AGM Script – 1 November, 2018

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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. 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 Acrux's 2018 Annual General Meeting. We would like to thank Pitcher Partners again for the use of their facilities for the AGM.

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:

My fellow Board members
- Our Chief Executive Officer and Managing Director Michael Kotsanis,
- Our three Non-Executive Directors: Geoff Brooke, Tim Oldham and Simon Green

and our CFO & Company Secretary – Tim Bateman.

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

As noted in our Annual Report, Acrux initiated a change in strategy in 2015. The Company had historically focussed on the development of improved forms of generic drugs utilising our patented delivery systems. The change in strategy still used our core expertise in drug formulation, but was focussed on developing a more extensive range of products, specifically addressing the generic market for transdermally and topically applied products.

The commercial logic underlying the strategy has been enunciated previously but it is worth repeating it and providing a brief commentary on its relevance to the continued implementation of our strategy. There are both external and internal factors to consider in the context of the Company's strategy and I will address the external factors first.

The first external consideration is the proportion of the US market share that topical generics hold relative to branded transdermal and topical pharmaceuticals. The relative market shares are 47% for generics compared to 53% for branded. This is significantly less than the comparative ratio for oral pharmaceuticals, which is approximately 80:20.

While there are a number of factors which influence these ratios, the relative ease of creating competitive oral generics has led to a high level of competition, which has in turn led to highly competitive pricing. The transdermal and topical generics market has not experienced the same level of competition and consequently there are more attractive commercial opportunities for companies with the relevant technical expertise in this sector of the market.

The second consideration in assessing the strategy is the time required to achieve a commercial return. Acrux's previous strategy was both high risk and high return. Given the competitive nature of the pharmaceutical sector, the risk element relates to the development process in terms of the ability to formulate a drug, prove it is safe, stable, effective, has no long term adverse effects and is cost-competitive. The medium term risks relate to whether it is perceived by both the licensee and patients as being worth using compared to competitors' alternate products and whether it is affordable on a medium to long term basis. The constant risk with all new products is whether their patent status will be upheld and whether regulators' concerns over safety will prevent marketing and/or sales of the product.

Generics do not generally share the same concerns: development is significantly simpler given the effective use of 'reverse engineering'. Safety and other concerns have already effectively been addressed by the prior approval of the Reference Listed Drug(s) (collectively, 'RLDs'), which are the drug(s) that were first to market with patent protection. Generics do not require or rely on patent protection so there is reduced risk associated with IP and if the regulatory body imposes requirements for further studies for safety and/or efficacy profiles, the generic drug manufacturers are not required to participate in those studies. These factors significantly reduce the risks normally associated with both the drug approval process and maintenance of the approval for generics.

The third consideration is the economics underlying health care provision to an aging demographic in the developed world and the impact this has on regulatory provisions and the operation of healthcare systems. RLD development is a lengthy and expensive process.

Unless the RLD under development offers a significant improvement over existing medications or it is addressing an unmet medical need, the approval process is unwieldy and slow. Generics offer Governments comparable treatments for a wide range of patients at significantly lower cost after RLD patent expiration. The US regulator is improving review times for generic drug applications to enable generics to get to market more quickly, which reduces the time required to achieve commercial returns on the products Acrux has in development.

The internal factors also determine Acrux's capacity to realise the commercial opportunity associated with the development of a transdermal and topical generics pipeline. The major consideration is the Company's capacity to retain and leverage the existing expertise and skill sets and complement these assets with additional resources with experience in the generics market.

Michael has done an excellent job in both respects since joining the Company and we have a committed team which has delivered the outcomes we have been targeting ahead of time and on budget. We released news of our first generic dossier's acceptance for review in August this year, our second dossier acceptance in October this year and we are targeting filing another dossier in the near term. As we advised shareholders last year, the 2018 financial year was going to have limited news flow but the 2019 financial year will be significantly more interesting.

One feature of the generics market is the lack of visibility of the commercial metrics. RLD licensing and distribution metrics are far more visible and analysts can determine product profitability and market trends more easily. Both Acrux's Board and our Senior Management have experience in the sector and we believe that the commercial merits of the Company's strategy will become clear as critical mass is achieved as the product pipeline matures. Generics provide a significantly quicker return than development of new drugs and with a much lower risk profile, both during the development phase and subsequent to their registration.

Commercial interest in our pipeline is the other material indicator of the validity of the strategy we have adopted and we are pleased with the level of interest we have received. Our cash position remains robust and we are looking forward to providing shareholders with more detail about our projects over the next twelve months.

I would like to extend my personal thanks to the Board for their input over the last year, which has been a demanding one. I would also like to extend the Board's appreciation to Michael and his team for their outstanding work in repositioning Acrux for growth.

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Mike Kotsanis – Chief Executive Officer and Managing Director

Thanks Ross.

Good morning and thank you for attending this year's Annual General Meeting and for your interest in Acrux.

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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, the outcome of legal proceedings and the effectiveness of patent protection.

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Last financial year we executed strongly on our operational goals.

I will touch on each of these highlights in turn.

We expanded our pipeline by 6 projects, growing the number from 7 projects to 13 over the financial year. This is very encouraging and if we continue to execute well the outcome will be a regular flow of regulatory submissions to the FDA, approvals and launches in the future. We will add additional projects to the pipeline during this financial year.

We filed our first Abbreviated New Drug Application (ANDA) in June 2018 right on schedule. The dossier was accepted by the FDA for review in August this year and is now part way through the regulatory review process. Indeed, we have had regular engagement on our first dossier since filing as we respond to questions from FDA from their various disciplines undertaking their scientific reviews. During the year we also successfully concluded a PK study on another generic topical product, that is yet to be submitted, that showed that the generic product that we had developed was bioequivalent to the Reference Listed Drug.

We are also pleased that we recently announced our second dossier filing for testosterone solution. Testosterone is a well known topical product to Acrux and we filed an ANDA or a generic dossier for testosterone solution in August and this was accepted for review in October. We look forward to the FDA review of this product.

Our R&D team grew in number along with the size of our pipeline. A number of those projects progressed through to new milestones in their development pathway and we are pleased with the overall progress that we have made. We have a committed, experienced team within Acrux and they have executed well over the course of the previous twelve months.

We have engaged with multiple contract manufacturers for our pipeline and by the end of this year we expect to have begun the tech transfer process for 6 additional where we transfer our formulation for each generic product to a manufacturer for scale up and exhibit batch manufacturing. A technical transfer is a vital step for us. It shows progress for our development and means we are now at the stage where we are satisfied with our analytical and formulation work to the extent that this can be transferred to a contract manufacturer (CMO). Our CMOs are contracted to manufacture exhibit batches which are used to produce data for inclusion in our regulatory dossier which is submitted for review to the FDA.

We know that our pipeline is of value to generic companies as they have expressed this to us as we begin our licensing discussions on various projects in our pipeline.

And finally, it was pleasing to note the appreciation in our share price and the high volume in trading of our shares with the confirmation of our first and second generic dossier submissions to the FDA. This is good evidence of our ability to execute projects from identification through to regulatory filing. We look forward to further communication around future dossier filings as well.

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From this slide of our share price you can see the direct impact of the announcements of our first two ANDA filings with the FDA. It is pleasing to see our share price respond. Over the last 12 months our share price has appreciated by 55%. We also note that as at end of June our cash backing was approximately 17 cents per share.

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When we expand our future pipeline of products, we use the information on sales data, competition level and development complexity to carefully select topical products to develop as generics. Our definition of topical products is those products that are applied topically, irrespective of the site of administration and includes drugs for a wide variety of approved indications. Using IQVIA data (which was formerly known as IMS prior to their merger with Quintiles) we know that there are 165 molecules that generate over US$10 million in annual revenue. Some of the 165 molecules have multiple dosage forms and strengths. There are 80 molecules that are applied topically that generate over $50 million in sales. And there is a group of products that we pay careful attention to and also study thoroughly which are the smaller but fast-growing topical products. We keep a close watch on these smaller molecules to determine their potential to add to our pipeline. At the end of June 2018 we had 13 topical generic development projects that have been carefully chosen in our pipeline, with two under FDA review so far.

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We see advantages for Acrux in the development of generics versus branded pharmaceutical products. Whilst a single branded product can have substantial sized market potential, we see generics achieving attractive royalty rates in the market with licensing terms that reflect the market potential for generic drugs. The development risk for novel drugs is well known and the risk of failure is high. Various statistics are published on the success rates for the development of new drugs, but only 12% of drug candidates successfully move into a Phase 1 clinical trial, and even after this phase success rates are relatively low.

A generic drug is effectively the same as a drug that is already approved and marketed. So development risks for generic products are relatively low. Timelines for development are quite fast with limited clinical trial work needed to confirm bio-equivalence for most generic products. Contrast this to the 10 plus years and high expense of developing new branded products and the risk and benefit equation for generics is quite clear.

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This slide shows the progression of our pipeline. Not all products in our pipeline progress at the same speed, but the more important aspect is whether we are making progress consistently across our pipeline towards dossier submission. And you can see we are making good progress. Some products we have internally prioritised over others due to their higher commercial potential, but we do not want to see all our efforts placed onto one product. A solid portfolio is more important than banking on one product in the generic market.

We do receive questions from shareholders as to whether there are additional Paragraph IV certification products in our pipeline and I can confirm that there is one product not yet submitted, which is under development and is considered by Acrux to be a Paragraph IV ANDA filing. That means that for the 13 products in our pipeline, 11 of our generic products will be submitted without a Paragraph IV certification, as will be no patents protecting the Reference Listed Drug when we launch.

This financial year we have already communicated that we expect to submit an additional two dossiers, one of which was just recently announced as testosterone solution, and as we have stated, we will announce additional dossier submissions in the future as these as they are accepted for review by the FDA. These submissions will lead to partnering discussions, which is why we believe that we will generate first revenues from our generic portfolio next calendar year.

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Our pipeline has an interesting mix of projects from a commercial perspective. You can see the green bar here represents products on the market with no direct competitors. The products may be a brand or they may be a generic where the brand has exited the market, leaving just the generic product available. Based on IQVIA sales data, the addressable market for products in our pipeline with no additional on-market competitors is over $1 billion in sales. This is over half the addressable market for our entire product pipeline of $1.4 billion and is also over half of the number of products in our pipeline. I believe that makes our pipeline very attractive.

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The pathway from dossier submission to a commercial royalty stream is illustrated on this slide. Once we submit the dossier to the FDA and that dossier is accepted for review, we are then in a solid position to discuss the asset, being the submitted ANDA dossier, with potential licensees. B2B licensing, where a company develops a generic and licenses it to an established generic company is a common business strategy and royalty rates or profit share arrangements on licensing are usually in the high double digits percentages. The FDA under their GDUFA 2 commitments have a goal to review 90% of dossiers within 10 months of receipt.

They may then approve the product or seek further clarification on the data that has been submitted supporting the dossier. We have seen FDA review times decrease significantly compared to the earlier part of this decade.

Once a licensing deal has been concluded and the product launched, Acrux will enjoy an ongoing annuity type revenue stream and this can then be invested in further product development and pipeline expansion.

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The first and second products from our pipeline have reached the stage where we have submitted the dossier for the products to the FDA. That was back in June and August.

The first project was started in early 2016 and by the second quarter of 2017 we began our technology transfer to our contract manufacturing partner. By June 2018 we had appropriate exhibit batch data and were able to complete the dossier and file this on the very first allowable day, which is linked to the market exclusivity for efinaconazole. This means we achieved a first to file status although we now know that there are multiple first filers and each will share market exclusivity for 180 days following Final Approval at some point in the future.

The process for a Paragraph IV filing can be summarised by quoting from the FDA website: *"To begin the FDA approval process, the generic applicant must: 1) certify in its ANDA that the patent in question is invalid or is not infringed by the generic product (known as "paragraph IV certification"); and 2) notify the patent holder of the submission of the ANDA. If the patent holder files an infringement suit against the generic applicant within 45 days of the ANDA notification, FDA approval to market the generic drug is automatically postponed for 30 months, unless, before that time, the patent expires or is judged to be invalid or not infringed. This 30-month postponement allows the patent holder time to assert its patent rights in court before a generic competitor is permitted to enter the market."*

Paragraph IV patent litigation is very common in the United States pharma market and the reward for this to generic companies is the 180 days of generic market exclusivity. On the FDA website there is a database of all Paragraph IV certifications on different drugs. The database is updated monthly. At my last count there were over 1300 Paragraph IV certifications on different patented drugs.

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This slide is a reminder of why we believe the topical market is attractive. Topically applied drugs are a niche within the US pharma market. They represent 4% of sales of the US pharmaceutical market, which in total is valued at over $450 billion today. But even this small percentage of the market is valued at $18 billion. It is interesting that the share of generics of the topical market is still evolving and the market will become more and more generic in orientation as generic products are launched against products and brands that have limited or no generic competition. Competition for generic drugs can be high, but the market for topically applied drugs is generally less competitive than the oral generic market for tablets and capsules. In terms of generic company profitability, even when the oral market is included, the average EBITDA margins for generic companies is roughly 25%. We believe the generic market is attractive in the long term and that the topical sector has some unique characteristics where we can leverage our core skill set.

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The team that is working to identify, develop and commercialise the topical generic market opportunities we are developing and submitting have strong generic market expertise. We also have a strong R&D focus in a team that has grown as our pipeline has expanded. We recently added up the years of experience our 25 people have in our development team and it equates to over 350 years of experience in developing topical drugs. That's an impressive number and it gives us confidence that we can tackle the various development challenges that our pipeline will have over time.

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Beside me are my fellow directors for Acrux. They are an experienced team of high-quality individuals who represent your interests well.

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At the end of each financial year we review our progress and set our objectives for the following financial year. During this current financial year we are targeting achievement of the following milestones. We plan to submit an additional generic dossier to the FDA making this the second dossier submitted during the current financial year and the third in total since we began working on our topical generic pipeline in Q3 2015. We will announce these dossier submissions when they are accepted for review by the FDA, which is generally up to 60 days after submission. We plan to begin the tech transfer process for 6 projects this year which is an important sign of progress of our portfolio. Tech transfer means we will be transferring our formulations for 6 products to our contract manufacturing partners. We will add additional products to our pipeline during the year as well and in fact have recently begun work on our 14th project. And during 2019, we also expect to receive our first revenues form our generic portfolio from the outcome of licensing discussions on our pipeline.

I will now hand over to Tim Bateman to discuss the financials for FY18.

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Financial Review
Tim Bateman – CFO & Company Secretary

Thanks, Michael.

Good morning.

Firstly, I would like to comment that I am pleased with the progression and continued investment in the research and development pipeline that the Group has made in a revenue compromised environment. I reiterate Michael's comments relating to the submission and acceptance for review of our first two dossiers, important external validation of the Group's development program. It is exciting for the Group as it moves closer to the first commercialisation events.

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I will now focus on providing more detail in relation to the performance for the financial year ended 30 June 2018.

The headline results for the financial year are as follows:

- Revenue of $3.4 million, down 85.7%
- Research and Development Investment costs of $10.6 million, up 14.9%
- Underlying Operating Loss Before Impairment Loss and Tax of $10.5 million

- Once off Non-Cash Impairment Loss of $5.6 million
- Net Loss After Tax (NPAT) of $14.2 million
- Basic and diluted loss per share was 8.52 cents
- Cash Reserves at the end of period $28.5 million down 16.2% from 30 June 2017

This underlying operational performance is reflective of the Group's expenditure on its generic product pipeline and the impact of losing the Axiron® royalty revenue, which was previously the Group's primary revenue source.

The non-cash impairment loss of $5.6 million is a result of a reassessment of the estimated future discounted cashflows from Axiron®, which were impacted by the termination of the licensing agreement following the U.S. Court of Appeals for the Federal Circuit affirming all aspects of the judgment by the United States District Court for the Southern District of Indiana. This loss was disclosed in the half year accounts released in February 2018.

The impact that the decline in global sales of Axiron® had on the Group revenue was material. Axiron® royalty revenue for the financial year was $2.32 million, a decrease of 90.2% on the prior financial year.

The balance of royalty revenue is derived from our other commercialised products, including Estradiol, branded as Lenzetto® (in Europe) and Evamist® (in the US). This product continues to build market share in existing regions, in particular Germany and via launches in new regions.

Other income comprised of interest earned on cash reserves invested and FX gain contributed $0.7 million for the financial-year.

Moving to our cost base:

R&D investment totalled $10.6 million, up 14.9% on prior financial year due to the progress with and an increase in development projects. Expenditure increased on the follow items:

i. contract manufacturing and procurement of API for the manufacture of exhibit batches
ii. engagement of clinical research organisation for bioequivalence trial
iii. IP strategy costs and
iv. increased laboratory headcount

Other operating costs were $2.7 million, up by 23.1% or $0.5 million due to non-recurring legal fees associated with the Axiron® patent appeal litigation, which was incurred in first half of the financial year. Previously these costs were borne by Eli Lilly and Company, however, the termination of the Axiron® licence agreement altered that position.

Income tax benefit of $1.9 million was recorded for the half year. This is driven by the higher operating loss and the reversal of the deferred tax liability associated with the impaired portion of Axiron® capitalised development costs.

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In relation to cash flow for the financial-year:

Cash received from product agreements was $7.9 million, down 63.9% on prior financial-year.

Increases in payments to suppliers & employees of 18.4% were incurred due to investment in R&D increasing and non-recurring legal fees.

Tax payments for the financial year were $1.0m or 83.7% lower than prior financial-year, reflecting a lower prior year operating result and the timing of tax payments.

Payments for property, plant & equipment are $0.3 million, which is 20.5% lower than prior financial year reflecting the timing of the expenditure as the Group carries out upgrades of existing laboratory assets to improve our internal analytical and testing capabilities to reduce our reliance on external providers.

As a result, cash reserves at the end of the financial-year were $28.5 million, down 16.2% or $5.5 million from 30 June 2017.

To recap, we are comfortable with the Group's financial position at the end of the financial-year, with cash reserves to provide the platform to support our growth and diversification strategy as we near commercialisation milestones in relation to our research development pipeline.