**ACRUX (ACR) - ASX ANNOUNCEMENT** **31 OCTOBER 2006**

# 2006 ANNUAL GENERAL MEETING - CHAIRMAN'S ADDRESS

Since last year's AGM, we have made significant changes to the management and Board to enable us to accelerate commercialisation of Acrux's technology. We are entering a new phase in the Company's growth and remain in a strong position, with cash reserves of $16.6 million. Our cash outflow in the last financial year was $8.3 million and we expect that to reduce this year as a result of reduced discretionary expenditure and increased licensing income.

There have been several changes to the Board's composition. In January 2006 I took over as non-executive Chairman from Nuno D'Aquino and Ken Windle became non-executive Deputy Chairman. During his tenure as Chairman, Nuno was instrumental in the Company's Initial Public Offering and its transition to a listed company. We have retained Nuno's skills through appointing him to Chair our Human Capital Committee. As I hold a significant shareholding in the Company I am deemed to lack independence as a Board member. Ken's appointment provides both a measure of independence and access to extensive pharmaceutical industry experience. Ken and I are standing for re-election to the Board as part of the continuing periodic rotation of Board members. USA-based director Jim Foght stepped down from the Board at the end of the year.

In May we announced the results of our Phase 3 trial in the USA of our first product and in September Vivus submitted a marketing application for EvaMist™ to the US Food and Drug Administration (FDA). This should enable product launch in late 2007. As we have already advised the market, the trial's success was a key milestone for the technology platform, as most of our products will employ the same delivery technology. In April 2006 the European Patent Office granted the core patent over the technology. Acrux already had patents granted in the US, but confirmation of IP protection in the world's second largest pharmaceutical market was a significant achievement.

To accelerate the commercialisation and licensing of Acrux's technology we appointed Richard Treagus as our new CEO. Richard played an integral role in the successful commercial expansion and market performance of both Sigma in Australia and Aspen Pharmacare in South Africa. He has made a number of changes to the Senior Management Team to improve business development and regulatory expertise. Richard has implemented a coherent, commercially oriented corporate culture within Acrux in recent months that will be germane to the Company's commercialisation initiatives.

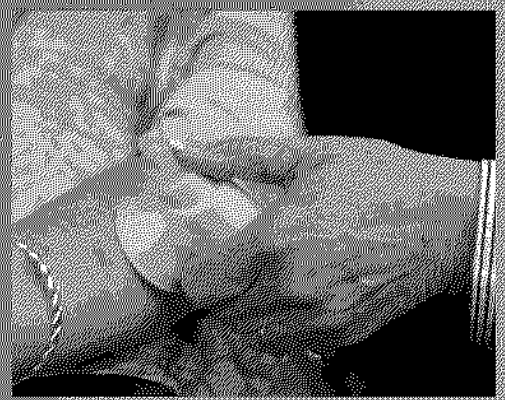
In September founders' shares were released from ASX escrow which led to an improvement in the Company's share register through institutional shareholding levels increasing to 40%.

This morning we are pleased to announce an expansion of our commercial agreement with Elanco Animal Health, the veterinary division of Eli Lilly and Company. In his presentation, Richard will expand on this development and other commercialisation activity. Our share price currently stands at 70 cents, compared with 68 cents at last year's AGM. This is clearly unsatisfactory from a Board perspective, although it is worth noting that recent sales are due to founders continuing to sell into a liquid market. We expect this selling to finish soon, with a concomitant recovery in the share price. The Board's confidence in the Company is reflected in recent buying activity.

Before I hand over to Richard, on behalf of the Board I would like to thank our shareholders for their support over the past year and our employees for their dedication to the success of the business.

# ACRUX

**AN INNOVATIVE AUSTRALIAN DRUG DELIVERY COMPANY, DEVELOPING AND COMMERCIALISING A RANGE OF PATIENT-PREFERRED, PATENTED PHARMACEUTICAL PRODUCTS FOR GLOBAL MARKETS**



**AGM 31 October 2006**

# FORWARD-LOOKING STATEMENTS

*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 and the effectiveness of patent protection*

# FUNDAMENTALS
# PROVEN TECHNOLOGY FOR GLOBAL MARKETS

## Proven technology

→ First product successfully through Phase 3 in USA and in registration

→ Other products use same delivery technology

## Access to major markets

→ Broad core patents to 2017 & 2022 granted in USA and Europe, pending elsewhere

→ New patents pending out to 2026

## Expert management

→ New leadership for next phase

→ Business aligned with commercial objectives

## Financial stability

→ $16.6 million cash reserves

→ 40% of shares with institutions

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# HIGHLIGHTS SINCE 2005 AGM
## PRODUCTS, PATENTS, PEOPLE, FINANCE

**Feb 2006** - New generation contraceptive Nestorone® licensed from Population Council

**Mar 2006** - US patent granted covering MDTS® applicator to 2022

**April 2006** - Core technology patent granted in Europe, earning $0.5m

**May 2006** - Positive results in EvaMist™ US Phase 3 trial

**May 2006** - Leadership change for next commercial phase

**August 2006** - Population Council agreement amended to permit commercialisation of multiple contraceptives using Acrux technology

# HIGHLIGHTS SINCE 2005 AGM
## PRODUCTS, PATENTS, PEOPLE, FINANCE

**Sep 2006** - Filed an Investigational New Drug Application with the FDA for Testosterone MD-Lotion

**Sep 2006** - EvaMist™ marketing application submitted to FDA, earning US$1m

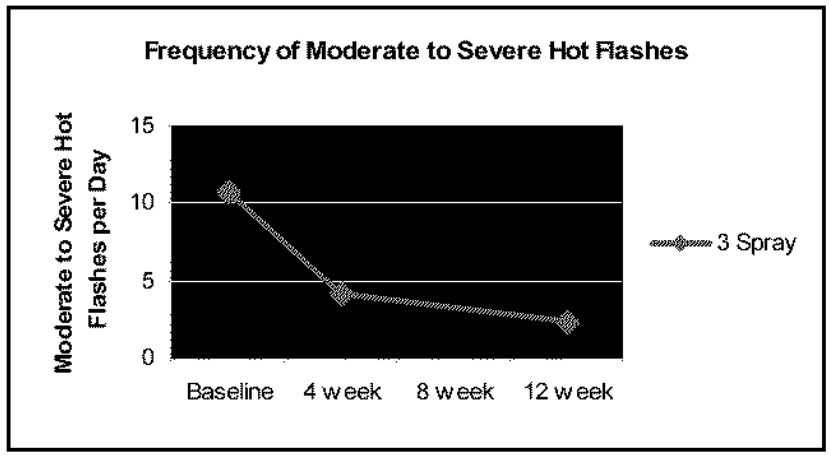
**Oct 2006** – Placement of escrowed share, institutional shareholding rises to 40%

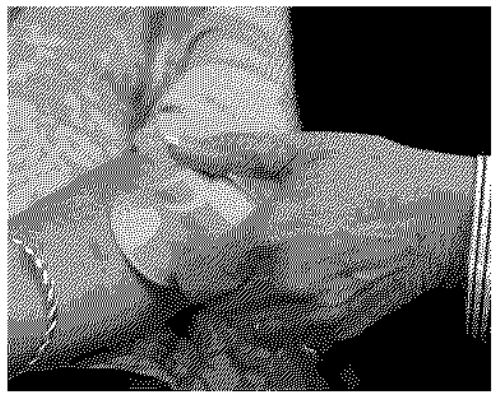
**Oct 2006** - Commenced US Phase 2 trial of unique testosterone lotion for men

**Oct 2006** – Expansion of the Elanco commercial agreement

# EVAMIST PHASE 3 TRIAL
## RESULT VALIDATES ENTIRE PORTFOLIO

- Statistical significance over placebo for all three dose levels - 1, 2 and 3 sprays per day, giving dosing flexibility
- Most effective dose 78% reduction in hot flashes (oral HT average 75%)



- All FDA efficacy and safety endpoints met
- Skin irritation incidence less than 1% (patches 10%-20%)

# CONTRACEPTIVE SPRAYS
## OPPORTUNITY EXPANDED

- Hormonal contraceptive market US$6.7 billion per annum
- Rapid uptake of transdermal patch in USA – now sells $0.5 billion
- Market characterised by numerous combination products – opportunity to license a range of contraceptive sprays to a range of partners
- Several combinations in development, including Nestorone® - a new generation contraceptive with potentially fewer side effects that can't be delivered orally
- Worldwide rights to Nestorone® licensed from Population Council – licence varied in August 2006 to enable Acrux to develop other contraceptives

Photo credit: Karen Tweedy-Holmes, Population Council

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# TESTOSTERONE MD-LOTION® FOR MEN
# COMPELLING COMMERCIAL PROSPECT

- Global market US$0.6 billion, dominated by Androgel®
- US market research confirms strong patient preference for Acrux's convenient and discreet lotion over current therapies
- Patent pending protects unique application to the armpit until 2026
- October 2006 - Phase 2 trial started in USA under IND
- Low risk development - no efficacy trials required by FDA - all pharmacokinetic trials
- US marketing application scheduled for H2 2008

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# COMPANION ANIMAL HEALTH
## PARTNERSHIP WITH LILLY EXPANDED

- Global licence for multiple products in multiple animal species with Eli Lilly (Elanco) - top 10 vet company by sales
- April 2006 - $500k received on grant of Acrux's core patent in Europe
- October 2006 - new therapy area added to licence; $150k additional fee
- First product final trials start H2 2007; several other products under evaluation
- Typical sales for a successful veterinary product ~ $50m p.a.

- A$8.25 million in milestones remaining + sales royalties

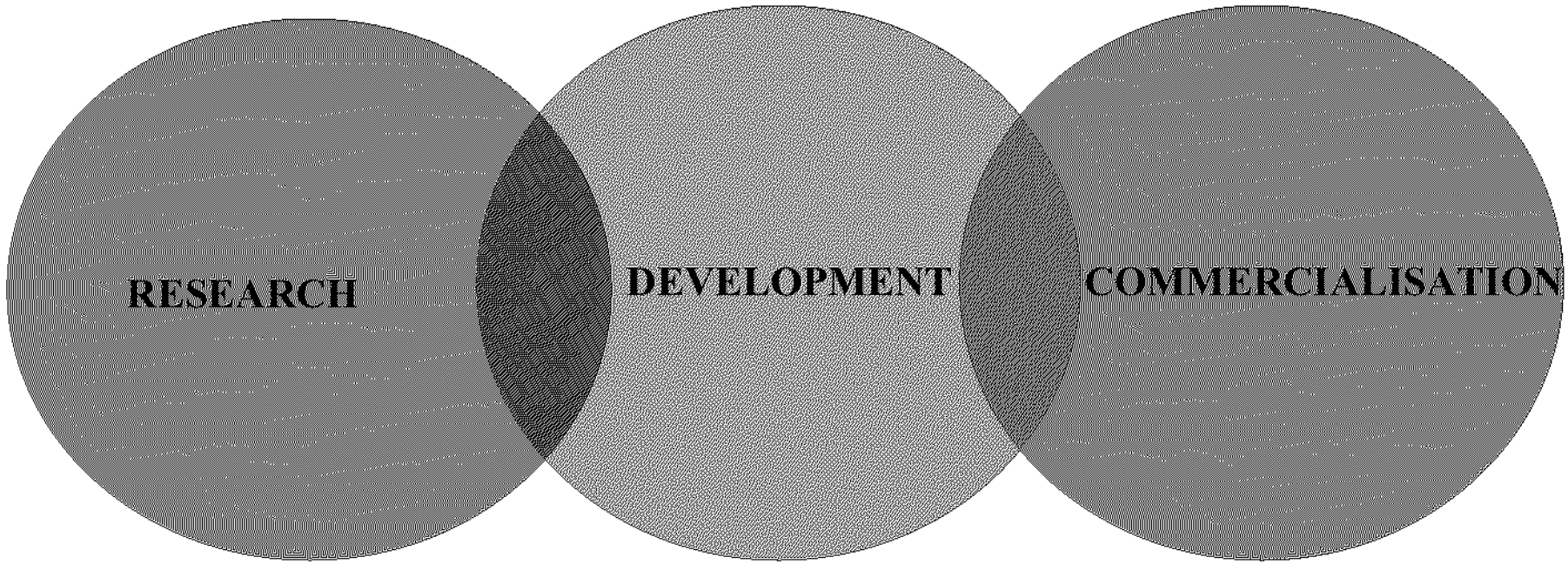
# FINANCE
## FOCUSING ON REVENUE GROWTH

| | Q1 Sep 2006 | FY June 2006 | FY June 2005 |
|---|---|---|---|
| Product revenues | 1.3 | 0.5 | 2.7 |
| Grant income | 0.3 | 1.0 | 0.8 |
| Interest and other income | 0.3 | 1.4 | 1.3 |
| **Total revenue** | **1.9** | **2.9** | **4.8** |
| **Total expenditure** | **(2.9)** | **(12.8)** | **(10.8)** |
| **Net loss** | **(1.0)** | **(9.9)** | **(7.3)** |
| **Net cash outflow before new capital** | **(3.1)** | **(8.8)** | **(6.4)** |
| **Net cash** | **16.6** | **19.7** | **28.1** |

- Net cash outflow expected to reduce in 2006/07 financial year
- Priority to grow revenue from new & existing licences
- Research and commercialisation are scalable at fixed cost – development costs are variable and controllable

# BUSINESS STRUCTURE
## FUNCTIONAL ACCOUNTABILITY

| Dr Adam Watkinson | Tim Saunders | Dr Richard Treagus |
|---|---|---|




| | | |
|---|---|---|
| →New compounds | →Testosterone MD-Lotion® | →Partner Performance |
| →Technology improvements | →Fentanyl UDTS™ | →New Licence Agreements |
| →Synergistic technologies | →Contraceptive sprays | →Collaborative Agreements |

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# BUSINESS STRUCTURE
## LEADERSHIP FOR NEXT COMMERCIAL PHASE

**Richard Treagus, Chief Executive Officer**
*Former Sigma, Aspen, Roche*

**Jon Pilcher, Chief Financial Officer**
*Former ANZ Bank, Celltech, Medeva*

**Adam Watkinson, Chief Scientific Officer**
*Former ProStrakan*

**Tim Saunders, Director of Project Management**
*Former Mayne Pharma, Fisons, Rhone-Poulenc*

**Nina Wilkins, Business Development Director (USA, Japan, ANZ)**
*Former Wyeth*

**Hugh Alsop, Business Development Director (Europe, Middle East, Asia)**
*Former Sigma, Mayne Pharma*

**Rosalie Cull, Director of Regulatory Affairs & Quality**
*Former Kendle, Mayne Pharma, CSL*

→ Increased emphasis on **commercialisation** and **initiating new products**

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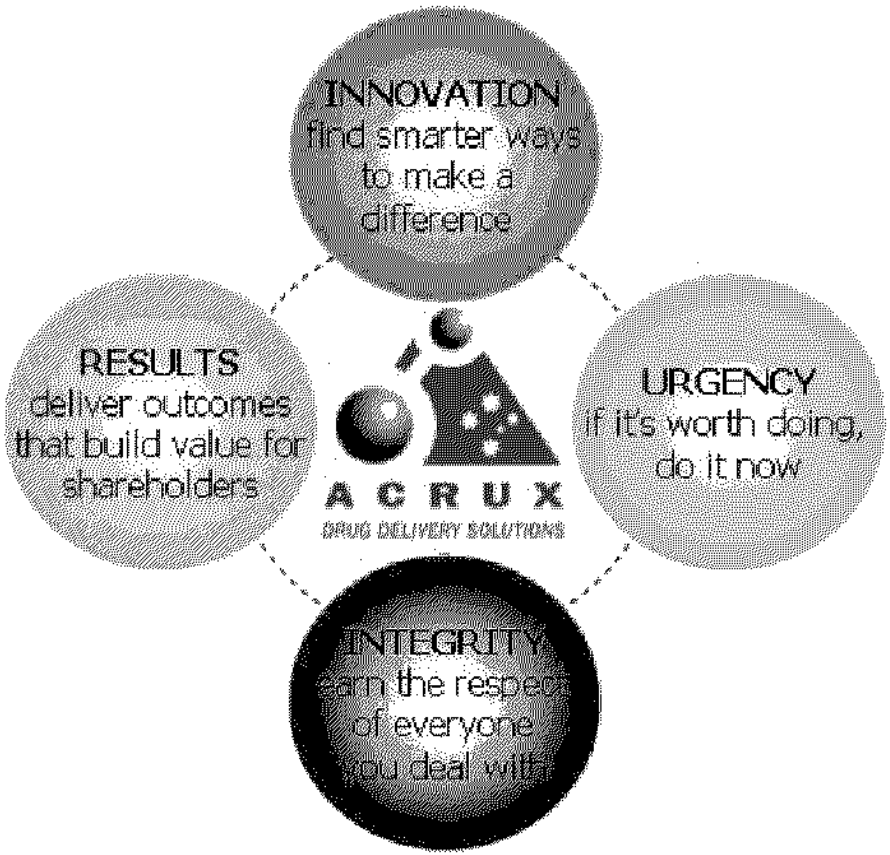
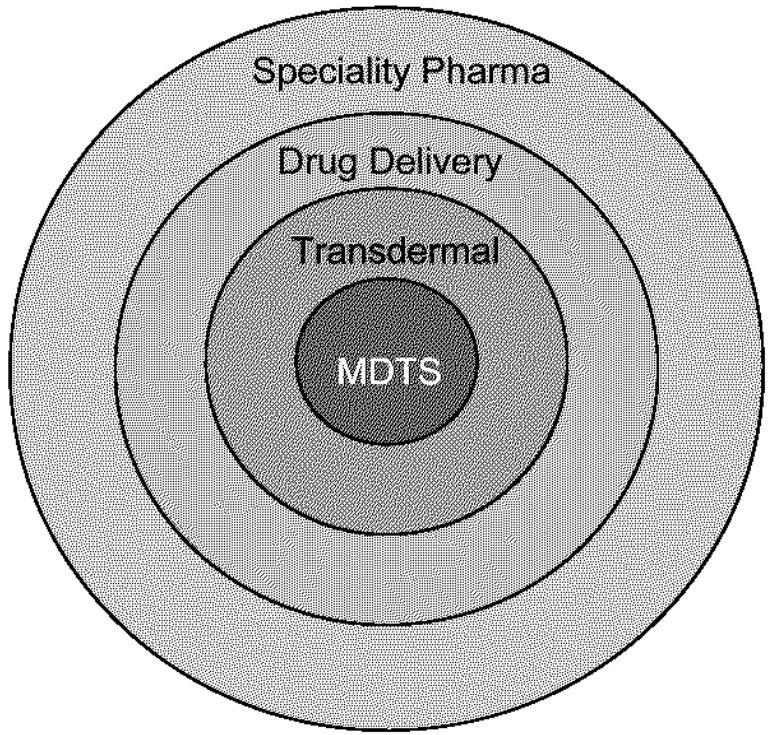
# PERFORMANCE CULTURE
## OUTCOMES FOCUSED

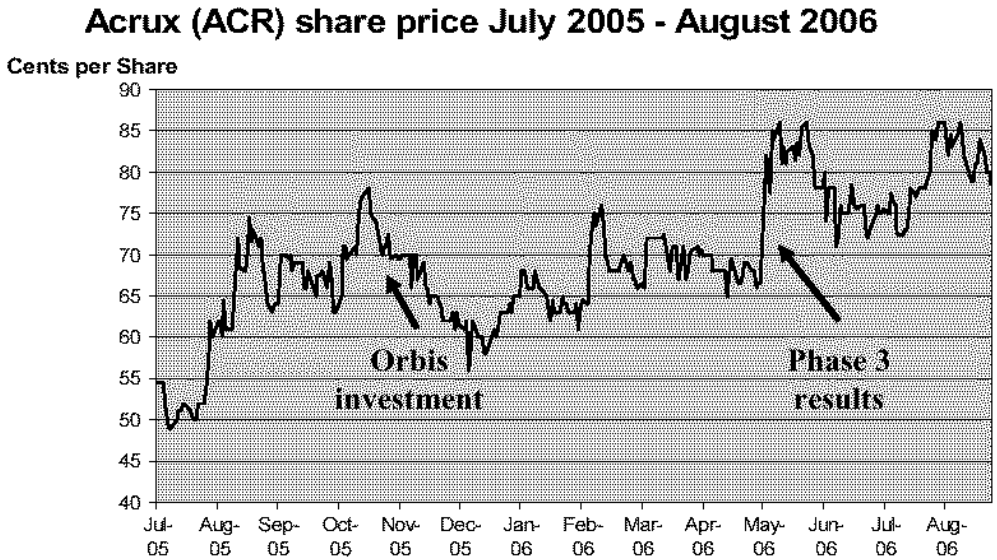


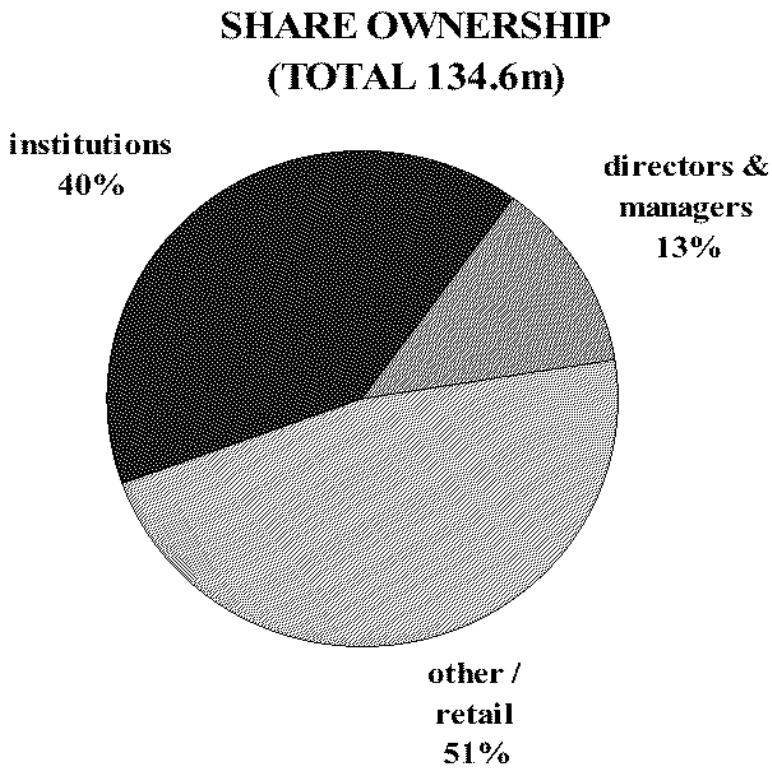
# SRATEGIC DIRECTION
## BUILDING VALUE AND RETURNING CASH

- Maximise value of the current transdermal technology
- Exploit the core competency of transdermal drug delivery
- New products added to the pipeline
- New license partnerships in all major markets
- Synergistic transdermal technologies



# INVESTORS
## SHARE PRICE AND REGISTER



# PROSPECTS
## BUSINESS OBJECTIVES FINANCIAL YEAR 06/07

1. **Licensing** - secure significant new deal
2. **Evamist™** - VIVUS files Evamist marketing application with FDA (achieved September 2006)
3. **Testosterone MDTS®** - VIVUS starts Phase 3 trials (H1 2007)
4. **Contraceptive sprays** - start proof of concept trials of combinations
5. **Testosterone MD-Lotion®** - complete Phase 2 trials (H1 2007)
6. **New products** - one successful proof of concept trial
7. **Fentanyl UDTS™** - open IND with FDA for Phase 2
8. **Cash** - maintain above $10 million at all times

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**ACRUX LIMITED**

**CEO's ADDRESS**

**AGM, 31ST OCTOBER 2006**

Thank you Mr Chairman.

It is my pleasure to report on the major developments at Acrux since the last AGM, as well as talk about the outlook for the business and the specific objectives that we have set ourselves for the year ahead.

**(Slide 1)** Acrux is focused on realising the value from its core competency of transdermal drug delivery. Our business model is underpinned by a validated technology platform, a robust intellectual property position, an experienced and highly committed management team and a strong cash position. In my last slide I will refer more specifically to our objectives and how we plan to go about this in the months ahead.

**(Slide 2)** *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 and the effectiveness of patent protection*

**(Slide 3)** The value in Acrux is a function of our technology, our product pipeline, the skilled people we employ and the business partnerships that we create and exploit. I am pleased to report on the progress made in these key areas over the last 12 months.

**(Slide 4)** The following achievements were announced during the course of the last year:

- In February, the new generation contraceptive, Nestorone, was licensed from the Population Council.
- In March, a US patent covering the MDTS applicator was granted, providing protection out to 2022.
- In April, a core technology patent was granted in Europe, earning a milestone payment from Eli Lilly of $0.5m.
- In May, positive results were reported for EvaMist in a Phase 3 study in the USA.
- In August, the Population Council agreement was amended, permitting commercialisation of multiple contraceptive compounds, using the Acrux spray technology.

- **(Slide 5)** In September, we filed an Investigational New Drug Application for Testosterone MD-Lotion with the FDA.

- And later the same month, the EvaMist marketing application was submitted to the FDA, earning Acrux a milestone payment from Vivus of US$1m. I can confirm that this payment has now been received.
- In the first week of October, we facilitated the placement of 3m escrowed shares, from company founders, to both existing and new institutional shareholders.
- And then in mid-October, we commenced a multi-centre Phase 2 clinical trial of our unique testosterone lotion, in the USA.
- Today we are pleased to announce the expansion of our commercial agreement with Elanco, the veterinary division of Eli Lilly and Company, earning a milestone payment of A$150,000.

I would like to give you more detail about some of these developments:

**(Slide 6)** EvaMist. Results from the pivotal Phase 3 clinical study, conducted in the USA, were announced in May. The results demonstrated a statistically significant reduction in hot flashes, for 1, 2 and 3 sprays per day, compared to placebo. The most effective dose achieved a 78% reduction, which compares very favourably to the results achieved with oral hormone replacement therapy, which in itself comprises 60% of the total estrogen-replacement market. As expected, skin irritation attributable to EvaMist was negligible, being recorded as less than 1%. Importantly, all FDA efficacy and safety endpoints were met.

The marketing application for EvaMist was submitted to the FDA on September 28th and we expect the approval process to be approximately 12 months. Subject only to the FDA approval, we can reasonably anticipate that EvaMist will be launched in the USA market in late 2007 or early 2008.

This milestone brings us to a pivotal point in terms of our partnership with Viuvs. The emphasis now shifts from one of product development towards their plans for an effective and optimum launch of our product. Quite appropriately, we are actively engaging Vivus on these details and I wish to reassure shareholders that we are applying the necessary diligence to ensure that our interests in relation to the marketing roll-out of EvaMist in the USA as well as the ROW are maximised.

**(Slide 7)** Contraception. The hormonal contraceptive market is worth US$6.7billion per annum and it is characterised by numerous combination estrogen/progestin products. The leading contraceptive patch in the USA, OrthoEvra, currently sells US$0.5 billion per annum.

Given Acrux's experience to date with both Estradiol and with Nestorone, this presented a compelling basis for us to expand our product development strategy to include a wider range of contraceptive sprays.

We moved swiftly to amend the Population Council Licence Agreement, which then allowed Acrux to develop and exploit a range of combination contraceptive products. I am pleased to report that good progress has been

made to date in terms of the initial formulation work in this area and initial discussions with large pharma have proven encouraging.

**(Slide 8)** Testosterone MD-Lotion. The market for testosterone supplementation in hypogonadal males is US$0.6 billion and growing at approximately 9% per annum. The market is dominated by one product, namely Androgel, which sells over US$320m in the USA alone.

Acrux has developed a convenient and discrete lotion that is applied into the patient's armpit. This contrasts markedly with the large area of the upper torso that the Androgel product has to be applied to.

The benefits of this unique, no-touch application were strongly endorsed by prescribers and patients, in market research that Acrux conducted in the USA. The findings were unequivocal, confirming that the Acrux product overcomes a number of the shortcomings usually associated with current treatment modalities.

Acrux has submitted patent applications for this novel drug application site and if granted, these patents will provide additional protection for our product out to 2026.

A phase 2 trial for the testosterone MD-Lotion was initiated this month in the USA, under an IND, and we expect the results to be available in the first half of next year. Given that the pivotal phase 3 study does not require clinical

efficacy endpoints, the development pathway for MD-Lotion is considered to be relatively low-risk and we anticipate being able to file a marketing application in the second half of 2008.

**(Slide 9)** Veterinary Health. We have an important and potentially very valuable partnership with Elanco Animal Health, a division of the global pharmaceutical group, Eli Lilly and Company. Elanco is developing a range of veterinary products for global markets, using Acrux's liquid technology to deliver drugs across the skin of animals.

Today we announced an expansion of the Licence Agreement with Elanco, in terms of which they are now able to exploit the Acrux technology in an additional therapeutic field. For these additional rights, Elanco will pay a further licence fee of $150,000 to Acrux.

We are encouraged by the progress being made by Elanco, and we are able to confirm that their lead product will enter pivotal phase 3 clinical trials in the USA and Europe in the second half of 2007, with several other additional drug candidates currently under evaluation.

The market for animal health products is worth more than US$14 billion per annum worldwide, with products for companion animals growing strongly. A successful animal health product would typically have annual sales of at least US$50 million, and so this part of our business has significant potential.

In terms of the partnership, Acrux may receive further milestone payments of up to $8.25 million and receive royalties on global sales of the products if regulatory authorities approve a number of products for marketing.

**(Slide 10)** The US$1 million milestone from VIVUS boosted our revenue for the first quarter of this financial year to $1.9 million, compared with $2.9 million for the whole of the last financial year. Expenditure for the first quarter of $2.9 million ran at a similar level to last year. We expect our net cash outflow for the full year to reduce from last year's $8.8 million before new capital. This will be driven by higher revenue from new and existing licences, which is a stated priority for us.

Our cash position remains strong and sufficient to fund the business to profitability, which will be achieved through multiple licensing deal revenues.

**(Slide 11)** I wish to turn to some of the changes that we have made with the senior management team as well as the culture within the business.

We have three functional areas within the business. Our research activity is led by Dr Adam Watkinson, our Chief Scientific Officer, the development activity by Tim Saunders, who joined us in March of this year, and the commercialisation activity led by myself. The business objectives in these key areas have now been clearly defined, and the appropriate accountabilities firmly established.

Since my appointment in May this year we have placed a far greater emphasis on two of these three functional areas, namely new product research and commercialisation. It is worth noting that revenue from additional licensing activity can be grown and similarly new products can be added to the pipeline without increasing our cost base and cash burn.

**(Slide 12)** In support of this revised approach, Hugh Alsop and Nina Wilkins now spearhead our global business development activities, working closely with myself on all prospective transactions and more recently Dr Rosalie Cull, formerly at Kendle, joined us as Director of Regulatory Affairs and Quality. I am pleased to report that we now have a complete skills set at a senior management level and just as importantly, the senior management team is fully engaged, aligned with the corporate objectives and appropriately incentivised.

**(Slide 13)** Across the broader business, clear individual objectives have been set with all staff. The corporate values have been simplified and revised and the basis of a performance and reward culture now firmly established. This level of clarity and alignment with the goals of the company and our shareholders has been positively embraced by all staff.

**(Slide 14)** Our strategic focus remains a commitment to deliver maximum value from the core transdermal technology that has been established within Acrux.

We will continue to actively develop new combinations of pharmaceutical compounds with our technology. Simultaneously, we will aggressively seek out appropriate commercial partnerships in all major markets. These partnerships not only provide the primary source of revenue for our business, but importantly, they can bring invaluable therapeutic expertise, an established market presence and commercial validation of our technology platform.

In addition, we have established a process internally whereby synergistic or adjunct transdermal technologies are now reviewed and evaluated. We will continue to critically assess these similar technologies, to ensure that we are well placed to fully exploit our core skills and infrastructure, as it relates to the broader field of transdermal drug delivery.

**(Slide 15)** Whilst our share price has responded positively over the last 12 months, in particular to the announcement of the EvaMist Phase 3 results, we maintain the view that the market is significantly undervaluing the Acrux business.

We are confident however, that with our combined objectives of building a strong product pipeline, ensuring optimum performance of existing partners, as well achieving commercial validation of our technology through additional licensing deals, the true value of the business will be more appropriately recognised by the markets.

At the end of September, a final tranche of shares was released from ASX escrow. This enabled a further transition of shares from founders to institutions. Our largest shareholder Orbis has increased their holding to 14% over the course of the year, and two new institutions have more recently taken up a position on the register. This has taken our total institutional shareholding to just on 40%.

**(Slide 16)** Finally, I wish to outline for you the specific objectives that we have set ourselves for the current financial year, ending June 2007.

1. Firstly, to secure at least one significant new **Licensing deal**.

   It is fair to say that the Acrux management team is working on a number of potential opportunities at any one point in time and we now have a clear set of objectives to align ourselves with partners that have established capabilities and the appropriate strategic intent and importantly, to conclude transactions on terms that are commercially acceptable to Acrux.
2. For VIVUS to **file the Evamist® marketing application** with the FDA. This was achieved on September 28th 2006.
3. For VIVUS to commence **the Phase 3 trial for Testosterone-MDTS®**. This we anticipate to start in H1 2007.
4. To commence the proof of concept clinical trials on our new **contraceptive spray combinations** that are currently in formulation.

5. To complete the **Phase 2 clinical trial on Testosterone MD-Lotion®.** We expect to report the results of this study in H1 2007.
6. To announce **one successful proof of concept trial** for a new pharmaceutical compound.
7. To open an IND with FDA for the Phase 2 study on **Fentanyl UDTS™.**
8. And finally, to maintain a **cash position above $10 million** at all times.

In concluding, I would like to thank all the employees of Acrux for their commitment to these business objectives and for the contribution that they have made over the last 12 months.

I specifically wish to thank the Chairman and the Acrux Directors for their continuous support and guidance, which has proven invaluable to the Acrux management team.

Finally, to our many shareholders, we thank you for your ongoing support and for your commitment to the Acrux business.

Thank you for your attention.

We are happy to answer any questions that you may have about this presentation.