



# **Acrux Ltd**

## **Annual General Meeting Presentation and Addresses**

### **23 November 2021**

Good morning ladies and gentlemen. My name is Ross Dobinson, and I am the Chairman of Acrux Limited. It is my pleasure to welcome shareholders to Acrux's 2021 Annual General Meeting. We are unable to welcome shareholders in person but we appreciate you joining us virtually today.

Firstly I would like to introduce my fellow Board members

- Our Chief Executive Officer and Managing Director, Michael Kotsanis
- Non-executive Directors: Geoff Brooke, Tim Oldham and Don Brumley
- and our CFO & Company Secretary – Joanna Johnson.

Also in attendance today are

- Mr Nick Bull from our auditors - Pitcher Partners and
- Representatives of our Share Registry - Link Market Services.

#### **Chairman's Address**

At last year's Annual General Meeting I provided an update on the corporate strategy we have been implementing since 2015. This strategy has been validated by the FDA approvals received and our recent product launch. Further product launches will be facilitated by this year's FDA approvals and Michael will refer to these in more detail in his CEO and Managing Director's Report.

We maintain our view that the knowhow which has been developed by the Company over the last twenty years of operations provides sustainable competitive advantages.

The Company has made solid progress towards achieving our FY 22 targets of further revenue growth from existing products, becoming cashflow positive by the close of calendar year 2022, the growth of new products in development and having additional products submitted for FDA review.

Commercial discussions with other prospective licensees will continue as we progress the development of our product pipeline. The pipeline will also be covered in more detail in Michael's Report. We remain confident that we have the capacity to maintain a consistent number of products under development as earlier projects are completed and licensed out. As noted previously, our pipeline will be expanded gradually after the initial product launches provide further validation of our business model.

As part of our product development strategy, we will continue to monitor topical drug market data for the products we are developing. Factors impacting market share and regulatory developments are key issues which could impact the commercial prospects of our new products. Items such as changes to the FDA Product Specific Guidelines (PSG) could present both opportunities and risks. As noted previously, a key commercial objective in generics development is the introduction of products early to market in order to gain commercial advantages over competitors. For some products which are first to market, exclusivity is received from the regulators for the first six months of those products' commercial lives under the FDA's Competitive Generic Therapies ('CGT') Guidance which was published in final form by the FDA in March 2020.

I would like to again thank my Board colleagues for their productive input over the last year. I would also like to extend the Board's appreciation to Michael and his team for their continued efforts and focus on moving our pipeline forward and in securing licensing partners for a significant proportion of the company's pipeline. The Company has made substantial progress in the development of this pipeline which should generate commercial outcomes in the next year.

#### **CEO's Address**

**Michael Kotsanis** – Chief Executive Officer and Managing Director

Good morning and thank you for attending this year's virtual Annual General Meeting and for your interest in Acrux. We welcome your attendance today and your participation. I trust that in future we will be able to hold hybrid meetings with face to face attendance as well as an online opportunity to attend for interstate or international shareholders.

Before I start, I refer you to our Disclaimer Statement.



### **IMPORTANT NOTICE AND DISCLAIMERS**

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.

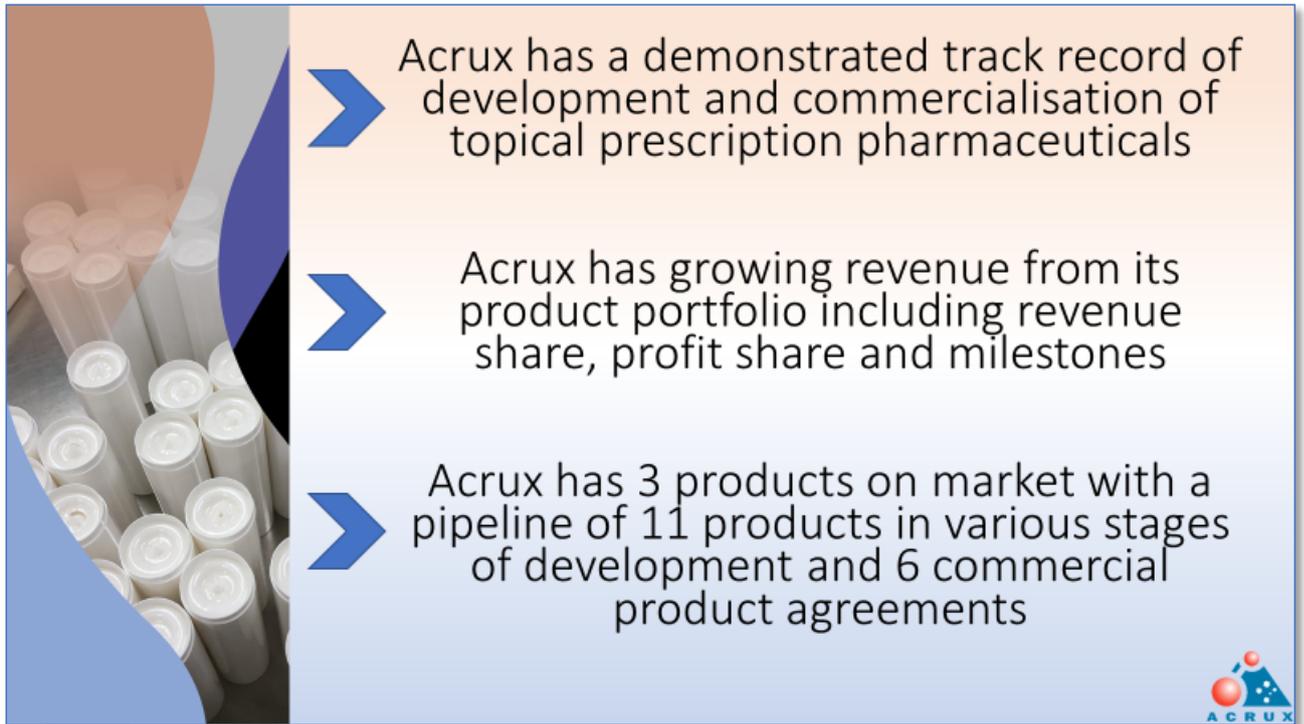
Such forward-looking statements are not guarantees of future performance and involve known and unknown risks, uncertainties, assumptions and other important factors, many of which are beyond the control of our Company, the Directors and our management.

We cannot and do not give any assurance that the results, performance or achievements expressed or implied by the forward-looking statements contained in this presentation will actually occur and investors are cautioned not to place undue reliance on these forward-looking statements.

We have no intention to update or revise forward-looking statements, or to publish prospective financial information in the future, regardless of whether new information, future events or any other factors affect the information contained in this presentation, except where required by law and under our continuous disclosure obligations.

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.





AcruX has a demonstrated track record of development and commercialisation of topical prescription pharmaceuticals

AcruX has growing revenue from its product portfolio including revenue share, profit share and milestones

AcruX has 3 products on market with a pipeline of 11 products in various stages of development and 6 commercial product agreements



## Overview

We can summarise AcruX in these three bullet points:

1. AcruX has a demonstrated track record of both successful development and commercialisation of topical prescription pharmaceuticals.
2. AcruX has a growing revenue stream from its product portfolio from milestones and revenue share agreements
3. AcruX has three products that are on market, 2 that are pending launch and a pipeline of 11 products in development with a number of commercial agreements in place

## Business overview

Acrux has a demonstrated track record of development and commercialisation of topical prescription pharmaceuticals

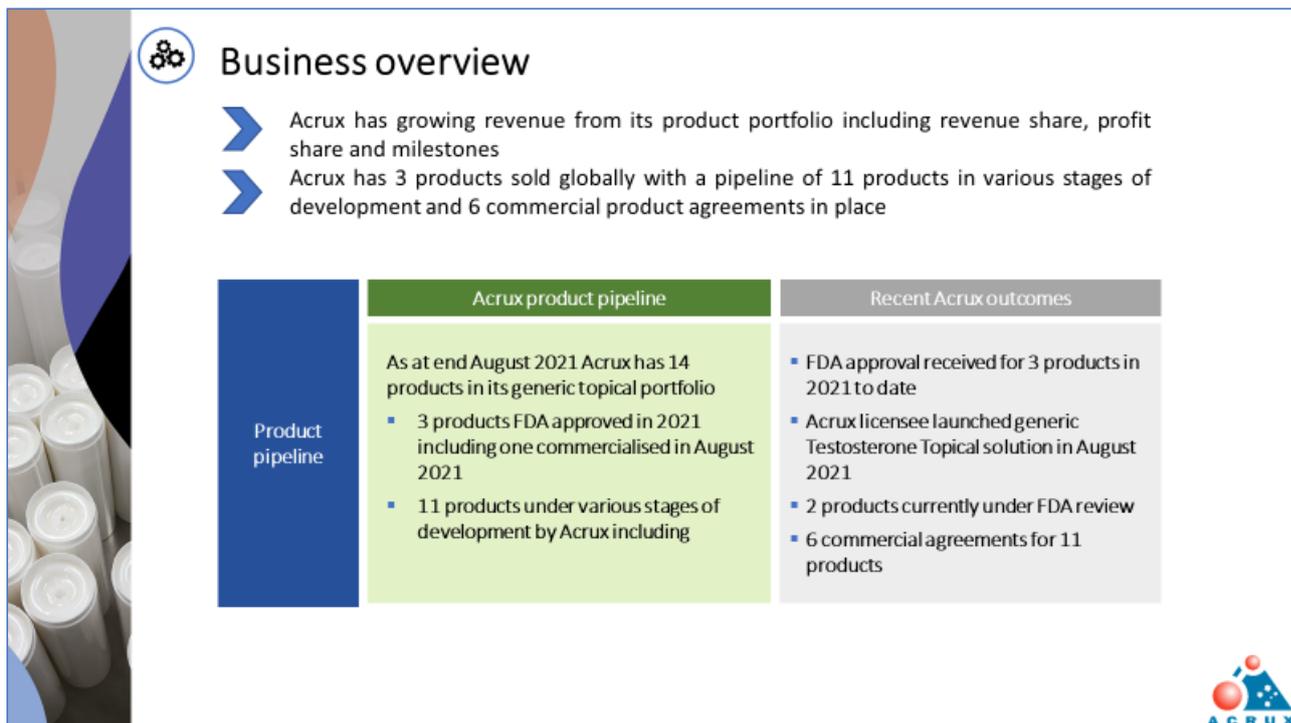
Products commercialised by Acrux	Acrux product history	Past Acrux outcomes
	<b>Testosterone solution</b> Was sold in 6 countries with revenue share and milestones received by Acrux from FY10 – FY18	<ul style="list-style-type: none"> <li>The product generated substantial returns for Acrux shareholders through payment of milestones and revenue share to the Company</li> </ul>
	Acrux currently marketed products	Recent Acrux outcomes
	<b>Estradiol spray</b> Currently sold as Evamist® in the United States  Currently sold as Lenzetto® in over 30 countries with milestones and revenue share received by Acrux from FY17 onwards	<ul style="list-style-type: none"> <li>Acrux revenue from its Lenzetto® grew 18% in FY21 over prior financial year</li> <li>Revenue share from Lenzetto® payable to Acrux exceeded \$1 million in FY21</li> </ul>

### Business Overview – Commercialised products

Our future success can be illustrated by our history. Our track record of development, registration and commercialisation of products is shown on this slide.

Our Testosterone solution product was sold in 6 countries by Eli Lilly, our licensee at the time, between 2011 and 2017. Returns to shareholders at the time were substantial.

Our Estradiol spray was our first product that was commercialised. The product has been marketed since 2016 by Gedeon Richter as Lenzetto in over 30 countries in Europe and other countries, including a number in Latin America. Our revenue from Lenzetto grew by 18% last year and exceeded \$1 million as forecast at last year’s AGM. Our product is also marketed by Padagis in the United States, which recently re-branded from the company formerly called Perrigo. Acrux receives a share of revenue on sales of estradiol in all markets.



## Business overview

- Acrux has growing revenue from its product portfolio including revenue share, profit share and milestones
- Acrux has 3 products sold globally with a pipeline of 11 products in various stages of development and 6 commercial product agreements in place

	Acrux product pipeline	Recent Acrux outcomes
Product pipeline	<p>As at end August 2021 Acrux has 14 products in its generic topical portfolio</p> <ul style="list-style-type: none"> <li>3 products FDA approved in 2021 including one commercialised in August 2021</li> <li>11 products under various stages of development by Acrux including</li> </ul>	<ul style="list-style-type: none"> <li>FDA approval received for 3 products in 2021 to date</li> <li>Acrux licensee launched generic Testosterone Topical solution in August 2021</li> <li>2 products currently under FDA review</li> <li>6 commercial agreements for 11 products</li> </ul>



### Business Overview – Product pipeline

In addition to the three products that we have commercialised and the 2 products which were approved in mid-2021 but are not yet launched, our product development pipeline features an additional 11 products under development including 2 that are under review by the FDA. The two products that we have under review by the FDA include dapstone gel 7.5% which was accepted for review by the FDA in April this year. That product targets a market of over US\$165 million in annual sales based on IQVIA data. We also have another dapstone product, the 5% gel that was accepted for review by the FDA in September this year. That product targets a market with US\$30 million in annual sales. For these products, the FDA recommends a combination of in vitro and in vivo studies with pharmacokinetic endpoints. Importantly, for both products we have successfully completed in-vitro permeation testing, also known as IVPT, to demonstrate bioequivalence. This is known in the pharmaceutical industry to be a very challenging technique and we are very pleased with the bioequivalence outcomes we have achieved for both products.

Our products in development exclusively target the United States market for topically applied prescription pharmaceuticals.

Our Testosterone Solution product was launched by our licensee Dash Pharmaceuticals in August this year and most of our later stage development products have already been licensed to generic companies for marketing in the United States.

Our development and commercialisation strategy is to repeatably bring products to market. We have 25 extremely capable scientific staff who have continued to work hard to bring our products through the development process to regulatory approval.

Since we started development on the first of our topical generic products, we have submitted the first five to the FDA for review and three of these have been approved by the FDA. As our products progress through the regulatory review process, licensing negotiations and launch, our objective remains to be cash flow positive by the end of 2022.

We are at an exciting stage of the company's transformation and are now beginning to commercialise additional products. Our launch planning is underway for further product launches, and we look forward to additional FDA approvals and launches in 2022 and beyond.

One additional point I'd like to make is that we are regularly approached by companies seeking licenses to our topical products for commercialisation in countries outside the United States and we will explore the benefit of working with these companies on a case by case basis. The potential commercial benefit that Acrux could receive from these discussions needs to be balanced against the additional cost in conducting the development work usually needed to register products in additional markets.

## Key Investment highlights

- Focus on specialised and lucrative topical generic market**
  - 3 products **on market** in over 30 countries including Testosterone Topical solution launched in August 2021 in the United States
  - 14 topical generic products in portfolio including 11 in various stages of development with an addressable market of ~US\$1.2bn<sup>1</sup>
  - The topical generic market provides **attractive returns with low-risk and low development costs** for highly specialised drug developers
  - The size of the topical generic market in the US is ~US\$16bn<sup>2</sup>
- Highly skilled development team**
  - TGA approved, Good Manufacturing Practice (GMP) facility with 25 specialised scientists creates a substantial competitive advantage in generic product selection, development and commercialisation
  - Proven commercialisation strategy to **bring a portfolio of products to market**
  - Led by an experienced management team, Acrux possesses **unique development and commercialisation know-how and capabilities**
- R&D investment in product pipeline entering commercialisation**
  - Products sold through **licensees** in Europe, the United States and other countries
  - FDA approvals received for Prilocaine/Lidocaine cream 2.5%/2.5% and Efinaconazole solution 10% in mid 2021
  - 6 commercial agreements with 6 different pharma companies for 11 products in place. All licensing agreements feature recurring revenue on commercialisation
  - Objective to be cash flow positive by end of 2022**

1. IQVIA Q2, 2021 MAT, US market sales (US\$) 2. US market sales by dosage form, IQVIA Q3, 2020 MAT, (US\$)

## Key Investment Highlights

We focus on the specialised and lucrative topical generic market

- We have 3 products **on market** in over 30 countries
- The topical generic market provides **attractive returns with low-risk and low development costs** for highly specialised drug developers
- We have **14 topical generic products** in our portfolio including 11 in various stages of development with an addressable market of **~US\$1.2 billion**
- The size of the topical prescription market in the United States in approximately US\$16 billion

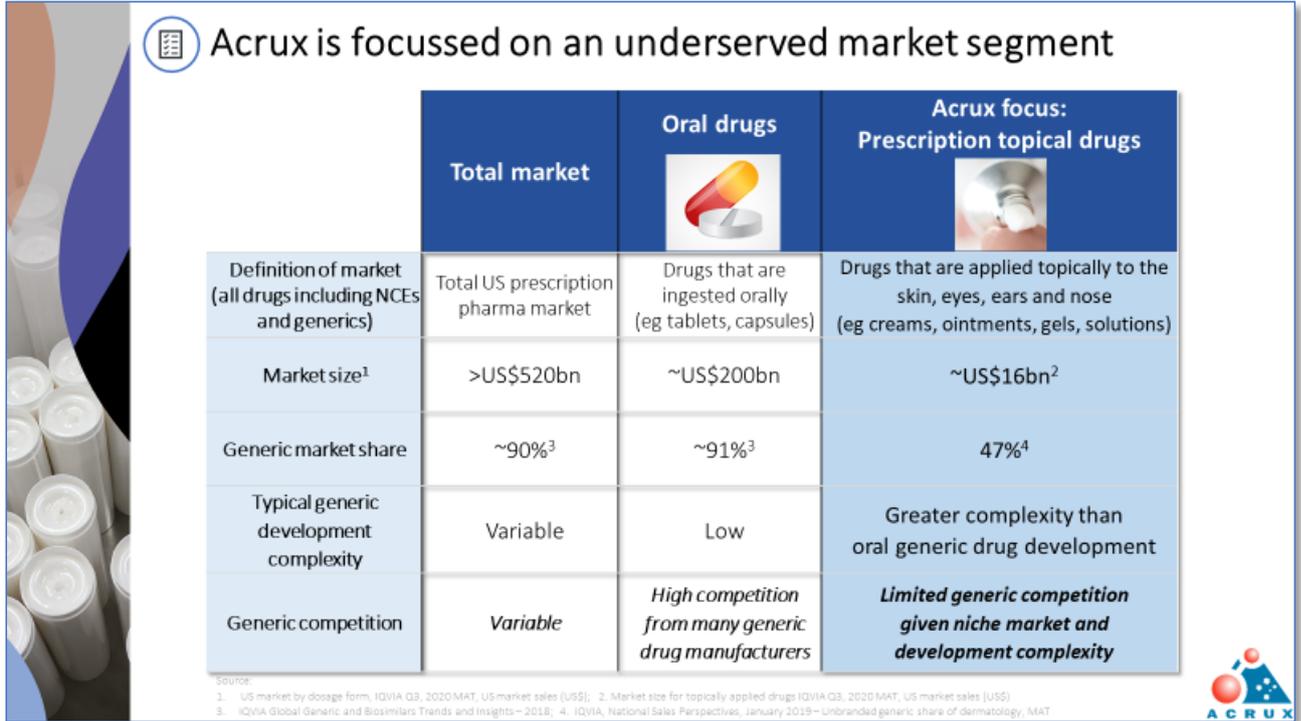
We have a highly skilled development team

- TGA approved, Good Manufacturing Practice (GMP) facility with 25 specialised scientists which creates a substantial competitive advantage in generic product selection, development and commercialisation
- Proven commercialisation strategy to **bring a portfolio of products to market**
- Led by an experienced management team, Acrux possesses **unique development and commercialisation know-how and capabilities**

Our R&D investment in our product pipeline is entering commercialisation

- **Products now sold through licensees** in Europe, the United States and other countries
- **FDA approvals for prilocaine/lidocaine cream 2.5%/2.5% and efinaconazole solution 10% both in mid 2021 and Testosterone Topical Solution, 30mg/1.5ml which was approved in January 2021 and launched this year**
- **Multiple product licensing deals with** different pharma companies for 11 products in place
- **Objective to be cash flow positive by end of 2022**

Whilst our licensing arrangement with Harris Pharmaceutical was terminated in October as a result of their bankruptcy, I am pleased to note that we are currently evaluating a non-binding Term Sheet with a well qualified licensee for the US rights to prilocaine/lidocaine 2.5% cream and we look forward to launching that product in 2022.



## Topical market is underserved

We believe the topical market is substantially differentiated from the other larger segments of the total US pharmaceutical market.

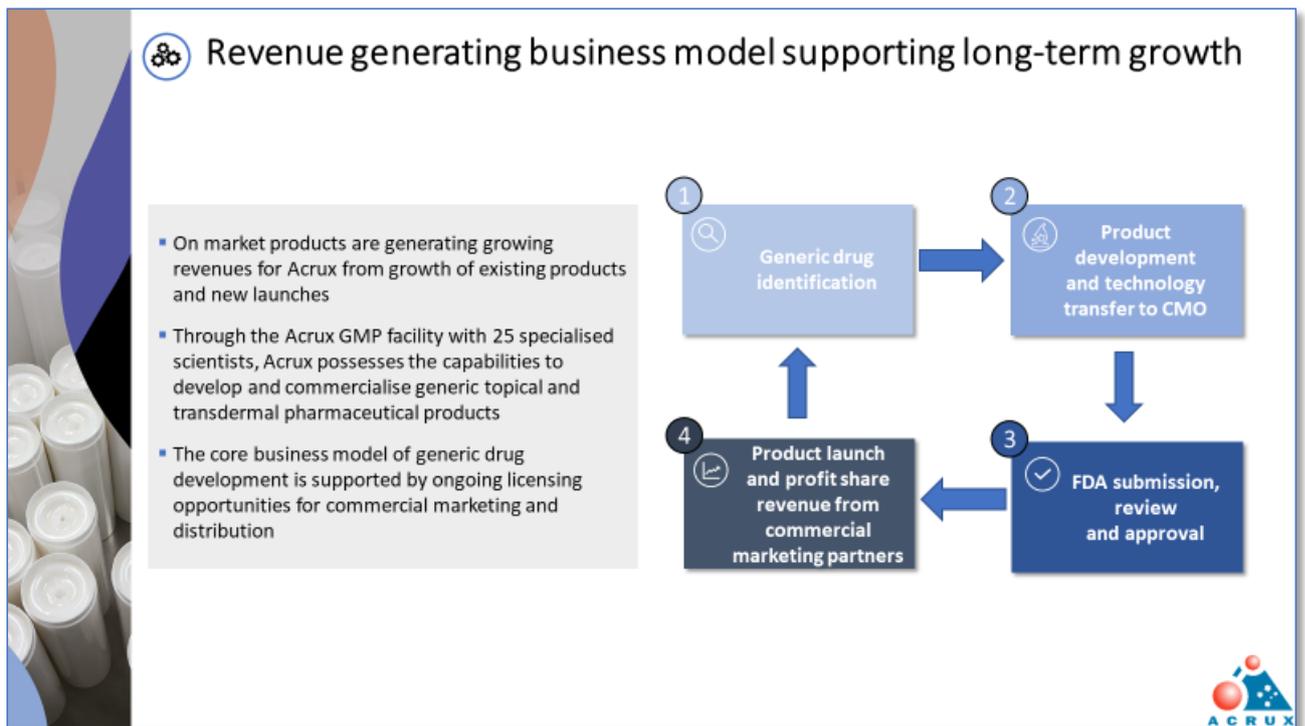
The total market (which excludes Covid 19 vaccines) in the United States generates over US\$520 billion in annual sales based on IQVIA data. The oral market for tablets and capsules forms the largest segment of the total market and generates approximately US\$200 billion in sales. In the United States 90% of prescriptions dispensed to patients as a tablet or capsule are generic products. Branded products in the United States rapidly lose share to generic competition once generics launch. The oral market for tablets and capsules contrasts with the smaller and less competitive market for products that are applied topically onto the skin or some type of mucosa. The topical market generates approximately US\$16 billion in sales but has a lower level of generic penetration than the oral market. Based on IQVIA data for the topical dermatology sector, only 47% of prescriptions dispensed in this market are generic.

What differentiates the oral market from the topical market is the overall size of the market, the relative size of individual products, the differing dosage forms and the more complex development process and methods for demonstrating bioequivalence of the generic product to the on-market brand. Oral generic drugs are often approved on the basis of pharmacokinetic studies that compare the branded product to the generic product. The oral products that have generic competition are generally heavily substituted for generics in the United States.

For topical drugs there are a wide variety of techniques the FDA recommends to demonstrate bioequivalence, including in vitro permeation testing and in vitro release testing both of which are challenging techniques to master and for which AcruX now has considerable experience,

having demonstrated success with both. The FDA also recommends pharmacokinetic studies, clinical endpoint studies and vasoconstrictor studies for some topical products to demonstrate bioequivalence as well, depending on the type of dosage form, the indication (or use) of the product and the systemic absorption profile of the (topically applied) product.

This topical sector is the exclusive focus of Acrux and reflects our experience and skill sets. We believe that this segment is an underserved segment of the US generic market.



## Revenue Generating Business Model

Our business model is summed up by this slide. We spend a significant amount of time evaluating different products as potential product development candidates. All the products we assess are topically applied prescription pharmaceutical products marketed in the United States. Our assessment of a product candidate includes a commercial and patent assessment, a technical assessment as well as an overall financial assessment.

Once we assess and identify a product for development, we begin the analytical and formulation work that underpins our scientific development process. Once this analytical and formulation work is complete, we contract an FDA approved manufacturer to transfer our formulation in what we term a technology transfer to a manufacturer for the product. The data we generate from batches of our product that are manufactured at the contract manufacturer are then included with our analytical and formulation development reports as well as our bioequivalence studies and submitted as part of the dossier to the FDA for review.

Our licensing deals with generic companies in the United States are for the rights to commercialise and sell our products in the United States. These licensing contracts will generate the recurring revenue that in future will drive our business forward.



## FY21 Profit and Loss

	2021	2020	Movement	Movement
	\$'000	\$'000	\$'000	%
<b>Revenue and Other Income</b>				
Revenue from licensing agreements	1,337	1,253	84	7%
R&D Tax Incentive Rebate	3,421	2,327	1,094	47%
Other income	398	365	33	9%
<b>Total Revenue and Other Income</b>	<b>5,156</b>	<b>3,945</b>	<b>1,211</b>	<b>31%</b>
<b>Less: Expenses</b>				
External R&D Expenses	8,928	5,012	3,916	78%
Salaries and Directors' Fees	6,109	5,712	398	7%
Depreciation and amortisation	664	707	(43)	-6%
Other Expenses	1,887	1,899	(12)	-1%
<b>Total Expenses</b>	<b>17,588</b>	<b>13,330</b>	<b>4,259</b>	<b>32%</b>
Income tax benefit/(expense)	(197)	(86)	(112)	131%
<b>Net loss for the year</b>	<b>(12,629)</b>	<b>(9,471)</b>	<b>(3,158)</b>	<b>33%</b>

- Growing Profit Share Income with increasing Estradiol market penetration and expansion in the number of territories
- Increased expenditure on development of new products reflected in increased R&D Tax incentive Rebate



## FY21 Profit and Loss

Successful commercialisation of the products currently under development and the resultant revenue growth following product launch is the key to Acrux's sustainability.

Revenues have trended upwards in FY21 with Estradiol Revenue Share Income growing by more than 16% over the prior year. This growth is attributable due to our partner's expansion into new countries as well as growth achieved in existing markets. We expect Estradiol will continue to achieve strong growth through FY22 and beyond.

As we move forward into FY22, Acrux income will be boosted by the launch of Testosterone Topical Solution by our partner Dash Pharmaceuticals in 2021, as well as the contribution from other products, including prilocaine/lidocaine 2.5% cream, which is expected to be launched in 2022.

The R&D Incentive Rebate provided by the Australian Federal Government remains an important revenue item for Acrux as it offsets eligible R&D expenditure and supports development of our product pipeline. The increase in this Incentive in FY21 reflects the higher level of R&D expenditure, which includes exhibit batches, bioequivalence study costs and other project expenses directly associated with FDA filings.

Earlier in November \$3.073m was received in relation to FY21 R&D Incentive, being \$250k higher than was estimated in our FY21 accounts and an increase of \$750k on FY20.

The value of Acrux's R&D expenditure and also staff salaries for FY21 are higher than the prior year due to the number of products under development but more importantly due to the stage of those projects. Later stages of projects, before FDA filing, tend to involve scale up at external manufacturers and are typically more costly than the early stages such as

formulation development which are typically conducted in our on site laboratories by Acrux staff members.

Other Expenses such as occupancy and insurance are carefully managed and are consistent with the prior year.

## FY21 Cashflow

	2021 \$'000	2020 \$'000	Movement \$
<b>Operating Activities</b>			
Receipts from product agreements	1,228	1,093	135
R&D tax incentive rebate received	2,924	2,015	909
Payments to suppliers and employees	(15,785)	(11,666)	(4,119)
Other income and expenditure	(50)	(388)	338
<b>Net Outflow from Operating Activities</b>	<b>(11,683)</b>	<b>(8,946)</b>	<b>(2,737)</b>
<b>Proceeds from capital raising</b>	<b>17,747</b>	<b>0</b>	<b>17,747</b>
<b>Net cash generated / (consumed)</b>	<b>6,064</b>	<b>(8,946)</b>	<b>15,010</b>
<b>Cash at end of year</b>	<b>15,270</b>	<b>9,206</b>	<b>6,064</b>

- Net cash surplus for FY21 and increase in Cash reserves due to successful capital raising
- Cashflows from operating activities closely follow operating profitability



## FY21 Cashflow

Acrux has reported a net increase in Cash and Cash Reserves of \$6.0m for FY21. This reflects the \$17.7m Capital Raising which was finalised in February 2021 as well as revenue from profit share income and other contractual entitlements in addition to Expenditure for Product Development for the year.

Ongoing profit share revenue growth from already commercialised products as well as the timing and success of planned product launches, particularly in the next 12 months is critical to the company's achievement of longer term sustainable revenues and projected cash reserves.



## 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*



### **Pooled Development Fund Benefits**

Overview of the Pooled Development Fund (PDF) and the potential benefits for Australian resident shareholders.

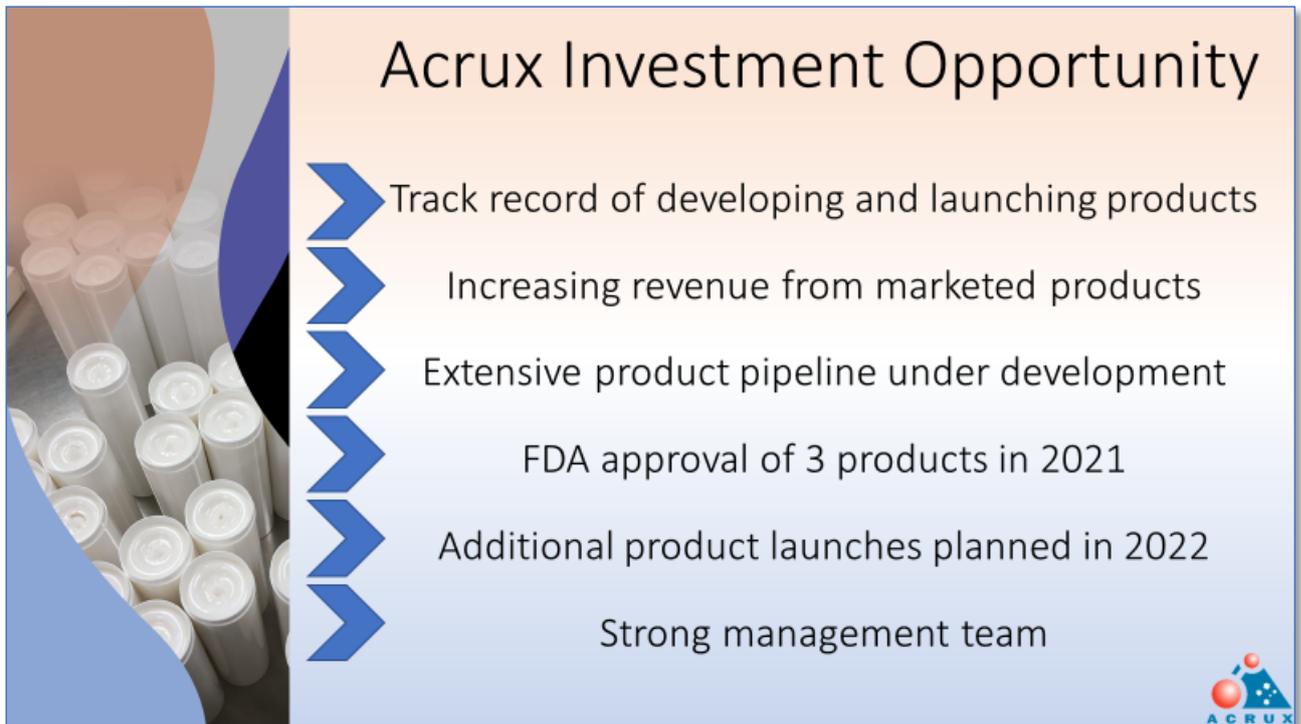
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Franked dividends will also be exempt from tax unless the shareholder elects to treat the franked dividend as taxable.

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

The graphic features a stack of white medical vials on the left side, partially obscured by a blue and orange abstract shape. To the right, the title 'Acrux Investment Opportunity' is displayed in a large, black, sans-serif font. Below the title, six blue chevron arrows point to the right, each followed by a line of text. The text points are: 'Track record of developing and launching products', 'Increasing revenue from marketed products', 'Extensive product pipeline under development', 'FDA approval of 3 products in 2021', 'Additional product launches planned in 2022', and 'Strong management team'. In the bottom right corner of the graphic, there is a small logo for Acrux, which consists of a stylized blue and red shape above the word 'ACRUX' in a small, blue, sans-serif font.

## Acrux Investment Opportunity

- Track record of developing and launching products
- Increasing revenue from marketed products
- Extensive product pipeline under development
- FDA approval of 3 products in 2021
- Additional product launches planned in 2022
- Strong management team

### **Conclusion – Acrux Investment Opportunity**

In summary, Acrux has:

- A strong track record of developing and launching products
- Increasing revenue from marketed products
- An extensive product development pipeline
- FDA approval received for 3 products in 2021
- Additional product launches planned in 2022
- A strong and experienced management team

In closing, I would like to thank our shareholders, the Acrux team and the Acrux Board for their efforts and support of the Company.

More recently, the Acrux team has been operating with the added complexity of the COVID-19 pandemic. Our laboratory team has continued its work from the company's laboratory throughout the pandemic, often in trying lockdown and socially distanced circumstances. Our administrative staff have largely worked from home for much of the past 18 months. As many of the Acrux development projects now involve contract manufacturers, raw material sources and commercial partners outside Australia, this has added to the complexity in planning and executing each project.

Continuity with some service providers has been disrupted by COVID-19 from time to time, temporarily impacting their ability to provide a continuous service in their country or state of operations. Where possible, Acrux has planned for contingencies including the assessment of alternate service providers and alternate locations of operations. The Acrux team has progressed its pipeline whilst also dealing with the challenges that COVID-19 has provided to the healthcare and general community in Australia and globally.

I would like to personally thank the Acrux team of employees and the Board for their continued efforts and focus on moving our pipeline forward and to assist in securing licensing partners for a significant proportion of the company's pipeline. The Acrux team look forward to the opportunities and challenges ahead.

