ISSN 1443-850X

**In this edition...**
This week, we report on convincing progress that is being made within the Australian biotech sector, showing a very clear direction for what will become an increasingly relevant sector for the Australian economy.

CSL announced its intention to buy blood products group Talecris for US$3.1 billion. Acrux secured a multiple product development partnership with KV Pharmaceutical. And IDT Australia delivered a record profit of $7 million, with the stock now trading on a PE of 12.6, growing at 30% and a returning a fully franked dividend yield of 6%. Now that's progress!

**Companies covered: ACR, AVX, BOS, CXD, IDT, NAN, UCM**

| | Bioshares Portfolio |
|---|---|
| Year 1 (May '01 - May '02) | 21.2% |
| Year 2 (May '02 - May '03) | -9.4% |
| Year 3 (May '03 - May '04) | 70.0% |
| Year 4 (May '04 - May '05) | -16.3% |
| Year 5 (May '05 - May '06) | 77.8% |
| Year 6 (May '06 - May '07) | 17.3% |
| Year 7 (May '07 - May '08) | -36% |
| Year 8 (May '08 - current) | -7.8% |
| **Cumulative Gain** | **92%** |
| **Av Annual Gain (7 yrs)** | **17.8%** |

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# Bioshares

**15 August 2008**
**Edition 276**

*Delivering independent investment research to investors on Australian biotech, pharma and healthcare companies.*

## *Acrux – Commercialisation Forges Ahead*

As investors wait for a return on the $2.5 billion plus that has been invested into the Australian biotech sector over the last four years, one company that increasingly looks to be one of the sector's success stories, Acrux (ACR: $1.20) which is capitalised at $191 million, is forging ahead with the successful commercialisation of its drug delivery technology.

### Multi-product development deal with KV Pharmaceutical

The company secured some major advances this week, with a multi-product development deal with **KV Pharmaceutical**, gaining the Phase III data for its lead product to allow commercialization outside of the US, and it has formed a manufacturing alliance with Orion Corporation that will allow the company to firmly control its product suite and slice and dice sales and distribution of its multiple product opportunities.

For Acrux, profitability now is within sight without the need to raise additional capital. The company had $34 million in cash at the end of June and royalties with now begin to be received from sales of the company's lead product, Evamist, being sold in the US as hormone replacement therapy (HRT) for the treatment of symptoms associated with menopause.

Evamist was released in April this year and the product has been very well received with a strong growth trend, selling 4000 scripts a month, as highlighted by ABN Amro Morgan. Acrux will receive a single digit royalty which will then increase to double digit royalties if sales reach a certain level (we estimate 12%-13% if sales reach US$100 million - US$125 million). Our view is that peak sales in the US could exceed US$200 million. Based on sales of US$125 million, Acrux will receive just under $19 million a year in royalties.

With an estimated wholesale price of US$42 per bottle, we estimate Evamist is generating annualised sales of $2.3 million in June after only three months of being on the market.

### Acrux accesses Phase III Evamist data

The deal with KV Pharmaceutical this week was highly significant on two fronts. Firstly Acrux gained access to the Phase III Evamist data. Commercialisation of this drug outside of the US (called Ellavie) can now proceed, after a stalemate between the two companies. Access to this data (the data belonged to KV Pharmaceutical and the product outside of the US to Acrux) has been a careful negotiation process for Acrux and has been gained without a cash or future royalty payment.

The deal is also very significant because KV Pharmaceutical is obviously impressed with the Acrux transdermal delivery technology and wants to develop up to six other transdermal products using this technology. For the first three of these products, Acrux will retain ex-US rights and pay KV Pharmaceutical a royalty. In the US, Acrux will receive a single digit royalty. The first of these is Duomist, a combination hormone therapy product.

*Cont'd over*

For the second group of three products, Acrux will only be entitled to a single digit royalty from sales of any products globally. Acrux will also receive milestone payments on all programs and KV will fund development of all products.

### Launch of Ellavie (Evamist in the US) in Europe

Acrux expects to file the HRT product Ellavie in Europe for approval by year's end. It has been working in parallel whilst negotiating Evamist data access to finding marketing and distribution partners for Europe and other regions including Japan, Korea, South Africa and Canada. It should be noted that Acrux owns 100% of this product outside of the US. The company expects some direction from the TGA as to the status of this product in Australia by year's end, with the product expected to be launched in Australia in 2009. It will be sold by **Aspen Pharmacare Australia**, a South African subsidiary company.

### Manufacturer appointed

An import part of commercializing the many potential products in global markets is securing control of supply the final product. Acrux has formed a manufacturing alliance with **Orion Corporation** in Europe. Orion is an established hormone product manufacturer that is FDA approved. Whilst Evamist is manufactured by a third party in California for KV Pharmaceutical, the estradiol spray Ellavie will be manufactured for Acrux by Orion for other markets, as will the male testosterone product which is in Phase III studies. Controlling the manufacturing will allow Acrux to execute on multiple licensing and supply deals.

Orion is a finished product manufacturer. The applicator will be manufactured by a third party (most likely in China) for Acrux. Orion also has a sales and distribution business in Europe, including male and female health products. It might also become a sales and distribution partner for Acrux.

### Organon alliance cancelled

At the end of this week, Acrux announced that an alliance with **Organon**, which had been acquired by **Schering Plough**, had been cancelled due to a portfolio review by Schering Plough. There were two development programs formed with Organon in March last year. Both were early stage with Acrux having received a US$1 million sign-on fee. The cancellation of the programs is disappointing although is not overly significant for the company.

### Summary

Acrux has one product on the market with two programs in or about to enter Phase III trials (male testosterone, and female testosterone partnered with Vivus). We expect continuous newsflow for this stock moving forward and FY2010 will start to see meaningful sales and royalty flow from the Evamist and Ellavie transdermal estradiol products. Further uplift should come from the commercialisation of the male testosterone product which is expected to be filed for approval in the US towards the end of next year.

*Bioshares* recommendation: **Speculative Buy Class A**



## *Avexa Clinical Trials on Track*

Avexa (AVX: 31.5 cents) looks to be progressing well with the first of its Phase III trials for its lead HIV drug candidate, apricitabine. Around 200 patients will be enrolled in the first part of this Phase III program, which is a dose ranging component. This first part of the trial is on track to be fully enrolled by the end of next month, with results expected in the first or second quarter of next year on the best dose.

Patients from this first trial will form part of one of the subsequent two Phase III programs. In total, up to 1800 patients will be enrolled in these trials.

Apricitabine is the only drug in its class in Phase III trials for second line therapy, a factor that should improve enrollment rates into the trial. The company now has a regulatory team of 15 people in the US and Australia which coordinates the trial in conjunction with the clinical research organization (CRO).

At the end of June, Avexa had $43 million in cash, and will be spending around $30 million a year moving forward, giving the company just under 18 months of cash. Initiation of the trial sites and the CRO has required a larger spend up front, with the company spending $26 million in the first six months of this year as accounted by operating cash flow.

Late last year Avexa indicated that its Phase III program had increased in size and cost and that a partner would be required to complete the trials. Avexa is in continuous discussions with potential partners. Avexa's drug is being trialed in patients who fail treatment on **GlaxoSmithKline's** Lamivudine or **Gilead's** Emtriva, making either of these companies possible partners or potential acquirors of the company.

### Needs to build competitive tension

For Avexa and potential partners, it now becomes a negotiation process. Avexa needs to build some competitive tension between interested parties. And those interested parties might wait until Avexa's cash balance falls and the necessity to make a deal increases for Avexa. Considerations such as Avexa's low share price may weigh towards an earlier bid for the company, with the potential for an increasing share price as equity markets improve and results begin to emerge from Avexa's Phase III program.

Although the Phase III trial is blinded, Avexa will know which dose delivers a better result from the current dose ranging study, which should deliver some information on the preferred dose over the other blinded arms and relative efficacy of the drug. This information, which should become available in the first half of next year, may be sufficient to secure a partnering agreement or sale of the business, if that doesn't occur beforehand. Investors should be conscious that the majority of the value in the company is held in the apricitabine program. Avexa is capitalised at $128 million.

*Bioshares* recommendation: **Speculative Buy Class B**

# *Five Stock Wrap*

| **Company** | IDT Australiia | **Code** | IDT | **CMP** | $2.05 | **Cap'n ($M)** | $88.1 | **Net Assets ($M)** | $32.86 | **SI** | **N.A** |
|---|---|---|---|---|---|---|---|---|---|---|---|
| • IDT is a manufacturer of APIs and finished product for the pharma industry in addition to specialised drug development services<br>• Full year results posted today record an 18% revenue increase and 30% growth in NPAT. IDT currently trading on PE of 12.6<br>• Full year revenue was $31.5 million: FY07 - $26.7 million<br>• Dividend payout increased 20% to 6.5 cents per share. Div yield is 6.2%. [Record Date is 10 Oct 2008]<br>• We expect new CEO Robyn Elliot to aggressivley expand and develop IDT's commercial and investment profile in coming months.<br>• Sales contracts are denominated in AUD; declining AUD increases IDT attractiveness to customers. | | | | | | | | | | | |
| Comment: IDT's excellent full-year figures reflect strong demand for the company's full range of services<br>Revenues for API materials expected to increase as new 4000 L capacity facility has been validated. | | | | | | | | | | | |
| *Bioshares* recommendation: **Buy** | | | | | | Timing Considerations - Record Date for Div. is 10 Oct 2008 | | | | | |

| **Company** | CathRx | **Code** | CXD | **CMP** | $0.75 | **Cap'n ($M)** | $32.0 | **Cash ($M)** | $18.00 | **SI** | **1.9** |
|---|---|---|---|---|---|---|---|---|---|---|---|
| • CXD is developing a range of modular catheters for the left and right sides of the heart to diagnose and treat irregular heart beats<br>• Product benefits include patient customisation and easier and faster procedures<br>• Initial market focus is on Europe, with diagnostic catheters to be followed by therapeutic catheters. CE Mark received for initial products<br>• Recently appointed new global marketing head, Ged Wallace, to bolster marketing efforts, with a focus on Europe initially<br>• While technology offer points of competitive difference, active and vigourous marketing on the ground is a significant challenge | | | | | | | | | | | |
| • Milestones: CXD is aiming to build 10% market share over two years commencing Sept 2008<br>• To complete three trials by end 2008, and three trials end 2009 | | | | | | | | | | | |
| Comment: CXD share price is sitting at attractive levels, having fallen 75% off 52-week high | | | | | | | | | | | |
| *Bioshares* recommendation: **Speculative Buy Class A** | | | | | | Timing Considerations - None | | | | | |

| **Company** | USCOM | **Code** | UCM | **CMP** | $0.26 | **Cap'n ($M)** | $9.9 | **Cash ($M)** | $2.5 | **SI** | **1.5** |
|---|---|---|---|---|---|---|---|---|---|---|---|
| • UCM markets non-invasive devices that measure cardiovascular function<br>• Marketing approvals for EU, USA , Japan and Australia for the USCOM 1A Hemodynamic monitor<br>• Growing numbers of publications supporting the technology have emerged. Pediatric applications are promising.<br>• Product has not penetrated commercial barriers in key markets due to inadequate reimbursement<br>• Sales of product have been lack-lustre: FY2006 - $1.2 M; 2007 - $0.87 M: 2008 $0.92 M<br>• CEO relocated to USA to pursue marketing partner alliance. This has not eventuated.<br>• Dominance of founder/chairman an investment risk (44% stake) | | | | | | | | | | | |
| Comment: UCM is a possible takeover target for a better resourced diagnostics devices firm with greater depth in marketing | | | | | | | | | | | |
| *Bioshares* recommendation: **Speculative Hold Class C** | | | | | | Timing Considerations - Look for UCM as acq. target | | | | | |

| **Company** | Nanosonics | **Code** | NAN | **CMP** | $0.22 | **Cap'n ($M)** | $42.8 | **Cash ($M)** | $24.2 | **SI** | **3.4** |
|---|---|---|---|---|---|---|---|---|---|---|---|
| • NAN's platform technology, NanoNebulant, enables disinfection devices or spaces with nano-droplets of hydrogen peroxide<br>• First product is an ultrasound probe disinfectant product<br>• New CEO David Radford, ex GE Healthcare and Recall Corporation, installed June 2008<br>• Distribution partners currently being established for Europe<br>• Thematic underpinning NAN is demand for disinfection technology that is more friendly to many modern resuable medical devices | | | | | | | | | | | |
| • Milestone: First product to be released in ANZ, followed by Germany, UK and France<br>• Expect TGA approval before end 2008 (CE Mark approval obtained in April 2008) | | | | | | | | | | | |
| Comment: Sales from NAN's first product may occur early in 2009. Company is cashed-up and attractive at current prices. | | | | | | | | | | | |
| *Bioshares* recommendation: **Speculative Hold Class B** | | | | | | Timing Considerations - None | | | | | |

| **Company** | Biosignal | **Code** | BOS | **CMP** | $0.05 | **Cap'n ($M)** | $5.6 | **Cash ($M)** | $1.20 | **SI** | **0.4** |
|---|---|---|---|---|---|---|---|---|---|---|---|
| • BOS has been attempting to develop applications for a class of compounds called furanones, derived from seaweed<br>• Furanones interfere with bacterial signalling and can halt the build of bacterial biofilms.<br>• Initial applications to the marine coatings industry were not viable and not progressed.<br>• Contact lense applications have experienced technical challenges, including the retaining of activity while lenses are used<br>• Head of Chemistry, Dr Michael Ironsides has departed the firm<br>• CIBA Speciality Chemicals explored the formulation of furanones into PVC. Program discontinued 6/8 because of complications.<br>• Oil and Gas industry anti-corrosion application development studies continue as does program with Saraya of Japan (airconditioning) | | | | | | | | | | | |
| Comment: There have been too many commercialisation setbacks for the furanone technology to warrant investment attention | | | | | | | | | | | |
| *Bioshares* recommendation: **Sell** | | | | | | Timing Considerations - None | | | | | |

*Notes: SI - Survival Index - refer to Bioshares 273 for explanations*

## *CSL Makes Sizeable Acquisition*

**CSL** this week announced its intention to acquire **Talecris Biotherapeutics Holdings Corporation** for US$3.1 billion. Talecris is a manufacturer and marketer of blood products. Last financial year it generated sales of US$1.2 billion with an EBITDA of US$258 million.

The acquisition price appears reasonable, with CSL able to gain synergy value from a merger of the businesses worth US$225 million a year for the first three years. The acquisition is expected to be earnings accretive in the first year. The deal still needs to gain approval from US anti-trust authorities. An equity raising for $1.75 billion was completed this week (what credit crisis!) at $36.75 a share as part of the funding for the acquisition. An SPP will also be conducted and the balance of the acquisition will be funded through a debt finance facility.

It is quite a major deal for CSL, the largest acquisition the company has attempted to date. However it does not diversify CSL out of the blood products area. The stronger currency of the Australian dollar against the US dollar has been an enabling factor this transaction.

*Bioshares* recommendation: Not formally covered

### Corrections

***Impedimed***

Impedimed was added to the portfolio last week at an incorrect price. The correct price was70 cents.

***Cytopia R&D Day Table - Page 4***

Under the section:
"Joint Novartis Cytopia Program (Selective JAK3 inhibitor for autoimmune indications)", the text box that referred to Pfizer's CP-690550 should read
"Phase III trials for renal transplant rejection, RA - neutropenia AE"
instead of
"Completed Phase II trials in lung, prostate and ovarian cancer. Commencing Phase III with Novartis".

**Bioshares Model Portfolio (15 August 2008)**

| Company | Price (current) | Price added to portfolio | Date added |
|---|---|---|---|
| Impedimed | $0.80 | $0.70 | Aug-08 |
| Antisense Therapeutics | $0.07 | $0.07 | Aug-08 |
| Mesoblast | $1.32 | $1.25 | Aug-08 |
| Avexa | $0.32 | $0.32 | Jun-08 |
| Cellestis | $2.22 | $2.27 | April 2008 |
| IDT | $2.05 | $1.90 | March 2008 |
| Circadian Technologies | $0.85 | $1.03 | February 2008 |
| Patrys | $0.23 | $0.50 | December 2007 |
| NeuroDiscovery | $0.12 | $0.16 | December 2007 |
| Bionomics | $0.33 | $0.42 | December 2007 |
| Cogstate | $0.12 | $0.13 | November 2007 |
| Sirtex Medical | $2.50 | $3.90 | October 2007 |
| Clinuvel Pharmaceuticals | $0.34 | $0.66 | September 2007 |
| Starpharma Holdings | $0.25 | $0.37 | August 2007 |
| Pharmaxis | $1.85 | $3.15 | August 2007 |
| Universal Biosensors | $0.70 | $1.23 | June 2007 |
| Biota Holdings | $0.72 | $1.55 | March 2007 |
| Probiotec | $1.36 | $1.12 | February 2007 |
| Peplin Inc | $0.42 | $0.83 | January 2007 |
| Arana Therapeutics | $1.07 | $1.31 | October 2006 |
| Chemgenex Pharma. | $1.05 | $0.38 | June 2006 |
| Cytopia | $0.27 | $0.46 | June 2005 |
| Optiscan Imaging | $0.26 | $0.35 | March 2005 |
| Acrux | $1.20 | $0.83 | November 2004 |
| Alchemia | $0.30 | $0.67 | May 2004 |

### *Portfolio Changes – 15 August 2008*

**IN:**
No changes.

**OUT:**
No changes.

## How Bioshares Rates Stocks

For the purpose of valuation, *Bioshares* divides biotech stocks into two categories. The first group are stocks with existing positive cash flows or close to producing positive cash flows. The second group are stocks without near term positive cash flows, history of losses, or at early stages of commercialisation. In this second group, which are essentially speculative propositions, *Bioshares* grades them according to relative risk within that group, to better reflect the very large spread of risk within those stocks.

### Group A

Stocks with existing positive cash flows or close to producing positive cash flows.

| | |
|---|---|
| **Buy** | CMP is 20% < Fair Value |
| **Accumulate** | CMP is 10% < Fair Value |
| **Hold** | Value = CMP |
| **Lighten** | CMP is 10% > Fair Value |
| **Sell** | CMP is 20% > Fair Value |

(CMP–Current Market Price)

### Group B

Stocks without near term positive cash flows, history of losses, or at early stages commercialisation.

***Speculative Buy – Class A***
These stocks will have more than one technology, product or investment in development, with perhaps those same technologies offering multiple opportunities. These features, coupled to the presence of alliances, partnerships and scientific advisory boards, indicate the stock is relative less risky than other biotech stocks.

***Speculative Buy – Class B***
These stocks may have more than one product or opportunity, and may even be close to market. However, they are likely to be lacking in several key areas. For example, their cash position is weak, or management or board may need strengthening.

***Speculative Buy – Class C***
These stocks generally have one product in development and lack many external validation features.

***Speculative Hold – Class A or B or C***

***Sell***

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