Acrux (ASX: ACR)

12 November 2014

ACRUX
DRUG DELIVERY SOLUTIONS

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.

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ACRUX (ASX: ACR) AT A GLANCE

- Market cap ~$180 million[1]
- Unique, patented technology for delivering drugs through the skin
- Products developed by Acrux, approved and launched in major markets:
  1. Axiron®, marketed by Lilly for hypogonadism in the US and other territories
  2. Estradiol Spray, marketed for menopausal hot flushes by Lumara Health in the US; Licensed to Gedeon Richter in Europe and other commercialisation partners in RoW
  3. Recuvyra®, marketed by Elanco for post operative pain (in dogs) in the US and Europe
- Profitable for the last 5 years
  - Dividends paid total 96 cents per share including 2 special dividends paid on milestones received (totalling 72 cents)
- Pooled Development Fund – capital gains and dividends exempt from tax
- Pipeline of patient-preferred products exploiting Acrux's proven capabilities

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[1] *Market Cap as at November 7, 2014*

FACILITIES, PROCESS AND CAPABILITIES

- R&D focus utilising existing assets
- Onsite laboratories and GMP manufacturing facility
- Early development process established
- Mid to later stage development capabilities:
  - Analytical method development and validation
  - Container closure selection and applicator or device development
  - Performing CMC activities, studies and documentation to support clinical trials and regulatory submissions
  - Manufacturing scale-up and technical transfer to commercial-scale facilities
- Clinical trial product manufacture and quality testing in Acrux's GMP facility and laboratory
  - Acrux has a current TGA license for manufacture of topical and transdermal products for Phase 2 and Phase 3 clinical trials
  - Most recent TGA audit was April 2012

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KEY FINANCIALS

A$m	FY14	FY13	% Change FY14 - FY13
Product Royalties	25.4	15.5	64%
Product Milestones and other revenue	28.5	1.2	2275%
Total Revenue	**53.9**	**16.7**	**223%**
Expenditure	10.0	6.6	52%
NPAT	**28.0**	**6.9**	**306%**
Net cash on hand	**25.8**	**22.8**	**13%**

Earnings per share	**17 cents**	**4 cents**

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Marketed Products

Axiron®

Axiron®
(testosterone)
topical solution

Evamist®

Recuvyra®

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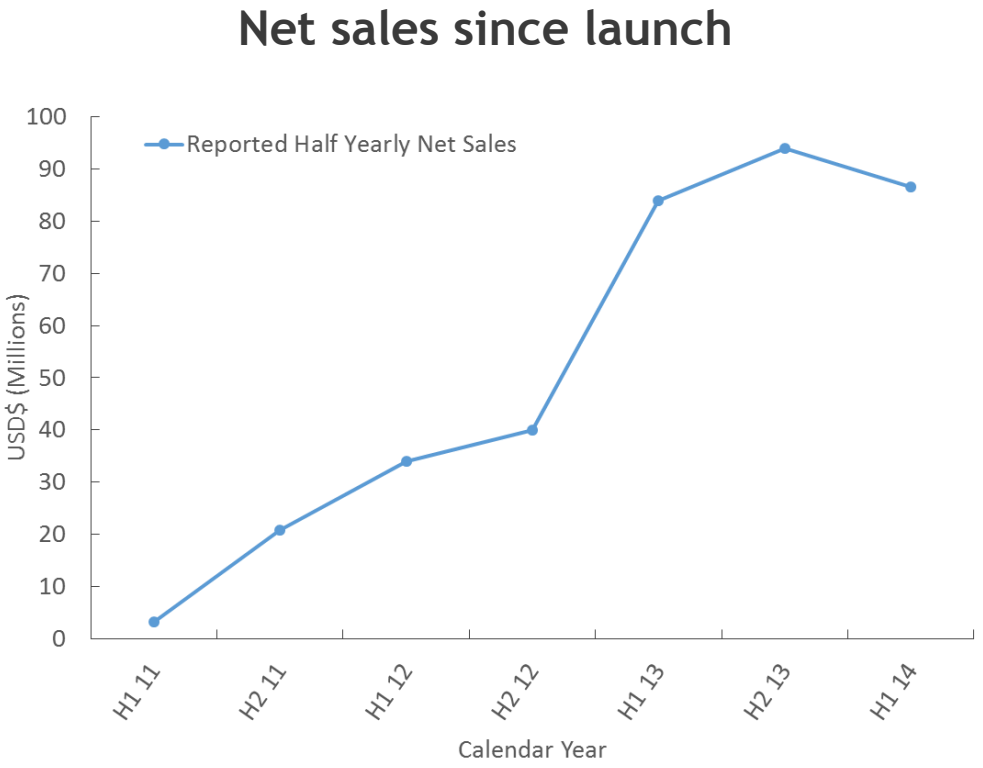
KEY UPDATE – AXIRON®

- Milestone payment received of US$25 million in March 2014 as net sales in the 2013 calendar year exceeded milestone threshold
- Maintained stable share of transdermal gel testosterone therapy prescriptions in United States (13.8% on IMS data[2])
- Regulatory reviews of testosterone
  - October 10, 2014
    - ***European Medicines Agencies*** Pharmacovigilance Risk Assessment Committee (PRAC) "review does not confirm increase in heart problems with testosterone medicines"
    - The committee considered that the benefits of testosterone continue to outweigh its risks and recommended that testosterone-containing medicines should continue to only be used where lack of testosterone has been confirmed by signs and symptoms as well as laboratory tests[3]
  - September 14, 2014
    - ***FDA's*** Bone, Reproductive and Urologic Drugs Advisory Committee and its Drug Safety and Risk Management Advisory Committee met to discuss the appropriate population for testosterone replacement therapy and the potential for adverse cardiovascular outcomes.[4] FDA will consider the Advisory Committee's recommendation

[2] *IMS share of total prescriptions for transdermal products*
[3] *http://www.ema.europa.eu/ema/*
[4] *http://www.acrux.com.au/IRM/Company/ShowPage.aspx/PDFs/1352-10000000/FDAAdvisoryCommitteeMeetingonTRT*

AXIRON GLOBAL NET SALES[5] SINCE LAUNCH

Axiron® (testosterone) topical solution CIII



- Net sales for FY2014 increased to US$181 million (US$124 million in FY2013)
- US testosterone replacement therapy market is valued at over $2 billion

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[5] *Net sales = invoiced sales less rebates, discounts, returns*

US TESTOSTERONE MARKET

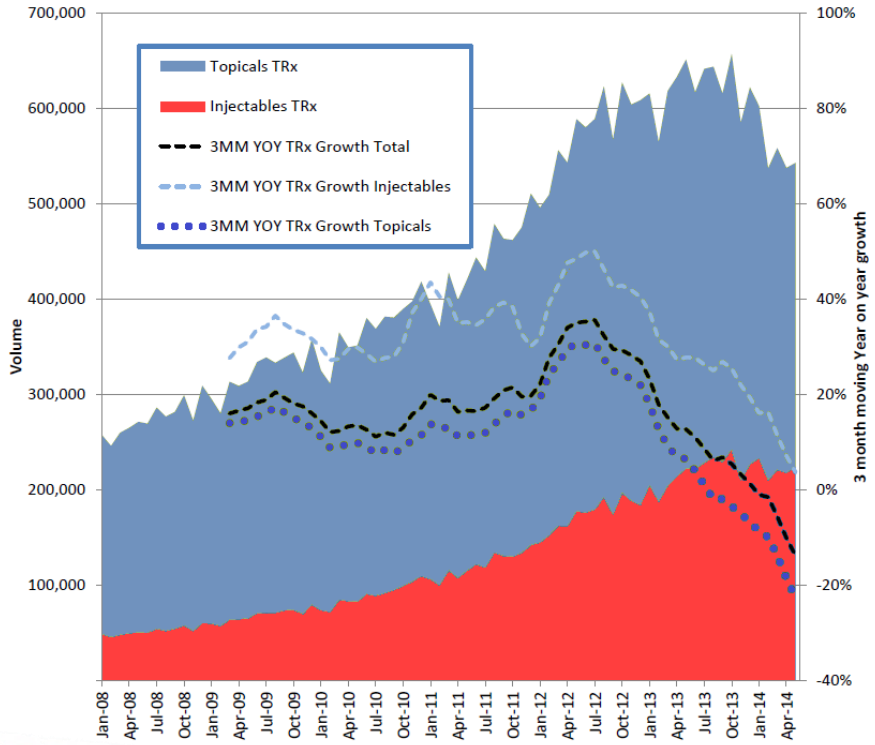
Axiron® (testosterone) topical solution

Share of Total Prescriptions (TRx) for transdermal products in US

	30 Jun 13	30 Jun 14	17 Oct 14
Non-Genericised			
• Axiron®	13.6%	13.9%	13.8%
• Androderm®	5.0%	5.0%	5.0%
• Total Androgel®	60.7%	63.1%	61.7%
Genericised			
• Testim®	13.1%	8.3%	6.8%
• Fortesta®	7.5%	6.2%	2.8%
• Generics *	0%	3.5%	9.9%

* *including Vogelxo, Vogelxo Authorised Generic (AG), Testim AG and Fortesta AG*
Market share based on weekly IMS data

- Axiron continued to hold steady share of market;
- Currently number two product in US transdermal testosterone replacement therapy sector



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AXIRON COMMERCIAL MANAGED CARE [6]

- Axiron's positioning with leading formularies improved in January 2014:
  - Axiron being the only transdermal testosterone replacement therapy registered as a preferred product on both ESI and CVS Caremark National Formularies (two of the leading insurers)
- The 2015 formulary contracts have been secured, with Axiron retaining its status as one of two preferred products

	Included
ESI	Axiron
	AndroGel
CVS Caremark	Axiron
	Fortesta

[6] *Note: the National formulary is one of multiple formularies offered to commercial members*

AXIRON PRICING

Axiron® (testosterone) topical solution

- After initiating at a recommended starting dose (RSD), patients may undergo dose titration to achieve an appropriate maintenance dose
- The daily maintenance doses and costs of different topical testosterone treatments were compared from US payer perspective

Measure in Month 4,[a] Mean (SD)	Axiron N=209	Androgel 1% N=614	Androgel 1.62% N=235	Testim N=558
Dose (mg) PPPD	68.45 (21.53)	56.68 (19.43)	51.18 (27.24)	59.24 (27.16)
Dose PPPD as a proportion of RSD	114.1% (36)	113.4% (39)	126.4% (67)	118.5% (54)
Cost PPPD[b]	$7.55 (3.25)	$9.47 (3.70)	$10.35 (6.27)	$9.60 (5.03)

Abbreviations: mg milligram; RSD recommended starting dose; SD standard deviation; PPPD per patient per day

a. Results were weighted by the proportion of days of testosterone supply per patient to the mean days of TTA supply within the cohort

b. Third party payments to providers

Third-party payer costs for the maintenance dose were lowest among Axiron patients[7]

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[7] *Kaltenboeck, A. et al., Differentiation of Daily Dose and Costs Associated with Maintenance Therapy of Topical Testosterone Agents, Poster session presented at: International Society for Pharmacoeconomics and Outcomes Research - 17th Annual European Congress November 8th-12th 2014, Amsterdam*

EXPANDING KNOWLEDGE OF AXIRON

Axiron® (testosterone) topical solution

Lilly is conducting clinical studies to evaluate potential benefits of Axiron treatment

- TSAT - Sex drive/energy levels – Phase III, 618 men
  - Study will measure the effects of testosterone solution on testosterone levels, sex drive and energy
  - Though not designed specifically to assess the risk of cardiovascular events, this study will collect information on any cardiovascular events that occur during the study
  - Initiated early 2013 and last patient visit completed in October 2014
  - Results due H1 2015
- TSBC - Suboptimal responders to other testosterone gels – Phase IV, 75 men
  - Research suggests that approximately 20% of patients fail to reach a normal testosterone (TT) level using certain topical gel formulations
  - Completed January 2014
  - At the conclusion of the study, 95% of men had achieved a mean total testosterone level within the normal range with Axiron
- Additional information about the above studies and other Axiron studies can be found on www.clinicaltrials.gov

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AXIRON IP LANDSCAPE IN UNITED STATES

Axiron® (testosterone) topical solution

- Existing transdermal products
  - Patent expiries - Androgel 2020(1%)/2026(1.62%), Testim 2023/25, Fortesta 2018
  - Androgel, Testim and Fortesta patents challenged by substitutable (ANDA) and non-substitutable (NDA) products – multiple litigations
  - Upsher Smith won appeal against Auxilium patent in December 2013; an authorised generic Testim gel was launched in June 2014, ahead of Upsher's Vogelxo product
  - Lilly/Acrux litigation against both Perrigo and Actavis (Watson) for infringement of Axiron patents by ANDA filing

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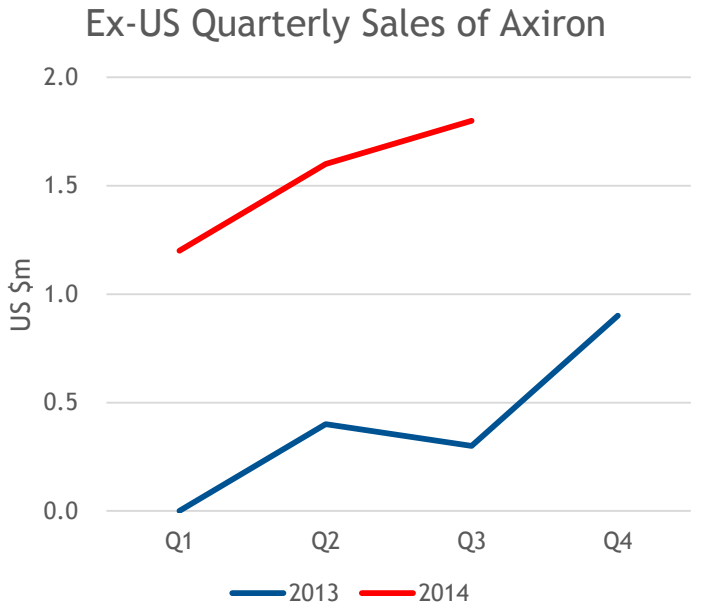
AXIRON POTENTIAL BEYOND THE US MARKET

Axiron® (testosterone) topical solution

- In last 12 months, Axiron launched in Germany, Brazil and South Korea
  - Previously launched in Canada and Australia
  - Collectively comprise more than half the current ex-US market by value
  - Ex-US YTD Q3 CY14 Net Sales: US$4.5 million
    Ex-US YTD Q3 CY13 Net Sales: US$0.7 million[8]



- Solid market share growth of Axiron in each of these markets
- Royalty rate tier and potential milestone thresholds based on global sales

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[8] *Lilly reported Quarterly sales*

Other Marketed Products

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EVAMIST®

Estradiol spray for menopausal symptoms in women

- US
  - Approved by FDA in July 2007
  - US launch by KV Pharmaceutical (Now Lumara Health) in April 2008
  - In September 2014 Lumara announced they had entered into a definitive agreement for the sale of its Women's Healthcare assets, including Evamist, to Perrigo Company Plc
  - Acrux is currently assessing a potential sub-license of the contract with Lumara to Perrigo
- Ex-US*
  - Approved in South Africa in August 2014;
  - Approvals pending in the EU, South Africa and South Korea;
  - Licensed in Europe and selected other ex-US territories to Gedeon Richter in May 2013; First sales expected 2015
    - US$1m upfront and up to US$2.6m in further regulatory milestones for the EU

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** Evamist will be marketed under alternate brand names outside the United States*

RECUVYRA®

Fentanyl solution for pain relief in dogs

- Marketed by Elanco, Lilly's Animal Health Division
- Approved by FDA in June 2012
- Approved in Europe in November 2011
- Product rolled-out in US and EU markets though 2012 and 2013
- Other animal companion health products in clinical development

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LOOKING AHEAD

- On-market products
  - Expected reduction in volume of testosterone market in US partially offset by pricing increases, likely USD:AUD Fx rates and ex-US volume growth
  - Revenue and milestones from additional launches of estradiol spray
- Expenditure
  - Royalty payable to Monash proportional to sales
  - Non-cash amortisation of capitalised R&D costs - $1.3m per annum
  - Acrux will inform the market prior to any significant changes to expenditure
- Pipeline
  - Focus on accelerating and prioritizing key pipeline projects within existing spend profile

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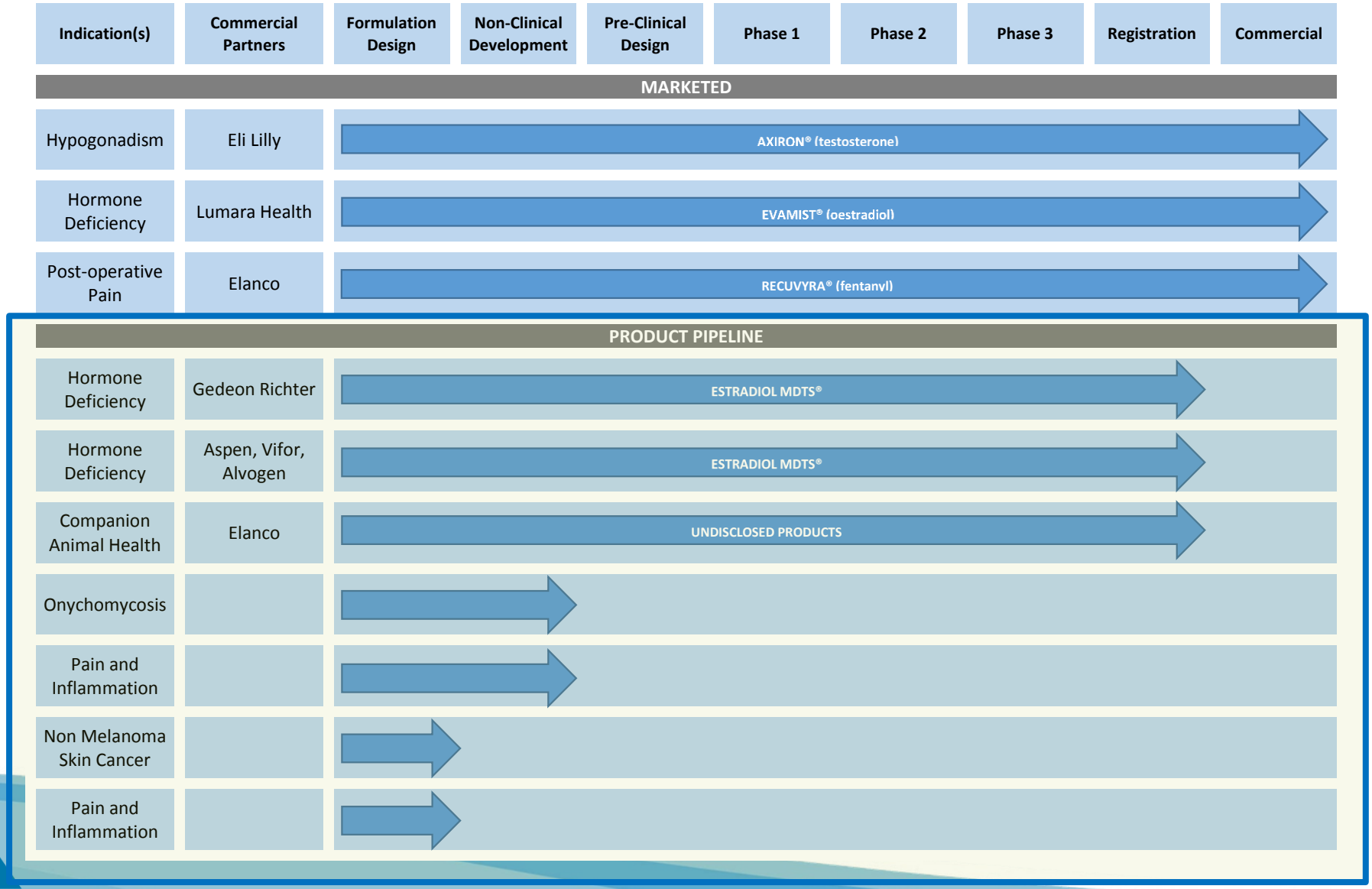
PRODUCT PORTFOLIO AND PIPELINE



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Appendix

KEY FINANCIALS

	30-Jun-14 $m	30-Jun-13 $m	30-Jun-12 $m
Product Royalty	25.4	15.5	9.0
Product Milestones	28.0	-	-
Interest, grant and other income	0.5	1.2	1.7
Total revenue	**53.9**	**16.7**	**10.7**
Royalties payable	-1.8	-0.5	-0.3
Capitalised development amortisation	-1.3	-1.3	-0.2
Other expenditure	-6.9	-4.8	-5.3
Total expenditure	**-10**	**-6.6**	**-5.8**
Profit before tax	**43.9**	**10**	**4.9**
Income tax (expense)/benefit	-15.9	-3.1	2.5
Profit after tax	**28**	**6.9**	**7.4**
Earnings per share	**17 cents**	**4 cents**	**4 cents**
Net cash inflow/(outflow) before financing	**36.3**	6.3	-2.5
Dividend paid - Ordinary	-13.4	-13.4	-
Dividend paid - Special	-19.9	-	-0.6
Total Dividend paid	**-33.3**	**-13.4**	**-0.6**
Net cash	**25.8**	**22.8**	**30.0**

- Earnings per share grew 17 cents on pcp
- Two dividends totalling 20 cents were paid during the 2013/14 financial year
- Profit after tax grew $33.9M on pcp, driven through an increase in Axiron royalties:
  - including US$25m milestone (net sales for Axiron exceeded US$100m in the 2013 calendar year)
- Increase in expenses largely driven by royalty payments due to Monash Investment Trust (in line with increased product income) $1.3m, Foreign exchange losses $1.3m and employee share options $0.6m
- Net cash grew 13.2% on pcp

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