AGM Script – 26 October, 2017

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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 the 2017 Acrux Annual General Meeting. We would like to thank Pitcher Partners for the use of their facilities today.

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,
- Non-Executive Director – Geoff Brooke
- Non-Executive Director – Simon Green

and our CFO & Company Secretary – Tim Bateman.

Non-Executive Director, Tim Oldham has requested that his apology be recorded.

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.

In September Acrux announced that the licensing agreement for Axiron had been terminated. This comes as a result of the impact of generic competition on Axiron reducing Axiron sales, which made the long term financial commitment required to conduct a Postmarketing Requirement (PMR) clinical trial amongst testosterone New Drug Application (NDA) holders unfeasible. With the commercial uncertainty of future sales of Axiron, a declining testosterone market and the long term and unclear financial commitment required to participate in the PMR consortium, Eli Lilly and Company withdrew the Axiron NDA from the US market.

These factors have reinforced the need for Acrux to continue to execute its strategy of developing and commercialising a diversified portfolio of products to avoid reliance on the majority of revenues being derived from one product in the future. Over the last twelve months Acrux has made solid progress with both the development of our generics pipeline and a superior antifungal product for the treatment of onychomycosis. While we are still waiting for the outcome of the Appeal process against the US District Court's decision on Axiron patents to be resolved, the commercial release of several generics of Axiron has significantly reduced the commercial value and prospective life of the product. Fortunately, we have built our cash reserves sufficiently to continue to fund the development of our pipeline.

Over the last year we have progressed both the technical development of our suite of products and the intellectual property strategy for our superior product. Development expenditure has increased significantly as we ramp up our generics program, with a range of additional candidates identified and prioritised internally.

As noted in last year's Annual Report, our current budget provides for the continuing development work on the pipeline to be conducted regardless of the outcome of the Appeal. We cannot comment on the Appeal, as it is still before the Courts and there are a range of scenarios possible.

Acrux is gradually expanding the development team as the initial product suite moves into the later development phases and new products are added to the pipeline. While the global generics industry has received some adverse publicity recently, the industry continues to expand and the pricing of products in our market segment continues to provide commercially attractive opportunities. Michael will address these developments in his presentation.

Acrux has a number of fundamental strengths that enable it to be highly competitive in this market segment. We have experienced staff and an efficient, well-provisioned development facility. Minimal capital expenditure has been required to upgrade our facility for the increased workload and our product selection methodology has been validated by the commercial profile of the markets being targeted. Acrux has not bought product opportunities from other market participants, but has identified the opportunities and initiated development internally. This approach minimises the cost of the products under development.

As we have stated since the Company was founded, our position has always been to maintain sufficient funding for working capital requirements and to distribute the balance as dividends. Our working capital requirements have increased significantly as the development pipeline has expanded and we expect this to continue for the foreseeable future.

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 a challenging external environment with respect to Axiron. Their efforts continue to be instrumental in repositioning Acrux for growth.

I will now hand over to Michael for a more detailed operating review.

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Michael Kotsanis – CEO and Managing Director

Thank you Ross.

Good morning. Thank you for joining us at the 2017 Annual General Meeting.

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I would like to formally note our Forward Looking Statement caveat by stating that…

…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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I trust that you all have had a chance to review the Company's Annual Report that we issued 4 weeks ago and I would encourage investors and shareholders to review this for full details of our Company's operational results and activities.

This presentation will address the following areas. I will provide an update on the status of Axiron, the termination of the license and withdrawal of the product and the patent appeal. This will be followed by a review of what we achieved during the 2017 financial year. Our CFO, Tim Bateman, will present the 2017 financial year P&L and cashflow statements and I will then address our pipeline and the progress we have made. I will conclude with the milestones we expect to achieve in the next 12 months and beyond.

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The termination of the Axiron license with Eli Lilly and Company represents a significant headwind to the company as Axiron represented the majority of revenue for the company. However, Axiron and the testosterone market have been in decline since the 2014 and 2015 FDA Drug Safety Communications and announcements relating to testosterone use. The recent launch of generic competition in the United States reduced Axiron revenue further and although these generics launched later than we had anticipated, the impact on Axiron has been significant. Against the background of an uncertain cost apportionment to participate in the consortium of NDA sponsor companies of testosterone to run the FDA mandated postmarketing requirement for a long-term safety study, the introduction of generic competition resulted in Eli Lilly withdrawing the NDA thereby halting US sales of Axiron in September.

I'd like to remind shareholders of the history of the Axiron patent litigation and other regulatory actions that have impacted the value of this product to Acrux. The original challenge to the Axiron patents and court action began in 2013 following the first generic filer's Paragraph IV patent certification. As we announced at the time, Acrux and Eli Lilly jointly sued both Actavis and Perrigo back in 2013. Additional generic companies, including Amneal and Lupin, subsequently filed dossiers for generics of Axiron with Paragraph IV certifications declaring that Axiron patents were either invalid or not infringed and these companies were also sued.

The 2016 District Court decision to invalidate the Axiron formulation and axilla site of application patents was immediately appealed. That Appeal was heard in the Federal Circuit in Washington DC earlier this month and we await a decision from the Court. There are four potential outcomes of the Appeal.

1. We could lose the Appeal
2. There could be a settlement with all or some of the parties
3. The Federal Circuit could overturn the District Court decision
4. or the judges can remand the case back to the District Court to be heard again

If ultimately successful in upholding our patents we will pursue damages against those generic companies that have launched a generic of Axiron. If unsuccessful, then the generic companies that have already launched will remain on the market. To date, two companies have launched generics of Axiron – Perrigo in July and Teva in August this year. Prasco launched an Authorised Generic, also in July. We would expect up to 9 companies to launch a generic of Axiron, based on ANDA filings from generic companies and pending the outcome of patent litigation. Acrux continues to believe that the Axiron axilla application patent is valid and enforceable, and Acrux is committed to asserting its intellectual property rights for Axiron. The Appeal proceedings occurred on 5 October 2017. Acrux and Lilly continue to stand by the safety and efficacy of Axiron when used as indicated.

Additional uncertainty was added to the testosterone market when, following an Advisory Committee meeting in 2014, the US Food and Drug Administration (FDA) required holders of new drug applications (NDAs) for approved testosterone products to conduct a well-designed Postmarketing Requirement (PMR) clinical trial to more clearly address the question of whether an increased risk of heart attack or stroke exists among users of testosterone products. The trial would need to be conducted independently or through a consortium of NDA holders. The FDA required a submission of the final PMR protocol by 5 September 2017. In the absence of a commitment to the PMR protocol, the FDA may take regulatory action against an NDA holder.

As a result of the commercial uncertainty related to the impact of generics, the continued decline in the testosterone market, and the uncertain apportioned costs to participate in the PMR consortium of testosterone NDA holders, Acrux and Eli Lilly and Company mutually agreed to terminate their licensing agreement for Axiron. Termination of the license in the US was effective 6 September with a request submitted by Eli Lilly to FDA to withdraw the NDA from the US market. Over 95% of Axiron sales were generated in the United States. Termination of license outside the US will be effective on 4 December and sales of the product will also cease globally by 4 December.

This dramatically highlights the risk of being reliant on one product for the bulk of revenue and the impact that external factors and events can have on that product. Our efforts for some time have been squarely focussed on expanding our product pipeline. We have continued to invest enormous organisational energy into our pipeline. Our pipeline has grown and all projects within that pipeline have made good progress against our expected plans.

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With the termination of the Axiron license and withdrawal of the product, The Board have taken the following actions.

You will note from our Annual Report that the majority of resource and expense within Acrux is directly allocated to progressing and expanding the pipeline of products. Our cash reserves at the end of the financial year were $34 million.

The Board have also reviewed the pipeline following the termination of the Axiron license. Our preparations for moving into the clinic with our onychomycosis specialty product were advancing well, having met with the FDA for a Pre-IND meeting in early October as well as recently applying for ethics approval for a Phase 1 trial in Australia. However, due to the longer horizon and higher cost profile of our onychomycosis specialty project compared to the substantially shorter timelines and lower costs from our generic pipeline, we have decided to suspend the development of the onychomycosis specialty project and focus our existing cash reserves on the continued expansion of the generic pipeline.

With sales and royalties from Axiron in decline for some years and generic competition challenging our patent validity, our clear focus for some time has been on a transformational change to our pipeline focus and breadth. At the end of the financial year we had 8 separate development projects in our pipeline - double the number from a year earlier – including 7 generic projects. Since the end of the 2017 financial year this has grown further. Our goal is to grow this number to 12 generic projects by the end of the 2018 financial year and 19 by the end of the following financial year. We have made good progress on our existing and newer pipeline projects and these are tracking to our internal expectations.

The first dossiers from our generic pipeline will be submitted within 12 months. I will talk more about the opportunity that we see with our pipeline of topical generics later in the presentation.

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Financially, the 2017 financial year was a solid year for Acrux. Revenue was $23.3 million and net loss after tax was $200 thousand, due to a non-cash impairment loss of $10.68 million relating to the Axiron intangible asset.

Our cash position at the end of the financial year was $34 million. For the 2018 financial year we expect to invest between $12 to 14 million to progress our growth strategy and development programs, which I will discuss later in my presentation.

Based on our expected expenditure, the Company is presently able to fund its R&D pipeline from cash reserves for the current projects in development, along with the 5 additional projects we expect to initiate during the 2018 financial year.

Acrux's investment decisions are based on the scale and merits of the opportunities the current R&D programs are expected to generate, the available cash reserves, the time to value realisation and the Board's assessment of the best interests of shareholders in this context.

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During the 2017 financial year, we initiated scale up activities for our first three generics and we are currently in the process of manufacturing exhibit batches for all three products at the contract manufacturer that we engaged earlier in 2017. These batches are required for regulatory submissions to the FDA and for any clinical bioequivalence trials that are needed for our generics.

We were pleased to see that Gedeon Richter has continued to launch Lenzetto in a number of countries throughout Europe. Country launches now total 17, with additional countries planned this year. Gedeon Richter is also filing regulatory submissions for the product in countries outside the European Union.

We drafted and submitted a new patent application for our improved efinaconazole formulation for onychomycosis.

In addition, whilst not every generic we are working on requires a clinical trial to demonstrate bioequivalence, our planning for our first bioequivalence study is complete, having identified the CRO and finalised the protocol with the trial initiation awaiting clinical trial material with sufficient shelf life from our exhibit batches.

Of course, we also expect the outcome of the Axiron Appeal in coming months.

I will now hand over to Tim Bateman, CFO & Company Secretary, to discuss our financial results in more detail.

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Tim Bateman - CFO & Company Secretary

Thanks, Michael.

I would like to add my welcome to our 2017 Annual General Meeting.

Firstly, I am pleased with the underlying operational performance of the Company for the financial year, which exceeded expectations due to the Axiron royalty revenue not being compromised by generic competition during this period.

In addition, the progression of and increased investment in research and development activities has been a material achievement for the Company as it moves closer to the commercialisation of the first products from its generic pipeline.

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Now I will provide you with more detail about the performance for the full-year ended 30 June 2017.

Recapping the headline results for the financial year:

- Revenue of $23.9 million down 16.2%
- Research and Development Investment costs of $9.2 million up 67%
- Underlying Operating Profit Before Impairment Loss and Tax of $10.6 million down 41.5%
- Once off Non-Cash Impairment Loss of $10.68 million
- Net Loss After Tax (NLAT) of $(0.2) million
- Cash Reserves at the end of period $34.0 million up 15.7% from 30 June 2017

This underlying operational performance is reflective of the Company's continued investment in its research and development pipeline, together with the impact of the declining US market for Axiron, which was the Company's material revenue source.

The non-cash impairment loss of $10.68 million is a result of a re-assessment of the estimated future discounted cashflows from Axiron, reflecting variables including the current market data for the testosterone market in the United States and generic market penetration since 6 July 2017.

An analysis of the revenue key movements shows:

- Axiron royalties at $22.8 million declined 10% from prior financial year, reflecting a decline in Axiron global sales by our commercial partner Eli Lilly and Company. On a constant currency basis royalty revenue from Axiron declined 6.1% or $1.4 million year on year.

- The balance of royalty revenue is derived from our other commercialised products including Estradiol, which is branded as Lenzetto (in Europe) and Evamist (in the US). Lenzetto continues to build market share in the European Union and particularly in Germany.

- No milestone revenue was expected or received, compared with the prior year.

- Other income comprised interest earned on cash reserves, which contributed $0.6 million for the financial-year.

Moving to our cost base, key points to note:

- R&D investment was $9.2 million, up 67% on the prior year due to the progression of existing projects, an increase in the number of research and development projects and a higher utilisation of external suppliers. Material investment increased in the following items:

    i. contract manufacturing and procurement of API for exhibit batches $1.7 million

    ii. IP strategy costs $1.1 million

- Operating costs have essentially remained flat year on year and non-operating costs, which comprise amortisation of capitalised assets and foreign exchange loss, reduced by 25% to $1.9 million.

- Income tax expense of $0.15 million was recorded for the financial year. This represents a 97.1% reduction on the prior financial year and is attributable to the lower operating profit (excluding the impairment loss) and the reversal of the deferred tax liability associated with the impaired portion of Axiron's capitalised development costs not being realised as initially contemplated.

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Our 2017 cash flow was solid. The launches of Axiron generics was later than expected.

A more detailed analysis of our cashflow shows:

- Cash received from product agreements was $21.8m, down 22.6% on prior year due to lower Axiron royalty receipts of $21.5m and the non-recurrence of the Lenzetto European approval milestones which were received in 2016.

- Increase in payments to suppliers & employees of 35.7% as investment in R&D is increased on our development pipeline.

- Tax payments for the financial year were $6.3m or 47.5% higher than prior year due to the payment of final 2016 tax liability, in 2017 financial year.

- Payments for property, plant & equipment are $0.6 million or 116.5% higher than prior financial year. This reflects the Company's objective of upgrading laboratory assets and improving our internal analytical and testing capability. This is necessary to reduce our reliance on external providers.

- As a result, cash reserves at the end of the financial year were $34 million, up 15.7% or $4.6 million from the prior financial year.

To recap, I am pleased with the Company's financial position at the end of the financial-year, as it provides the resource to support the investment in our growth and diversification strategy.

The Company has already invested a significant amount of capital in our development pipeline. The continued prudent management of these resources is an imperative as we near the first commercialisation events of our development pipeline.

Now let me return to Michael.

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Michael Kotsanis – CEO and Managing Director

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Thanks Tim.

I appreciate that a number of investors would like to better understand our approach to our generic pipeline.

It is important to reinforce that generics are just as effective and just as safe as their brand name equivalents. In an environment of ever increasing healthcare costs, generics offer consumers a cost-effective alternative to those brands. On this slide is an FDA statement along with a statement from the American Medical Association on generics.

Our goal when we develop a generic is to ensure that the generic will have exactly the same profile and the same active ingredients as the brand name drug.

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Generic pharmaceuticals dominate the United States market. It is also worth pointing out that the generic industry in the United States is a highly sophisticated sector that accounts for 9 in every 10 prescriptions in that country. That trend, as you can see, has been increasing for the last decade as more and more products come off patent. Generics offer the consumer choice and savings versus branded drugs.

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The value of generics is further depicted on this slide. The European Generics Medicines Association recently undertook a health economics study and some of the key outcomes are shown here. Whilst these therapeutic areas are not specific targets for Acrux, the themes apply across the generic sector.

On the left hand side of the slide, using the example of hypertension, or high blood pressure; with the availability of generics, more patients can be treated with the same expenditure.

Using the example of breast cancer; with the availability of generics, the same number of patients can be treated with less expenditure.

And on the right hand side of the slide, using the example of depression, with the availability of generics, more patients can be treated with a small increase in healthcare expenditure.

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The generic market in the United States has many opportunities for growth in the future with continued patent expiration for existing drugs.

This slide depicts the brand sales value of products losing patent protection. In the coming few years, over $50 billion of sales of branded products will lose patent protection and will be subject to competition from the launch of generics. Prices of those products will be lower with generic competition. Savings will be substantial from these patent expirations. That creates a tremendous opportunity for generic companies in the United States.

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The reason that generic companies targeted Axiron is that it reached a sales level which became attractive for them. Although this is now history, we can be genuinely encouraged that Acrux's technology and know how generated substantial in-market sales of its commercialised products and Acrux has both received and paid out a significant dividend stream in the past.

Our core capability is the development of topically applied pharmaceuticals. This is evidence by the past approvals of Axiron, Evamist and Lenzetto. Our know-how around topical and transdermal drugs has resulted in continued commercial approvals and launches with Lenzetto launches continuing during the last financial year.

The active pharmaceutical ingredient in Axiron – testosterone, and in Lenzetto and Evamist – estradiol, are good examples of how Acrux has taken an existing drug and brought it to market. Those products also incorporated alternative topical delivery methods to result in a differentiated product offering of a known existing drug. Our generic pipeline requires similar formulation and development capability. We are developing generic versions of existing topically applied drugs. We have demonstrated that we are capable of developing known drugs such as testosterone and estradiol and gaining approval in major markets around the world. Our pipeline continues to leverage the core skills within Acrux. The Acrux team are committed to achieving further regulatory approvals and commercial successes through our own generic pipeline in the future. Acrux has demonstrated strong capabilities in the development of pharmaceutical products that are applied topically. This gives us a high degree of confidence on the products in our pipeline.

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This slide shows the US market by dosage form. The majority of sales in the pharmaceutical industry are from drugs administered orally. Injectables are the next biggest category of pharmaceutical products.

Drugs which are applied topically in the US generate a little under $18 billion in sales. This can be further broken down into the branded and generic sectors. Our generic pipeline reflects our focus on developing generic versions of existing branded or generic topical or transdermal products that are currently marketed in the United States.

Generics, which are submitted to the regulator called the FDA in the United States are called Abbreviated New Drug Applications (or ANDAs for short). Generics leverage the clinical data for the same products that have already been approved by the regulator. This allows the development process for generics to be much quicker, less expensive and with lower overall development risk than the development of branded novel drugs.

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We further analyse the market as depicted by this chart. There are 472 drugs on the market in the United States that are applied topically. Of those, 165 generate more than US$10 million in sales and 80 generate sales in excess of US$50 million. There is also a group of products that generate much less than $50 million in annual revenue each, but where the markets are fast growing and we also pay close attention to these as well. Each molecule can be marketed in a number of different presentations including creams, ointments, liquids, lotions and patches. We also consider the level of competition when selecting the products which we are going to develop, preferring to focus on products with low to modest levels of competition.

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At the end of the 2017 financial year, our seven initial generic products had an addressable market in the United States of around $1 billion, based on IMS data. We have carefully considered each new development project and the costs of the development relative to the potential revenue from each product. We actively consider projects that can be approved through a waiver of in vivo clinical bioequivalence, small pharmacokinetic studies and also projects that encompass a Paragraph IV patent strategy.

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On this slide we further break up our pipeline into segments based on the number of generics that are marketed for each molecule. In other words, this slide on the right hand side shows the competitive profile for each product.

You will note that the majority of products we are developing have low to modest levels of competition.

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Some examples of therapeutic areas that topical drugs are used for are shown in this slide. Topical drugs are used for indications far wider than dermatology diseases. For example, hormones are administered topically as are drugs for rheumatoid arthritis, acne, pain and fungal infections. The list of indications is substantial, and is also reflected in the wide variety of indications our pipeline addresses. However, the indication for the generic projects we are working on is generally less important than the commercial profile of the products we are developing.

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This slide shows the progress we are making in our generic pipeline. We break our projects up into highly detailed project plans that actually include hundreds of activities and steps. At a high level we summarise this detail into 5 major areas – formulation development, process development and then the establishment of bioequivalence, which may involve a clinical trial, but in some cases can rely on in-vitro assessment only. The next step is a regulatory submission to the FDA in the United States and then finally on approval the product is able to be launched.

In mid 2017 we had 7 generic under development. Three of these were in the process development stage, with 4 projects added during the financial year into formulation development.

If we fast forward to mid-2018, for our lead three products we will be preparing our regulatory dossiers for submission to the FDA. We will have an additional three into process development and have six projects in the formulation development stage.

We see the generic portfolio as an attractive opportunity for Acrux to leverage its existing skills and know how in developing topically applied products. Overall the development of generic products is a lower risk and lower cost exercise than the development of novel products. We are avoiding the heavily commoditised segments where there is substantial pricing pressure and whilst the topical segment is not immune from price reductions, we generally see less competition within that sector compared to the larger generic segments in the United States.

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Our growing pipeline is consistent with our previously disclosed strategy to diversify our portfolio and we will continue to execute on our pipeline as aggressively as possible. It will be an exciting moment to file the dossier for the first of our generics, which is scheduled mid 2018 with subsequent filings soon afterwards. The Axiron Appeal decision is expected most likely in early 2018 but the time varies on a case by case basis.

From our pipeline, assuming the FDA reviews our dossiers in a reasonable timeframe, we would expect to receive initial revenue from the pipeline at the back end of 2019. The number of projects in our pipeline will grow to 12 generic projects by the end of the 2018 financial year. And by the end of the following financial year we will have grown our pipeline to 19 products in development.