
Plant and equipment	1 to 16 years	2.5 to 14 years

(h) Leases

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

Operating Leases

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

(i) Intangibles

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

Intellectual Property

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

Research and Development

Expenditure during the research phase of a project is recognised as an expense when incurred. Product development costs are capitalised only when all of the following specific criteria can be demonstrated:

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

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

The estimated useful life and total economic benefit for each asset are reviewed at least annually. The useful life of capitalised development costs for Estradiol, for which amortisation has commenced, is approximately 7 years. Amortisation expense is included in 'Depreciation and amortisation expenses' of the Consolidated Statement of Comprehensive Income.

(j) Impairment of non-financial assets

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

An impairment loss is recognised where the carrying amount of the asset exceeds its recoverable amount. The recoverable amount of an asset is defined as the higher of its fair value less costs to dispose and its value in use. Impairment loss is disclosed as a separate line item on the Consolidated Statement of Comprehensive Income.

(k) Income tax

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

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

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

Notes to the Consolidated Financial Statements continued

For the financial year ended 30 June 2019

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

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

The subsidiary companies of Acrux Limited are subject to the general corporate company tax rate of 27.5%.

Income tax benefit for the financial year was $0.010 million (2018: benefit $1.943 million). The change from the prior financial year is mainly attributable to the higher operating loss and the reversal of the deferred tax liability associated with the amortisation and impairment of Axiron® capitalised development costs.

(l) Provisions

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

(m) Employee benefits

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

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

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

Bonus

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

Share-based payments

The Group operates an Employee Share Option Plan, Chief Executive Option Plan and an Omnibus Equity Plan. The fair value of the options and performance rights are recognised as an expense in the Consolidated Statement of Comprehensive Income in the period(s) during which the employee becomes entitled to exercise the options. The fair value of options at grant date is determined using a binomial option pricing model, and is recognised as an employee expense over the period during which the employees became entitled to the option (the vesting period). The fair value of performance rights at grant date is determined using a Monte Carlo simulation pricing model, and is recognised as an employee benefit expense over the period during which the employees became entitled to the performance rights (the vesting period).

Termination benefits

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

(n) Comparatives

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

(o) Financial instruments

Initial recognition and measurement

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

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

Classification of financial assets

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

(a) the group's business model for managing the financial assets; and

(b) the contractual cash flow characteristics of the financial asset.

Trade and other receivables

Trade and other receivables arise from the group's transactions with its customers and are normally settled within 30 days. Consistent with both the group's business model for managing the financial assets and the contractual cash flow characteristics of the assets, trade and other receivables are subsequently measured at amortised cost.

Impairment of financial assets

The following financial assets are tested for impairment by applying the 'expected credit loss' impairment model:

(a) receivables from contracts with customers and contract assets.

The group applies the simplified approach under AASB 9 to measuring the allowance for credit losses for both receivables from contracts with customers and contract assets. Under the AASB 9 simplified approach, the group determines the allowance for credit losses for receivables from contracts with customers and contract assets on the basis of the lifetime expected credit losses of the financial asset. Lifetime expected credit losses represent the expected credit losses that are expected to result from default events over the expected life of the financial asset.

Financial Liabilities

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

(p) Foreign currency translations and balances

Functional and presentation currency

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

Transactions and balances

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

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

Notes to the Consolidated Financial Statements continued

For the financial year ended 30 June 2019

(q) Goods and services tax (GST)

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

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

(r) Rounding amounts

The Company and the Group have applied the relief available under ASIC Corporations (Rounding in Financial/Directors' Reports) Instrument 2016/191 and accordingly, the amounts in the consolidated financial statements and in the Directors' Report have been rounded to the nearest thousand or million dollars, or in certain cases, to the nearest dollar (where indicated).

(s) New and Revised Accounting Standards Effective at 30 June 2019

The group has applied all new and revised Australian Accounting Standards that apply to annual reporting periods beginning on or after 1 July 2018, including AASB 9 Financial Instruments (AASB 9) and AASB 15 Revenue from Contracts with Customers (AASB 15).

AASB 9 replaces AASB 139: *Financial Instruments: Recognition and Measurement.* The key changes introduced by AASB 9 in relation to the accounting treatment for financial instruments include:

- simplifying the general classifications of financial assets into those measured at amortised cost and those measured at fair value;
- permitting entities to irrevocably elect, on initial recognition, for gains and losses on equity instruments not held for trading to be presented in other comprehensive income (OCI);
- Introducing a new 'expected credit loss' impairment model (replacing the 'incurred loss' impairment model of previous accounting standard).

In accordance with the transition requirements of AASB 9, the company has elected to apply AASB 9 initially at 1 July 2018. The cumulative effect of applying the new standard is recognised in opening retained earnings as at 1 July 2018 and, as such, is not reflected in the 30 June 2018 statement of financial position.

The application of AASB 9 has not materially impacted the classification and measurement of the company's financial assets and financial liabilities.

Further details of the company's accounting policies in relation to accounting for financial instruments under AASB 9 are contained in note 1(o).

AASB 15 provides (other than in relation to some specific exceptions, such as lease contracts and insurance contracts) a single source of accounting requirements for all contracts with customers, thereby replacing all current accounting pronouncements on revenue. The core principle of AASB 15 is that an entity recognises revenue to depict the transfer of promised goods or services to a customer in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. Under the previous accounting standard, AASB 118 Revenue, revenue from the sale of goods was recognised when the significant risks and rewards of ownership of the goods transferred to the buyer, and revenue from the rendering of services was recognised by reference to the stage of completion of the transaction at the end of the reporting period.

In accordance with the transition requirements of AASB 15, the group has elected to apply AASB 15 retrospectively to each prior reporting period presented in the financial statements, with the cumulative impact, if any, of initially applying the new standard recognised as at the beginning of the earliest prior period presented (i.e., as at 1 July 2017).

The application of AASB 15 has not materially impacted the recognition and measurement of the group's revenue from contracts with customers.

(t) Accounting standards issued not yet effective

AASB 16 Leases

AASB 16 introduces a single lessee accounting model that will require a lessee to recognise right-of-use assets and lease liabilities for all leases with a term of more than 12 months, unless the underlying asset is of low value. Right-of-use assets are initially measured at their cost and lease liabilities are initially measured on a present value basis. Subsequent to initial recognition:

- Right-of-use assets are accounted for on a similar basis to non-financial assets, whereby the right-of-use asset is accounted for in accordance with a cost model unless the underlying asset is accounted for on a revaluation basis, in which case if the underlying asset is:
  - investment property, the lessee applies the fair value model in *AASB 140: Investment Property* to the right-of-use asset; or
  - property, plant or equipment, the lessee can elect to apply the revaluation model in *AASB 116: Property, Plant and Equipment* to all of the right-of-use assets that relate to that class of property, plant and equipment; and
- Lease liabilities are accounted for on a similar basis as other financial liabilities, whereby interest expense is recognised in respect of the liability and the carrying amount of the liability is reduced to reflect lease payments made.

The Group has one operating lease that relates to office, laboratory and warehouse facilities.

The Group, after its initial assessment of the impact arising from AASB 16 anticipates that upon adoption of this standard:

- The Group's Consolidated Statement of Financial Position will be grossed up (both assets and liabilities) to reflect the rights and obligations relating to the Group's lease. For leased properties occupied by the Group, the Consolidated Statement of Financial Position will hold a depreciating non-financial asset and the associated payable under the lease. Refer to the current lease expenditure existing commitments Note 21 in the financial report for an indicator of the impact of the gross up.
- In the Consolidated Statement of Comprehensive Income, net rental expense will be replaced by a 'front-loaded' net interest expense and a straight-lined depreciation expense.

2. Significant accounting estimates and judgements

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

(a) Income tax

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

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

(b) Impairment testing

The Group uses discounted cash flow models to determine that the capitalised development costs in the Group are not being carried at a value that is materially in excess of recoverable value. The models value each product by estimating future cash flows, risk adjusted as appropriate and discounting the future net cash flows for the risks specific to the assets as well as for the time value of money. The following approach and assumptions have been applied:

- Revenue from a product is estimated using current market data and projections of market volumes, product price and market share, adjusted for the impact of generics entering the market based on external analysis of the market effect of generics.
- The cash flow forecasts are over 11 years.
- The cash flows have been discounted using a post-tax rate of 12%.
- The Group recorded a non-cash impairment loss of nil (2018: $5.647 million) for the financial year.

Notes to the Consolidated Financial Statements continued

For the financial year ended 30 June 2019

(c) Employee benefits

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

(d) Share based payments

The Group operates two employee share option plans and an omnibus equity plan for issuance of performance rights. The bonus element over the exercise price for the grant of options is recognised as an expense in the Consolidated Statement of Comprehensive Income in the period(s) when the benefit is earned. The value of the bonus element is calculated using a binomial option pricing model. The value of performance rights issued is recognised as an expense in the Consolidated Statement of Comprehensive Income in the period(s) when the benefit is earned. The value of the performance right is calculated using either a Monte Carlo or Black and Scholes simulation pricing model. These pricing models require the input of a number of variables including an estimate of future volatility and a risk free interest rate. Volatility is estimated based on the historical movements in the Company's share price since listing on the Australian Stock Exchange. The risk free interest rate is the Reserve Bank of Australia's cash rate at the options grant date(s).

3. Financial risk management and fair value measurements

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

(a) Interest rate risk

(b) Currency risk

(c) Credit risk

(d) Liquidity risk

(e) Fair Values

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

(a) Interest rate risk

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

The Group's exposure to interest rate risks and the effective interest rates of financial assets and financial liabilities at 30 June 2019 are shown in the table on the following page. Cash is the only financial asset or liability that is exposed to interest rate risk. A change in the average effective interest rate of 1% would change the net loss and equity of the Group by approximately $0.2 million (2018: $0.3 million).

	Weighted average effective interest rate[1]		Floating Interest Rate		Fixed interest rate maturing in: 1 Year or less		Non interest bearing		Total carrying amount per balance sheet	
Financial Instruments	2019 %	2018 %	2019 $'000	2018 $'000	2019 $'000	2018 $'000	2019 $'000	2018 $'000	2019 $'000	2018 $'000
(i) Financial Assets										
Cash	2.5	2.1	148	869	18,000	27,600	4	1	18,152	28,470
Receivables			–	–	–	–	2,301	261	2,301	261
Total Financial Assets			148	869	18,000	27,600	2,305	262	20,453	28,731
(ii) Financial Liabilities										
Trade Creditors			–	–	–	–	901	731	901	731
Sundry Creditors and Accruals			–	–	–	–	968	1,235	968	1,235
Total Financial Liabilities			–	–	–	–	1,869	1,966	1,869	1,966

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

(b) Currency risk

Currency risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in foreign exchange rates. The Group is exposed to currency risks due to revenue and costs denominated in US dollars and Euro. Currency risk management strategies are regularly reviewed.

Bank accounts denominated in US dollars are maintained in order to facilitate receipts and payments. US denominated cash reserves at 30 June 2019 totalled A$0.003 million (2018: A$0.2 million). A change of 10% in the AUD/USD exchange rate at 30 June 2019 would result in an immaterial change the net profit and equity of the Group (2018: immaterial).

The balance of receivables at 30 June 2019 includes the right to receive US$0.01 million (2018: US$0.02 million) of USD denominated royalties and EUR0.11 million (2018: EUR0.06 million) of EUR denominated royalties in relation to the fourth quarter of the 2018/19 financial year. A change of 10% in the AUD/USD and AUD/EUR exchange rate at 30 June 2019 would change the consolidated net profit/(loss) and equity immaterially (2018: immaterial).

The Group does not enter into forward exchange contracts. At balance date, there were nil (2018: nil) forward exchange contracts. The accounting policy for forward exchange contracts is detailed in Note 1(p).

In future periods, amounts of revenue are expected to be received, and costs are expected to be incurred, in foreign currency.

(c) Credit risk

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

Cash reserves form the majority of the Group's financial assets at 30 June 2019. Acrux Limited is a Pooled Development Fund. The Pooled Development Fund Act restricts the investment of cash reserves to deposits with an Australian bank licensed to take deposits. This policy is also followed for all cash held by the other companies within the Group.

Credit risk for receivables from contracts with customers is managed undertaking credit checks for all new customers. Outstanding receivables are regularly monitored for payment in accordance with credit terms.

For credit risk management purposes, the group applies credit risk rating grades to its financial assets. The credit risk rating grade is the group's rating of credit risk based on the risk of a default occurring on the financial instrument. The group's credit risk rating grades are outlined in the following table:

Credit risk rating grade	Criteria applied by the group	Basis of recognising allowance for credit losses
Low risk (performing)	The counterparty has an external 'investment grade' credit rating (if available) of BBB or higher, or otherwise is assessed by the group to have a strong financial position and no history of past due amounts from previous transactions with the group.	Life-time expected credit loss (for receivables from contracts with customers and contract assets) 12-month expected credit losses (for other financial assets subject to impairment testing)

Notes to the Consolidated Financial Statements continued

For the financial year ended 30 June 2019

(d) Liquidity risk

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

The financial liabilities of the Group at the balance date are all expected to mature within three months of the balance date. The Group has sufficient cash reserves, $18.152 million (2018: $28.470 million), to settle these liabilities and to fund operating expenditure for at least 15 months based on current cashflow forecasts. The Group does not have an overdraft or loan facility. The maturity profile of the Group's cash term deposits is actively managed and compared with forecast liabilities to ensure that sufficient cash is available to settle liabilities as they fall due.

(e) Fair values

The fair value of financial assets and financial liabilities approximates their carrying amounts as disclosed in the Consolidated Statement of Financial Position and notes to the consolidated financial statements. Financial assets and liabilities measured and recognised at fair value have been determined by the following fair value measurement hierarchy:

Level 1: Quoted prices (unadjusted) in active markets for identical assets or liabilities.

Level 2: Input other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly.

Level 3: Inputs for the asset or liability that are not based on observable market data.

4. Revenue

	2019 $'000	2018 $'000
Revenue from Contract with Customers		
Revenue from licensing agreements	631	2,687
Other revenues		
Interest	579	671
Grant revenue – R&D tax incentive[1]	4,072	–
Foreign exchange gain	4	74
Total revenues from non-operating activities	4,655	745
Total revenue from continuing operations	5,286	3,432

1. R&D tax incentive includes 2018 rebate which was received and accrued in the 2019 financial year. An amount has been accrued for the 2019 financial year.

5. Loss from continuing operations

	2019 $'000	2018 $'000
Loss from continuing operations before income tax has been determined after the following specific expenses:		
Employee benefits expense		
Wages and salaries	4,217	4,108
Superannuation costs	397	314
Other employee benefits expense	430	298
Total employee benefits expense	5,044	4,720
Depreciation of non-current assets		
Plant and equipment	316	226
Total depreciation of non-current assets	316	226
Amortisation of non-current assets		
Buildings	3	3
Capitalised research and development	107	389
Total amortisation of non-current assets	110	392
Total depreciation and amortisation expenses	426	618
Impairment losses	–	5,647
Rental expense on operating leases	313	303
Foreign exchange loss	–	192

(a) Research and development related costs

The Company incurs the following expenditure, which is related to product research and development including direct costs and indirect management and overhead costs.[1]

	2019 $'000	2018 $'000
Employee costs	4,557	4,190
Laboratory costs	5,070	3,921
Facility costs	1,049	943
Other costs	241	1,525
Research and development related costs	10,917	10,579

1. This differs from the classification of research and development costs pursuant to AASB138 which only comprises direct costs.

Notes to the Consolidated Financial Statements continued

For the financial year ended 30 June 2019

6. Income tax

	2019 $'000	2018 $'000
(a) Income tax recognised in profit or loss:		
Current tax	–	–
Deferred tax	(10)	(1,789)
(Over)/under provision in prior years	–	(154)
Income tax (benefit)/expense attributable to profit or loss	(10)	(1,943)

(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:

	2019 $'000	2018 $'000
Loss before tax from continuing operations	(8,335)	(16,125)
Prima facie income tax payable on loss before income tax at 27.5% (2018: 27.5%)	(2,292)	(4,434)
Add/(subtract) tax effect:		
Non-deductible expenses	3	66
Research and development tax incentive	(1,120)	–
(Over)/under provision in prior years	–	(154)
Effective change in tax rates	–	(288)
Tax losses utilised not previously brought to account	–	–
Tax losses not brought to account net of deferred tax liability reversed in relation to the amortisation and impairment of Axiron® capitalised development costs	3,337	2,917
Parent entity net adjustment and tax losses and temporary differences not brought to account	62	(50)
	2,282	2,491
Income tax (benefit)/expense attributable to loss	(10)	(1,943)

(c) Current tax

	2019 $'000	2018 $'000
Opening balance	(51)	1,136
(Over)/under provision in prior years	–	(154)
Provision for current year	–	–
Prior year refund received	–	36
Tax payments	51	(1,069)
Current tax (assets)/liability	–	(51)

	2019 $'000	2018 $'000
(d) Deferred tax		
Deferred tax relates to the following:		
Deferred tax assets		
The balance comprises:		
Accruals and provisions	205	136
Leasehold improvements	138	146
Patent expenses	1,102	786
Exchange differences	3	9
Tax losses/research and development tax offset	914	820
	2,362	1,897
Deferred tax liabilities		
The balance comprises:		
Exchange differences	–	–
Intangible assets	(471)	–
Prepayments	–	5
Accrued interest	–	11
	(471)	16
Net deferred tax assets/(liabilities)	1,891	1,881

(e) Deferred tax assets not brought to account

	2019 $'000	2018 $'000
Temporary differences	(194)	(157)
Tax losses	16,059	12,722
	15,865	12,565

7. Dividends

	2019 $'000	2018 $'000
(a) Dividends paid and declared		
Nil dividends were paid during the financial year (2018: nil)	–	–

(b) Franking account

Balance of franking account on a tax paid basis at financial year-end adjusted for franking credits arising from payment of income tax and dividends recognised as receivables, franking debits arising from payment of dividends and any credits that may be prevented from distribution in subsequent years:	43,835	43,887

Notes to the Consolidated Financial Statements continued

For the financial year ended 30 June 2019

8. Loss per share

	2019 $'000	2018 $'000
Loss from continuing operations	(8,325)	(14,182)
Loss used in calculating basic and diluted earnings per share	(8,325)	(14,182)

	No. of shares	No. of shares
Weighted average number of ordinary shares used in calculating basic earnings per share	166,577,711	166,521,711
Effect of dilutive securities:		
Employee Share Options and Performance Rights	–	–
Adjusted weighted average number of ordinary shares used in calculating diluted earnings per share	166,577,711	166,521,711

Basic loss per share (cents)	(5.00)	(8.52)
Diluted loss per share (cents)	(5.00)	(8.52)

9. Cash and cash equivalents

	2019 $'000	2018 $'000
Cash at bank	152	870
Deposits at call	18,000	27,600
	18,152	28,470

10. Receivables

	2019 $'000	2018 $'000
Receivables from contracts with customers	198	155
Allowance for credit losses	–	–
	198	155
Other receivables	2,103	106
Allowance for credit losses	–	–
	2,103	106
	2,301	261

(a) Impairment of receivables from contracts with customers and other receivables

The group applies the simplified approach under AASB 9 to measuring the allowance for credit losses for both receivables from contracts with customers and contract assets. Under the AASB 9 simplified approach, the group determines the losses for receivables from contracts with customers and contract assets on the basis of the lifetime expected credit losses of the instrument. Lifetime expected credit losses represent the expected credit losses that are expected to result from default events over the expected life of the financial asset. The group determined there to be to no expected credit loss as at 30 June 2019.

11. Other current assets

	2019 $'000	2018 $'000
Other current assets		
Prepayments	487	179
	487	179

12. Plant and equipment

	Notes	2019 $'000	2018 $'000
Leasehold improvements			
At cost		1,151	1,151
Accumulated amortisation		(1,124)	(1,121)
Total leasehold improvements	12 (a)	27	30
Plant and equipment			
At cost		1,593	1,213
Accumulated depreciation		(714)	(398)
Total plant and equipment	12 (a)	879	815
Total plant and equipment		906	845

(a) Reconciliations

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

	2019 $'000	2018 $'000
Leasehold improvements		
Carrying amount at beginning	30	27
Additions	–	6
Amortisation expense	(3)	(3)
	27	30
Plant and equipment		
Carrying amount at beginning	815	751
Additions	380	290
Depreciation expense	(316)	(226)
	879	815

Notes to the Consolidated Financial Statements continued

For the financial year ended 30 June 2019

13. Intangible assets

	Notes	2019 $'000	2018 $'000
Intellectual Property			
At cost		–	1,200
Accumulated amortisation		–	(1,200)
	13 (a)	–	–
Capitalised development			
Estradiol			
External development expenditure capitalised		1,071	1,071
Accumulated amortisation		(375)	(268)
	13 (a)	696	803
Axiron®			
External development expenditure capitalised		–	23,171
Accumulated amortisation and impairment losses		–	(23,171)
	13 (a)	–	–
Net carrying amount		696	803
Total intangible assets		696	803

(a) Reconciliations

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

Intellectual Property		
Carrying amount at beginning	–	–
Amortisation	–	–
	–	–
Capitalised development		
Estradiol		
Carrying amount at beginning	803	911
Additions	–	–
Amortisation	(107)	(108)
	696	803
Axiron®		
Carrying amount at beginning	–	5,928
Additions		
Amortisation	–	(281)
Impairment losses recognised	–	(5,647)
	–	–

The remaining useful life of Estradiol Capitalised Development is approximately 6 years.

Further details of the impairment loss please see note 2(b) of the financial report.

14. Payables

	2019 $'000	2018 $'000
Current		
Trade creditors	901	731
Sundry creditors and accruals	968	1,235
	1,869	1,966

15. Provisions

	2019 $'000	2018 $'000
Current		
Employee entitlements	547	518
Non-current		
Employee entitlements	81	35
Aggregate employee entitlements liability	628	553

16. Contributed equity

	2019		2018	
	No. of shares	$'000	No. of shares	$'000
(a) Issued and paid up capital				
Ordinary shares fully paid	166,577,711	95,873	166,521,711	95,873
(b) Movements in shares on issue				
Beginning of the financial year	166,521,711	95,873	166,521,711	95,873
Issued during the year:				
– Employee performance rights	56,000	6	–	–
Less Capital Raising Expenses	–	–	–	–
Fair value of shares issued on exercise of employee share options	–	–	–	–
Contributions from share issues	56,000	6	–	–
At reporting date	166,577,711	95,879	166,521,711	95,873

(c) Share options and performance rights

Employee Share Option Plan

The Group operates two Employee Share Option Plans. During the financial year no options were exercised (2018: Nil). Nil new options were issued under the plans during the financial year (2018: Nil). Options hold no participation rights, but shares issued on exercise of options rank equally with existing shares. At 30 June 2019, 1,000,000 options were held by key management personnel (2018: 2,000,000).

Omnibus Equity Plan

The Group operates an Omnibus Equity Plan, approved by shareholders at the 2017 Annual General Meeting. During the financial year 1,604,000 performance rights were issued under the plan (2018: 4,836,000). Performance rights hold no participation rights, but shares issued on exercise of performance rights rank equally with existing shares. At 30 June 2019, 5,330,000 performance rights were held by key management personnel (2018: 4,485,000).

The closing market value of an ordinary Acrux Limited share on the Australian Stock Exchange at 28 June 2019 was $0.185.

Notes to the Consolidated Financial Statements continued

For the financial year ended 30 June 2019

	2019 No.	2018 No.
(i) Movement in the number of share options held under Employee Share Option Plan are as follows:		
Opening balance	2,000,000	4,774,000
Granted during the financial year	–	–
Exercised during the financial year	–	–
Lapsed during the financial year	(1,000,000)	(2,774,000)
Closing balance	1,000,000	2,000,000

	$'000	$'000
(ii) Details of share options exercised during the financial year:		
Proceeds from shares issued	–	–
Fair value as at issue date of shares issued during the financial year	–	–

	2019 No.	2018 No.
(iii) Details of lapsed options		
Key management personnel	1,000,000	2,330,000
Employees	–	444,000
Lapsed during the year	1,000,000	2,774,000

	2019 No.	2018 No.
(iv) Movement in the number of performance rights held under Omnibus Equity Plan are as follows:		
Opening balance	4,836,000	–
Granted during the financial year	1,604,000	4,836,000
Exercised during the financial year	(56,000)	–
Lapsed during the financial year	(149,000)	–
Closing balance	6,235,000	4,836,000

	2019 $'000	2018 $'000
(v) Details of performance rights exercised during the financial year:		
Proceeds from shares issued	–	–
Fair value as at issue date of shares issued during the financial year	6	–

	2019 No.	2018 No.
(vi) Details of lapsed performance rights		
Key management personnel	–	–
Employees	149,000	–
Lapsed during the year	149,000	–

(d) Capital management

When managing capital, the Directors' objective is to ensure the entity continues as a going concern and optimises returns to shareholders and benefits for other stakeholders. During 2019 financial year, the Board paid dividends of nil (2018: nil).

The amounts and ratio of future dividends have not been determined.

17. Share based payments

(a) Employee Share Option Plans

Details of the options granted are provided below:

Grant date	Expiry date	Exercise price	Balance at beginning of the year	Granted during the year	Exercised during the year	Expired during the year	Balance at end of the year	Exercisable at end of the year
22-Jul-15	22-Jul-18	$1.11	1,000,000	–	–	(1,000,000)	–	–
22-Jul-16	22-Jul-19	$0.96	1,000,000	–	–	–	1,000,000	1,000,000
			2,000,000	–	–	(1,000,000)	1,000,000	1,000,000

The weighted average remaining contractual life for share options outstanding at the end of the period was 0.06 years.

The fair value of the options granted on 22 July 2016 was 19 cents per option at the date of grant. Fair value was determined using the binomial option pricing model. The following inputs were utilised:

Exercise price: $0.96

Grant date: 22 July 2016

Expiry date: 22 July 2019

Share price at grant date: $0.78

Expected price volatility of the Company's shares calculated using the movement in the share price over a 12 month period: 44%

Expected dividend yield: nil

The fair value of the options granted on 22 July 2015 was 23 cents per option at the date of grant. Fair value was determined using the binomial option pricing model. The following inputs were utilised:

Exercise price: $1.11

Grant date: 22 July 2015

Expiry date: 22 July 2018

Share price at grant date: $0.94

Expected price volatility of the Company's shares calculated using the movement in the share price over a 12 month period: 64%

Expected dividend yield: 8.99%

Notes to the Consolidated Financial Statements continued

For the financial year ended 30 June 2019

(b) Omnibus Equity Plan

Details of the performance rights granted are provided below:

Grant date	Expiry date	Balance at beginning of the year	Granted during the year	Exercised during the year	Expired during the year	Balance at end of the year	Exercisable at end of the year
26-Oct-17	14-Nov-24	4,000,000	–	–	–	4,000,000	1,000,000
25-Jan-18	25-Jan-25	836,000	–	(56,000)	(112,000)	668,000	668,000
23-Nov-18	01-Jan-23	–	800,000	–	–	800,000	200,000
04-Feb-19	04-Feb-26	–	804,000	–	(37,000)	767,000	–
		4,836,000	1,604,000	(56,000)	(149,000)	6,235,000	1,868,000

The weighted average remaining contractual life for share options outstanding at the end of the period was 3.77 years.

The fair value of the performance rights granted on 14 November 2017 was 9 cents per performance right at the date of grant. Fair value was determined using the Monte Carlo simulation pricing model. The following inputs were utilised:

Grant date: 14 November 2017

Expiry date: 14 November 2024

Share price at grant date: $0.17

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

Expected dividend yield: nil

Risk free rate: 2.24%

The fair value of the performance rights granted on 25 January 2018 was 11 cents per performance right at the date of grant. Fair value was determined using the Monte Carlo simulation pricing model. The following inputs were utilised:

Grant date: 25 January 2018

Expiry date: 25 January 2025

Share price at grant date: $0.17

Expected price volatility of the Company's shares calculated using the movement in the share price over a 60 month period: 64%

Expected dividend yield: nil

Risk free rate: 2.45%

The fair value of the performance rights granted on 23 November 2018 was 19 cents per performance right at the date of grant. Fair value was determined using the Black and Scholes simulation pricing model. The following inputs were utilised:

Grant date: 23 November 2018

Expiry date: 1 January 2023

Share price at grant date: $0.19

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

Expected dividend yield: nil

Risk free rate: 2.31%

The fair value of the performance rights granted on 4 February 2019 was 8 cents per performance right at the date of grant. Fair value was determined using the Monte Carlo simulation pricing model. The following inputs were utilised:

Grant date: 4 February 2019

Expiry date: 4 February 2026

Share price at grant date: $0.18

Expected price volatility of the Company's shares calculated using the movement in the share price over a 12 month period: 78%

Expected dividend yield: nil

Risk free rate: 1.82%

	2019 $'000	2018 $'000
(c) Expenses recognised from share-based payment transactions		
The expense recognised in relation to the share-based payment transactions was recorded within share options expense in the statement of comprehensive income were as follows:		
Options issued under the Employee Share Option Plans	–	57
Performance rights issued under the Omnibus Equity Plan	284	171
Total expenses recognised from share based payment transactions	284	228

18. Reserves and accumulated losses

	Notes	2019 $'000	2018 $'000
Share based payment reserve	18 (a)	639	581
Accumulated losses	18 (b)	(74,582)	(66,483)

(a) Share based payment reserve

(i) Nature and purpose of reserve

This reserve is used to record the value of equity benefit provided to employees and Directors as part of their remuneration. Refer note 16 for details.

(ii) Movement in reserve

	2019 $'000	2018 $'000
Balance at the beginning of year	581	1,215
Employee share option expense for the year (including adjustment for service conditions not met)	–	–
Employee performance rights expense for the year	284	228
Employee share options previously expensed, that lapsed during the year	(226)	(862)
Balance at end of year	639	581

(b) Accumulated losses

	2019 $'000	2018 $'000
Balance at the beginning of year	(66,483)	(53,163)
Employee share options that lapsed during the year	226	862
Net loss attributable to members of Acrux Limited	(8,325)	(14,182)
Accumulated losses at reporting date	(74,582)	(66,483)

Notes to the Consolidated Financial Statements continued

For the financial year ended 30 June 2019

19. Cash flow information

	2019 $'000	2018 $'000
(a) Reconciliation of the cash flow from operations with loss after income tax:		
Loss from ordinary activities after income tax	(8,325)	(14,182)
Non-Cash Items		
Depreciation and amortisation	426	618
Share options expense	284	228
Unrealised foreign exchange (gains)/losses	–	(74)
Impairment losses	–	5,647
Changes in assets and liabilities		
Decrease in tax liabilities	51	(1,187)
Decrease/(Increase) in trade and other receivables	(2,040)	5,271
Increase in other current assets	(308)	(88)
Increase/(decrease) in payables	(86)	147
Increase in employee entitlements	70	128
Increase in deferred tax assets	(10)	(1,789)
	(1,613)	8,901
Net cash (outflows)/inflows from operating activities	(9,938)	(5,282)

(b) Reconciliation of cash

Cash at the end of the financial year as shown in the statement of cash flows is reconciled to the related items in the statement of financial position is as follows:

	2019 $'000	2018 $'000
– Cash at bank	152	870
– At call deposits with financial institutions	18,000	27,600
Closing cash balance	18,152	28,470

(c) Credit stand-by arrangement and loan facilities

The Group has credit card facilities with financial institutions available to the extent of $120,000 (2018: $120,000). As at 30 June 2019 the Group had unused facilities of $112,798 (2018: $108,631).

20. Non-controlling interests

The Group holds nil (2018: nil) non-controlling interests at balance date.

21. Commitments

	2019 $'000	2018 $'000
Lease expenditure commitments		
Operating leases non-cancellable and contracted for but not capitalised in the accounts:		
– Not later than one year	324	315
– Later than one year and not later than five years	677	994
Aggregate lease expenditure contracted for at reporting date	1,001	1,309

The operating lease relates to office, laboratory and warehouse facilities for which the lease was renewed by Acrux DDS Pty Ltd for a period of 4 years from 1 June 2018, with options to extend for a further two periods of 3 years each. Acrux DDS Pty Ltd does not have an option to purchase the leased asset at the expiry of the lease period.

22. Key management personnel compensation

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

	2019 $	2018 $
Compensation by category:		
Short-term employment benefits	1,547,091	1,732,040
Post-employment benefits	107,971	109,798
Equity	174,310	179,885
	1,829,372	2,021,723

23. Loans to key management personnel

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

24. Related party disclosures

Wholly owned group transactions

Loans

Loans were made between Acrux Limited and its subsidiaries under normal terms and conditions. The aggregate amounts receivable from controlled entities by the parent entity at the end of the reporting period was $126,388 (2018: $105,503).

Non-interesting bearing loans were made by Acrux Commercial Pty Ltd to its subsidiary, Fempharm Pty Ltd. The aggregate amount receivable from Fempharm Pty Ltd at the end of the reporting period was $59,389 (2018: $40,023).

Other transactions with Key Management Personnel and their personally related entities

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

Notes to the Consolidated Financial Statements continued

For the financial year ended 30 June 2019

25. Auditor's remuneration

	2019 $'000	2018 $'000
Amounts paid and payable to Pitcher Partners for:		
(i) Audit and other assurance services		
– An audit or review of the financial report of the entity and any other entity in the Group	95	112
– Taxation compliance and consulting	58	32
– Other non-audit services	–	–
	153	144

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 its revenue from developing and commercialising products using unique technology to administer drugs through the skin.

Geographical segment information	2019 $'000	2018 $'000
Revenue		
Australia	583	745
Switzerland[1]	–	2,231
Germany	311	245
United States	50	129
Other	270	82
	1,214	3,432

1. Axiron revenue is receivable from a Swiss subsidiary of Eli Lilly and Company.

All assets are located in Australia.

Product information	2019 $'000	2018 $'000
Revenue by product group/service		
Axiron	–	2,231
Lenzetto	581	327
Other	633	874
	1,214	3,432

27. Controlled entities

	Country of incorporation	Percentage owned 2019	Percentage owned 2018
Parent Entity			
Acrux Limited	Australia		
Subsidiaries of Acrux Limited			
Acrux DDS Pty Ltd	Australia	100%	100%
Acrux Pharma Pty Ltd	Australia	100%	100%
Acrux Commercial Pty Ltd	Australia	100%	100%
Subsidiaries of Acrux Commercial Pty Ltd			
Fempharm Pty Ltd	Australia	100%	100%

28. Parent entity details

	Parent entity 2019 $'000	Parent entity 2018 $'000
Summarised presentation of the parent entity, Acrux Limited, financial statements:		
(a) Summarised statement of financial position		
Assets		
Current assets	7,355	8,304
Non-current assets[1]	7,112	8,855
Total assets	14,467	17,159
Liabilities		
Current liabilities	375	866
Non-current liabilities	22	8
Total liabilities	397	874
Net assets	14,070	16,285
Equity		
Share capital	95,879	95,873
Profit reserve	7,390	7,390
Accumulated losses	(89,838)	(87,559)
Share based payments reserve	639	581
Total equity	14,070	16,285
(b) Summarised statement of comprehensive income		
Loss for the financial year	(2,279)	(10,871)
Other comprehensive income for the financial year	–	–
Total comprehensive income for the financial year	(2,279)	(10,871)

1. Investment in subsidiaries are recognised initially 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 which can subsequently be reversed in certain conditions.

Notes to the Consolidated Financial Statements continued

For the financial year ended 30 June 2019

29. Contingencies

There were no contingencies at 30 June 2019 (2018: Nil).

30. Subsequent events

In June 2019, Acrux submitted an ANDA to seek approval from the FDA to market its generic version of lidoncaine 2.5% and Prilocaine 2.5%. On 19 August 2019 the Company announced that the FDA had accepted the ANDA for review.

31. Company details

The registered office of the company is:

Acrux Limited
103 – 113 Stanley Street
West Melbourne VIC 3003

Directors' Declaration

The directors declare that:

1. In the Directors' opinion, the financial statements and notes thereto, as set out on pages 20 to 68, are in accordance with the *Corporations Act 2001*, including:
   (a) complying with Australian Accounting Standards and the Corporations Regulations 2001, and other mandatory professional reporting requirements;
   (b) as stated in Note 1(a) the consolidated financial statements also comply with International Financial Reporting Standards; and
   (c) giving a true and fair view of the financial position of the Group as at 30 June 2019 and of its performance for the year ended on that date.
2. In the Directors' opinion there are reasonable grounds to believe that Acrux Limited will be able to pay its debts as and when they become due and payable.

This declaration has been made after receiving the declarations required to be made by the Chief Executive Officer and Chief Financial Officer to the Directors in accordance with section 295A of the *Corporations Act 2001* for the financial year ending 30 June 2019.

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

Ross Dobinson
Non-Executive Chairman

Melbourne
Dated this 23rd day of August 2019

Geoff Brooke
Non-Executive Director

Melbourne
Dated this 23rd day of August 2019

Independent auditor's report to the members of Acrux Limited

ACRUX LIMITED
AND CONTROLLED ENTITIES
ABN 72 082 001 152

INDEPENDENT AUDITOR'S REPORT
TO THE MEMBERS OF
ACRUX LIMITED

Report on the Audit of the Financial Report

Opinion

We have audited the financial report of Acrux Limited "the Company" and its controlled entities "the Group", which comprises the consolidated statement of financial position as at 30 June 2019, the consolidated statement of profit or loss and other comprehensive income, the consolidated statement of changes in equity and the consolidated statement of cash flows for the year then ended, and notes to the financial statements, including a summary of significant accounting policies, and the directors' declaration.

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

(a) giving a true and fair view of the Group's financial position as at 30 June 2019 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* "the Code" that are relevant to our audit of the financial report in Australia. We have also fulfilled our other ethical responsibilities in accordance with the Code.

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

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

Key Audit Matters

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

ACRUX LIMITED
AND CONTROLLED ENTITIES
ABN 72 082 001 152

INDEPENDENT AUDITOR'S REPORT
TO THE MEMBERS OF
ACRUX LIMITED

Key Audit Matter	How our audit addressed the key audit matter
Assessment of impairment of Intangible Assets Refer to page 40 consolidated balance sheet, note 2(b) on page 49 and note 13 on page 58.	
The Group has $0.7 million ($0.8 million as at 30 June 2018) of capitalised development costs as at 30 June 2019 after impairment loss. We view intangible assets in relation to capitalised development costs to be a Key Audit Matter due to the management judgement required in making Discounted Cash Flow (DCF) model assumptions such as discount rate, growth rate, foreign exchange rate and forecast cashflows.	Our procedures included amongst others: • Critically evaluating management's DCF model methodology and their key assumptions utilised; • Testing the mathematical accuracy of the DCF model and assessing forecast cash flows to external data; • Performing sensitivity analysis around the discount rate, growth rates and foreign exchange rate used in the DCF model; • Understanding and evaluating management's processes and controls around the impairment of intangible assets; and • Assessing the appropriateness of the disclosures included in Notes 2 and 13 to the financial report in respect of impairment testing and sensitivity analysis.

Independent auditor's report to the members of Acrux Limited continued

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INDEPENDENT AUDITOR'S REPORT
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Key Audit Matter	**How our audit addressed the key audit matter**
Recoverability of Deferred Tax Assets Refer to note 1(j) on page 45, note 2(a) on page 49 and note 6 on page 54.	
The Group has $1.9 million of deferred tax assets recognised at 30 June 2019 ($1.8 m at 30 June 2018) relating to timing differences and Research and Development offset incurred by the subsidiary Acrux DDS Pty Ltd. The ability to recognise the deferred tax assets is dependent upon the probable generation of sufficient future taxable profit in order for the benefits of the deferred tax assets to be realised, in accordance with AASB 112. These benefits are realised by reducing tax payable on future taxable profits. We view the deferred tax assets as a Key Audit Matter due to the management judgement required in forecasting future taxable profit. Management's assumptions include but are not restricted to: • Ongoing profitable contract research and development activities; • Successful commercialisation of generics; and • The number of competitors in the market, market share and royalty rates.	Our procedures included but were not limited to: • Reviewing and assessing management's key assumptions relating to the forecasts of future taxable profit and evaluating the reasonableness of these assumptions; • Undertaking sensitivity analysis around the forecast cashflows in order to challenge management's assumptions; • Understanding and evaluating management's processes 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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Other Information – The annual report is not complete at the date of the audit report

The directors are responsible for the other information. The other information comprises the Directors Report which was obtained as at the date of our audit report, and any additional other information included in the Company's annual report for the year ended 30 June 2019, but does not include the financial report and our auditor's report thereon.

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

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

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

Responsibilities of the Directors for the Financial Report

The directors of the Company are responsible for the preparation of the financial report that gives a true and fair view in accordance with Australian Accounting Standards and the *Corporations Act 2001* and for such internal control as the directors determine is necessary to enable the preparation of the financial report that gives a true and fair view and is free from material misstatement, whether due to fraud or error.

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

Auditor's Responsibilities for the Audit of the Financial Report

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

Independent auditor's report to the members of Acrux Limited continued

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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:

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

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

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

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

Report on the Remuneration Report

Opinion on the Remuneration Report

We have audited the Remuneration Report included in pages 29 to 36 of the directors' report for the year ended 30 June 2019. In our opinion, the Remuneration Report of Acrux Limited and its controlled entities, for the year ended 30 June 2019, 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.

S WHITCHURCH
Partner

PITCHER PARTNERS
Melbourne

23 August 2019

An independent Victorian Partnership ABN 27 975 255 196
Level 13, 664 Collins Street, Docklands VIC 3008
Liability limited by a scheme approved under Professional Standards Legislation

Pitcher Partners is an association of independent firms
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Shareholder information

Additional information required by Australian Securities Exchange Listing Rules and not disclosed elsewhere in this report, as at 19 August 2019:

Shareholders

The Company has 166,732,711 ordinary fully paid shares on issue, held by 5,856 shareholders, and 5,940,000 performance rights outstanding held by 30 people. The Company does not have any other equity securities on issue. Only the holders of ordinary shares are entitled to receive dividends as declared from time to time and are entitled to one vote per share at shareholders' meetings. No voting rights attach to the share options or performance rights.

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

Distribution Schedule

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

Category	Number of Shareholders	Securities
1 to 1,000	1206	651,776
1,001 to 5,000	2005	5,877,782
5,001 to 10,000	956	7,768,959
10,001 to 50,000	1215	28,877,761
50,001 to 100,000	241	17,483,016
100,001 and Over	233	106,073,417
Total	**5856**	**166,732,711**

2,238 shareholders hold less than a marketable parcel of fully paid ordinary shares (being the Company's main class of securities), based on the market price at the date set out above.

Substantial Holders

Name	Number of fully paid ordinary shares
Samuel Terry Asset Management Pty Ltd	10,232,371
DDH Graham Ltd	9,767,196

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.

Twenty Largest Holders of Fully Paid Ordinary Shares in Acrux Limited

	Shareholder	Number of fully paid ordinary shares	Percentage of total capital
1	J P MORGAN NOMINEES AUSTRALIA PTY LIMITED	12,723,804	7.63
2	DDH GRAHAM LIMITED	9,767,196	5.86
3	MR PAUL COZZI	3,500,000	2.10
4	MNM CAPITAL PTY LTD	2,759,672	1.66
5	ASHWOOD RIVER PTY LTD	2,600,000	1.56
6	CITICORP NOMINEES PTY LIMITED	2,075,577	1.24
7	DURBIN SUPERANNUATION PTY LTD	2,060,000	1.24
8	MR IAN VICTOR LANCINI & MRS DEBRA ANN LANCINI	2,045,000	1.23
9	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED	2,009,589	1.21
10	MR CHRISTOPHER MURRAY ABBOTT	1,600,000	0.96
11	ASIA UNION INVESTMENTS PTY LIMITED	1,500,000	0.90
12	NEWECONOMY COM AU NOMINEES PTY LIMITED	1,486,300	0.89
13	MR MICHAEL SCOTT SYLVESTER & MRS RECHAELLE SARAH SYLVESTER	1,450,000	0.87
14	HISHENK PTY LTD	1,400,000	0.84
15	ADAM JAMAL	1,218,727	0.73
16	MR DAVID ANDREW SLOBOM & MRS LINDA JANE SLOBOM	1,218,513	0.73
17	MORGAN STANLEY AUSTRALIA SECURITIES (NOMINEE) PTY LIMITED	1,214,942	0.73
18	MS LINLIN LI	1,193,000	0.72
19	MR GARY LESTER HANIKERI	1,150,000	0.69
20	BNP PARIBAS NOMINEES PTY LTD	1,079,894	0.65
		54,052,214	**32.44**

Market Listing

Acrux Limited is quoted on the Australian Securities Exchange (ASX). Share prices can be obtained from most Australian national newspapers and from the ASX website (www.asx.com.au). The shares of the Company are not quoted on any other stock exchange.

The following are the share prices for the end of each quarter of the financial year ending 30 June 2019:

Quarter ended 30 September 2018 – 22.0 cents

Quarter ended 31 December 2018 – 18.0 cents

Quarter ended 31 March 2019 – 18.5 cents

Quarter ended 30 June 2019 – 18.5 cents

The closing share price on 19 August 2019 was 19.0 cents

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 summary.

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

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

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

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

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

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

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

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

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

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

Glossary

Term	Abbreviation	Description
Abbreviated New Drug Application	ANDA	Abbreviated New Drug Applications (ANDAs) are termed "abbreviated" because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and effectiveness of a generic drug product. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent (i.e., performs clinically in the same manner as the innovator drug). Once approved, an applicant may manufacture and market the generic drug product to provide a safe, effective, low cost alternative. All approved products, both innovator and generic, are listed in FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book).
Active Pharmaceutical Ingredient	API	Also known as drug substance. A substance used in a finished pharmaceutical product, intended to furnish pharmacological activity or to otherwise have direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease, or to have direct effect in restoring, correcting or modifying physiological functions in human beings.
Addressable market		Sales value for a pharmaceutical product and dosage form. The data is obtained from IQVIA for products for which an Acrux product will directly compete when approved.
Axiron®		Brand name for Acrux's testosterone replacement therapy solution product that was formerly licensed globally to Lilly. The Axiron® trademark is owned by Eli Lilly.
Bioequivalence/ Bioavailability		Bioequivalence studies compare the bioavailability of the proposed drug product with that of the Reference Listed Drug (RLD) product containing the same active ingredient. Bioequivalence is defined as the absence of a significant difference in the rate and extent to which the drug (active ingredient) becomes available at the site of drug action when administered at the same dose under similar conditions.
Competitive Generic Therapies	CGT	The *FDA Reauthorization Act of 2017* (FDARA) created a new pathway by which FDA may, at the request of the applicant, designate a drug with "inadequate generic competition" as a competitive generic therapy (CGT). At the request of the applicant, FDA may also expedite the development and review of an abbreviated new drug application (ANDA) for a drug designated as a CGT. FDARA created a new type of 180-day exclusivity, different from 180-day patent challenge exclusivity, for the first approved applicant of a drug with a CGT designation for which there were no unexpired patents or exclusivities listed in the Orange Book at the time of original submission of the ANDA.
Contract Manufacturing Organisation	CMO	A CMO is a company that serves other companies in the pharmaceutical industry on a contract basis to provide services that include product scale and commercial drug manufacturing.
Estradiol		Estradiol is a form of estrogen, a female sex hormone produced by the ovaries. Estrogen is necessary for many processes in the body.
Evamist®		Brand name for Acrux's unique estradiol spray product in the United States. The Evamist® trademark is owned by Lumara Health.
Ellavie®		Alternative brand name for Acrux's estradiol spray product. The Ellavie® trademark is owned by Acrux.
Food and Drug Administration	FDA	The FDA is responsible for protecting and promoting public health through the regulation and supervision of prescription, over-the-counter pharmaceutical drugs (medications), vaccines, biopharmaceuticals and veterinary products in the United States.
Gedeon Richter		Gedeon Richter Plc., headquartered in Hungary, is a major pharmaceutical company in Central Eastern Europe, with an expanding direct presence in Western Europe. Richter's consolidated sales were approximately EUR 1.4 billion, while its market capitalization amounted to EUR 3 billion in 2018. The product portfolio of Richter covers almost a range of therapeutic areas, including gynaecology, central nervous system, and cardiovascular areas. Richter is a significant player in the female healthcare field worldwide.
Generic medicine		A generic medicine is a medicine that provides the same quality, safety and efficacy as the original brand name product and which undergoes strict scrutiny before it is licensed and given market approval by national regulatory authorities.
In-vitro Permeation Testing	IVPT	In-vitro permeation testing studies across biological membranes for formulations that are applied to the skin are vital to guide product development and establish product bioequivalence. IVPT is a critical tool for understanding drug delivery into the various layers of skin and can aid in formulation selection.

Glossary continued

Term	Abbreviation	Description
In-vitro Release Testing	IVRT	Measurement of drug release from complex dosage forms intended for topical application is important for some drug product bioequivalence testing. IVRT allows for targeted and systematic drug development and guides the establishment of therapeutic equivalence. IVRT involves subjecting the drug formulation to a set of conditions that will induce drug release across a membrane and quantitating the amount of drug released under those conditions. In development, it is an essential test in assessing differences between formulations, predicting the timeframe of API release, and modelling in vivo behaviour.
IQVIA		IQVIA, formerly Quintiles and IMS Health, Inc., is a US based multinational company serving the combined industries of health information technology and clinical research. IQVIA provides, on a subscription basis, an analytics platform that lets you analyse pharmaceutical industry-leading sales data from over 90 countries in a standardised and comparable way.
Lenzetto®		Brand name for Acrux's unique estradiol spray in the European Union. The Lenzetto® trademark is owned by Gedeon Richter.
New Drug Application	NDA	New Drug Application. When the sponsor of a new drug believes that enough evidence on the drug's safety and effectiveness has been obtained to meet FDA (or other national health regulator) requirements for marketing approval, the sponsor submits to the regulator a new drug application (NDA). The application must contain data from specific technical viewpoints for review, including chemistry, pharmacology, medical, biopharmaceutics, and statistics. If the NDA is approved, the product may be marketed in the in that country.
Onychomycosis		Onychomycosis is a fungal infection of the toenails or fingernails that may involve any component of the nail unit, including the matrix, bed, or plate. Onychomycosis can cause pain, discomfort, and disfigurement and may produce serious physical and occupational limitations, as well as reducing quality of life.
Orange Book		The publication Approved Drug Products with Therapeutic Equivalence Evaluations is commonly known as the Orange Book and identifies drug products approved on the basis of safety and effectiveness by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act and related patent and exclusivity information.
Paragraph IV filing or Paragraph 4 filing	PIV	A type of ANDA submitted during the patent term of the originator product. The filing asserts that either the patents supporting the originator product are invalid or that they are not applicable ("not infringed") to the product that is the subject of the ANDA.
Pharmacokinetic	PK	Pharmacokinetics is defined as the study of the time course of drug absorption, distribution, metabolism, and excretion.
Pooled Development Fund	PDF	Refer to separate section in the Annual Report for an overview of PDF or the following website www.business.gov.au/assistance/pooled-development-funds
Product-Specific Guidance	PSG	To further facilitate generic drug product availability and to assist the generic pharmaceutical industry with identifying the most appropriate methodology for developing drugs and generating evidence needed to support ANDA approval, FDA publishes product-specific guidances describing the FDA's current thinking and expectations on how to develop generic drug products therapeutically equivalent to specific reference listed drugs.
Reference Listed Drug	RLD	An RLD is an approved drug product to which new generic versions are compared to show that they are bioequivalent.
Testosterone		Testosterone is a naturally occurring sex hormone that is produced in a man's testicles.
Transdermal		Transdermal is a route of administration wherein active pharmaceutical ingredients are delivered across the skin for systemic distribution. Examples include Axiron, Evamist and Lenzetto.
Topical		Topical is a route of administration wherein active pharmaceutical ingredients are applied to, or affect a localised area of the body.

Corporate Directory

Acrux Limited and Subsidiary Companies

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Australia

T: + 61 3 8379 0100

www.linkedin.com/company/acrux

www.acrux.com.au

Australian Stock Exchange code "ACR"

Information about the Company, including disclosures to the Australian Stock Exchange, can be found on the Company's website.

If you require further information about Acrux, please contact Deborah Ambrosini, the Company's Chief Financial Officer & Company Secretary on +61 3 8379 0100.

Share Registry

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Victoria 3008
Australia

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ACRUX

DRUG DELIVERY SOLUTIONS