



ASX Release

29 November 2023

Address of Chairman and CEO to Annual General Meeting

Melbourne, Australia; Acrux Limited (ASX:ACR): In accordance with ASX Listing Rule 3.13.13, Acrux Ltd is pleased to release the addresses to be given by our Chairman, Ross Dobinson, and our Chief Executive Officer and Managing Director, Michael Kotsanis, at the Company's AGM from 10:00am this morning.

Authorised for release by the Board of Acrux Limited.

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. Drawing on 25 years of experience 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 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 Ltd

Annual General Meeting Presentation Wednesday 29 November 2023

Good morning ladies and gentlemen. My name is Ross Dobinson and I am the Chairman of Acrux Limited.

It is my great pleasure to welcome Acrux shareholders and guests to our 2023 Annual General Meeting, which is being held today in the offices of our auditors, Pitcher Partners.

This AGM is convened to address the items detailed in the Notice of 2023 Annual General Meeting which was circulated to shareholders on 27 October 2023.

**ACRUX Ltd
Annual General Meeting
29 November 2023**

Acrux is a specialty pharmaceutical company with a successful track record of developing and commercialising a pipeline of topically applied pharmaceutical products.

I am joined by my fellow Directors, Michael Kotsanis, our Chief Executive Officer and Managing Director, and Non-executive Directors: Geoff Brooke, Tim Oldham and Don Brumley. Also attending are Joanna Johnson, our CFO & Company Secretary, and representatives from our auditor, Pitcher Partners and our Share Registry, Link Market Services, acting as Returning Officer and assisting to conduct the polls.

The agenda for today's Meeting is as follows:

- Firstly, I will present my address
- Michael Kotsanis will then review the Company's activities and milestones achieved over the past 12 months in the CEO's Report
- We will then conduct the formal business of the Meeting.

Chair's Address

The past 12 months have seen the achievement of several milestones in building a diversified portfolio of marketed topical generic pharmaceutical products that are capable of generating revenues to support the progression of other pipeline products and strategic opportunities.

These milestones include:

- The launch of Prilocaine 2.5% and Lidocaine 2.5% Cream in December 2022
- Receipt of FDA approval of Dapsone 5% Gel and
- Acceptance of our 7th dossier for FDA review, Nitroglycerin 0.4% Ointment.

Acrux has 2 additional products which are currently progressing through the FDA's review process, Dapsone 7.5% Gel and Acyclovir 5% Cream, and there are a further 7 products which are in earlier stages of development.

As this pipeline moves through the product development cycle towards approval and commercialisation, Acrux is making tangible progress towards our objectives of launching multiple products and building a sustainable future revenue stream.

Thank you to our shareholders and guests who have attended our AGM today, I now ask Michael Kotsanis to further detail this progress in the CEO's report.

Michael Kotsanis – Chief Executive Officer and Managing Director

Good morning. I'd like to give a warm welcome to all shareholders and guests who join us this morning at this year's Annual General Meeting.

Before I start my presentation, I refer you to our Disclaimer Statement. Please review this statement carefully.

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.



FY23 Key Milestones

Reported progress towards strategic objective of building a sustainable revenue stream capable of funding development pipeline:



Launched

- Lidocaine 2.5% and Prilocaine 2.5%, Cream a generic of topical anaesthetic EMLA® launched in December 2022



Approved

- Dapsone 5%, Gel a generic of topical acne treatment Aczone®, approved by the FDA in June 2023



Accepted for review

- Acyclovir 5%, Cream a generic of cold sore product Zovirax®, accepted for review by FDA in August 2022
- Nitroglycerin 0.4%, Ointment a generic of anal fissure pain treatment Rectiv®, accepted for review by FDA in July 2023



Monetised

- In January 2023, the Lenzetto® royalty stream for contracted territories was sold to our licensee for EUR4.1million



In the prior financial year, Acrux made strong progress towards its goals of launching multiple products and building a sustainable revenue stream.

In December 2022, through our licensee, Acrux launched Prilocaine and Lidocaine Cream. This product is used as a local anaesthetic in the United States. Shortly after this product was launched, one of the competitors in that market with 60% market share, announced their bankruptcy and cessation of supply of all products to the US market. That presented an opportunity to fill the supply gap that event caused and to meet the market demand which is considerable.

In June this year, Acrux received FDA approval for Dapsone 5%, Gel and these launch plans are well progressed. We look forward to announcing the actual launch of this product in the New Year.

Over the prior financial year, we have had two products accepted for review by the FDA. Acyclovir Cream was accepted for review in August 2022. That product is prescription only in the United States and is approved for the treatment of cold sores. We also had Nitroglycerin Ointment accepted for review by the FDA in June this year. Nitroglycerin Ointment is approved in the United States for the treatment of moderate to severe pain due to chronic anal fissure.

Finally, in January this year, we decided to monetise the future royalty stream for Lenzetto®. Our agreement with Gedeon Richter was announced in 2013 and at the time Acrux had agreed to a royalty stream that would last 10 years from first commercial launch which was in January 2016. With the end date for royalties approaching in early 2026, Acrux agreed to monetise the future royalty stream and received Euro 4.1 million. Lenzetto® continues to be sold by Gedeon Richter under license from Acrux in over 40 countries around the world, excluding the United States, Australia and some other smaller markets.

Acrux portfolio

The Company now has:

- 16 products in its portfolio
- 6 approved products of which 2 are revenue generating currently
- 3 products currently being reviewed by the FDA

Acrux intends to maintain a pipeline of 10–12 products

Progression of Acrux's portfolio of products

	FY20	FY21	FY22	FY23
Revenue generating ¹	2	2	3	2
Approved	2	4	5	6
Under review by FDA	5	2	3	3
In development	8	11	8	7
Total products in portfolio	15	17	16	16

1. Revenue generating products are also included in the Approved category

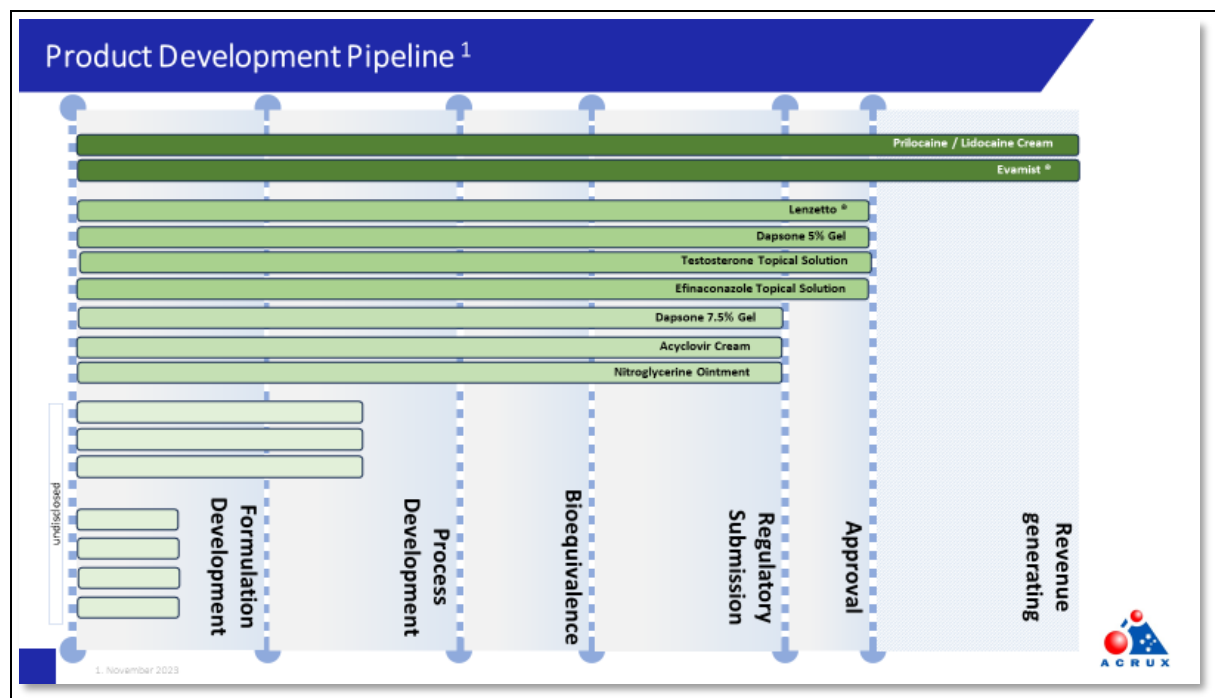


Summarising our portfolio today, Acrux has 16 products in its portfolio.

Six of those products are approved and two of these are generating revenue for the Company – Prilocaine and Lidocaine Cream as well as Evamist, both of which are marketed under license by Padagis in the United States.

Acrux also has three products currently under FDA review and we intend to maintain 10 – 12 products in our development pipeline, which includes those under FDA review.

This table shows the progression of our product development initiatives over time from selection through to commercialisation.








Our pipeline is illustrated above, showing the stage of development of each product through to the commercialisation stage.


We disclose the details of the products which have been accepted for review by the FDA, those that have been approved or those that have been commercialised. There are a further 7 products which are in our development pipeline at various stages of either formulation development or process development.

Our intention is to continue to progress products from early stage development through to FDA submission, review and ultimately commercialisation. Although we have focussed our development efforts on later stage products in recent times, our intention is that we will maintain a balanced number of products through the various stages of development, so that a regular number of products reach commercialisation and add to our growing recurring revenue stream.

Acrux is focused on an underserved market segment

	Total market	Oral drugs (tablets, capsules) 	Topical drugs (creams, gels, ointments, solutions) 
Definition of market	Total US prescription pharma market	Drugs that are ingested orally	Drugs that are applied topically to the skin, eyes, ears and nose
Market size ¹	>US\$520bn	~US\$200bn	~US\$16bn ²
Generic development complexity	Variable dependent on dosage form and drug	Low	Greater complexity than oral generic drug development
Competition	Variable	High competition from many generic drug manufacturers	Limited generic competition given niche market and development complexity
Acrux product development focus			

Source:
1. US market by dosage form, IQVIA Q3, 2020 MAT, US\$ market sales
2. Market size for topically applied drugs/IQVIA Q3, 2020 MAT, US\$ market sales



The market that Acrux targets is focussed and niche, but substantially large enough to be attractive for Acrux to target. We believe this market segment is attractive on the basis of generally lower numbers of generic products, including products that generate reasonable annual sales that have very limited or no generic competition despite no patent protection for many years.

Our competence and focus since our inception as a company over 25 years ago, has been the delivery of drugs that are applied topically on part of the human body.

The total pharmaceutical market in the United States exceeds US\$500 billion in sales, as measured by IQVIA. Generic development techniques vary by dosage form and indication. Acrux does not target the entire generic market, as this slide illustrates.

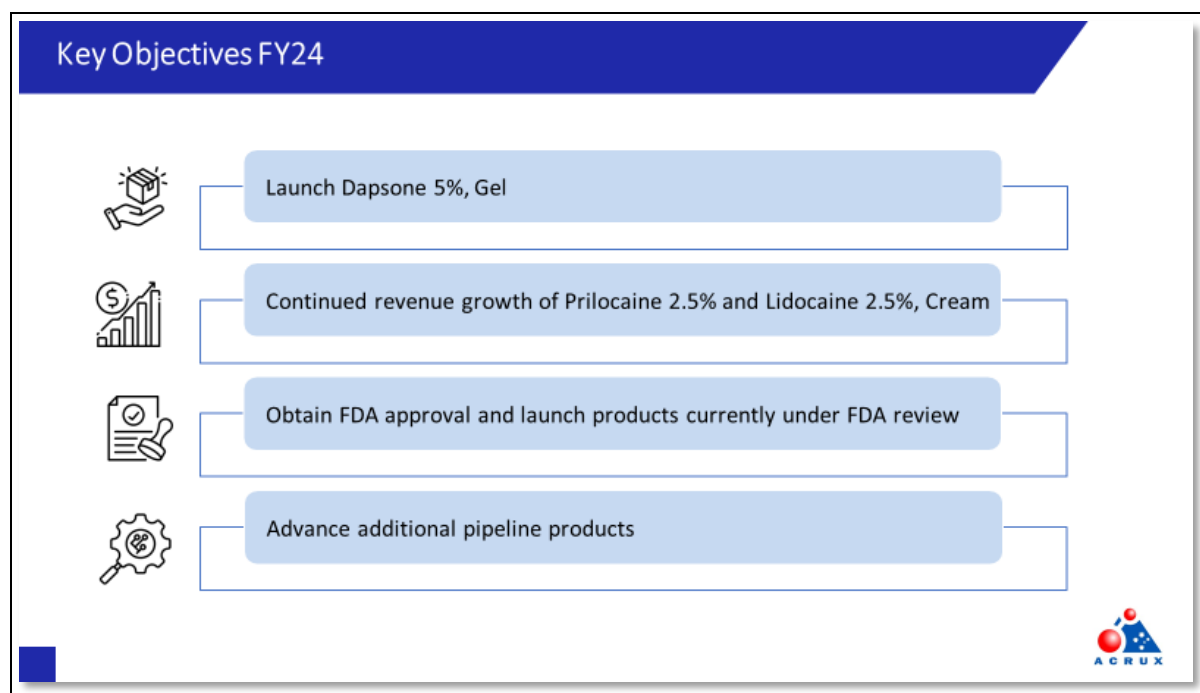
The biggest sector for the pharmaceutical market in the United States is the market for drugs taken orally, usually by tablet or capsule. That sector has annual sales of approximately US\$200 billion. The technique to demonstrate bioequivalence between the branded or Reference Listed Drug compared to a generic version of that drug is well understood and has been repeated many

thousands of times by different generic companies. Generics in the oral segment of the market account for around 9 in every 10 prescriptions dispensed in the United States.

Acrux targets pharmaceutical products in the sector that are applied topically. That sector generates approximately US\$16 billion in annual sales. Products in the topical sector generally have smaller annual sales compared to oral drugs and bioequivalence techniques are variable depending on the drug, the dosage form and the therapeutic use of the product.

Topically applied drugs are available in a number of dosage forms, including creams, ointments, solutions, pastes, gels and suspensions. They can be applied to a variety of areas of the body including the skin, eyes, ears, nose and other parts of the body. This variety of dosage forms and therapeutic uses results in a high degree of variability of bioequivalence technique that the FDA expects generic companies to use to demonstrate bioequivalence.

Often products in this topical segment have limited competition due to development complexity and size of market. For Acrux, with its development capability and focus, this segment is attractive. Acrux is well versed in demonstrating bioequivalence for topical drugs and meeting FDA Product Specific Guidances, as evidenced by our multiple approvals we have received for generic products in this segment of the market.



The key objectives for the Company over the course of the current financial year are as follows:

One of our important goals is to launch Dapsone 5%, Gel early in the New Year. The addressable market for this product is currently US\$19 million.

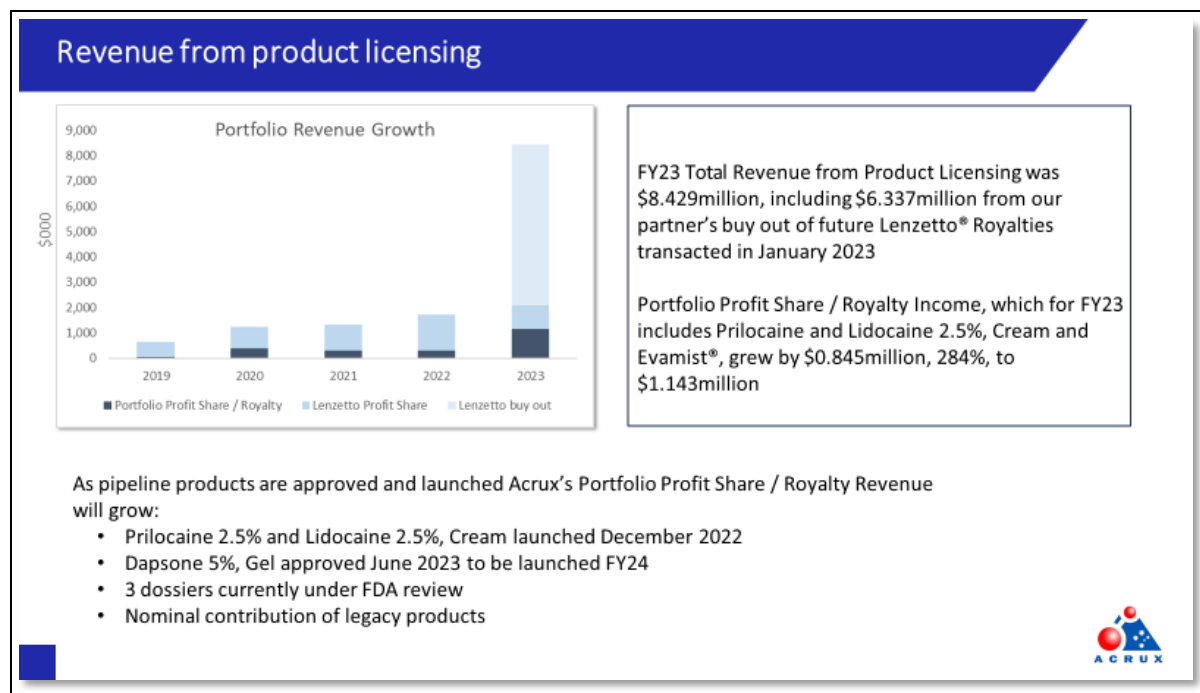
We also expect to see continued growth in revenue from Prilocaine 2.5% and Lidocaine 2.5% Cream through our efforts to increase the resilience in the supply chain following a competitor's market withdrawal. The addressable market for this product is currently US\$38 million and has shown year on year growth.

We will continue to push our programs through the FDA review process to achieve approvals which then allow us to coordinate product launches through our commercial licensees.

And we also intend to add new products to our development pipeline. We regularly and routinely screen the topical market for new product candidates and have a basket of products under review through an initial scoping phase. Once that technical scoping phase is complete, we then will add that product to our pipeline as our resources allow.

I now invite Joanna Johnson to present the FY23 financial results of the Company.

Joanna Johnson – CFO and Company Secretary



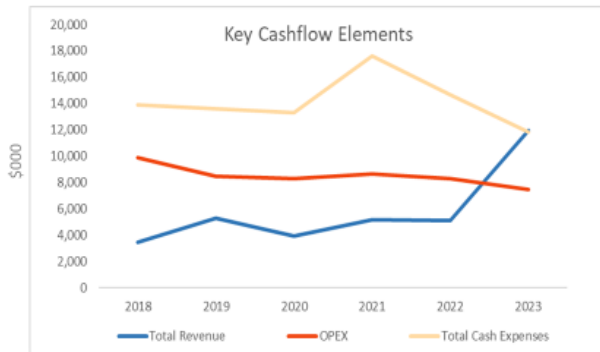
This slide highlights progress towards Acrux's objective of sustainable revenue growth as derived from the currently marketed products, Prilocaine and Lidocaine Cream and Evamist® and which is in addition to revenue which is attributable to Lenzetto®.

For FY23, Total Revenue from Product Licensing was \$8.429 million. This included \$6.337 million proceeds following our partner's buy out of future Lenzetto® Royalties which was transacted in January 2023.

Growth of Portfolio Profit Share and Royalty Income, as is denoted by the darkest blue band in this graph, grew by \$0.845 million, 284%, to \$1.143 million. For FY23 this includes Evamist® and the initial contribution of Prilocaine and Lidocaine 2.5%, Cream.

Continued growth of revenue derived from Prilocaine and Lidocaine Cream as well as following the launch of new products in FY24 and beyond, for example Dapsone Gel 5% which is planned for early next year, are the keys to achieving our objective of sustained and sustainable portfolio revenue growth.

Profitability and Cash Generation



	2022 \$'000	2023 \$'000
Client revenue	1,719	8,429
Other Revenue	3,383	3,499
Total Revenue	5,103	11,928
COGS	-	558
External R&D	6,371	3,813
OPEX	8,313	7,448
Total Cash Expenses	14,684	11,818
Estradiol Impairment	-	321
Profit Before Tax	(9,582)	(212)

Total Revenue growth, which includes Portfolio Revenue, RDTI and the one time Lenzetto® royalty buy out, coupled with control over operating costs and the timing of R&D expenditure has resulted in reported Cash and Cash Equivalents increasing by \$0.401 million through FY23 to \$6.232million.

Cash Generation Highlights:

- Positive cash generated from operating activities \$0.703million, total \$0.401million
- No Capital or Debt raising in FY22 or FY23.







In FY23 AcruX has reached a pivotal point, the growth in Total Revenue, which includes Portfolio Revenue, the Research and Development Tax Incentive Rebate received from the ATO and the one time Lenzetto® royalty buy out, coupled with tightly controlled operating expenses and the timing of R&D project expenditure has not only materially improved our reported Loss before Tax from \$9.582 million in the prior financial year to \$0.212 million in FY23 but has also resulted in AcruX adding \$0.401 million to reported Cash and Cash Equivalents.

Thankyou, I will now hand the presentation back to Michael Kotsanis to conclude the presentation.

AcruX investment opportunity

Track record of developing and commercialising products to deliver growing recurring revenue streams

-  **Strong pipeline** of products under development
-  3 products currently **under evaluation** by the FDA
-  Received **FDA approval** of 4 products since 2021
-  Lidocaine 2.5% and Prilocaine 2.5% cream, **launched** in December 2022



To summarise our presentation, AcruX has a strong track record of developing and commercialising products. We have had 4 products approved since 2021 and our most recent launch of Prilocaine and Lidocaine Cream is performing well in the market.

Our pipeline is strong and progressing and we are close to a tipping point in terms of our goals to grow recurring revenue streams.

In closing, I would like to thank our shareholders for their support of the Company and also Acrux's employees and the Board for their continued efforts and focus on moving our products through development phases to commercialisation.

The whole Acrux team looks forward to the opportunities and challenges ahead.