## In this edition...

A noted life sciences venture capitalist CM Capital has made its first investment in a listed life sciences company, Sunshine Heart. This investment was handsomely supported by a follow-on round from another VC, GBS Ventures. For a number of cash-strapped listed biotechs, this may be very good news indeed. It is certainly welcome to see VCs supporting their investee companies in difficult times.

We also observe the powerful ability of the market to force discipline in companies, as CyGenics hones its focus on its cord blood banking business, a move that can see it potentially shift it to profitability

## The editors Companies covered: COH, CYN, ELX, PEP, SHC

	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 (from 5 May '06)	-17.6%
Cumulative Gain	141%
Average Annual Gain	20.9%

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# Bioshares 8 September 2006

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

# CyGenics Focuses on Cord Blood Banking Business

CyGenics (CYN: 27.5 cents) has announced that it intends to focus the company on its core cash generating business of tissue and cord blood banking and GMP manufacture of cell products. The company will out-license its therapeutic products program. The company recently also announced the sale of its non-tissue banking business (Cell Sciences) to a Malaysian firm **DNApro Sdn Bhd**, in exchange for a 20% equity stake. It will also receive \$450,000 from the divestment of Cell Sciences.

In June, CyGenics paid \$388,000 for an initial 20% stake in **Pharmacell BV**, a Netherlands based company that operates a GMP facility for the manufacture of cell base products. CyGenics has an option to acquire the remaining 80% stake. On the basis of the CyGenics investment, Pharmacell is valued at \$1.9 million.

# Growth in cord blood business

Several factors have contributed to this decision to refocus. The first factor is that the company's tissue and cord blood banking business has posted respectable quarterly growth figures over the last eight quarters. The company posted cash receipts in the course of operations of \$7.9 million for the year ending June 30, 2006, with \$4.2 million originating from sales of its tissue and cord blood banking business. We estimate sales (cash receipts basis) were \$324,000 in the September quarter, 2004. Sales increased to \$1.4 million in the last quarter. Year on year growth for the banking business on a cash basis was 165%, but a 115% increase on an accruals basis. Growth is expected to be boosted in FY2007 from the opening of cord blood banking services by the company in India. Expansion into China is also an ambition of the company.

When CyGenics listed in June 2004, it anticipated that by mid-2006, it would be overseeing two Phase III trials, one evaluating the company's artificial bone marrow or stem



cell expansion technology and another evaluating the company's artificial Thymus, or T-cell production technology. CyGenics' clinical trial program has been slowed down considerably because of issues raised by the FDA, which has asked additional pre-clinical studies to be conducted.

Cont'd over

The company's share price has declined 73% from its IPO price of \$1.00, due in part to delays in the clinical trial program. Earlier this year the company repaid a \$2.175 million license fee plus \$561,000 in interest to a licensor for the cancellous bone technology that is a key component CyGenics' cell expansion technology. This is a significant sum of money for CyGenics and has no doubt played a role in the decision to out-license the cell therapy program, along with the absence of a stronger share price to support additional fund raising activities.

#### Focus benefits investor attitudes

Yet another reason that may lie behind CyGenics' restructure is that the company can now be more clearly understood by investors as well as managed more efficiently. The company now is essentially a cash generating business and sales growth can be tracked closely.

CyGenics is capitalised at \$18.7 million, and held \$5 million in cash at June 30, 2006. With the announcement of plans by CyGenics to become a more tightly focused company, we have revised our recommendation from Speculative Hold Class B to Speculative Buy Class B. Investors should also note that 16 million shares (from a total of 68 million) shares were released from escrow this week, and that this may be a source of weakness in the price, if previously escrowed shareholders choose to sell.

Bioshares recommendation: Speculative Buy Class B

**Bioshares** 

# VC's Invest in Sunshine Heart

Sunshine Heart (SHC: 16 cents) is set to be the beneficiary of significant investment by two venture capitalist firms. A first tranche of funds will see **GBS Venture Partners**, an existing VC investor, invest \$4.2 million, **CM Capital** invest \$4.8 million (its first investment intp a listed company) and other investors

**Sunhine Heart Cash Position** 

Net Op. Cash Flow FY'06	<b>\$M</b> -\$6.3
Cash -June 30	\$4.5
Cash -August 31	\$3.0
Change	\$1.5
Tranche 1	\$14.0
Issue Costs	-\$0.3
Cash (post T1)	\$16.7
Survival Index -assume FY06 NOCF	2.6
Tranche 2	\$6.0
-subject to FDA IDE approval	

place \$5 million, a total of \$14 million.

Sunshine Heart is developing the C-Pulse, an implantable heart assist device, to treat moderate heart failure. It consists of an inflatable balloon and cuff that wraps around the aorta. It helps the heart to pump blood by contracting and expanding in a pump like fashion around the aorta. An external de-

vice drives the balloon and power is supplied through a lead that passes from the driver through the skin, and up to the balloon cuff. A perceived key benefit, and arguably very significant benefit of the device, is that it does not come in contact with blood, reducing and perhaps eliminating a patient's requirement for life long anti-coagulant medication. Another major benefit is that the device can be turned off without risk of sudden device-related patient death. Yet a third benefit is that the surgery required to implant the C-Pulse device is far less invasive and takes less time than conventional L-VAD heart assist devices.

A second tranche of funds totalling \$6 million would be supplied by CM Capital (\$3.2 million) and GBS Ventures (\$2.8 million) when Sunshine Heart receives an Investigational Device Exemption (IDE) approval from the FDA, which is required so that a feasibility trial in the US can be conducted.

Of the funds, \$6 million is be applied to clinical trials and \$4 million towards development of the device driver. Making the driver device lighter, more compact and more efficient is an important consideration for the company in developing a more patient friendly device.

## Analysis

The investment by CM Capital (and follow-on funding by GBS) is the second of two major VC investments made in listed Australian life science firms this year. The other was by **MPM Capital**, which intends to invest a total of \$20 million in **Peplin**, and will achieve a 15% stake in that company, assuming its second round of funds flow through (excluding options). Should GBS Ventures and CM Capital's second investment tranches be secured, then these investors will own 28% and 25% respectively of Sunshine Heart's ordinary shares.

In contrast listed peptide company Phylogica recently failed in its bid to raise \$5 million. While Phylogica may have been unsuccessful approaching the equities market because the market was at that particular time highly averse to biotech investment stories, a major difference between Phylogica and Peplin and Sunshine Heart, is that Peplin and Sunshine Heart are well into human clinical trials. An important point to note is that for both companies the end market and path to market is relatively well defined.

#### Summary

From a funding perspective, Sunshine Heart is now in a very strong position, with resource issues well and truly to the side. With two patients implanted with the C-Pulse device in Australia, one in June and one more recently in August, the company's clinical program is back on track, following infection setbacks with an earlier patient The progress of these two most recent patients deserves to be monitored closely.

On a fully diluted basis, post Tranche I, Sunhsine Heart is capitalised at \$35 million. Exlcuding options, the company is capitalised at \$28 million, which implies that, net of cash, the company's technology value is \$11.2 million.

Bioshares recommendation: Speculative Buy Class B

	biosnares
The Bioshares 20 Index	
Change from June 30, 2006	-1.1%
Change - week ago	0.0%
Change - 13 June (Low)	2.3%

 $D^{\pm} = -1$ 

# **Strategies & Issues**

# **Recovery After a Share Price Shock**

Generally, stock prices move in small positive or negative increments of up to 1% or 2% a day. Biotech stock prices are often subject to greater movements in share prices, and daily changes of 5% are more common. However, a quite different type of price movement is when a price is impacted by a shock event, causing a 20% or greater fall in one day, or cumulatively even more over two or three trading days. Shock events can take several forms, including profit down grades, the genuine 'out of left field' surprise that is disruptive to the underlying business and more particular to biotech, the 'prepared for' shock that can occur when a biotech stock releases negative clinical trial data at an anticipated date.

A number of life science stocks have experienced greater than 20% share price declines in a day, caused by a shock event, in the last few years. In light of **Alchemia's 31%** price fall on August 28, it is worth studying several examples for the duration of impact of the shock event on a share price.







### Cochlear (COH: \$52)

Cochlear's share price fell by 24% on December 16, 2003, from \$28.40 to \$21.70, when the company announced that sales growth would be flat, and profits slightly lower for the half year ending December 31, 2004. The company attributed some of the weak performance to the release of a new product by a competitor. However, Cochlear's share price commenced a turn around eight months later, when a major competitor was forced to announce a product recall. And 14 months after the profit down grade announcement, the stock had surpassed its pre-shock price.

## Ellex Medical Lasers (ELX: \$0.605)

Like Cochlear, Ellex Medical Lasers, also suffered a major price fall following a profit downgrade announcement. The Ellex share price fell 44% on November 4, 2002, from 86 cents to 48.5 cents, after it said sales would be down 10% for the quarter, and net profit would be down 20% for the half year. Ellex's problems, for the most part, stemmed from financial difficulties being experienced by a trading partner, Lumenis, to whom it supplied opthalmic lasers that were sold under the Lumenis brand. After 37 months, the Ellex share price began a recovery, but it has not yet surpassed its pre-shock price level

# Peplin (PEP: 64 cents)

On October 8, 2004, Peplin announced that its US partner **Allergan** would be dis-continuing development of its topical skin cancer drug. When trading resumed on Monday October 11, the share price fell 27% from 67 cents to 49 cents. Peplin acted quickly to regain control of the compound. Nine months later, the stock began to move positively again, in anticipation of the release of clinical trial data.

## Conclusion

The duration of a shock on a share price can not be predicted. What investors can learn at least from the Peplin example is that anticipated future news flow that is supported by positive outcomes has the potential to restore a stock price to pre-shock levels.

Company	Event	Date	Price Fall	Months to turn	Months to equal
Cochlear	Profit downgrade	16/12/03	-24%	8	14
Peplin	Program handback	11/10/04	-27%	9	13
Ellex Med. Lasers	Profit downgrade	4/11/03	-44%	37	

Company	Price (current)	Price added to
		portfolio
Acrux	\$0.79	\$0.83
Agenix	\$0.15	\$0.22
Alchemia	\$0.56	\$0.67
Avexa	\$0.200	\$0.15
Bionomics	\$0.15	\$0.210
Biosignal	\$0.18	\$0.22
Cytopia	\$0.685	\$0.46
Chemgenex Pharma.	\$0.42	\$0.38
Evogenix	\$0.430	\$0.47
Optiscan Imaging	\$0.485	\$0.35
Mesoblast	\$1.250	\$1.27
Neuren Pharmaceuticals	\$0.41	\$0.70
Pharmaxis	\$2.03	\$1.90
Prima Biomed	\$0.065	\$0.09
Sirtex Medical	\$2.30	\$1.95

**Bioshares Model Portfolio (8 September 2006)** 



TIMOR GATHERING 2006 Paul Kelly & The Boon Companions and The Hoodoo Gurus

# Sunday 8 October Athenaeum Theatre 188 Collins Street, Melbourne

Paul Kelly & The Boon Companions and The Hoodoo Gurus join forces at Melbourne's Athenaeum Theatre on Sunday 8 October in a charity fundraiser for Timor-Leste.

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<b>v Bioshares Rates Stocks</b> he purpose of valuation, <i>Bioshares</i> divides biotech stocks into tw gories. The first group are stocks with existing positive cash flows or to producing positive cash flows. The second group are stocks out near term positive cash flows, history of losses, or at early es of commercialisation. In this second group, which are essentia ulative propositions, <i>Bioshares</i> grades them according to relative within that group, to better reflect the very large spread of risk in those stocks.	early stages commercialisation.  Speculative Buy – Class A
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	e ment 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.
up A ks with existing positive cash flows or close to producing positive cash s.	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
CMP is 20% < Fair Value	management or board may need strengthening.
umulateCMP is 10% < Fair ValueIValue = CMP	<i>Speculative Buy – Class C</i> These stocks generally have one product in development and lack man
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CMP is 20% > Fair Value	Speculative Hold – Class A or B or C
P-Current Market Price)	Sell
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