



ACRUX INVESTOR PRESENTATION (ASX: ACR)

August 2020



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.

KEY INVESTMENT HIGHLIGHTS

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



Focus on specialised and lucrative topical generic market

- 2 products **on market** in 35 countries
- The topical generic market provides **attractive returns with fast, low-risk and low development costs** for highly specialised drug developers
- The size of the topical generic market in the US is **~US\$18bn***
- **13 products** now in the pipeline of generic products, with an addressable market of **~US\$1.3bn***
- Licensing deals executed with recurring revenue and milestone payments for selected products



Highly skilled development team

- 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**
- TGA approved, Good Manufacturing Practice (GMP) facility with 25 specialised scientists creates a substantial competitive advantage in generic product selection, development and commercialisation



R&D investment in product pipeline entering commercialisation

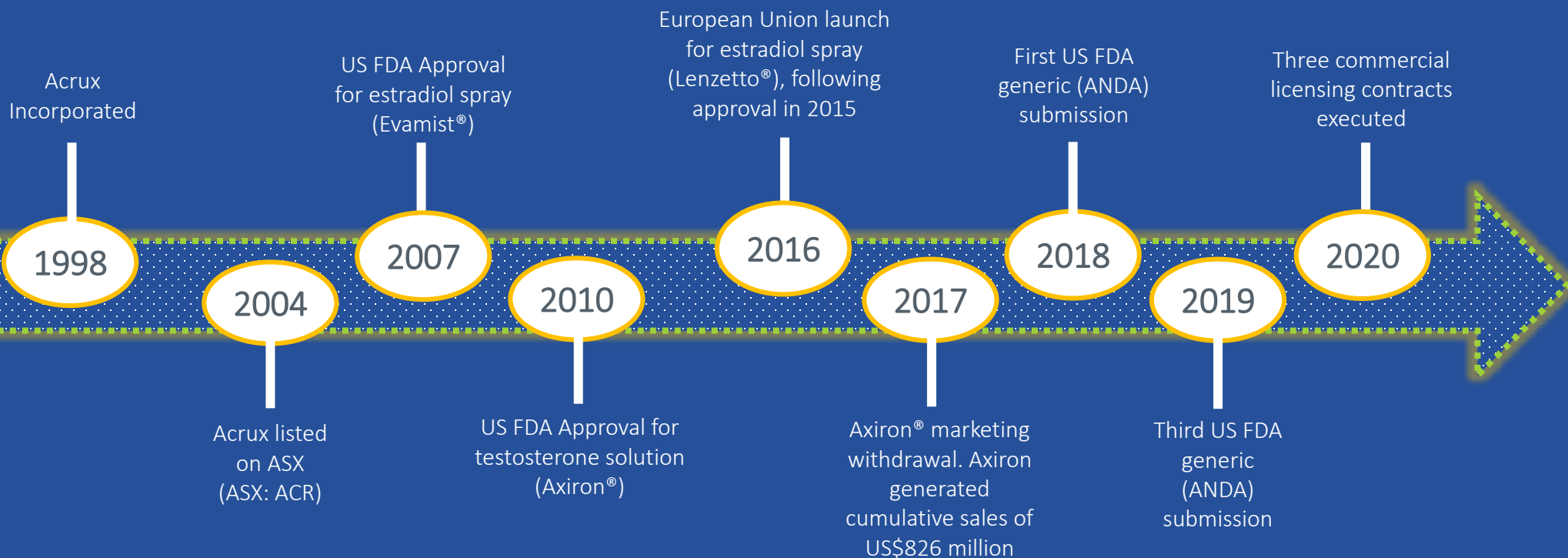
- **Two products currently sold through licensees** in Europe, the United States and other countries
- **Additional products** nearing FDA approval
- **2 product licensing deals executed** with 2 different pharma companies in FY 2020
- **Additional product licensing deals in FY21**
- **Objective to be cash flow positive by 2022**

* 12 months sales to end Q1, 2020 based on IQVIA.

IQVIA is formerly Quintiles and IMS Health, Inc., and provides, on a subscription basis, pharmaceutical industry-leading sales data from over 90 countries in a standardised and comparable way.

ACRUX HISTORY

- Acrux has over 20 years of experience in the development and commercialisation of topical and transdermal pharmaceuticals
- Acrux products are currently sold in 35 countries





EXPERIENCED MANAGEMENT TEAM WITH A PROVEN HISTORY OF COMMERCIALISING GENERIC DRUGS

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



Michael Kotsanis BSc, MBus
CEO & Managing Director

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

Synthon

Hospira

+Faulding®

maynepharma



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

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

+Faulding®



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)

Hospira

maynepharma

gsk



Deborah Ambrosini, CA
CFO & Company Secretary

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

GLOBAL HEALTH

Connecting Clinicians and Consumers

pwc



Mark Hyman,
Project and Technical Director

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

SANDOZ

maynepharma

Hospira



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**
- Formally CCO for Synthon Holding BV and President, Europe for Hospira
- Holds a BSc and a MBus



Ross Dobinson
*Non-Executive
Chairman*

- Experience in capital markets, advising, establishing and growing life sciences companies



Geoff Brooke
Non-Executive Director

- Founded GBS Venture Partners
- Former President and Co-founder of Medvest Inc, a VC group partnered with Johnson & Johnson



Tim Oldham
Non-Executive Director

- Former CEO of Cell Therapies
- Former President, Asia Pacific for Hospira Inc and previously various senior positions with Mayne Pharma



Norman Gray
Non-Executive Director

- Former Vice Air Marshall, Royal Australian Air Force
- Former CEO, Thales Australia





BUSINESS OVERVIEW

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

	Acrux products	Recent Acrux outcomes
Products commercialised by Acrux	<ul style="list-style-type: none">▪ Estradiol spray Sold as Lenzetto® in 34 countries with royalties and milestones received by Acrux from FY17 onwards. Sold as Evamist® in the United States.▪ Testosterone solution Sold in 6 countries with royalties and milestones received by Acrux from FY10 – FY18. Peak annual sales were US\$179 million in 2013.	<ul style="list-style-type: none">▪ Acrux revenue from its Estradiol licensees grew 48% in FY20 over prior financial year▪ Royalties payable to Acrux are expected to further grow and exceed \$1 million in FY21
Acrux Pipeline	<ul style="list-style-type: none">▪ Acrux has a development pipeline of 13 topical generic pharmaceuticals with 3 of these products submitted to the FDA	<ul style="list-style-type: none">▪ Multiple licensing deals executed in FY20▪ Profit share payable to Acrux following product launches with milestones on selected products pre and post commercialisation



STRONG AND CONSISTENT RETURNS

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

	Acrux's generic portfolio strategy	Novel drug development
Commercial Strategy	<p><u>Portfolio Strategy</u></p> <p>Sophisticated screening of generic drug candidates along with development and commercialisation track record underpin Acrux's de-risked portfolio strategy</p>	<p><u>Single Drug Strategy</u></p> <p>Novel drug development will remain speculative given high costs and risks of development</p>
Development Process	<ul style="list-style-type: none">■ Acrux rigorously screens market data for drug candidates in attractive markets where Acrux can leverage its drug development and commercialisation track record	<ul style="list-style-type: none">■ Less than 12% of novel drug candidates make it into Phase I clinical trials¹
Time, Cost and Value	<ul style="list-style-type: none">■ Acrux is able to develop and commercialise a generic drug for ~AUD\$3-4m within ~4 years■ Once a licensing deal is executed and a product launched royalty/profit share revenue is expected to grow strongly	<ul style="list-style-type: none">■ Developing a novel drug takes 10+ years¹■ Drug development involves multiple expensive long-term trials



TOPICAL GENERICS: AN ATTRACTIVE US\$18B MARKET

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

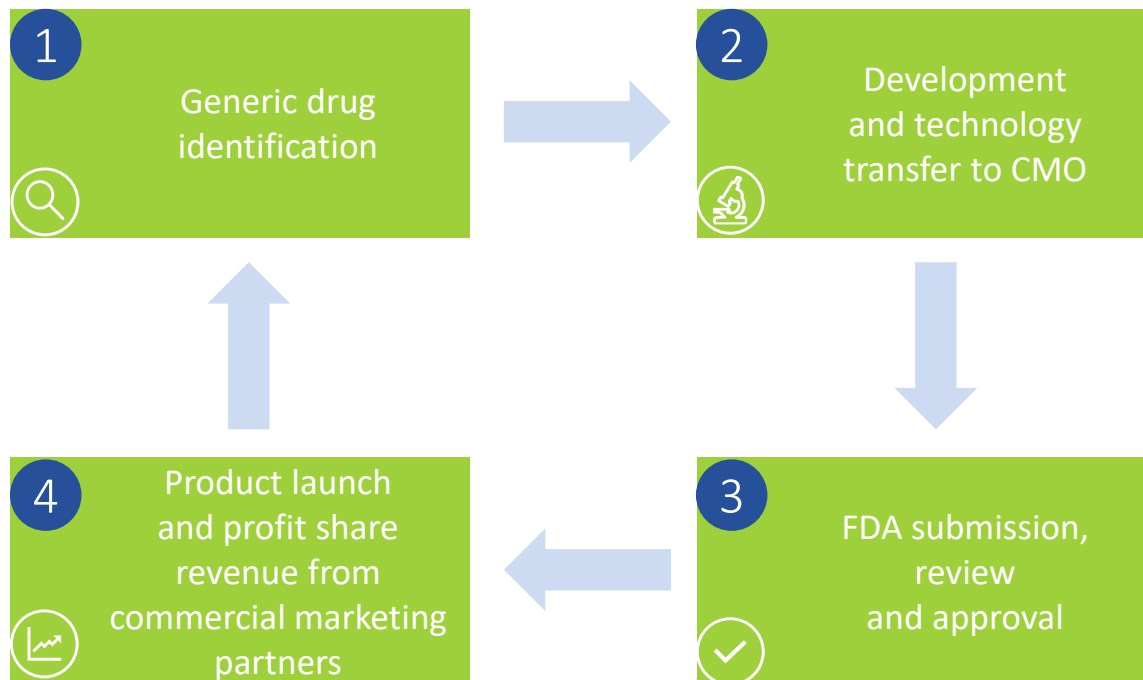
Source:

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



REVENUE GENERATING BUSINESS MODEL SUPPORTING LONG-TERM GROWTH

- On market products are generating growing royalty revenues for Acrux
- Through the Acrux GMP* facility with 25 specialised scientists, Acrux possesses the capabilities to develop and commercialise generic topical and transdermal pharmaceutical products
- Acrux has 5 licensees with products commercialised in 35 countries
- The core business model of generic drug development is supported by ongoing licensing opportunities for commercial marketing and distribution





Acrux has a drug development pipeline of generic pharmaceuticals with 8 products licensed to commercial partners for the United States market.

Acrux currently receives royalties on sales from 2 of its commercial partners with on market products in the United States, the European Union and a number of additional countries.



- 13 products in generic topical portfolio
- 1 product accepted for review by the FDA during FY20

 Progress as at FY19

 Progress during FY20

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



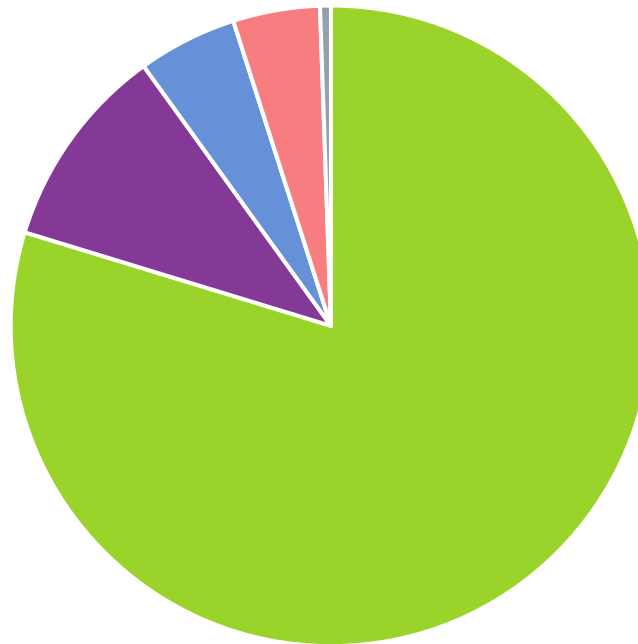
ACRUX PRODUCT PIPELINE'S \$1.3 BILLION ADDRESSABLE MARKET

Acrux's investment in R&D unlocks a \$1.3bn market in topical drugs

Addressable market value of pipeline¹ (US\$bn)

*# of commercialised generic (ANDA)
competitors approved and on the market²*

- > 4 Generics
- 4 Generics
- 2 Generics
- 1 Generic
- No Generics



Addressable market

US\$1.3 bn

Based on 13 products currently in the Acrux topical generic pipeline

Fewer generic products on the market creates favourable economics

- ✓ Capture higher market share for products with lower competition
- ✓ More than half of Acrux's portfolio have no commercialised generic equivalents

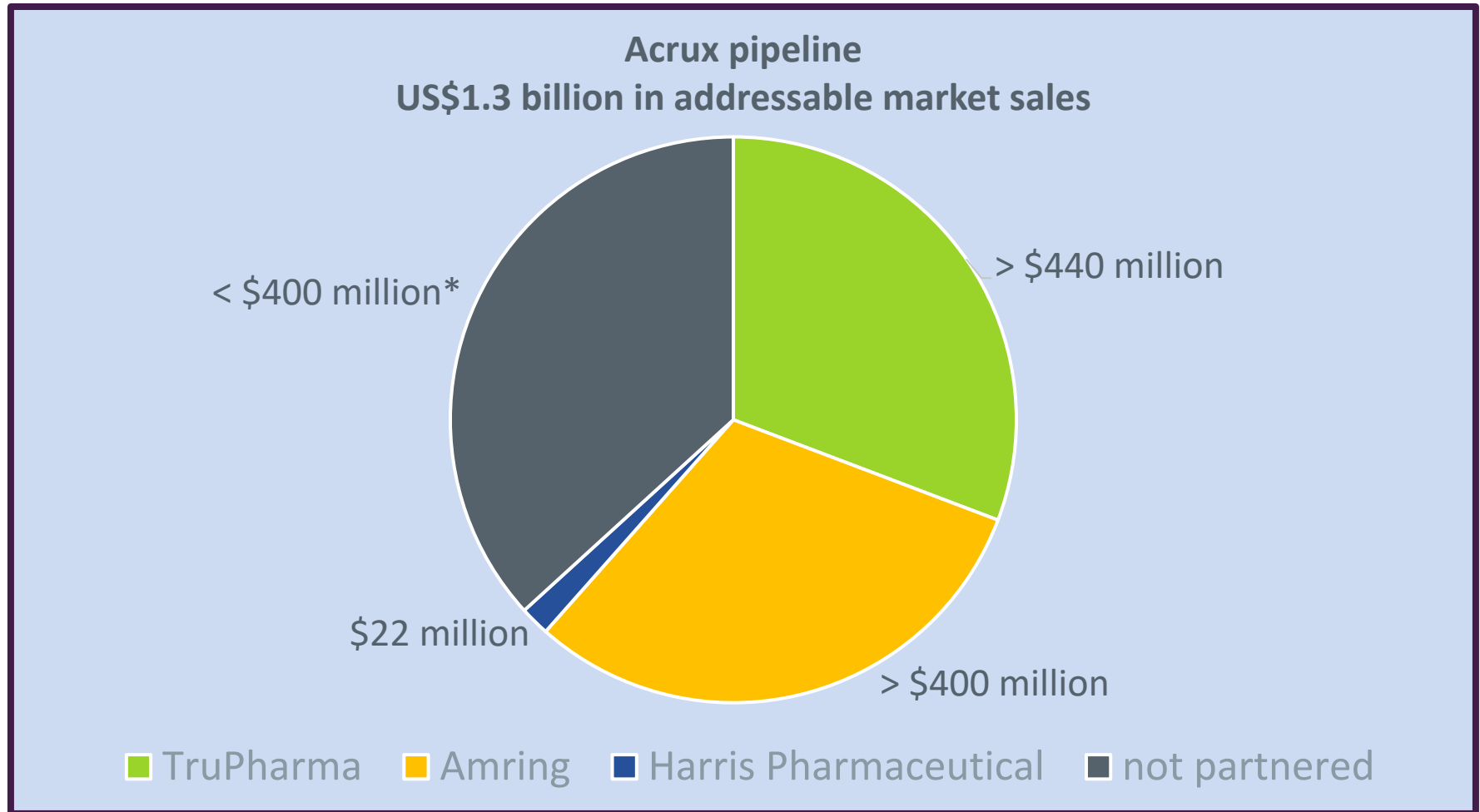
1. August 2020 pipeline addressable market based on twelve months sales to end March 2020 based on IQVIA sales data

2. As at March 2020 based on IQVIA sales data. As at August 2020 there are currently 10+ dossiers submitted to the FDA for a generic version of Jublia® with none commercialised



ACRUX PARTNERED PIPELINE ADDRESSABLE MARKET

Over US\$860 million of addressable market value licensed to TruPharma, Amring Pharmaceuticals and Harris Pharmaceutical in 2020. Profit share payable to Acrux following product launches with milestones on selected products pre and post commercialisation





OVERVIEW OF CURRENT LICENSEES



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



- Co-development with Acrux for of 1 product for the US market



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



GEDEON RICHTER

- Sells Lenzetto® in 34 countries including most EU countries



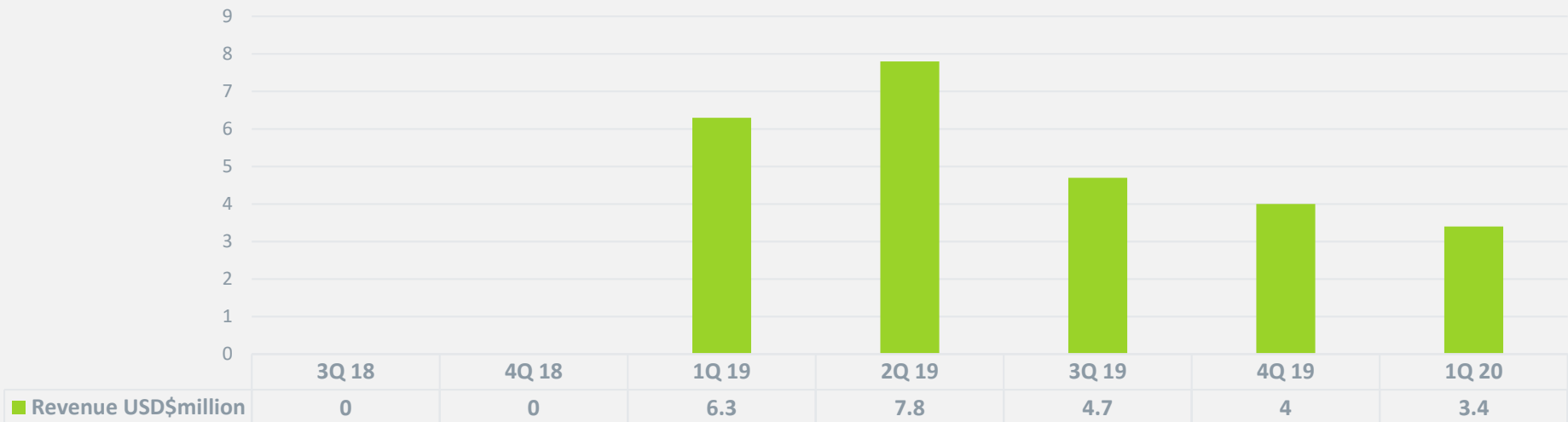
- Sells Evamist® in the United States

CASE STUDY: SOL-GEL'S REVENUE FROM ITS FIRST GENERIC PRODUCT LICENSED TO PERRIGO



- A small clinical-stage dermatology company focused on **identifying, developing and commercialising branded and generic topical drug products**
- **Announced FDA approval for first and currently only generic product in February 2019**, in a profit share licensing contract with Perrigo
- Profit share split is disclosed by Sol-Gel as 50% of Perrigo's gross profits related to the sale of the generic version of Zovirax® (acyclovir) cream, on a quarterly basis






Sol-Gel Revenue USD\$million





PLATFORM FOR GROWTH ESTABLISHED

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

	Acrux Product Status		Description
 ON MARKET	2	2 products sold in 35 countries	Acrux is receiving royalties on a quarterly basis. Revenue from estradiol licensees <u>grew by 48%</u> in FY20 v FY19
 LAUNCH	8	3 product licensing deals executed in CY2020 for 8 products	Acrux expects a typical licence agreement to consist of an <u>recurring profit share stream</u> and on selected products, milestones pre and post commercialisation
 APPROVE	3	Products accepted for FDA review in CY18, 19	Following initial review there may be additional FDA questions to be answered prior to approval ² . Products can be launched following Final Approval.
 DEVELOP	10	Generic products in development	<u>R&D team</u> with highly specific topical expertise drive development. Acrux has unique capabilities for topical drug development.
 IDENTIFY	53 94	Identified topical drugs, Each >US\$100m in sales Identified topical drugs, Each \$10-100m in sales	Continue to screen market to <u>identify</u> high potential prescription topical products

1. CMO: Contract Manufacturing Organisations;

2. Under GDUFA II, the FDA has committed to review 90% of Abbreviated New Drug Applications (ANDA) applications within 10 months. ANDA approval will follow if the FDA is satisfied during the review process



FUTURE CATALYSTS



ACRUX STRATEGY

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

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



FY 2021 OBJECTIVES

- Continued royalty growth of existing on market products
- 3 additional products under FDA review
- 2 product launches with profit share and other payments to Acrux
- Additional licensing deals executed



FY 2022 OBJECTIVES

- Continued royalty growth of existing on market products
- Cash flow positive by 2022
- Ongoing screening and initiation of new products in development
- 4 additional products under FDA review

CORPORATE OVERVIEW

Acrux has a proven track record of commercialising products, and is entering a new phase of value creation for shareholders following 5 years of R&D

Trading information

Share price (as at 21 August 2020)	A\$0.17
Shares outstanding	168.7m
Market capitalisation	A\$29m
Cash (as at 30 June 2020)	A\$9m
Enterprise value	A\$20m

Major shareholders

Shareholder	%
Samuel Terry Asset Management	6.14
DDH Graham Ltd	5.79
MNM Capital Pty Ltd	2.70

Share price performance (last 12 months)





BENEFITS OF A POOLED DEVELOPMENT FUND

1

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

2

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

3

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

4

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

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

THANK YOU

Michael Kotsanis

CEO & Managing Director

Acrux Limited

P: + 61 3 8379 0100

E: michael.kotsanis@acrux.com.au

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

Follow us on LinkedIn:

