Acrux Annual General Meeting Script
12 November 2020

Slide 1 – Welcome Page

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Ross Dobinson – Non-Executive Chairman

Introduction

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

It is my pleasure to welcome shareholders to Acrux's 2020 Annual General Meeting.

These are extraordinary times that call for innovative and flexible ways of doing things. While the virtual format may be familiar for some shareholders, I acknowledge that some of you would prefer to attend in person and are not as comfortable with the online environment so I thank you for joining us today.

I confirm that you will have the same opportunity to participate today as you would at a physical meeting. This includes being able to ask questions through the online platform and to vote using an electronic voting card. I also encourage you to download the online portal guide from the Company's website if you haven't already done so.

Online Platform

Voting on the resolutions being put to the Meeting will be conducted by way of a poll using the electronic voting card you should receive after clicking the 'Get a Voting Card' button. Company Secretary Ms Deborah Ambrosini will provide more information on the voting procedure later in the Meeting.

Shareholders can submit written questions during the Meeting by clicking the 'Ask a Question' button. I do encourage shareholders who have questions to submit them as soon as possible.

General shareholder questions submitted online during the meeting will be addressed after the formal business of the Meeting is completed. If we aren't able to address all of the issues during the Meeting, or if there are specific questions that would be better addressed on an individual basis, we will respond to them after the Meeting.

If you have any trouble using the platform, please check the online portal guide or contact the help lines shown on screen.

As the time is now 10.00 am and as there is a quorum of members present, I formally declare the Meeting open.

I would like to introduce my colleagues who are also attending virtually:

My fellow Board members

- Our Chief Executive Officer and Managing Director Michael Kotsanis,
- Our Non-executive Directors: Geoff Brooke, Tim Oldham and Norman Gray and our CFO & Company Secretary – Deborah Ambrosini.

At last year's Annual General Meeting I referenced the macro factors the Board has assessed in determining our corporate strategy and material developments since initiating that strategy in 2015. Our strategy remains valid and unchanged. Over the past year we have achieved significant progress, which has confirmed the commercial viability of our strategy moving forward. Michael will address these in more detail in his CEO and Managing Director's report, so I will only reference the broader issues in my introduction.

During 2020 Acrux signed licensing deals for 9 of its 13 product pipeline. Commercial discussions with prospective licensees are continuing for additional products. Our product pipeline will be covered in more detail in Michael's report and we are confident that we have the capacity to maintain a consistent number of products in development in our pipeline as earlier projects are completed and licensed out. To optimise shareholder value, our pipeline will be expanded gradually after initial licensing activity validates our business model.

The Company monitors topical drug market data for products that we are developing, particularly in relation to the competitive landscape and FDA guidance documents on issues which could impact Acrux's commercial prospects with these products. Relevant issues include changes to the FDA Product Specific Guidelines (PSG), which could present both opportunities and risks. As noted in previous guidance that Acrux has issued to shareholders, a key commercial objective in generics development is the early introduction of products to market in order to gain commercial advantages over competitors. For some products which are first to market, exclusivity is received from the regulators for the first six months of those products' commercial lives under the FDA's Competitive Generic Therapies ('CGT') Guidance, which was published in final form by the FDA in March 2020.

The knowhow which has been developed by the Company over the last twenty years of operations provides sustainable competitive advantages. Acrux has specialised capabilities for *in vitro* drug development including IVRT (*in vitro* release testing) and IVPT (*in vitro* permeation testing). For some products, the FDA has recently included the option to use *in vitro* testing (i.e., as an alternative development approach to expensive clinical endpoint studies) to demonstrate bioequivalence for topical generics. This enables Acrux to utilise its capabilities to develop eligible drugs and demonstrate bioequivalence efficiently and cost-effectively.

I would like to again extend my personal thanks to the Board for their input over the last year, which has been a very productive one. I would also like to extend the Board's appreciation to Michael and his team for their continued efforts and focus on moving
our pipeline forward and to assist in securing licensing partners for a significant proportion of the Company's pipeline. The Company has made substantial progress in the development of its product pipeline and we are expecting commercial outcomes in the next year.

This will demonstrate material commercial progress. We look forward to providing shareholders with validation of the commercial potential of the Company's development program.

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Michael Kotsanis – Chief Executive Officer and Managing Director

Thanks Ross.

Good morning and thank you for attending this year's online Annual General Meeting and for your interest in Acrux. We welcome your attendance and your participation.

Slide 4 – Important Notice

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.

Slide 5 – Business Overview

Acrux is a revenue generating company with two products marketed in 38 countries through two licensees.

Revenue from its Estradiol licensees grew in excess of 48% over the prior financial year. We see continued growth this year and beyond and expect that our royalties will exceed $1 million this financial year.

There are 13 products in different stages of development in the Acrux pipeline. Multiple licensing agreements have been executed in 2020 which will lead to profit share payments to Acrux on commercialisation. In some

cases milestones are also payable to Acrux on achievement of specific pre and post commercialisation milestones.

Slide 6 – Topical Generic Market – an attractive $18 billion market

Acrux focuses exclusively on the development of pharmaceutical products that are applied topically. We believe that the topical market is substantially differentiated from the other larger segments of the total US generic pharmaceuticals market, by way of market size, generic market share and number of competitors. The total pharmaceutical market in the United States generated over US$510 billion in annual sales, based on IQVIA pharmaceutical sales data for the twelve month period to March 2020. The largest segments of the market are for pharmaceuticals that are ingested orally and those that are injected. Both segments generate over US$200 billion in annual sales. 90% of prescriptions dispensed to patients in the United States who are prescribed a tablet or capsule are generic products.

Branded products in the United States rapidly lose share to generic competition once these generics are launched. The oral market for tablets and capsules contrasts with the smaller and less competitive market for products that are applied topically onto the skin or some type of mucosa. The topical market generates approximately US$18 billion in sales, but currently has a lower level of generic penetration than the oral market. Based on IQVIA data for the topical dermatology sector, only 47% of prescriptions dispensed in this market are generic.

What differentiates the oral market from the topical market is the overall size of the market, the relative size of individual products and the more challenging development processes and methods for demonstrating bioequivalence of topical products to the on-market brand. The topical market also has substantially less competition than other generic market segments, based on its smaller size and more complex generic development processes than the oral sector of the market. This topical prescription segment is the exclusive focus of Acrux.

Pricing of products and generic market share of products is generally linked to the level of competition for a given pharmaceutical product. In general, the more generic competitors that supply a substitutable product, the lower that prices and therefore product gross margins will be. We see less competition in the generic topical market compared to the oral and injectable market segments. That can be demonstrated by the lower generic market share for topical products, the number of topical products that are off patent with no generic competitors in addition to the smaller market sizes for topical pharmaceutical products compared to market sizes for oral and injectable products.

Slide 7 – Acrux History

Some shareholders have been shareholders in the Company for many years and know the history of Acrux. Other shareholders are newer to the Company. This slide also demonstrates our product development and commercialisation track record as well as our extensive and exclusive focus on the development products that are applied topically.

Acrux was incorporated in 1998 and listed on the Australian Securities Exchange (ASX) in September 2004. Our first approval was for Estradiol spray in the United States in 2007. That product is now sold by Perrigo in the United States under the Evamist® brand.

In 2010 Acrux received approval for its testosterone solution product, which was branded as Axiron® by Eli Lilly, our licensee for the product. Axiron® was sold by Eli Lilly in 6 countries, with the majority of sales derived from the United States. The approval of Axiron® was followed by the European approval for our Estradiol spray in 2016. That product is now marketed as Lenzetto® by our licensee, Gedeon Richter, in 37 countries. In 2017,

Eli Lilly withdrew Axiron® from the market. Up to that point Axiron® had generated cumulative sales of US$826 million for Eli Lilly. In 2018, Acrux filed its first generic or Abbreviated New Drug Application (ANDA) with the FDA. By 2019 we had filed our third ANDA with the FDA. In 2020 we announced four licensing agreements with 4 different generic distributors in the United States for 9 products from our existing pipeline. All of these licensing contracts will see Acrux receive a share of profits generated from sales of these products and in some cases, milestone payments will also be payable to Acrux on achievement of certain objectives.

Slide 8 – Revenue Generating Business Model

Our business model is summed up by this slide.

We spend a significant amount of time evaluating different products as potential product development candidates. All the products we assess are topically applied prescription pharmaceutical products marketed in the United States.

Once we initially identify a product for development, we begin the analytical and formulation work that underpins our scientific development process. Once this analytical and formulation work is complete, we contract an FDA approved manufacturer to transfer our formulation in what we term a technology transfer. This is when we transfer our formulation and analytical knowhow to the contract manufacturing organisation (CMO). The data we generate from batches of our product that are manufactured at the contract manufacturer are then included with our analytical and formulation development reports and submitted as part of the dossier (ANDA) to the FDA for review.

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

Slide 9 – Acrux Product Portfolio

Today we have 2 products on market and 3 products under review by the FDA. A further 10 products are either in development at Acrux or at various stages of technology transfer to our contracted manufacturing partners. In FY21 we expect to submit to the FDA another 3 products for review. As we submit products for review, our intention is to add additional products to the initial development stage at Acrux, maintaining a relatively similar number of products in active development.

Last year we communicated that we expected 1-3 commercial licensing deals to be executed in 2020. We have concluded 4 commercial licensing contracts to date in 2020 with 4 different companies for 9 products. Profit share will be payable to Acrux for the duration of the term of those licence agreements following ANDA approval and subsequent product launches, with milestones receivable from selected products pre and post commercialisation based on the achievement of certain events.

Slide 10 – Strong and Consistent Returns

Generic product development carries substantially less development risk than novel drug development.
We screen the market for product development candidates based on a number of factors that include market size, competitive landscape, development complexity, cost of development and the intellectual property or patents for the product.

Our development record to date shows that we have developed and submitted three products to the FDA since we started work on our generic topical pipeline in August 2015. This contrasts with novel drug development, where the probability of clinical success - the likelihood that a drug entering clinical testing will eventually be approved - is estimated to be less than 12%.

For Acrux, the development process from start to submission costs approximately A$3-4 million and should take 3-4 years. Our recent product submissions to the FDA are all Abbreviated New Drug Applications, called ANDAs. The process for developing an ANDA usually avoids large scale clinical trials and the associated expense, time and risk. Contrast this with novel drug development for new chemical entities or new biological entities, which usually takes 10+ years with multiple expensive long-term trials.

We believe that our topical generic drug development and portfolio strategy provides more certainty than novel drug development.

Slide 11 – Acrux Partnered Pipeline

Our pipeline of 13 products is targeting products with annual sales of US$1.3 billion in the United States as measured by IQVIA in the 12 months to March this year. That is an average targeted addressable market of $100 million of sales for each product. Nine of these products we have developed have now been licensed to commercial partners. Once launched, Acrux expects a steady revenue stream from our share of the profits that are generated by each product, with that profit share governed by the licensing contracts that we have recently executed.

Our pipeline can be broken up into a pie chart as shown on this slide. The slide depicts the current market sales of the pharmaceutical products that we are targeting, broken into segments for each of our 4 licensees for our pipeline products.

Of the total market of $1.3 billion in annual sales that our pipeline is targeting, the 6 topical products we have licensed to TruPharma will directly compete with products that currently generate over US440 in annual sales, as measured by IQVIA. The product we are co-developing with Amring generates over US$400 million in annual sales. The product we have licensed to Harris Pharmaceutical generated US$22 million in sales in the twelve months to March 2020. The most recent licensing contract that we executed and announced was with Dash Pharmaceuticals and the product under that agreement will compete in a market that generates over US$30 million in annual sales. In total over $890 million of our pipeline addressable market value has been licensed to commercial partners this year, which is pleasing and puts us another step closer to commercialising our next group of products.

Slide 12 – Current Licensees

This slide summarises our partners and the products which are now under license to those partners (where we have been able to disclose them). Currently Acrux has 6 licensees for 11 products. Gedeon Richter market Lenzetto® in 37 countries around the world. They first launched our Estradiol spray in the European Union in 2016 and sales and royalties payable to Acrux have grown steadily since that time. Perrigo market Evamist® in the United States. Combined with Gedeon Richter, royalties payable to Acrux from the Estradiol spray products grew last year by over 48% and we expect royalties to continue to grow and exceed $1 million this financial year.

Earlier in this calendar year we announced the first of our four new licensees.

1. In May 2020, Acrux announced that it had signed an exclusive licensing and distribution agreement with Trupharma for 6 of its products.
2. In June 2020, Acrux announced it had signed a co-development agreement with Amring Pharmaceuticals for one product from its pipeline.
3. In August 2020, Acrux announced it had signed an exclusive licensing and distribution agreement with Harris Pharmaceuticals for one of its products.
4. Most recently in October 2020, Acrux announced it had signed an exclusive licensing and distribution agreement with Dash Pharmaceuticals for one its products.

We are excited by these four recent licensing agreements that we have executed with well respected companies that are active within the generic market in the United States and we look forward to launching our products with these partners in future.

Slide 13 – Key Investment highlights

Acrux is an experienced and proven developer of pharmaceutical products that are applied topically.

There are three key elements to our business.

1. Our focus on the niche topical sector of the pharmaceutical marker with our existing commercialised products.
2. Our development team, who are working on our pipeline of new products
3. Our investment into our pipeline of products which now has a number entering the commercialisation phase

Our Estradiol spray is commercialised by Gedeon Richter in 37 countries in Europe and other markets, including a number in Latin America and by Perrigo in the United States.

Our development pipeline exclusively targets the United States market for topically applied prescription pharmaceuticals. The overall market for topical prescriptions products in the United States is US$18 billion. We now have 13 products in active development in our pipeline and have recently announced 4 licensing agreements with companies to sell 9 different products from our pipeline in the future.

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

Since we started development on the first of our topical generic products in August 2015, we have submitted the first three products to the FDA for review. As our products progress through the regulatory review process and licensing negotiations, our objective is to be cash flow positive by the end of 2022.

We are at an exciting stage of the Company's transformation. With significant investment in our topical generic pipeline, we expect to launch two products in the first half of the 2021 calendar year through the licensees that we have recently announced. Our launch planning has begun for these products and we await FDA approvals, which are expected in the near future.

Slide 14 – Platform for Growth Established

Our platform for future growth is now well established and is illustrated by this slide.

We have identified 94 pharmaceutical products in the United States that are applied topically and that individually generate between $10 million and $100 million in annual sales. In addition, there are 53 further topically applied pharmaceutical products that generated over $100 million in annual sales. Of those 147 products, we have ongoing development of 13 products.

Three of these products that we have developed to date have been submitted to the FDA and accepted for review. We have a further 10 products that have not yet been submitted for FDA review.

We have executed 4 licensing contracts for 9 products and currently have two marketed products sold through licensees. That number of commercialised products will grow in the near future as we anticipate FDA approvals shortly. Once granted Final Approval by the FDA, our plans are already underway for the launch these products.

Slide 15 – Experienced Management Team

The Acrux senior management team that is guiding Acrux forward and executing the company's strategy are highly experienced. All of us have substantial experience in the areas for which we are responsible.

I will now hand over to Deborah Ambrosini to discuss the financials for FY20.

Slide 16 – Financial Review

Deborah Ambrosini – CFO & Company Secretary

Thanks, Michael. Good morning.

Slide 17 – FY20 P&L

I will now focus on providing more detail in relation to the performance for the financial year ended 30 June 2020.
The results for the financial year are as follows:

- Revenue from licensing agreements of $1.25 million, up 98.6% on prior year
- Research and Development Investment costs of $10.6 million in line with prior year expenditure
- Net Loss After Tax of $9.47 million up 12.6%
- Basic and diluted loss per share was 5.65 cents
- Cash Reserves at the end of period $9.2 million down 49.5% from 30 June 2019

Revenue generated from the sales of Lenzetto® in Europe and Evamist® in the United States grew over 48% compared to the prior year. These products continue to build market share in existing regions, specifically in key European markets and via launches in new countries and regions.

Acrux received its first revenue from its recently licensed generics products with $0.362 million received in co-development revenue from Amring Pharmaceuticals during the year.

Total expenses were comparable year on year.

R&D expenditure decreased marginally while depreciation and amortisation expenditure increased after the Company adopted accounting protocols required under IFRS 16 Leases. The new standard requires the Company to recognise nearly all leases on balance sheet which reflects the Company's right to use an asset for a period of time and the associated liability for payments. The associated amortisation of that asset will be recognised in the Company's profit and loss.

Slide 18 – FY20 Cashflow

In relation to cash flow for the financial year:

Cash received from product licensing agreements was $1.093 million, up 89.8% on prior financial year.

The Group paid $11.66 million to suppliers and employees in the current year, reflecting the continued investment in our R&D pipeline.

The Group received $2.015 million in relation to the R&D tax incentive rebate from the Australian Tax Office for the 2019 financial year.

As a result, cash reserves at the end of the financial year were $9.2 million, down 49.5% or $9.0 million from 30 June 2019.

We are comfortable that the Group's financial position at the end of the financial year can provide the platform to support our pipeline development as we continue to progress the commercialisation of our development pipeline.

Now let me hand you back to Michael.

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Michael Kotsanis – Chief Executive Officer and Managing Director

Slide 20 – Future Catalysts

Thanks Deborah.

Our future catalysts are shown on this slide.

We are rapidly approaching new commercialisation events for our generic products.

That will be characterised by FDA approvals and product launches, which will be communicated to shareholders as they occur. Revenue for Acrux will be generated from profit share agreements with our commercial partners.

In FY2021, we expect:

- Continued revenue growth from existing on market products
- 3 additional products under FDA review
- 2 product launches

In FY2022, we expect:

- Continued revenue growth, driven by our existing and new on market products
- Cash flow positive by the end of 2022
- 4 additional products in development, and
- Depending on how many products are approved, between 1 – 5 products under FDA review
- We also anticipate additional product licensing deals to be executed

Slide 21 – Pooled Development Fund Benefits

My final slide is an overview of the Pooled Development Fund Act ('PDF Act') and the potential benefits for Australian resident shareholders.

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

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

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

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.

Slide 22 – Conclusion

In closing before I hand back to the Chairman, I would like to thank shareholders, the Acrux management team and staff and the Acrux Board for their efforts and support of the Company.

More recently, the Acrux team have been operating with the added complexity of the COVID-19 pandemic. Our laboratory team have continued their work from the Company's laboratory, whilst administrative staff have largely worked from home. As many of the Acrux development projects now involve contract manufacturers, raw material sources and commercial partners outside Australia, this has added to the complexity in planning and executing each project. Continuity with some service providers has more recently been disrupted by COVID-19 through from temporary impacts on their ability to provide a continuous service in their country or state of operations. Where possible, Acrux has planned for contingencies, including the assessment of alternate service providers and/or alternate locations of operations. The broader Acrux team has progressed its pipeline whilst also dealing with the challenges that COVID-19 has provided to the healthcare and general community in Australia and globally.

I would like to personally thank the Acrux team of employees and the Board for their continued efforts and focus on moving our pipeline forward and to assist in securing licensing partners for a significant proportion of the Company's pipeline. This financial year is a pivotal one at Acrux and we look forward to the opportunities and challenges ahead.