



# **Acrux**

# **Annual General Meeting**

**17 November 2015**

# Introduction: Ross Dobinson

## *Non-Executive Chairman*



# Company review: Michael Kotsanis *CEO & Managing Director*



## Forward looking statements

*This presentation includes forward looking statements that are subject to risks and uncertainties. Such statements involve known and unknown risks and important factors that may cause the actual results, performance or achievements of Acrux to be materially different from the statements in this presentation. Actual results could differ materially depending on factors such as the availability of resources, the results of clinical studies, the timing and effects of regulatory actions, the strength of competition and the effectiveness of patent protection.*

# Business milestones

\$11.1 million – Acrux records its sixth consecutive profitable year

\$23.1 million – cash reserves at end June, 2015

Estradiol – approved in Europe. Milestones of US\$2 million triggered FY16

Topical generic pipeline – portfolio identified

NSAIDs – superior formulations developed

\$1.02 per share – total capital returned to shareholders over the past 5 years

# Financial review: Sharon Papworth

## *CFO & Company Secretary*



# Financial Summary



	FY15	FY14
	\$ Million	\$ Million

<b>Cash</b>	<b>23.1</b>	<b>25.8</b>
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<b>Revenue</b>	<b>25.4</b>	<b>53.9</b>
Milestone	-	28.7
Royalty	24.6	24.7
Other	0.8	0.5
<b>Expenses</b>	<b>(8.6)</b>	<b>(10.0)</b>
NPBT	16.8	43.9
<b>NPAT</b>	<b>11.1</b>	<b>28.0</b>

<b>EPS (cents per share)</b>	<b>6.7</b>	<b>16.8</b>
<b>Dividends (cents per share)</b>	<b>6.0</b>	<b>20.0</b>

- Strong financial position
  - Cash flow positive – generate solid cash inflows from existing product portfolio
  - Profitable business – Net Profit After Tax (NPAT) \$11.1 million
  - Strong balance sheet - \$23.1 million cash reserve and no debt
- Earnings Per Share (EPS): 6.7 cents
- 6c/share Dividend paid September 2015
- Comparison to prior year
  - Event triggered milestone occurred during FY14. No milestone triggered during FY15.

NPBT: Net Profit Before Tax

NPAT: Net Profit After Tax

# Income and Cash flow analysis



	\$ Million	% Net Income
Royalty received	25.2	
Royalty payments	(0.9)	
<b>Net product income</b>	<b>24.3</b>	
Interest received	0.6	
Other	0.2	
<b>Other income received</b>	<b>0.8</b>	
<b>Net income received</b>	<b>25.1</b>	100%
Tax paid	(8.9)	(35%)
Cash operating costs including R&D	(5.5)	(22%)
Other	(0.1)	(<1%)
Less non-cash costs & payment timing	0.5	
<b>Net Profit After Tax</b>	<b>11.1</b>	
<b>Dividend paid</b>	<b>(13.3)</b>	(53%)
Add back non-cash costs & payment timing	(0.5)	
<b>Net cash outflow</b>	<b>(2.7)</b>	

The table above captures cashflow during the year ended 30 June 2015, unless otherwise denoted. Non-cash costs include amortisation on intangible assets, depreciation and share option expense. Payment timing refers to payments made outside the reporting period.



## Cash received from Operating Activities:

- Income continues to be generated from commercialised products
  - Axiron volumes have stabilised
  - Milestone triggered, US\$2 million on marketing authorisation of Lenzetto® by Gedeon Richter in Europe. No further milestones are expected during financial year 2016.

## Cash Outflows from Operating Activities:

- Cash operating costs excluding Monash royalty and tax payments expected to be similar to FY15
- Investment in research and development continuing
  - commercially attractive
  - consistent with our growth strategy
- Expenditure will increase as projects move into clinical development. Acrux will update the market as this occurs.

# Company review: Michael Kotsanis

## *CEO & Managing Director*





# Growth Strategy

**Acrux is building a sustainable business model with a broader portfolio which leverages its existing topical expertise in compelling market segments**

## **How:**

- Core competency – utilise current technology, skills and capabilities
- Highly experienced formulation team
- Product development focused on commercially compelling opportunities
- Partner with strong and capable licensees

## **Measures of success:**

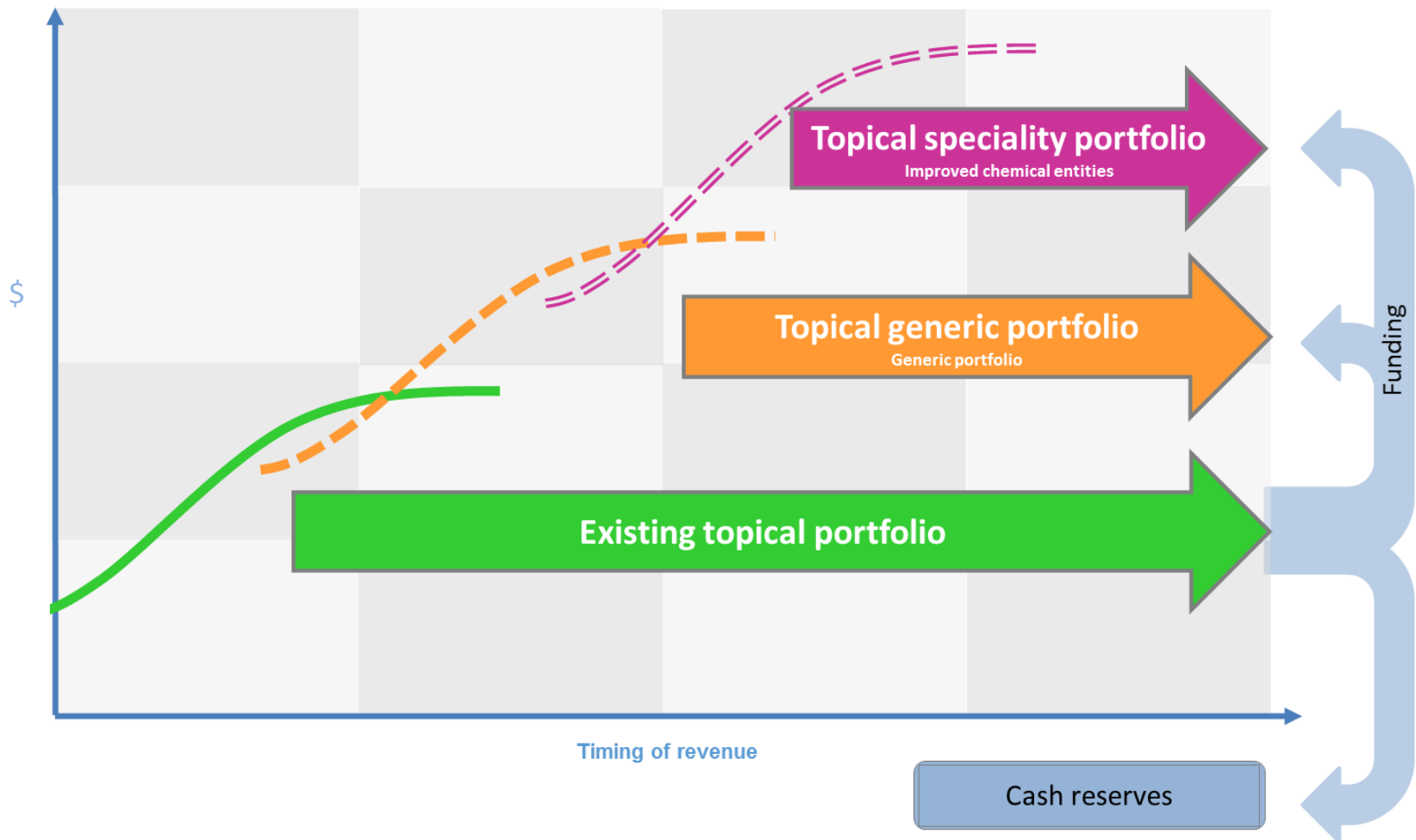
- Portfolio with multiple products in various stages of development
- Valuable products licensed and commercialised
- Profitable and sustainable business

# Growth Strategy

## Framework for continued growth

Existing topical portfolio

- Includes Axiron<sup>®</sup>, Lenzetto<sup>®</sup>, Evamist<sup>®</sup>
- Strong cash inflow – facilitating our growth strategy
- Territory expansion being executed



# Existing Topical Portfolio



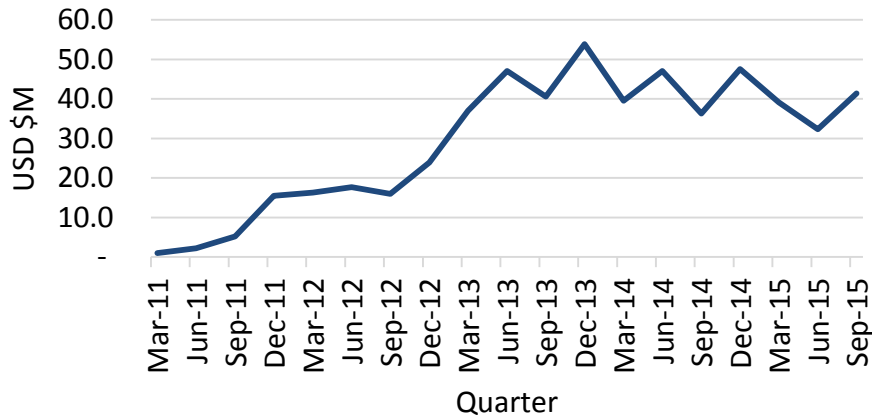
Axiron

# Existing Topical Portfolio

## Axiron volume and market share

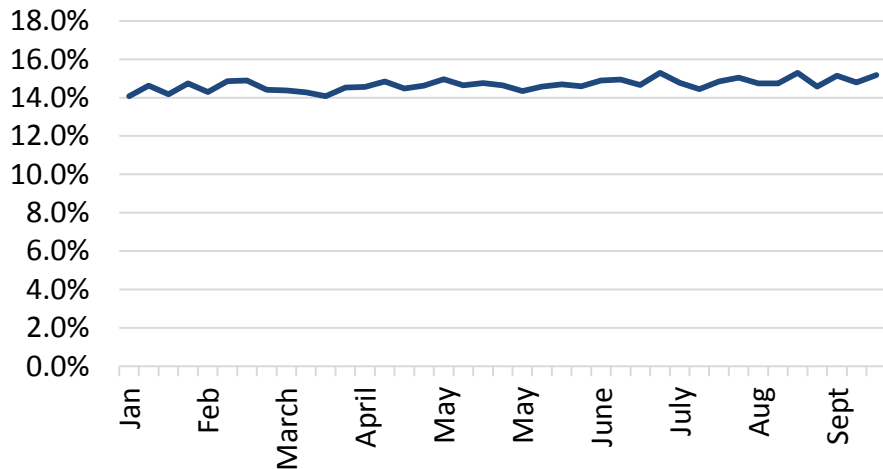


Axiron Net Sales

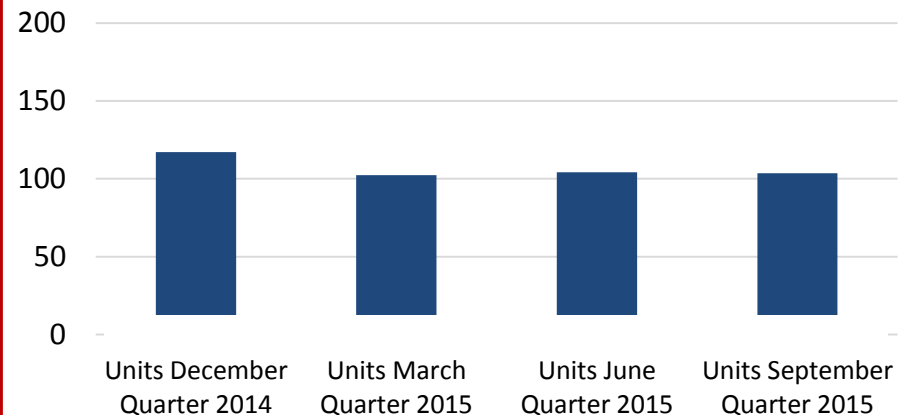


- Most recent testosterone FDA Drug Safety Communication in March 2015
- FDA and sponsors working towards collaborative long term safety trial
- Testosterone replacement therapy market remains attractive and substantial in size
- Axiron volume in 2015 higher than expected

Axiron volume market share 2015 YTD



Axiron quarterly prescriptions – prior 4 quarters (thousands)



# Existing Topical Portfolio

## Axiron IP litigation



- Axiron patents
  - Axiron is protected by multiple patent families, which expire in 2017, 2027 and 2030
- Axiron litigation
  - Lilly and Acrux have filed lawsuits against generic companies attempting to market an infringing Testosterone Metered Dose Transdermal Solution. The lawsuits include infringement claims relating to, *inter alia*, the application of testosterone formulations to the underarm
  - Trial scheduled June 2016



# Existing Topical Portfolio



Estradiol

# Existing Topical Portfolio

## Estradiol spray approved in Europe

- Initial European regulatory approvals granted
- US\$2 million milestones received
- First product launches scheduled from Q1, 2016
- Topical estrogen-only HRT market is valued at over EURO 85 million

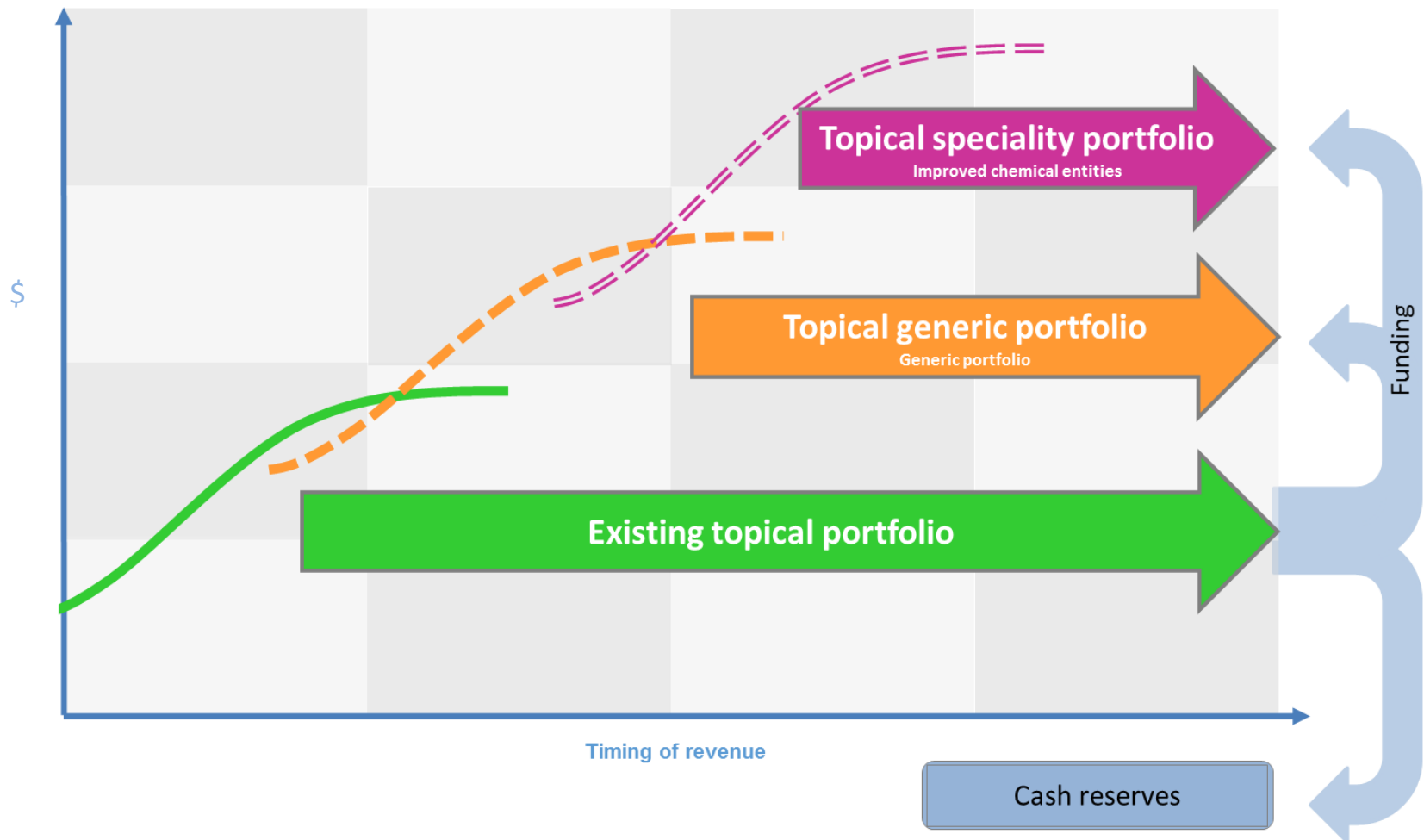


# Growth Strategy

## Framework for continued growth

### Topical generic portfolio

- New portfolio opportunities
- Leverage existing topical and transdermal capabilities
- Lower development costs, lower return however quicker time to market than topical specialty portfolio



# Topical Generic Portfolio



- New portfolio being built, developing topical generic products in commercially attractive markets
- Reduced development timeframes compared to topical speciality portfolio
- Generic development opportunities identified through screen of marketed topical/transdermal products
- Initial portfolio of 12 potential products identified, development has been initiated. Current market value US\$2.4 billion
- Building portfolio of topical generic programs with sustainable returns

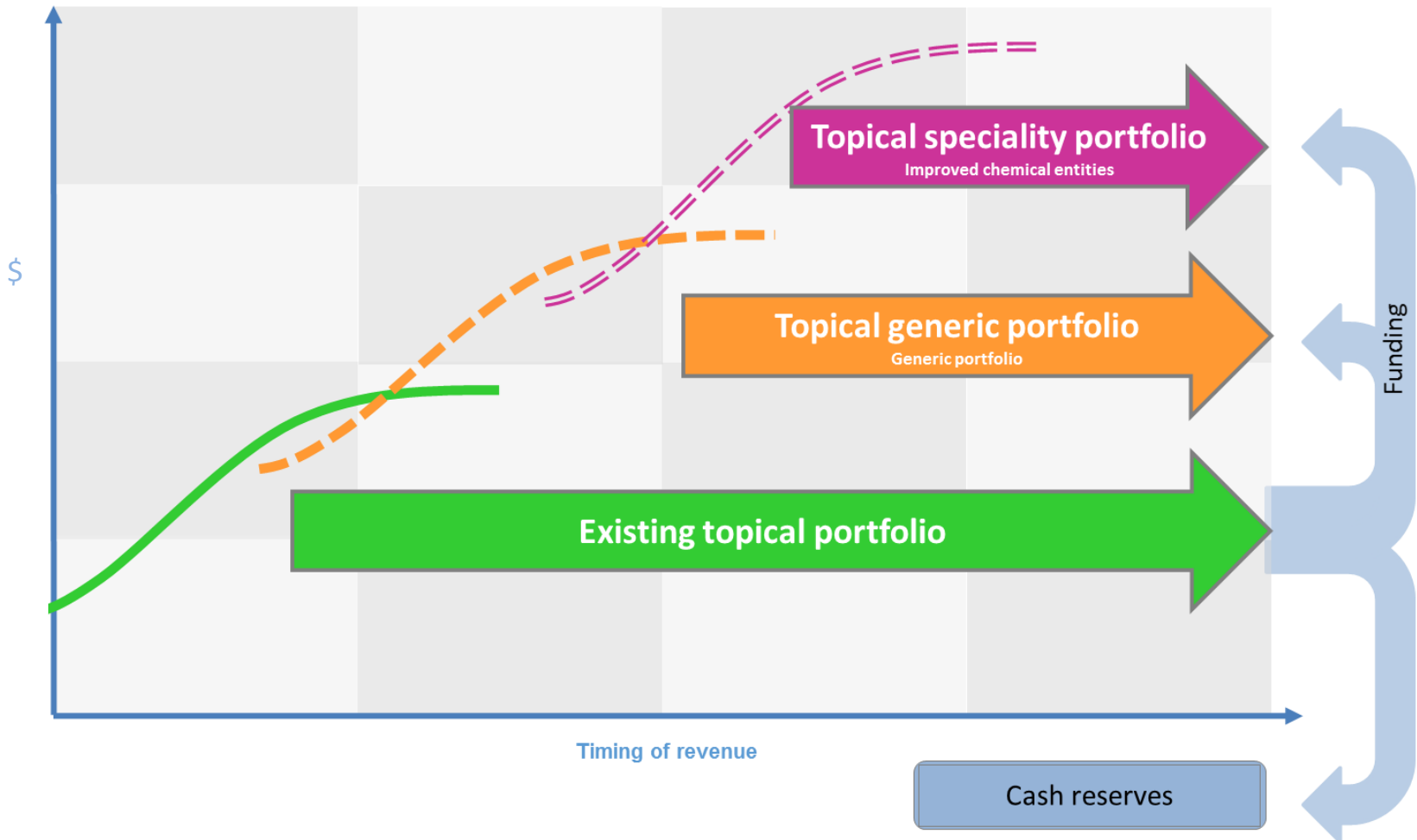
**Our topical generic pipeline is commercially compelling**

# Growth Strategy

## Framework for continued growth

### Topical specialty portfolio

- Patent protected development
- Leverage existing topical capabilities
- Higher development costs & greater return however longer time to market than generics, shorter than new chemical entities



# Topical Specialty Portfolio

## Acrux Antifungal Proposition



### Acrux antifungal development

#### Indication

For treatment of onychomycosis in toenails and fingernails

#### Formulation

Solution for topical administration

#### Target profile

- Fast drying time with no residue
- Easy and convenient delivery
- Better efficacy than comparator product
- Once daily application
- Low systemic absorption
- Long patent life, with new IP

**Acrux is targeting best in class efficacy in an attractive growing market**

# Topical Specialty Portfolio

## Acrux diclofenac and ibuprofen (NSAID) formulations



Acrux non steroidal anti-inflammatory development

### Indication

For fast local relief of acute joint pain caused by sprains, strains and sports injuries

### Formulation

Solution for topical administration

### Target profile

- Superior delivery profile
- Fast drying time with no residue
- Better efficacy than comparator product
- Low systemic absorption
- Long patent life

**Acrux spray and gel formulations have shown substantially superior permeation profiles to leading approved comparator products**

# Growth Strategy Product Pipeline



	Indication	Product Name	Formulation design	Pre-clinical development	Phase 1	Phase 2	Phase 3	Registration	Commercial	Partner
Existing Topical Portfolio	Hypogonadism	Axiron®								Eli Lilly
	Menopausal symptoms	Estradiol MDTS® USA – Evamist®								Perrigo
	Post-operative pain in dogs	Recuvyra®								Elanco
Topical Speciality Portfolio	Menopausal symptoms	Estradiol MDTS® Europe – Lenzetto®								Gedeon Richter
	Onychomycosis	ACR-065								
	Diclofenac	ACR-046								
	Ibuprofen	ACR-048								
Topical Generics Portfolio	Various	Initial generic portfolio*								

\* Development work has started on 3 generic products





# Summary



1. Acrux is investing to support future growth, leveraging our current capabilities
2. Acrux has increased its focus on internally developed product candidates utilising Acrux technology and know how
3. After considering its near term development expenditure, Acrux declared a 6 cent per share dividend

# Formal Business: Ross Dobinson

## *Non-Executive Chairman*



## RESOLUTION 1

### Adoption of Remuneration Report

*Proxy votes received prior to the meeting are as follows:*

For	41.9 m votes	85.4% of available votes
Open	6.3 m votes	12.9% of available votes
Against	0.8 m votes	1.7% of available votes

## RESOLUTION 2

### Re-election of Bruce Parncutt as Director

*Proxy votes received prior to the meeting are as follows:*

For	38.9 m votes	79.2% of available votes
Open	6.4 m votes	13.1% of available votes
Against	3.8 m votes	7.7% of available votes

## RESOLUTION 3

### Employee Share Option Plan

*Proxy votes received prior to the meeting are as follows:*

For	29.1 m votes	59.3% of available votes
Open	6.4 m votes	13.1% of available votes
Against	13.5 m votes	27.6% of available votes



AGM Script – 17 November, 2015

**Ross Dobinson** – Non-Executive Chairman

## **Welcome**

Good afternoon ladies and gentlemen. My name is Ross Dobinson, and I'm the Non-Executive Chairman of Acrux Limited. Before we commence proceedings could I ask that you turn off your mobile phones for the duration of the meeting.

It is my pleasure to welcome shareholders to the 2015 Acrux Annual General Meeting. We would like to thank Pitcher Partners for the use of their facilities today.

The time is now 2.00 pm and as there is a quorum of members present, I formally declare the Meeting open.

I would like to introduce my colleagues:

My fellow Board members

- Our Chief Executive Officer and Managing Director Michael Kotsanis,
- Non-Executive Director – Tim Oldham,
- Non-Executive Director – Bruce Parncutt,

and also our CFO & Company Secretary - Sharon Papworth.

Before we proceed to the formal business of the meeting I would like to provide a brief overview of progress since the last AGM before introducing Michael to give a more detailed presentation and commentary on progress with the implementation of our growth strategy for the Company.

I am pleased to confirm that the testosterone market appears to have stabilised, following the disruption to the market following the FDA's Drug Safety Communication in January last year. The FDA subsequently initiated a requirement for amended labelling of these products on the 15<sup>th</sup> May this year, specifying that the therapies are only approved for men with low testosterone levels caused by certain medical conditions. As a consequence of the FDA's Drug Safety Communication issuance, prescription of male testosterone therapies has

been curtailed, with testing of blood testosterone levels recommended prior to prescription of the products. The effect of the FDA's recommendations is that prescription patterns of the relevant products have altered. One of the consequences of these changes is that endocrinologists and urologists are playing a more prominent role in prescriptions than they had previously, with a concomitant reduction in the role played by primary care practitioners.

These changes have had a material impact on the distribution and marketing for Axiron. Growth in the market is no longer driven by direct to consumer marketing and the sales force for the product has been restructured accordingly. The changes resulting from the FDA actions have consistently driven sales volumes down since the FDA's Drug Safety Communication was first announced, but during the last quarter there has been an increase in sales value, resulting in a 28% improvement on the previous quarter. While the sales figure is driven by a range of factors, we believe that the current trend is the first indication of market consolidation since the Drug Safety Communication was released. This is encouraging and timely, given our program for product diversification, which is designed to reduce our almost sole reliance on the revenue stream from Axiron.

Having noted that, since the launch of Axiron, Acrux has had strong cashflows from milestones and royalties derived from Axiron sales. This has enabled the Company to maintain a consistently strong dividend stream, keep a strong balance sheet and to consistently invest in research and development to broaden our product base. The expenditure over the last two years in onychomycosis is indicative of our commitment to broadening our product base. We have not capitalised any of our research and development expenditure, despite making good headway with the onychomycosis project and improving our intellectual property position.

As noted at last year's AGM, following the changes in the regulatory requirements for testosterone products, the Company has intensified its focus on broadening our product portfolio to provide scope for capital growth and diversification of revenue streams. During the year Acrux made significant progress in identifying a range of complementary products that could benefit from the application of Acrux's delivery technology. The formal screening and



project development mechanism that was described to shareholders at the last AGM has generated a number of product opportunities which are now in development phase. Several of these opportunities will be covered in some detail in Michael's presentation.

These development opportunities are based on Acrux leveraging its key strengths of formulation infrastructure, expertise and know-how, intellectual property, and human capital. While we have had a small increase in staff to accelerate the development of these candidates, we are continuing development in the topical drug delivery area, where we have expertise and the development risk associated with the candidates is low relative to the risks associated with developing new chemical entities.

As I mentioned, we have made significant progress with the onychomycosis project which has been described to shareholders previously. We are now accelerating the development work on the project, which has very significant commercial potential. We have been developing candidates that have no commonality with the candidate we have previously worked on with Hexima Limited and we are very pleased with progress achieved to date.

The Board is confident that the Company is now well positioned to generate a significantly improved product suite with a relatively low development risk and material commercial potential, while concurrently progressing our high value development project for onychomycosis.

Michael's appointment as CEO has been timely, given his extensive background in the commercialisation of generics and recent internal innovation in Acrux's drug delivery platform. While there has been constant assessment of alternative development projects since the development of Axiron, the generics portfolio described today represents the best prospect in terms of risk/reward that we have identified in over a decade. We are optimistic about the prospects for our onychomycosis project. The project is still potentially high value with relatively low development risk as we are focussed on an improved delivery method for currently registered molecules. This provides the project with some similarities to the generic product candidates, albeit with a longer time and higher

development costs, but both initiatives are far removed from the development profile of new chemical entities and we are able to leverage our technology platform efficiently.

Material expenditure on these development initiatives will only be incurred when there is a high level of confidence in the development path for the product candidates. It is important to reference our history in product development – we have successfully developed both estradiol and testosterone products. Other product development candidates have been worked on over the last decade but major development expenditure has not been incurred when the prospects for commercial success have not warranted the expenditure. We are continuing to work to our strengths – our focus is on leveraging our key capabilities and intellectual property and knowhow through improved delivery systems for recognised pharmaceuticals. We are not generating new chemical entities which have high development costs, long time frames for development and very high risk profiles.

Michael will provide more detail of our strategy in his presentation.

**Michael Kotsanis** – CEO and Managing Director

Slide 3

Thank you Ross.

Good afternoon, everyone. And thank you for joining us at the 2015 Annual General Meeting. Presenting with me and sitting on my left is Sharon Papworth, Chief Financial Officer and Company Secretary.

Slide 4

I would like to formally advise on our Forward Looking Statement caveat by stating that....

*...This presentation includes forward-looking statements that are subject to risks and uncertainties. Such statements involve known and unknown risks and important factors that may cause the actual results, performance or achievements of Acrux to be materially different from the statements in this presentation.*

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

#### Slide 5

I hope that you all have had a chance to review the Company's Annual Report that we issued 4 weeks ago and I would encourage investors and shareholders to review this for full details of our Company's operational results and activities.

We will start with the review of our recent accomplishments as well as actions we've taken to create value and further sharpen our focus on our development opportunities. We will follow that with the highlights of our 2015 financial results and then a detailed review of our strategy. After our prepared remarks, we'll look forward to taking your questions.

Acrux, amongst Australian listed biotech companies, is in the enviable position of generating significant income from its commercial products.

For the year to 30 June 2015, Net Revenue was \$25.4 million and net profit was 11.1 million, which is our sixth consecutive profitable year.

As can be seen the company is presently able to very comfortably fund its R&D and general and administrative expenditures from its royalty income stream leaving a balance of income and cash flow available for distribution to shareholders via a dividend.

In addition to this very comfortable cash flow position, the company continues to hold significant cash reserves, which at the end of the year were \$23.1 million.

As the current R&D pipeline generates candidates for further development, the company expects to have the option of funding this from either cash reserves or cash flow. Such future funding decisions will depend on the scale and merits of the opportunities the current R&D might generate and the Board's assessment of the best interests of shareholders in this context.

Around the middle of the calendar year we received the good news that our partner, Gedeon Richter, began to receive approvals for our estradiol spray in Europe. The first three of these approvals triggered milestones totalling US\$2 million, which was invoiced and has been received in the current 2016 financial year.

We have also made solid progress in addressing the near-term strategic priorities that we believe will enable us to achieve our objective of broadening our product portfolio. Firstly, we have identified a portfolio of generic topical and transdermal product opportunities which are financially attractive projects. Secondly, our formulations of several non-steroidal anti-inflammatory drugs showed superior permeation results to market leading products. I will share more detail on these projects later in the presentation.

And as Ross mentioned, after considering our positive cash balance, expected cash inflows and expected development spend for 2015 and 2016, we were pleased to announce a final dividend for the 2015 financial year of 6 cents per share.

With our September dividend payment of 6 cents, the total capital that has been paid to shareholders over the past five years is \$1.02 per share.

Slide 6

I will now hand over to Sharon to summarise the financial results for last year.

**Sharon Papworth** - CFO & Company Secretary

Thanks, Michael.

Slide 7

I would like to add my welcome to our 2015 Annual General Meeting. Today I will provide a summary of our financial results for the year ended 30 June 2015 and will also provide an update on the Company's outlook.

As Michael highlighted, our financial position is strong. We continue to generate profits, have solid cash inflows from our commercialised product portfolio and continue to maintain a healthy balance sheet.

Our net profit after tax was \$11.1 million for the 2015 financial year with earnings of 6.7 cents per share. Revenue for the year was \$25.4 million, which primarily comprises royalties and interest received on cash holdings. Royalty income totalled \$24.6 million, compared to \$24.7 million in the prior year. The vast majority of our royalty income is derived from sales of Axiron by our licensee Eli Lilly, which were US\$155.4 million. Although US denominated royalty income from Axiron declined 14% over the financial year, the impact was offset by changes in foreign exchange rates.

Interest income improved marginally to \$600k for the year and we continue to actively manage our cash investments through term deposits.

Turning to our operating cost base, our total expenditure, including non-cash costs and the royalty paid to Monash University declined 14% relative to last year to \$8.6 million. The two key drivers of this favourable result were lower Monash royalties payable on lower income and a foreign exchange loss of \$1.2 million realised during the 2014 year. Our cost base is well controlled and we remain committed to maintaining this low operating cost model.

Finally, the effective tax rate for accounting purposes for the 2015 year is 33.8%, which is clearly higher than the standard company tax rate of 30%. This is largely due to expenses incurred which are non-deductible for tax purposes and the fact that we are a Pooled Development Fund ('PDF') and as a result we are unable to consolidate at a group level for tax purposes. As you are aware, there are obvious tax advantages to our shareholders resulting from our PDF status.

When compared to last year, our net profit after tax is down by \$16.9 million. The reduction in earnings is largely explained by the receipt in the previous year of two one-off milestones. Firstly, US\$25 million was received upon Axiron sales exceeding US\$100 million for the 2013 calendar year and secondly, US\$0.6 million was received from Gedeon Richter following their regulatory filing for Acrux's estradiol spray in Europe.

#### Slide 8

Our cash flow is strong. We continue to actively manage our existing product portfolio through licensees, providing an income stream to execute our strategy.

The vast majority of cash inflows were received from royalties on product sales. During the 2015 financial year, royalties of \$25.2 million were received. The Company pays royalties to Monash investment trust which are calculated as a percentage of royalty income. Last year, payments to Monash University totalled \$0.9 million.

In addition, we also received cash inflow from other sources, largely interest on cash investments.

Net income received from these activities totalled \$25.1 million and provided sufficient funds to meet all financial obligations.

The company has allocated its cash disbursements into 3 main segments. Firstly, payment of tax on net income. Tax payments of \$8.9 million were made during the 2015 financial year.

Secondly, cash operating costs including research and development were \$5.5 million last year. This includes maintenance of our laboratory, staff costs, preclinical activities, rent and other operational expenditure. During the year, we strengthened our development capability and preclinical capacity which will enable us to achieve our longer term development objectives. As a result, cash operating costs have increased 10% when compared to the 2014 year.

Thirdly, the Company paid a dividend of \$13.3 million during the financial year ended 30 June 2015.

The receipt and allocation of cashflows resulted in a year-end cash balance of \$23.1 million.

#### Slide 9

Looking forward, we will continue to utilise the cash generated from our commercialised products to invest in future growth. Acrux will continue to rely on royalties predominantly from Axiron until such time as other products are capable of generating commercial returns. Axiron prescription volumes are consistent in the context of the last three quarters ended March, June and September 2015. Earlier this year we announced the registration of Lenzetto (which is the brand name for our estradiol spray) in Europe. This event triggered a single milestone payment of US\$2 million which we received during the first quarter of the 2016 financial year. No other milestone receipts are expected during the year ahead.

At this stage there is no anticipated increase in preclinical costs over the next 12 months and we expect 2016 cash operating costs to be broadly consistent with the 2015 financial year. It is highly likely that our cash needs will change when we progress to clinical development of our targeted products. We will update the market and provide further details of commercialisation initiatives when this occurs.

In closing, I would like to summarise our financial achievements for the 2015 year. Firstly, Acrux generated a net profit after tax of \$11.1 million – our 6<sup>th</sup> consecutive profitable year. Secondly, Acrux continues to hold a strong balance sheet with no loans and cash reserves totalling \$23.1 million at year-end. Thirdly, Acrux was able to return a 6 cent dividend to shareholders, based on 2015 financial year earnings of 6.7 cents per share. And last, but certainly not least, we have considered both the risks and growth opportunities for the business and are implementing strategies that will diversify our product portfolio. We recognise that not all preclinical programs result in a commercialised product, but our approach is lower risk and should enable the Company to rapidly progress a diversification of our product offerings through leveraging our core competencies.

Slide 9

Now let me return to Michael.

**Michael Kotsanis** – CEO and Managing Director

Slide 10

Thanks Sharon.

Slide 11

I will spend the next part of the presentation describing our growth strategy.



## Slide 12

With volumes of Axiron having plateaued recently after last year's decline in sales, we are focussed on moving new development opportunities through our pipeline ultimately towards commercialisation in order to further grow our Company. Our focus to-date has been on lower risk development opportunities. To explain that in a little more detail, we believe that we can leverage and utilise our core existing transdermal technology competencies, intellectual property and knowhow on a number of new product development candidates. We can apply this to known marketed drugs in attractive market segments. This is a safer alternative than focusing on riskier research activities on new chemical entities. We believe that this is a better way to utilise our cash and manage the development risks that are inherent in the biotech industry. Our goals are to move our development projects into clinical trials and over time to develop a portfolio with multiple products in various development stages, leading to partnerships and licensing deals and ultimately further commercial success through milestones and royalties.

## Slide 13

We frame our portfolio into three categories. The existing topical portfolio as shown by the lower green arrow, the topical generic business, as shown in orange and the topical specialty portfolio as shown in purple. The slide reflects the framework for company growth based on these 3 categories versus the expected relative timing of revenue contribution.

The existing topical portfolio, highlighted in green, is cash flow positive. Whilst we maintain a high level of commercial focus on this portfolio, our development work is complete. This portfolio incorporates Acrux products that are on the market and commercialised by our partners, which includes Axiron in a number of countries, Evamist in the US and in Q1 2016, Lenzetto in Europe.

The cash generated from our existing topical portfolio of products is selectively used to fund projects in our topical generic and topical specialty pipelines. Excess cash over the needs of our pipelines contributes to our cash reserves.

#### Slide 14

Turning to our most important product – Axiron.

#### Slide 15

Sales in the US of Axiron - the major market for testosterone replacement therapies – declined in the 2014 calendar year. The interest of the FDA and other national regulatory groups in the safety of the testosterone class has been well documented and discussed previously. The sales decline in 2014 in the US was slightly offset by growth outside the US and of course the royalty paid to Acrux is converted from US dollars to Australian dollars, with the recent decline in the exchange rate helping our year on year royalties remain consistent.

By mid-2016 we expect the US sponsors of testosterone replacement therapies, including our licensee Lilly, to have agreed a protocol collectively with the FDA for the long term assessment of safety of testosterone replacement therapy. The results of this trial will take some years to be known. Following the FDA Drug Safety Communication in March this year, we have seen Axiron sales volumes stabilise after the declines we saw during 2014. Market share has been consistent for quite some time now. Volumes to date in 2015 have been higher than many people anticipated, which is encouraging.

#### Slide 16

Recently we announced that Lilly and Acrux have sued a number of generic companies for potential infringement of the patents protecting Axiron in the US.

As a reminder, Axiron is protected by a number of granted patents, including for the formulation of testosterone, for the underarm site of application (axilla), and for the applicator by which Axiron is applied to the skin. There are now 4 parties that have been sued – Actavis, Perrigo, Amneal and Lupin. The trial will be held in June 2016 and the decision will be known and communicated roughly three months after the trial.

#### Slide 17

Turning to the recent approval for our estradiol spray in various European markets. The brand that will be used in Europe will be Lenzetto.

#### Slide 18

We were very pleased a few months ago to announce the first regulatory approvals in Europe for Lenzetto. Based on 2014 IMS sales data, the European market for hormone replacement therapy for all dosage forms is significant, with the topical estrogen-only HRT market, including Russia, generating annual sales of over EUR 85 million. We have received the contractual milestones of US\$2 million at a favourable exchange rate and we look forward to the first wave of launches of Lenzetto by our licensee Gedeon Richter in the first quarter of calendar year 2016. Gedeon Richter is a large and well known European pharmaceutical company with a strong heritage in women's health.

In the United States, Perrigo has now assumed sales and marketing responsibilities from earlier this year. With their marketing efforts that we have seen, we are confident that we will see an uptick in their sales results in coming quarters.

#### Slide 19

The second group of products depicted in our portfolio incorporates our topical generic portfolio.

#### Slide 20

We are enthusiastic about the prospects for this new group of projects which generally have a shorter development horizon resulting in a faster filing of a regulatory dossier than the improved chemical entities in the topical specialty portfolio. We expect the initial commercial milestones from these products in 2019. We have identified and begun working on this series of generic topical and transdermal products. The initial portfolio that we identified of 12 products has a combined local market value in the markets we will target of US\$2.4 billion, based on current industry sales data. Each of these products we are targeting is an existing topical or transdermal product and each represents an attractive and solid opportunity. We are utilising our existing development skills and technology base to exploit these opportunities and we will develop these opportunities sequentially. For competitive reasons and as is consistent with industry practice for generics, we have not publicly identified these target molecules at this point.

#### Slide 21

And in our third group are our topical specialty projects. These are our most valuable franchise projects. These projects take longer to develop than generics due to the clinical trial programs which are required to support a regulatory application. They will leverage either existing or new intellectual property and usually enjoy a longer term sales horizon than in the topical generic portfolio.

## Slide 22

The most important project in the topical specialty portfolio is our antifungal project. We have continued to move forward on this project which is targeting fungal infection of the nail bed in toes and fingers. This is also known medically as onychomycosis. Our development efforts have been focussed on assessing different known active drugs and the permeation of those drugs through the nail. So far we have achieved excellent nail penetration with different formulations of existing antifungals in our proprietary penetration model, and we continue to focus on optimising our formulations in line with our assessment of the IP landscape. We are taking a disciplined approach. Only when we are satisfied with our intellectual property position, product formulation and the resulting permeation results will we move into the clinical development phase. To assess the IP landscape we have local and US IP experts providing us with advice.

A key reason for our interest in the onychomycosis market is the growth in the market for onychomycosis, especially in the United States where after many years of little innovation, two new topical antifungals products were approved and launched for onychomycosis. Independent forecasts for the onychomycosis market indicate that this market will grow to US\$3.7 billion in sales by 2017. This is despite the new and existing topical treatment options showing limited complete cure results in clinical trials. We are targeting this market aiming for a best in class therapeutic option.

## Slide 23

We have developed formulations of two different non-steroidal anti-inflammatory drugs, which are also known as NSAIDs. For diclofenac, we have shown a similar permeation profile when compared to existing approved and commercialised products but with a much lower dose.

We have shown an improved profile of a different NSAID – ibuprofen. When we compared our formulation to a marketed formulation of ibuprofen, we saw a faster onset of action demonstrated by faster permeation through full thickness human skin as well as a higher peak permeation.

Both ibuprofen and diclofenac are well known drugs. For both we have shown we are able to develop efficient formulations. Importantly, the formulations we have developed fall within our more recent IP developed by Acrux.

For both products we have decided to assess the attractiveness of early partnering of these formulations rather than continuing to further develop these products.

#### Slide 24

Combining these projects into our pipeline slide, our focus is clearly on adding commercial value through the formulation and development of these projects and moving them through clinical trials. Commercial value will be added progressively with first commercial events from our pipeline expected in 2019.

#### Slide 25

Finally, during the year we expanded our leadership team through the appointment of Felicia Colagrande to head our R&D team. Felicia has been with Acrux for many years and is thoroughly familiar with our technology and the company. In addition we welcomed to the Acrux team Charlie O'Sullivan to run our portfolio selection and management process. Charlie joins us with solid pharmaceutical industry experience and is a qualified and experienced hospital pharmacist as well. Along with other new appointments in our organisation, we have refreshed and strengthened our team and positioned our organisation well for the development opportunities we are focussed on moving into clinical trials.

Before I hand back to the Chairman and we start the question-and-answer period of our AGM, I would like to close with a few brief thoughts.

The new management team has been progressively put in place over the past 12 months. A significant proportion of employees are new to the company or are in new roles within the company. We have had the opportunity to review our

business, meet with partners and assess clear strategies to diversify and grow our business.

First, we are investing to support future organic growth. As we've detailed in today's presentation, we have a profitable and cash-flow positive underlying business within Acrux and we have a disciplined approach to supporting the current commercial products and well planned development projects within our business. Second, we continue to increase organisational focus on our product development portfolios and are focussed on the compelling projects within our pipeline.

Third, we have returned cash in excess of our short term needs to shareholders through the payment of a 6 cent per share fully franked dividend in September.

With that I will hand over to Ross to chair the remainder of the meeting and our question-and-answer period.

Slide 26

**Ross Dobinson** – Non-Executive Chairman

This concludes the operational reports and we will now proceed to the formal business of the meeting. I will take the Notice of the Meeting, including Explanatory Notes, and the Financial Report, the Directors' Report and Auditor's Report as read.

Shareholders should be aware that the Company has received proxies representing over 6 million shares for each of the resolutions. Details of these proxies will be provided in the overhead slides prior to each resolution being put to the meeting. If you wish to speak to a motion or ask a question, please raise your hand. When you have been acknowledged, please identify yourself before speaking and I would ask that you only raise one topic at a time. If a poll is required on any resolution, it will be held at the appropriate time.

The Notice of Meeting was mailed to all registered members on the 14<sup>th</sup> of October. I will take the Notice of Meeting, including Explanatory Notes and the Financial Report, the Directors' Report and the Auditors' Report as read.

**Item 1 - To receive and consider the Financial Report, and the Reports of the Directors and Auditor for the year ended 30 June 2015**

The first item of business is to receive and consider the Financial Report and the Reports of the Directors and Auditor for the year ended 30 June 2015.

This item of business does not require a resolution to be put to the meeting and so I will not be calling for mover or seconder.

I will now open this item for discussion. Would anyone like to address any questions to the Company or to representatives of Pitcher Partners, the Company's Auditor, who are present at this meeting?

**Item 2 – Adoption of the Company's Remuneration Report**

The *Corporations Act* requires the Directors' Report to include certain information relating to director and executive remuneration in a "Remuneration Report".

The *Corporations Act* further requires that each Australian listed public company put to a vote at its annual general meeting a resolution that the Remuneration Report be adopted. The vote is advisory only and does not bind the Directors of the Company.

The Remuneration Report can be found at pages 30 to 34 of the Company's 2015 Annual Report. I note that a vote must not be cast on this resolution by or on behalf of a member of the Company's key management personnel, details of whose remuneration are included in the Remuneration Report, and their closely related parties, unless the vote is cast as a proxy in accordance with the directions contained in the proxy and the vote is not cast on behalf of a member of the key management personnel or their closely related parties. As a member of the key management personnel of the Company, I am not permitted to cast



any votes in respect of this resolution that arise from any undirected proxy in accordance with the direction contained in the proxy.

Accordingly I move:

*That the Company's Remuneration Report for the year ended 30 June 2015 be adopted.*

Are there any questions or comments in relation to the Remuneration Report?

If there are no (further) questions or comments, you will now see on the screen the proxy votes in relation to this resolution.

I now put the resolution.

All those in favour?

All those against?

I declare the resolution passed.

### **Item 3 – Re-election of Bruce Parncutt as a Director**

The next resolution relates to the proposed re-election of Bruce Parncutt to the board. Bruce was appointed as a Non-Executive Director of the Company on 30 April 2012. The resolution is confirming his re-election by the Board.

Accordingly I move:

*That Bruce Parncutt, who in accordance with clause 56 of the Company's constitution offers himself for re-election as a Director, be re-elected as a Director of the Company.*

Are there any questions or comments in relation to the resolution?

If there are no (further) questions or comments, you will now see on the screen the proxy votes in relation to this resolution. I also wish to inform the meeting that I intend to vote any undirected proxies in favour of this resolution.

I now put the resolution.

All those in favour?

All those against?

#### **Item 4 – Grant of Options to Employees**

The Board resolved to grant options to Employees under the Employee Share Option Plan (ESOP). The Plan provides for the issue of up to 2.4M Options (1.44% of Company shares) over 3 years, granted in 3 tranches of up to 0.8M per annum. The share price for each tranche at grant will be determined based on a 30 (calendar) day volume weighted average price (VWAP) up to and including the date of grant. The exercise price will be calculated based on a 15% premium to the face value at grant for each tranche. Options will vest 12 months post grant, providing the following performance conditions are achieved: Firstly the eligible employee continues to be employed by the Company. Secondly, Total Shareholder Return for the Company exceeds its peer group, measured on the first anniversary post tranche grant date. The Company is now seeking member approval to the grant of the Options under Listing Rule 10.14.

Accordingly I move:

*That approval is given for the grant of Options to Employees under the Company's Employee Share Option Plan as referred to in the Notice of Meeting and previously described.*

Are there any questions or comments in relation to this resolution?

If there are no (further) questions, you will now see on the screen the proxy votes in relation to this resolution.

I note that a vote must not be cast on this resolution by or on behalf of a member of the Company's key management personnel, details of whose remuneration are included in the Remuneration Report of the Company, and their closely related parties, unless the vote is cast as a proxy in accordance with the directions contained in the proxy and the vote is not cast on behalf of a member of the key management personnel or their closely related parties.

As a member of the key management personnel of the Company, I am not permitted to cast any votes in respect of this resolution that arise from any undirected proxy. I will, however, vote any directed proxy in accordance with the direction contained in the proxy.

I now put the resolution.

All those in favour?

All those against?

**Close of formal business**

As that concludes the formal business, I declare the meeting closed.

We will be happy to now take questions from the floor, or further discussion over coffee.