



ASX/Media Release

18 September 2018

Acrux investor presentation

Melbourne, Australia; 18 September 2018: Acrux Limited (ASX:ACR, “Acrux” or the “Company”) is pleased to release a new investor presentation.

Investment highlights

- Diverse portfolio of 13 topical generic products, with an addressable market of US\$1.4bn+
- First ANDA submission to the FDA for a generic version of Jublia® in June which was accepted for review in early August
- Multiple upcoming value catalysts, first revenues expected in 2019
- Topical market is worth ~US\$18b in the US alone
- Generic product development is faster and lower risk when compared to branded products

For more information, please contact:

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About Acrux

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

For further information on Acrux, visit www.acrux.com.au



**ACRUX
INVESTOR
PRESENTATION
(ASX: ACR)**

September 2018



INVESTMENT HIGHLIGHTS



High potential topical generic portfolio

- **13 products** in the generic topical portfolio, up from **7** in October 2017
- Addressable market of pipeline assets is **>US\$1.4bn**



Delivering on strategy

- **Strong execution building the topical generic pipeline since 2015, submitting first product in 2018**
- First submission to FDA in June, with acceptance for review in August, **in line with guidance**



Attractive \$18bn market

- Generic products have **low development risk** and are typically **faster to develop** than branded products
- Topical generic market in the US alone worth **~US\$18bn**
- Generic manufacturers typically achieve **excellent EBITDA margins (+25%)**



Multiple value catalysts

- **First revenues expected in calendar year 2019**
- Multiple new FDA ANDA submissions in **FY19** and beyond



Commercialisation in progress

- Generic pharma companies place high value on generic portfolios
- Licensing interest received from several parties

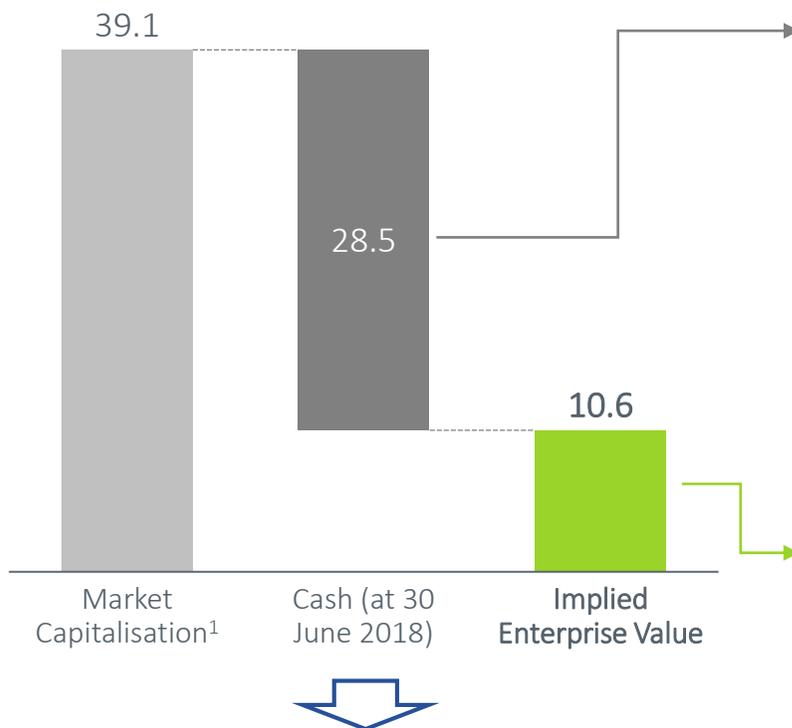


Enterprise value of <\$11m

- Cash balance of \$28.5m at 30 June 2018
- Current market cap. of \$39.1m as at 14 September 2018
- Implied enterprise value of \$10.6m

HIGH VALUE PIPELINE OF 13 PRODUCTS – IMPLIED ENTERPRISE VALUE OF <\$11M

Implied enterprise value breakdown (A\$m)



With \$28.5m cash as at 30 June, management reasonably expects there to be sufficient funding to progress the current pipeline through to launch

- Typical costs for commercialisation of a generic product between ~\$3-4m
- Typical time to develop a generic product is ~3 years

The Board is of the view that Acrux's topical generic portfolio is being undervalued by the market

Overview of Acrux's generic equivalent to Jublia®² (1 of 13 products)

- Accepted for review by the FDA (announced August 2nd 2018)
- Management believe it will be granted shared 'First-to-File' status, granting it shared sales exclusivity for 180 days
- Historically, generic products with 'First-to-File' status rapidly achieve ~50%+ market share³
- Addressable market - annual sales of Jublia® are ~US\$280m⁴
- Based on past experience management believes that significant double digit royalty rates are achievable⁵
- Several parties have already expressed interest in licensing agreements

EV <\$11m despite pipeline of 13 drugs that has been developed over 3+ years

1. Market capitalisation as at 14 September 2018

2. Jublia® (efinaconazole) Topical Solution, 10% is a prescription antifungal medicine indicated for the topical treatment of onychomycosis of the toenail(s).

3. Citi Research – Generics Landscape Chart Pack (Jan 2017);

4. Twelve months sales to end March 2018 based on IQVIA (Quintiles and IMS Health) sales data;

5. Management estimates

OUR APPROACH

Acrux is developing a diversified portfolio of topically applied generic products



IDENTIFY

Market screening to identify high potential prescription topical products



165

identified molecules, each with >US\$10m in sales



DEVELOP

R&D team with highly specific topical expertise drive development



13

molecules in development



LAUNCH

1 product already under FDA review, with several related commercial partnering discussions ongoing

MULTIPLE ADVANTAGES FOR GENERIC PRESCRIPTION PRODUCT DEVELOPMENT

	Traditional development	Acrux's generic development portfolio
Market size 	A new drug may have a significant market opportunity, however...	Attractive market and licensee terms <ul style="list-style-type: none">• Market value of drugs in pipeline >US\$1.4bn• Future revenue derived from milestones and royalties
Speed 	...it takes ~10 years¹ to develop a new drug, involving multiple expensive trials...	Fast development and low cost <ul style="list-style-type: none">• ~3 years to submission from project initiation• ~\$3-4m (on average) to develop each generic
Risk 	...and typically less than 12% of drug candidates make it into Phase I clinical trials ¹	Lower risk than branded development <ul style="list-style-type: none">• Efficacy of drug has already been demonstrated

ACRUX IS MAKING EXCELLENT PROGRESS ACROSS ITS GENERIC TOPICAL PORTFOLIO

In FY19, Acrux intends to:

- ✓ Submit 2 additional dossiers to the FDA for review
- ✓ Scale up 6 projects from Acrux laboratory to CMOs¹
- ✓ Add additional products to the ACR generic portfolio



Acrux expects to generate first revenues from its generic portfolio in CY19

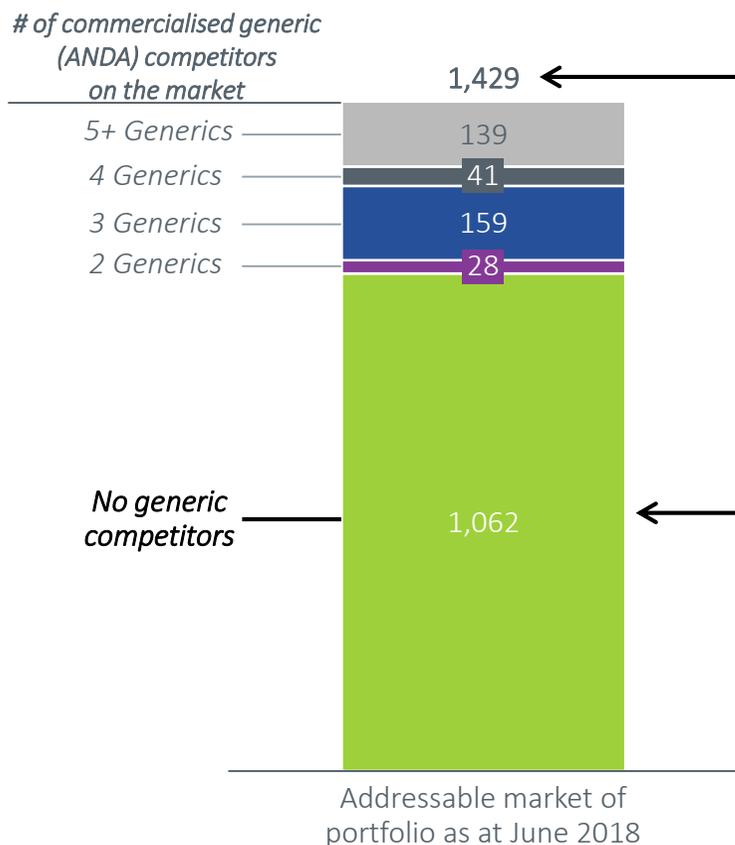
Overview of Acrux's current generic topical portfolio of 13 assets



Legend: Progress as at FY17 Progress during FY18

ACRUX PIPELINE REPRESENTS A LARGE MARKET WITH RELATIVELY LOW COMPETITION

Acrux topical generic pipeline addressable market value ¹ (\$USm)



Acrux's portfolio (13 products) is targeting a significant addressable market

- ✓ Addressable market of +US\$1.4 billion (based on 13 products currently in the Acrux topical generic pipeline)
- ✓ Portfolio has increased from 7 products and addressable market of +US\$1.0 billion in October 2017

Fewer generic products on the market creates favourable economics for Acrux

- ✓ Addressable market with no approved and commercialised generics exceeds US\$1bn
- ✓ FDA priority for review is given to applications with three or less approved generics
- ✓ Acrux expects to capture higher market share for products with lower competition and more than half of its portfolio has **no commercialised generics**

FIRST GENERIC TOPICAL PRODUCT TO REACH 'FDA REVIEW' IS TARGETING A ~US\$280m MARKET

What is Jublia®?



Jublia® (efinaconazole) Topical Solution, 10% is a prescription antifungal medicine used to treat fungal infections of the toenails (Onychomycosis)

Development timeline overview



Product and market highlights

US\$280m
addressable market²

~10%
of population affected³

First-to-File
180 days sales exclusivity on approval by FDA⁴

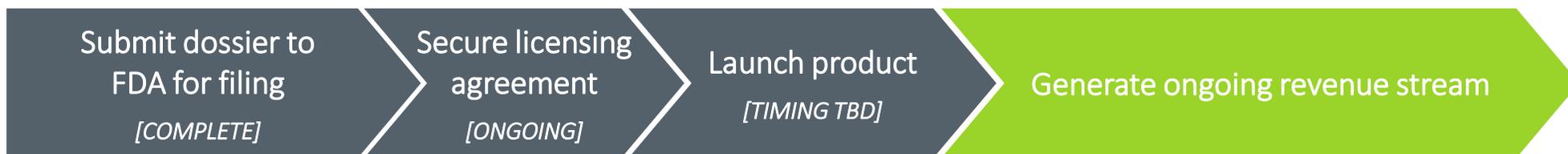
1. CMO: Contract Manufacturing Organisation

2. Twelve months sales to end March 2018 based on IQVIA (Quintiles and IMS Health) sales data

3. Westerberg DP, Voyack MJ (Dec 1, 2013). "Onychomycosis: current trends in diagnosis and treatment". American Family Physician. 88 (11): 762–70. PMID 24364524.

4. Market exclusivity is shared with any other companies that submitted a generic dossier (ANDA with Paragraph IV certification) on the same day with the FDA, and are also granted First-To-File Status

ILLUSTRATIVE VIEW OF COMMERCIALISATION PATH FOR ACRUX'S GENERIC VERSION OF JUBLIA®



- ✓ AcruX submitted dossier for review in June
- ✓ In August the FDA accepted the dossier for review
- ✓ AcruX believe the product will receive First-to-File status¹

Note: A number of other parties have also submitted dossiers to the FDA

- ✓ AcruX will seek to partner with a large generic company who will market and sell the product in the US
- ✓ Several parties already expressed interest in licensing agreements

- ✓ AcruX likely to undergo legal proceedings initiated by the current patent holder
- ✓ FDA target review period is less than 12 months. Following FDA review and Tentative Approval, Final Approval is linked to shorter of:
 - legal outcome
 - 30 month stay

- Market size is currently ~US\$280m p.a.²
- Historically, generic products with First-to-File status can rapidly achieve 50% market share³ (see slide 10)
- Royalty rates in the generic market are typically higher than branded pharma royalty rates⁴
- AcruX's ongoing costs upon Final Approval are expected to be minimal
- *Note: Revenues will also be impacted by the number of other generic companies that submitted dossiers for review and also receive First-to-File status (currently this number is not clear)*



AcruX is confident that it's generic version of Jublia® can generate a profitable revenue stream

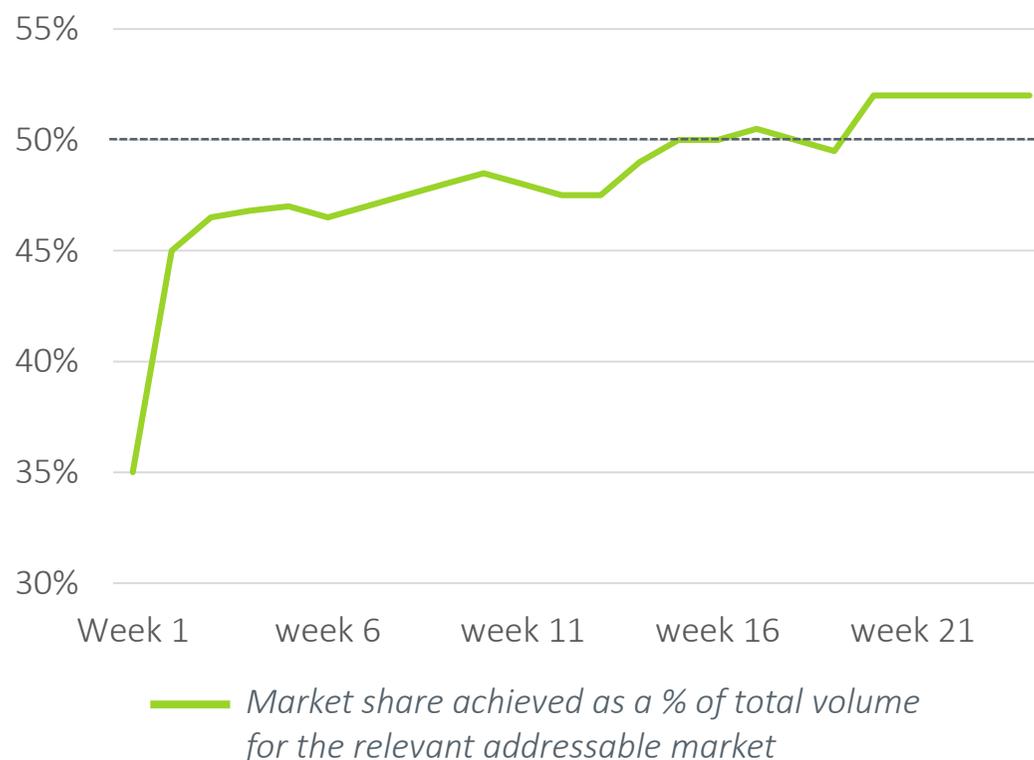
1. First-to-File status grants AcruX with 180 days exclusivity on approval by the FDA. First-to-file status and subsequent exclusivity period can be shared with other Paragraph IV ANDAs filed on same day
 2. Twelve months sales to end March 2018 based on IQVIA (Quintiles and IMS Health) sales data (US\$)
 3. Citi Research – Generics Landscape Chart Pack (Jan 2017);
 4. Management estimates

RAPID MARKET SHARE GAINS TYPICALLY ACHIEVED BY NEW GENERIC PRODUCTS

Acrux's generic version of Jublia® is expected to be granted First-to-File status and benefit from exclusivity

- ✓ Acrux is confident that if approved, it should be granted First-to-File status which would lead to 180 days of generic market exclusivity²
- ✓ Rapid market share gains are usually achieved during this exclusivity period
- ✓ Citi Research suggests that 50% market share is possible within weeks (see graph)

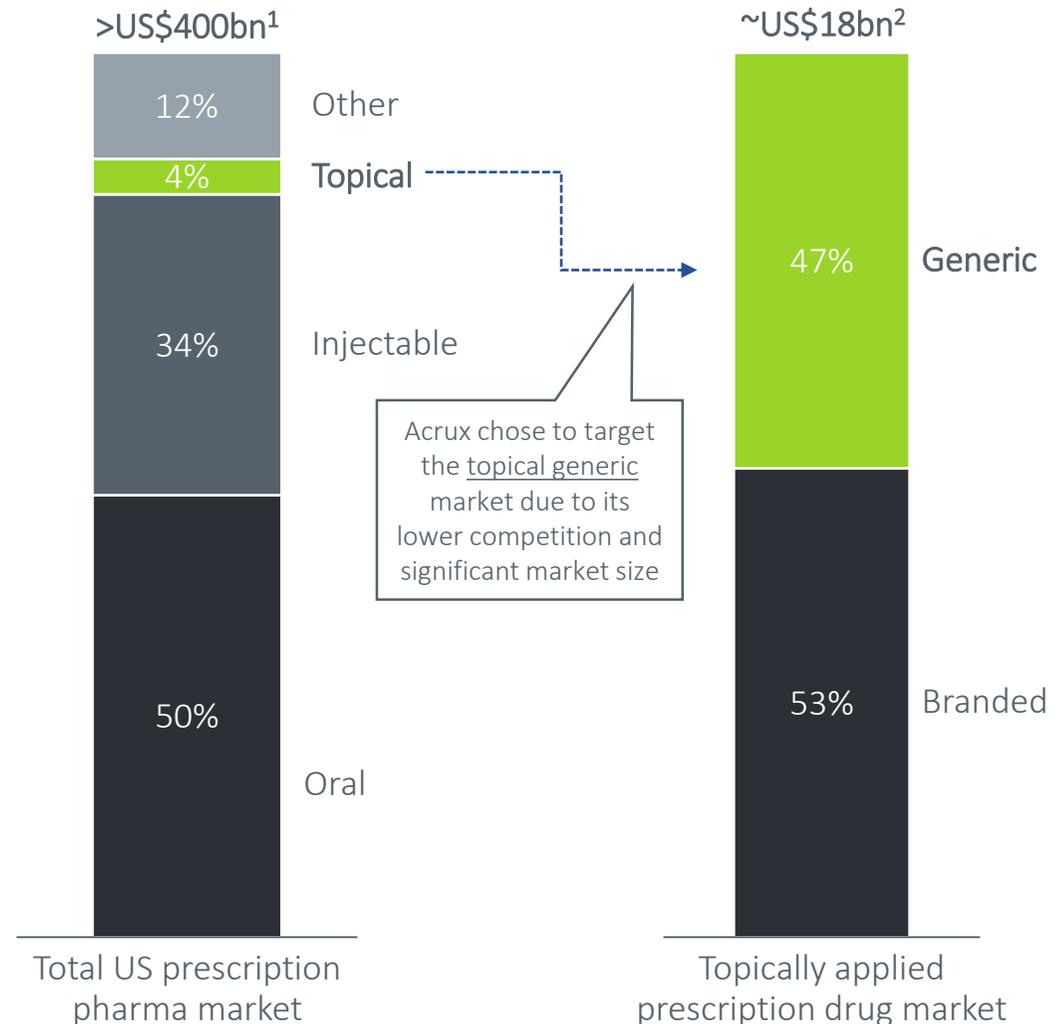
Generics with exclusivity reached a peak market share of >50%¹ on average during the exclusivity period



ACRUX IS OPERATING IN AN ATTRACTIVE US\$18bn MARKET

Topical generics represent an attractive and significant market opportunity

- ✓ US\$18bn market opportunity
- ✓ Currently, generics make up only 47% of the topical market, this is expected to grow
- ✓ Technical expertise required to develop and manufacture topicals as products can come in many different forms, **increasing barriers to entry**
- ✓ Acrux has established in-house development capabilities
- ✓ Generic manufacturers achieve excellent EBITDA margins (+25%)³

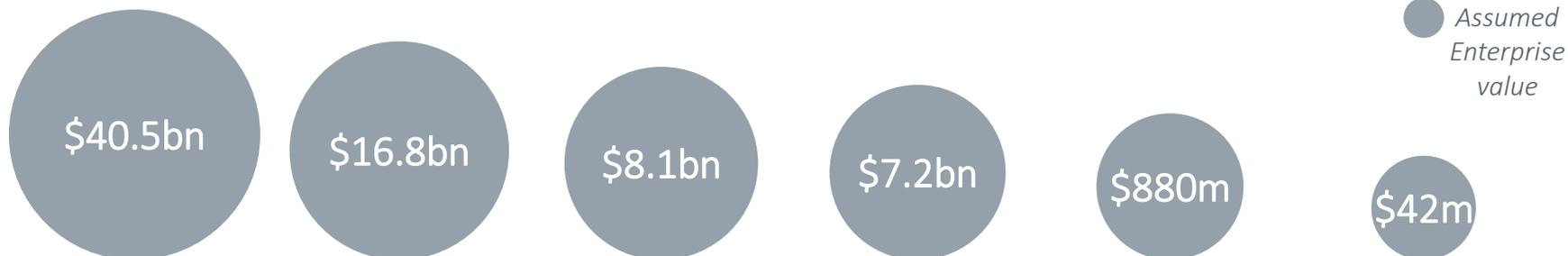


1. US market by dosage form, IQVIA Q2, 2015 MAT. US market sales (US\$)

2. Market size for topically applied drugs IQVIA Q3, 2017 MAT (US\$)

3. Citi Research – Generics Landscape Chart Pack (Jan 2017)

GLOBAL GENERIC COMPANIES PLACE HIGH VALUE ON GENERIC PRODUCTS AND GENERIC PORTFOLIOS



EBITDA multiple ¹	15x	20x	19x	13x	26x	Not released
Deal date	Aug 2016	Sep 2015	Sep 2015	Aug 2016	Jul 2015	May 2015
Target					 	
Acquirer						
Summary	Acquisition between two leading generics businesses with cost synergies and tax savings of approx. US\$1.4bn	Pfizer see acquisition as way to gain access to US\$70bn generic sterile injectables market via Hospira	Par Pharmaceutical was one of the fastest growing generics businesses at the time	Meda developed and manufactured branded, over-the-counter and generic drugs	Deal used to expand Lupin's presence in US generics market	Silarx manufactures liquid generic products. 4 ANDA's with FDA approvals pending

1. Enterprise values and multiples shown assume that the target's enterprise value is equal to the size of the transaction
 Source: Company releases; annual reports; literature review; Cogent Valuation Q3, 2017 Pharmaceuticals Generic Report
 Note: Analysis not exhaustive

EXPERIENCED MANAGEMENT TEAM WITH A PROVEN HISTORY OF MEETING OPERATIONAL MILESTONES

Management team



Michael Kotsanis BSc, MBus
CEO & Managing Director



Experienced leader in the pharmaceuticals industry with demonstrated success commercialising generic products



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



Deep experience in pharmaceutical operations, dermal drug development, analytical development and production. Felicia leads and facilitates all technical aspects of pharmaceutical product development including R&D, analytical development, project management and CMC development



Charles O'Sullivan, B. Pharm
Portfolio Director



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)



Tim Bateman CA
CFO & Company Secretary



Extensive financial experience and senior finance role. Tim was the Group Chief Financial Officer at Vix Technology for 10 years where his responsibilities included financial management, corporate governance, supporting strategic planning, M&A activities and capital raising

World class topical R&D team

*"I am extremely proud to lead an **expert topical drug development team**. Our in-house skill set provides us with an **unique advantage**, supported by robust processes, competent regulatory acumen and our ability to **deliver products through development to commercialisation**."*



Felicia Colagrande, Product Development and Technical Affairs Director



25 researchers with experience in developing pharma products

350+ years of combined experience in drug development

1 common goal: develop high-value topical generics

STRATEGIC DIRECTION LED BY A BOARD WITH HIGHLY RELEVANT EXPERTISE



Michael Kotsanis
CEO & Managing Director



- Experienced leader in the pharmaceuticals industry with demonstrated success **commercialising generic products**
- Michael was formally the Chief Commercial Officer 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**



Ross Dobinson
Non-Executive Chairman



Capital markets expert with a wealth of experience advising and establishing life science companies



Simon Green
Non-Executive Director

- Extensive biotech drug development and commercial manufacturing experience
- Formerly senior vice president and general manager, CSL Ltd



Geoff Brooke
Non-Executive Director

- Founded GBS Venture Partners
- Former president of Medvest Inc, a venture capital group he founded with Johnson & Johnson



Tim Oldham
Non-Executive Director

- Former CEO of Cell Therapies Pty Ltd
- Former president of Asia Pacific for Hospira Inc and previously held a variety of senior management roles with Mayne Pharma Ltd

CORPORATE OVERVIEW

Trading Information

Share price (as at 14 September 2018)	A\$0.235
Shares outstanding ¹	166.5m
Market capitalisation	A\$39.1m
Cash (as at 30 June 2018)	A\$28.5m
Implied enterprise value	A\$10.6m

Major Shareholders

Shareholder	%
Samuel Terry Asset Management	6.14
Mr Paul Cozzi ²	3.87
Mr Christopher M Abbott ²	2.94
Ashwood River Pty Ltd ²	1.56

Share price performance (last 12 months)



Source: IRESS & AcruX 2018 Appendix 4E & Financial Results

1. Excludes 1m options expiring in July 2019

2. As at 25 July 2018

MULTIPLE UPCOMING VALUE CATALYSTS

Upcoming news flow

Acrux will keep the market updated as it continues development of its current pipeline of 13 generic topical drugs.

Potential news flow includes:

- ✓ Dossier acceptance for review by the FDA
- ✓ Acrux securing a deal with a key partner (licensing, etc.)
- ✓ Litigation initiation by patent holders following Paragraph IV filing²
- ✓ Product approvals
- ✓ Product launches

Acrux objectives

FY19



2 additional dossiers

Submit 2 additional dossiers to the FDA for review



6 technical transfers

Scale up 6 projects from Acrux laboratory to CMOs¹



Additional new products

Add further products to the ACR generic portfolio

CY19



First generic revenues

Acrux expects to generate first revenues from its generic portfolio in CY19

1. CMO: Contract Manufacturing Organisation
2. Acrux pipeline contains products that will not require a Paragraph IV certification

THANK YOU

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