



# ACRUX LIMITED

(ASX: ACR)

## ANNUAL GENERAL MEETING

12 November 2020

# Chairman – Ross Dobinson



# CEO – Michael Kotsanis

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This presentation contains forward-looking statements which are identified by words such as 'may', 'could', 'believes', 'estimates', 'expects', or 'intends' and other similar words that involve risks and uncertainties.

These statements are based on an assessment of present economic and operating conditions, and on a number of assumptions regarding future events and actions that, as at the date of this presentation, are expected to take place.

Actual results could differ materially depending on factors such as the availability of resources, the results of non-clinical and clinical studies, the timing and effects of regulatory actions, the strength of competition, the outcome of legal proceedings and the effectiveness of patent protection.

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These forward looking statements are subject to various risk factors that could cause our actual results to differ materially from the results expressed or anticipated in these statements.



# Business overview

1. Acrux is a specialty topical and transdermal drug development and commercialisation company
2. Acrux is a revenue generating pharmaceutical company with an extensive product pipeline of topical generic pharmaceuticals creating additional regulatory and commercialisation milestones

	Acrux products	Recent Acrux outcomes
Products commercialised by Acrux	<ul style="list-style-type: none"><li>▪ <b>Estradiol spray</b> Sold as Lenzetto® in 37 countries with royalties and milestones received by Acrux from FY17 onwards. Sold as Evamist® in the United States.</li><li>▪ <b>Testosterone solution</b> Sold in 6 countries with royalties and milestones received by Acrux from FY10 – FY18. Peak annual sales were US\$179 million in 2013.</li></ul>	<ul style="list-style-type: none"><li>▪ Acrux revenue from its Estradiol licensees grew 48% in FY20 over prior financial year</li><li>▪ Royalties payable to Acrux are expected to further grow and exceed \$1 million in FY21</li></ul>
Acrux Pipeline	<ul style="list-style-type: none"><li>▪ Acrux has a development pipeline of 13 topical generic pharmaceuticals with 3 of these products submitted to the FDA</li></ul>	<ul style="list-style-type: none"><li>▪ Multiple licensing deals executed in FY20</li><li>▪ Profit share payable to Acrux following product launches with milestones on selected products pre and post commercialisation</li></ul>



# Topical Generics – an attractive \$18 billion market segment

	Total market	Oral drugs	Acrux focus: Prescription topical drugs
Definition of market (all drugs including NCEs and generics)	Total US prescription pharma market	Drugs that are ingested orally (eg tablets, capsules)	Drugs that are applied topically to the skin, eyes, ears and nose (eg creams, ointments, gels, solutions)
Market size <sup>1</sup>	>US\$510bn	~US\$200bn	~US\$18bn <sup>2</sup>
Generic market share	~90% <sup>3</sup>	~91% <sup>3</sup>	47% <sup>4</sup>
Typical generic development complexity	Variable	Low	Greater complexity than oral generic drug development
Generic competition	<i>Variable</i>	<i>High competition from many generic drug manufacturers</i>	<i>Limited generic competition given niche market and development complexity</i>

Source:

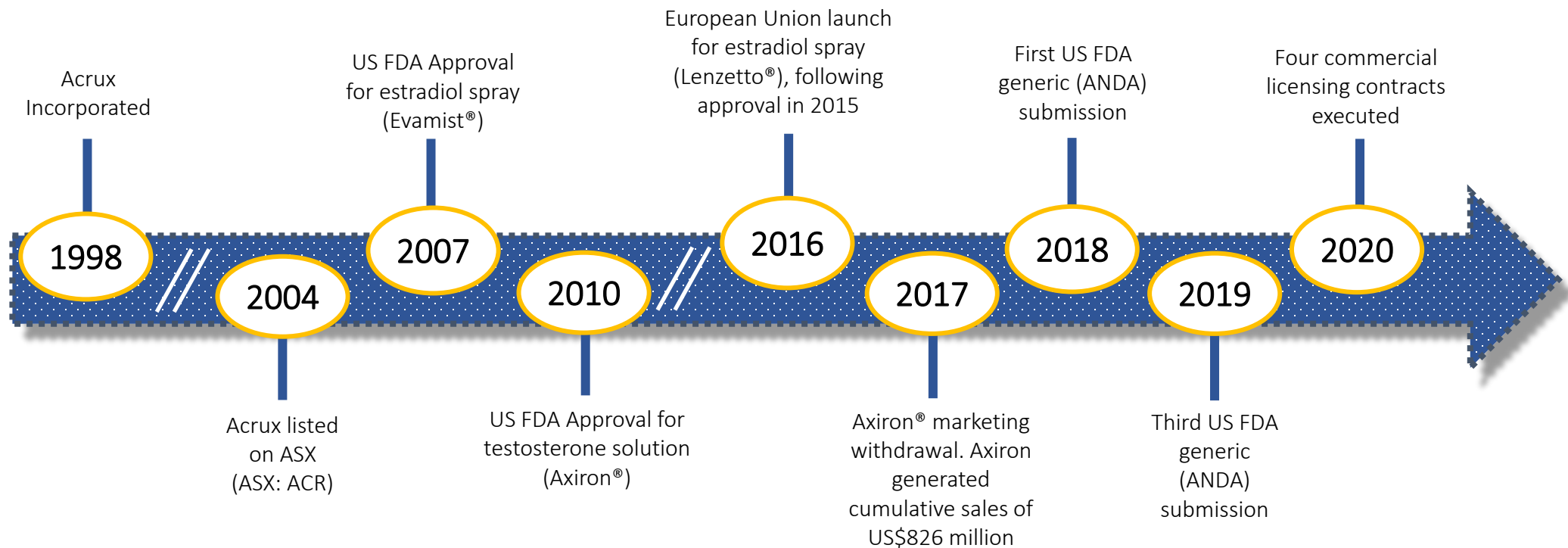
1. US market by dosage form, IQVIA Q1, 2020 MAT, US market sales (US\$)
2. Market size for topically applied drugs IQVIA Q1, 2020 MAT, US market sales (US\$)
3. IQVIA Global Generic and Biosimilars Trends and Insights – 2018
4. IQVIA, National Sales Perspectives, January 2019 – Unbranded generic share of dermatology, MAT





# Acrux history

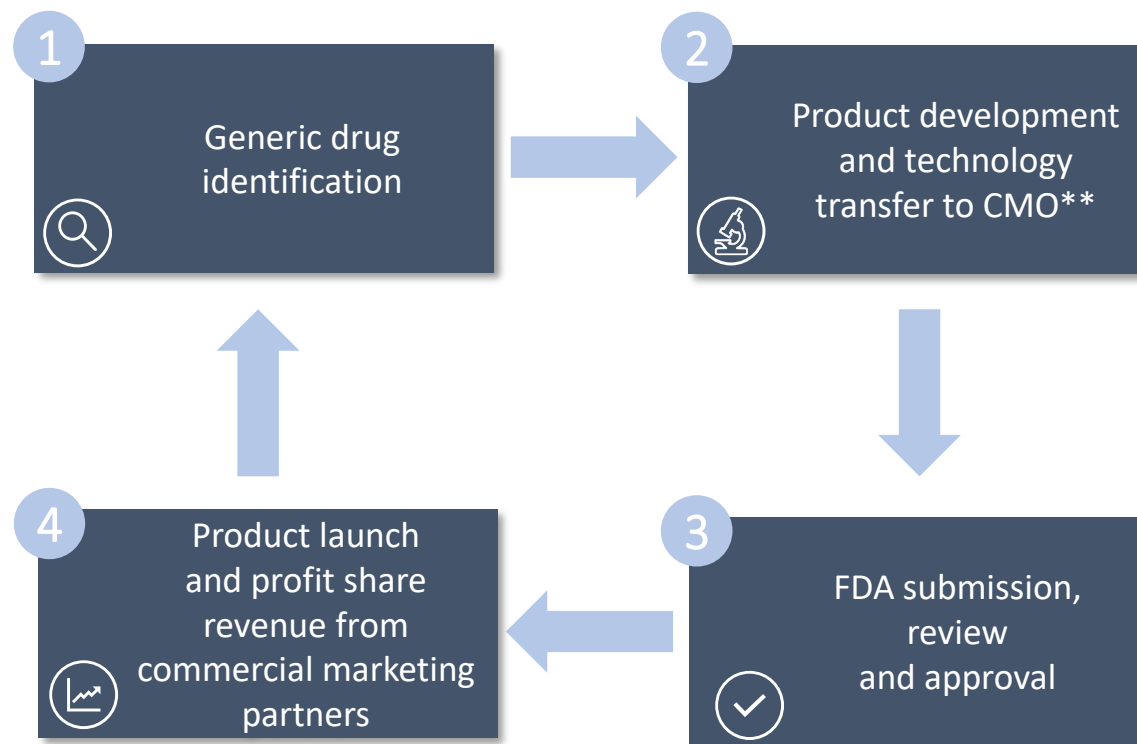
- Acrux has over 20 years of experience in the development and commercialisation of topical and transdermal pharmaceuticals
- Acrux products are currently sold in 38 countries





# Revenue generating business model supporting long-term growth

- On market products are generating growing royalty revenues for Acrux
- Through the Acrux GMP\* facility with 25 specialised scientists, Acrux possesses the capabilities to develop and commercialise generic topical and transdermal pharmaceutical products
- Acrux has 6 licensees with products commercialised in 38 countries
- The core business model of generic drug development is supported by ongoing licensing opportunities for commercial marketing and distribution







# Acrux product portfolio



**The Acrux pipeline will add to the commercialised portfolio of products sold through the Acrux network of licensees**

- Evamist® sold by Perrigo in the United States and Lenzetto® sold by Gedeon Richter in the European Union and a number of other countries outside the EU
- 6 products licensed from pipeline to TruPharma
- 1 product licensed to Amring Pharmaceuticals
- 1 product licensed to Harris Pharmaceutical
- 1 product licensed to Dash Pharmaceuticals
- Profit share payable to Acrux for the duration of the term of the licence following ANDA\*\* product launches with milestones on selected products pre and post commercialisation



# Strong and Consistent returns

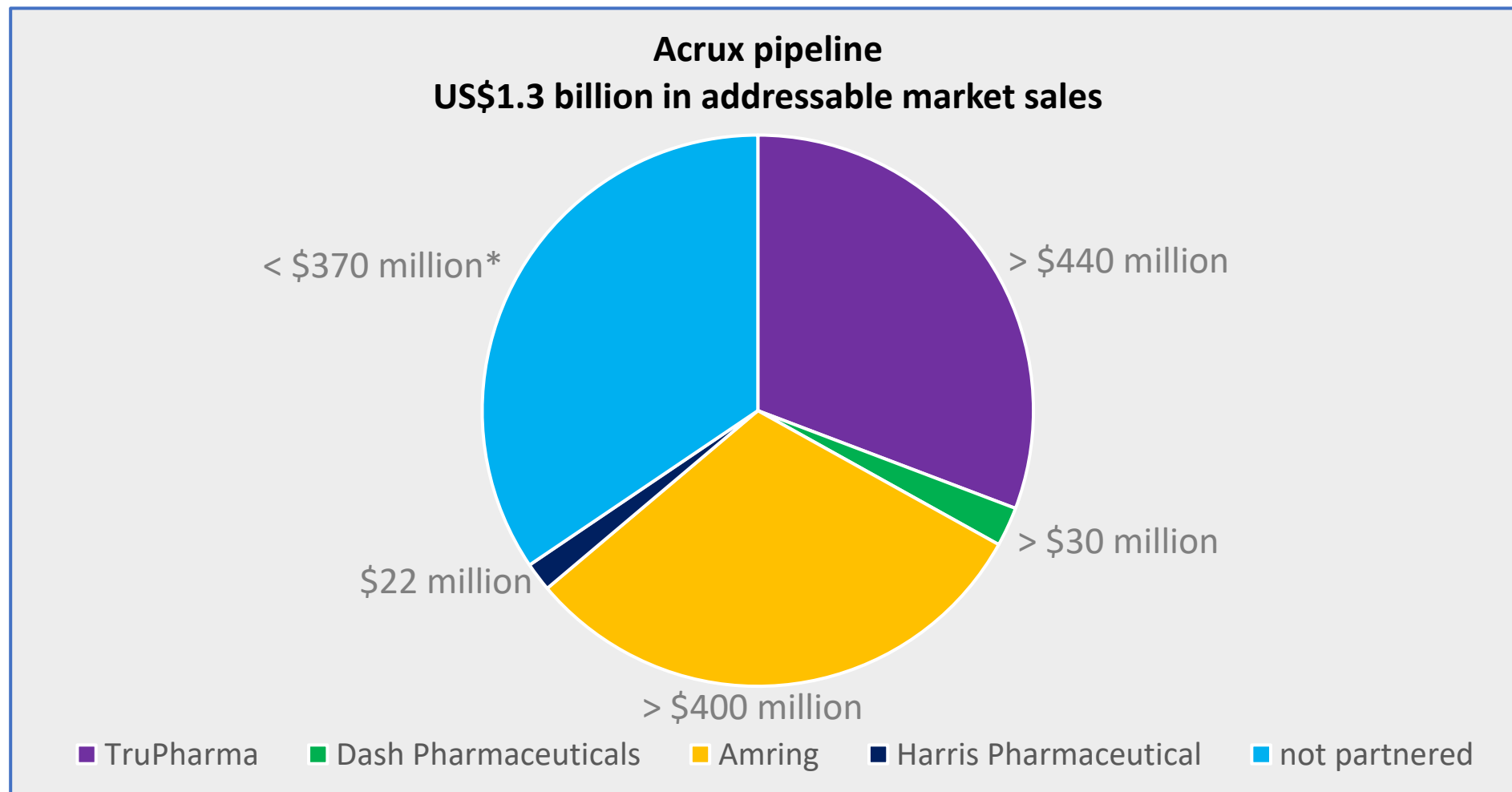
Acrux's diversified drug development strategy provides more certainty than novel drug development

	Acrux's generic portfolio strategy	Novel drug development
Commercial Strategy	<p><b><u>Portfolio Strategy</u></b></p> <p>Detailed screening of generic drug candidates along with development and commercialisation track record underpin Acrux's de-risked portfolio strategy</p>	<p>Novel drug development will remain speculative given high costs and risks of development</p>
Development Process	<ul style="list-style-type: none"><li>■ Acrux rigorously screens market data for topical drug candidates in attractive markets where Acrux can leverage its drug development and commercialisation track record</li></ul>	<p>The overall probability of clinical success is estimated to be less than 12%<sup>1</sup></p>
Time, Cost and Value	<ul style="list-style-type: none"><li>■ Acrux is able to develop and commercialise a generic drug for ~AUD\$3-4m within ~4 years</li><li>■ Once a licensing deal is executed and a product launched royalty/profit share revenue is expected to grow strongly</li></ul>	<p>Developing a novel drug takes 10+ years<sup>1</sup></p> <p>Drug development involves multiple expensive long-term trials</p>



# Acrux partnered pipeline addressable market

Over US\$890 million of addressable market value licensed to TruPharma, Amring Pharmaceuticals, Harris Pharmaceutical and Dash Pharmaceuticals in 2020. Profit share payable to Acrux following product launches with milestones on selected products pre and post commercialisation





## Overview of current licensees



- Licensed 6 products to sell in the US when approved by the FDA



- Co-development for 1 product to sell in the US when approved by the FDA



- Licensed 1 product to sell in the US when approved by the FDA



- Sells Lenzetto® in 37 countries including most EU countries



- Sells Evamist® in the United States






- Licensed 1 product to sell in the US when approved by the FDA



# Key Investment highlights

**Acrux is a revenue generating pharmaceutical company with an extensive product pipeline of topical generic pharmaceuticals nearing additional regulatory and commercialisation milestones**

 <b>Focus on specialised and lucrative topical generic market</b>	<ul style="list-style-type: none"><li>▪ 2 products <b>on market</b> in 38 countries</li><li>▪ The topical generic market provides <b>attractive returns with fast, low-risk and low development costs</b> for highly specialised drug developers</li><li>▪ The size of the topical generic market in the US is <b>~US\$18bn*</b></li><li>▪ <b>13 products</b> now in the pipeline of generic products, with an addressable market of <b>~US\$1.3bn*</b></li><li>▪ Licensing deals executed with recurring revenue and milestone payments for selected products</li></ul>
 <b>Highly skilled development team</b>	<ul style="list-style-type: none"><li>▪ Proven commercialisation strategy to <b>bring a portfolio of products to market</b></li><li>▪ Led by an experienced management team, Acrux possesses <b>unique development and commercialisation know-how and capabilities</b></li><li>▪ TGA approved, Good Manufacturing Practice (GMP) facility with 25 specialised scientists creates a substantial competitive advantage in generic product selection, development and commercialisation</li></ul>
 <b>R&amp;D investment in product pipeline entering commercialisation</b>	<ul style="list-style-type: none"><li>▪ <b>Two products currently sold through licensees</b> in Europe, the United States and other countries</li><li>▪ <b>Additional products</b> nearing FDA approval</li><li>▪ <b>2 product licensing deals executed</b> with 2 different pharma companies in FY 2020</li><li>▪ <b>Licensing contracts with Harris Pharmaceutical and Dash Pharmaceuticals</b> executed to date in FY21</li><li>▪ <b>Objective to be cash flow positive by 2022</b></li></ul>






\* US market by dosage form, IQVIA Q1, 2020 MAT, US market sales (US\$)





# Platform for growth established

Through investment in the platform over the past 5 years Acrux has a competitive advantage in the identification, development, registration and launch of generic topical drugs

	Acrux Product Status	Description
 ON MARKET	2 2 products sold in 38 countries	Acrux receives royalties on a quarterly basis. Revenue from estradiol licensees <b>grew by 48%</b> in FY20 v FY19
 LAUNCH	9 4 product licensing deals executed in CY2020 for 9 products	Acrux expects a typical licence agreement to consist of an <b>recurring profit share stream</b> and on selected products, milestones pre and post commercialisation
 APPROVE	3 Products accepted for FDA review in CY18, 19	Following initial review there may be additional FDA questions to be answered prior to approval <sup>1</sup> . Products can be launched following Final Approval.
 DEVELOP	10 Generic products in development	<b>R&amp;D team</b> with highly specific topical expertise drive development. Acrux has unique capabilities for topical drug development.
 IDENTIFY	53 94 Identified topical drugs, Each >US\$100m in sales Identified topical drugs, Each \$10-100m in sales	Continue to screen market to <b>identify</b> high potential prescription topical products





# Experienced management team with a proven history of commercialising generic drugs

CEO & MD Michael Kotsanis leads a team of highly credentialed experts in generic drugs



**Michael Kotsanis BSc, MBus**  
*CEO & Managing Director*

- **Experienced leader** in the pharmaceuticals industry with demonstrated success **commercialising generic products**
- Formally CCO for Synthon Holding BV, an international pharmaceutical company and a **leader in the field of generic medicines**
- Prior to Synthon Michael was President, Europe for Hospira - the **largest global generic injectable company**, before its acquisition by Pfizer

Synthon

Hospira

Faulding

maynepharma



**Felicia Colagrande, BSc(Hons), MBA**  
*Product Development and Technical Affairs Director*

Faulding

Significant pharmaceutical operations, dermal drug development, analytical development and production experience. Leads all technical aspects of pharmaceutical product development including R&D, analytical development, project management and CMC development



**Charles O'Sullivan, B. Pharm**  
*Portfolio Director*

Hospira

maynepharma

gsk

Experienced healthcare executive with senior and international leadership roles in scientific affairs, medical affairs, health economics and government affairs. Previously Asia Pacific Director of Medical and Government Affairs for Hospira (now Pfizer)



**Deborah Ambrosini, CA**  
*CFO & Company Secretary*

GLOBAL HEALTH  
Connecting Clinicians and Consumers

pwc

Over 20 years' experience in accounting and business development spanning the biotechnology, mining, IT communications and financial services. Experience in senior management roles ASX listed PDFs



**Mark Hyman,**  
*Project and Technical Director*

SANDOZ

maynepharma

Hospira

Diverse background with more than 30 years' industry experience, previously holding leadership positions in Product Development, Project Management and Commercial Development. Expertise is project and technical management.

# CFO – Deborah Ambrosini

# Full Year Profit and Loss

	30 June 2020 \$'000	30 June 2019 \$'000	Mvt
<b>Revenue and Other Income</b>			
Revenue from licensing agreements	1,253	631	98.6%
Other income	2,692	4,655	-42.2%
	3,945	5,286	-25.4%
<b>Less: Expenses</b>			
R&D investment	(10,640)	(10,917)	-2.5%
Other operating costs	(1,976)	(2,189)	-9.7%
Non Operating Costs	(714)	(515)	38.6%
	(13,330)	(13,621)	-2.1%
<b>Loss before income tax</b>	<b>(9,385)</b>	<b>(8,335)</b>	12.6%
Income tax benefit/(expense)	(86)	10	-960.0%
<b>Net loss for the year</b>	<b>(9,471)</b>	<b>(8,325)</b>	13.8%
<b>Basic loss per share</b>	<b>(5.65)</b>	<b>(5.00)</b>	
<b>Cash reserves</b>	<b>9,206</b>	18,152	

# Full Year Cashflow

	30 June 2020 \$'000	30 June 2019 \$'000	Mvt
<b>Operating Activities</b>			
Receipts from product agreements	1,093	576	89.8%
Payments to suppliers and employees	- 11,666	- 13,233	-11.8%
Interest received	216	611	-64.6%
Income taxes refunded/paid	-	51	-100.0%
Finance costs	- 191	-	
Grant income	2,015	2,057	-2.0%
<b>Net cash used in operating activities</b>	<b>- 8,533</b>	<b>- 9,938</b>	<b>-14.1%</b>
<b>Net cash used - property, plant and equipment</b>	<b>- 254</b>	<b>- 380</b>	<b>-33.2%</b>
<b>Net cash used in financing activities</b>	<b>- 159</b>	<b>-</b>	
<b>Net decrease in cash and cash equivalents</b>	<b>- 8,946</b>	<b>- 10,318</b>	<b>-13.3%</b>
Cash at beginning of year	18,152	28,470	-36.2%
<b>Cash at end of year</b>	<b>9,206</b>	<b>18,152</b>	<b>-49.3%</b>



# CEO – Michael Kotsanis



# Future catalysts



## ACRUX STRATEGY

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

- Commercial launch and cash flow generation from new generic drugs
- Licensing and profit share agreements with generic pharmaceutical companies
- FDA approvals for new products
- Ongoing screening and initiation of new products in development



## FY 2021 OBJECTIVES

- Continued royalty growth of existing on market products
- 3 additional products submitted for FDA review
- 2 product launches with profit share and other payments to Acrux
- Licensing contracts with Harris Pharmaceutical and Dash Pharmaceuticals executed



## FY 2022 OBJECTIVES

- Continued royalty growth of existing on market products
- Objective to be cash flow positive by 2022
- Ongoing screening and initiation of new products in development
- 4 additional products submitted for FDA review





# BENEFITS OF A POOLED DEVELOPMENT FUND

1

Companies with PDF status are taxed at 15% on their income and capital gains received from their investments

2

Australian resident shareholders are exempt from capital gains tax after selling their shares

3

Unfranked dividends received by an Australian resident shareholder from the Company will be exempt from tax in the hands of the shareholder

4

Franked dividends will also be exempt from tax unless the shareholder elects to treat the franked dividend as taxable

*Shareholders should seek professional advice from their tax advisor regarding Pooled Development Funds and the benefits specifically available to their situation*

# Thank you

Michael Kotsanis

CEO & Managing Director

Acrux Limited

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Visit our website: <http://www.acrux.com.au/>

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# Chairman – Ross Dobinson

# Formal Business

To receive and consider the Financial Report and the Report of the Directors and Auditor for the year ended 30 June 2020.

# Resolution 1

Re-election of Mr Ross Dobinson as a Director

# Resolution 2

## Adoption of Remuneration Report



# Resolution 3

Approval of 10% Placement Capacity - Shares

# Resolution 4

Approval of Omnibus Equity Plan – to refresh approval as required by the ASX Listing Rules

# Resolution 5

Grant of rights to Mr Norman Gray