#### In this edition...

Reporting season has begun and the big three stocks in the sector - Cochlear, CSL and Resmed - have produced mixed results, with Resmed charging ahead with a 30% increase in net profit, Cochlear posting a 19% gain and CSL limping forward with a 3% increase. The exchange rate has been cited as a key impact on CSL's profit result. News has emerged that a US biodegradable stent company, Reva Medical, is looking to list on the ASX, reportably doing so on a pre-money valuation of \$250 million. The Andrew Forrest-backed Allied Medical from Perth is flagging a listing in 12 months time, and that it is on the look-out for additional investments. And we lead the edition with coverage of Phylogica's discovery deal with AstraZeneca.

#### The Editors

Companies Covered: BKL, BTA, CSL, COH, PYC, RMD, Allied Medical, Reva Medical

	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 - May '09)	-7.3%
Year 9 (May '09 - May '10)	49.2%
Year 10 (May '10 - Current)	-6.2%
Cumulative Gain	171%
Av Annual Gain (9 yrs)	18.5%

Bioshares is published by Blake Industry & Market Analysis Pty Ltd.

Blake Industry & Market Analysis Pty Ltd ACN 085 334 292 PO Box 193 Richmond Vic 3121 AFS Licence No. 258032

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Individual Subscriptions (48 issues/year) \$350 (Inc.GST) Edition Number 373 (20 August 2010) ISSN 1443-850X

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# Bioshares

20 August 2010 Edition 373

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

# Phylogica Signs Second Drug Discovery Collaboration With Major Partner

Phylogica signed its second drug discovery collaboration in eight months with a major pharmaceutical company. **AstraZeneca** will pay Phylogica an upfront US\$750,000 with a further US\$750,000 in committed research funding over the next year. If the collaboration is successful with a product reaching market, Phylogica stands to gain a further US\$98 million from clinical and sales-based milestones.

Phylogica will use its unique peptide libraries to screen for potential drug candidates against the bacterium *Pseudomonas aeruginosa*. This bacteria is the cause of one of the most common hospital acquired infections and is also the cause of around 70% of lung infections experienced by patients living with cystic fibrosis. The prevalence of multidrug resistant strains of this bug is becoming an increasingly threatening problem.

# **Potent Drug-like Properties**

What has likely given AstraZeneca confidence in Phylogica's abilities is that Phylogica had previously found a number of peptide hits when working on an in-house program on another related bacterial target. Phylogica believes that its peptides, derived from ancient bacterial genomes, have been pre-selected through evolution to offer potent drug-like properties with strong multiple binding sites to targets. This potentially makes the peptides very good candidates for combating emerging drug resistant bacteria, where the strength of the binding to the target site becomes the determinant issue in drug efficacy over infection.

In December last year Phylogica signed a collaboration with **Roche**, where the focus was on exploring how peptides could transport biologic drugs into cells. The company is confident it will be successful in this first stage of the collaboration and expects to send its report to Roche shortly. The Roche deal involved an upfront payment (of \$411,000 according to the company's cash flow statement) with an option to move the collaboration to a second stage, which would presumably involve another upfront payment. The deal could be extended to a number of intracellular targets using Roche's biological drug candidates.

Phylogica believes it now has a sustainable business model that can deliver a profitable business in the medium-term rather than the long-term commercial timelines involved in traditional in-house drug discovery then development. At the *Bioshares* Thredbo Biotech Summit last month, CEO Paul Watt pointed to several drug library, discovery companies that are generating significant revenue streams from collaborative work with biotech and pharmaceutical companies.

These included **Morphosys** which generated revenues of 81 million Euros in 2009, **Galapagos** (100 million Euro in 2009), **Evolva** (CHF \$19 million in 2009) and **Evotec** (more than 40 million Euro in 2009).

- Cont'd on page 5

# Reva Medical Inc To List On ASX

Investment sentiment for new biotech listings is about to be tested in Australia. This week an article in *The Wall Street Journal* indicated that the American company Reva Medical was seeking to list on the ASX trading as CHESS Depository Interests (CDIs). The company has filed an S-1 registration statement with the SEC in the US, indicating that it was seeking to raise at least A\$65 million. To date much of the funding for the company has come from venture capital funds, with the company raising US\$42 million in 2007, and from medical device groups **Medtronic** and **Boston Scientific**.

Reva has been developing a biodegradable stent for over 10 years, having spent \$111 million in the process. The stent is made from an iodinated, tyrosine-derived polycarbonate material. The company has tested nearly 1,000 of its stents in animal models and is looking to conduct human trials in the first quarter of 2011.

The global stent market is worth US\$5.3 billion. Reva has an arrangement with Boston Scientific whereby Boston Scientific has an option to acquire Reva if Reva does not list on an exchange by 7 December, 2010. Boston Scientific also has a option to sell the Reva product although this option terminates on the achievement of clinical milestones.

US companies trading through CDIs on the local market are increasing in popularity. **Axon Instruments** was the first US-domiciled Australian biotech to list on the ASX in 2000, and back then it was quite a complicated process. There are a number of biotechs that are officially domiciled in the US and their principal exchange

is the ASX. These include **Universal Biosensors**, **Sunshine Heart**, and **Heartware International**. Peplin and Heartware both made the conversion from Australian domiciled businesses to US based companies with stock market success; Peplin was sold for over \$300 million last year to **Leo Pharma** and Heartware is currently capitalised at \$960 million.

One appeal of a US domicile is that companies that are incorporated in the State of Delaware require only a 50.1% approval from shareholders to sell the business, compared to 90% in Australia or 75% in Australia under a Scheme of Arrangement.

Reva will trade only on the ASX. The link to the ASX is that two of the directors of Reva, Robert Thomas and Robert Stockman, were both previously on the board of Heartware Ltd and then Heartware International Inc when it redomiciled to the US. Also in common with Heartware is that both companies have several venture capital groups on their register.

Reva is reportedly seeking to raise funds at a pre-money valuation of around \$250 million. At that price it will be one of the largest biotech floats on the ASX and will certainly test current biotech investment sentiment.

**Bioshares** 

# Allied Medical - A New Investment Cycle in Biotech R&D Begins

Andrew Forrest's Allied Medical has put its hand up to address the funding gap for early stage life sciences investment. The company recently announced that it would invest in **Coridon**, a company started by Professor Ian Frazer to develop vaccines. Coridon has a preclinical DNA vaccine platform that has the potential to work as a therapeutic and preventative vaccine across a number of diseases.

Allied Medical was spun out of Fortescue in 2005. It has around 2200 shareholders and Forrest maintains a 46% interest in Allied Medical.

Allied Medical has made two investments in revenue-generating life science companies which generate sales of \$4.1 million, growing at 20% and returning a profit of \$550,000. Allied recently acquired medical device and equipment group **Medevco**.

The aim for Allied Medical is to grow both its immediate revenue generating businesses both organically and through M&A, in parallel with growing its portfolio of longer term biotech R&D platform technology groups such as Coridon. The company intends to focus only on Australian businesses.

Allied Medical invested \$3 million in Coridon to take its stake to 38% with an option to increase that stake to 55%. That funding should allow Coridon to complete a Phase I study and to bring the second program to a stage ready for clinical testing. Coridon is developing a DNA-based vaccine that would be used for both prevention and treatment of infections.

Allied Medical's aim is to list on the ASX in around 12 months.

**Bioshares** 

# Profit Reporting Companies FY2010 - Part 1

CSL			CMP	\$31.50
CSL Cap'n (\$M)		\$17,315	PE	16
	FY2007	FY2008	FY2009	FY2010
Sales (\$M)	\$3,172.4	\$3,556.7	\$4,622.4	\$4,455.8
Change	11%	12%	30%	-4%
EBIT (\$M)	\$918.7	\$1,108.4	\$1,368.0	\$1,357.0
Change	78%	21%	23%	-1%
Net Profit (\$M)	\$539.3	\$701.8	\$1,019.9	\$1,052.9
Change	359%	30%	45%	3%
Net Op. Cash PS	\$0.88	\$1.30	\$1.78	\$2.03
Change	-7%	48%	37%	14%

# **CSL – Exchange Rate Dampens Earnings**

CSL reported a dip in sales of 4% for the full year ending June 30, 2010. Full years sales were \$4.45 billion compared to \$4.62 billion in FY2009.

Net profit edged up marginally by 3% to \$1.053 billion. Exchange rate effects had a significant effect on CSL earnings, with the company registering a \$187 million negative currency impact. If restated at FY2009 exchange rates, CSL's net profit was \$1.24 billion, up 22%. One revenue line showing a weaker performance was IP revenue, with royalties from the HPV vaccine Gardasil decreasing by 75% to \$47 million for FY2010.

CSL CEO Brian McNamee estimated that healthcare reforms in the US and Europe contributed to \$30 million in lost earnings for the company.

CSL has \$1 billion cash at hand, against debt of \$462 million. Growth in cash flow has been a noteworthy feature of the CSL accounts, with net operational cash flow per share growing at a CAGR of 32% from FY2007.

After completing a \$1.8 billion share buy-back to in effect return funds raised for the acquisition of Talecris that was stopped by the US Federal Trade Commission, CSL has now announced a further share buy-back of up to \$900 million in value (approximating 5% of stock or 27 million shares).

CSL has given guidance of earnings for FY2011 of between \$980 million and a \$1.030 billion, at current exchange rates.

Cochlear	Cochlear		CMP	\$68.88
COH	Cap'n (\$M)	\$3,896	PE	25
	FY2007	FY2008	FY2009	FY2010
Sales (\$M)	\$556.2	\$600.1	\$708.4	\$690.5
Change	23%	8%	18%	-3%
EBIT (\$M)	\$153.58	\$162.63	\$174.65	\$219.35
Change	33%	6%	7%	26%
Net Profit (\$M)	\$97.68	\$115.23	\$130.54	\$155.15
Change	25%	18%	13%	19%
Net Op. Cash PS	\$1.40	\$1.53	\$2.63	\$3.19
Change	-26%	9%	72%	21%

# Cochlear - Posts a 19% Lift in Net Profit

Sales of Cochlear's hearing products eased slightly, with a decrease of 3% recorded for FY2010, in contrast to an 18% increase in the previous year. Full year sales were \$708.4 million, and total revenues were \$734.8 million for FY2010.

However, Cochlear's EBIT margin (on sales) increased from 25% in FY2009 to 32% in FY2010.

Cochlear reported a net profit of \$155. 2 million FY2010, which was 19% higher than the figure reported for the previous year.

Unit sales of Cochlear implants totalled 21,023 for FY2010, an increase of 13% from the previous year. According to the company, second half unit sales increased by 20%, boosted by the launch of the new Nucleus 5 system in FY 2010 H1. The system is now sold in 50 countries, including the USA.

Cochlear's net debt was \$113.9 million, and when debt associated with the company's new headquarters at Macquarie University is subtracted (repayment is due H1 FY 2011), net debt falls to \$41.1 million, implying a gearing ratio of 9%.

R&D expenditures were \$94.9 million for FY2010, roughly in line with the \$96 million incurred in the previous year. Cochlear closed the year with cash at hand of \$43 million.

# Profit Reporting Companies FY2010 - Part 1 (cont'd)

Resmed	CMP	\$3.57	CMP (\$US)	\$62.27
RMD	Cap'n (\$M)	\$3,031	PE	28
	FY2007 FY2008 FY2009		FY2009	FY2010
	US\$	US\$	US\$	US\$
Sales (\$M)	\$716.3	\$835.4	\$920.7	\$1,092.4
Change	18%	17%	10%	19%
EBIT (\$M)	\$104.45	\$167.91	\$190.31	\$240.38
Change	-21%	61%	13%	26%
Net Profit (\$M)	\$66.30	\$110.30	\$146.45	\$190.09
Change	-25%	66%	33%	30%
Net Op. Cash PS	\$1.15	\$1.71	\$2.93	\$2.26
Change	-12%	49%	71%	-23%

Blackmores			CMP	\$24.05
BKL	Cap'n (\$M)	\$401	PE	17
	FY2007	FY2008	FY2009	FY2010
Sales (\$M)	\$171.7	\$178.8	\$200.3	\$214.9
Change	16%	4%	12%	7%
EBIT (\$M)	\$24.24	\$26.97	\$30.34	\$36.75
Change	15%	11%	12%	21%
Net Profit (\$M)	\$16.67	\$19.09	\$20.78	\$24.30
Change	15%	14%	9%	17%

Biota			CMP	\$0.93
BTA	Cap'n (\$M)	\$166	PE	11
	FY2007	FY2008	FY2009	FY2010
Op. Rev. (\$M)	\$53.3	\$36.1	\$57.6	\$65.1
Change	359%	-32%	60%	13%
EBIT (\$M)	-\$11.20	\$15.05	\$38.89	\$17.81
Change	-17%	-234%	158%	-54%
Net Profit (\$M)	\$20.18	-\$6.49	\$38.18	\$15.18
Change	-278%	-132%	-688%	-60%

# Resmed - A Strong Result

Sleep-disordered breathing products company Resmed clipped the billion dollar mark in sales for the first time, recording sales of US\$1.092 billion, an increase of 19% from the previous year.

Growth in sales was driven by new products, including the S9 Autoset and Elite flow generators, which were launched in February 2010. Sales of flow generators totalled US\$634 million, an increase of 19% from the previous year.

Operating expenses increased by 14% in FY2010 from FY2009.

Net profit was US\$190 million, an increase of 30% from FY2009. Over FY2007 to FY2010, Resmed's CAGR for net profit was 42%.

The company spent US\$75.2 million on R&D in FY2010, compared to US\$63.1 million in FY2009. Resmed's cash at hand at June 30, 2010 was US\$489 million.

Resmed has announced a two-for-one stock split, which will come into effect on or about August 30, 2010.

# Blackmores - Solid Growth

Complementary medicines and supplements company Blackmores posted a 7% increase in sales for FY2010, locking in sales of \$215 million. EBIT of \$33.9 million represented a 13% increase from the previous year.

The company recorded a net profit result of \$24.3 million, an increase of 17% in FY2009.

Blackmores launched 80 new products in FY2010.

The company's Asian business now contributes 15% of sales (\$31.2 million). An agreement was signed in FY2010 Q4 with **Eu Yan Sang** for distribution of Blackmore's products into the Traditional Chinese Medicine market in Malaysia and Singapore.

# **Biota - Increased Spending on Programs**

Biota Holdings' operational revenue comprises royalty payments and partnering and research revenue.

Operational revenue rose 13% for FY2010 to \$65.1 million for FY2010. In contrast, total revenue of \$68.9 million decreased by 14%, influenced by the receipt of a one-off settlement payment from **GlaxoSmithKline** of \$20 million in FY2009.

Net profit decreased 60% to \$15 million, reflecting both the impact of the one-off GSK payment in FY2009 and a substantial increase in spending on research programs (\$21.7 million) and the amortisation of costs of acquisitions made during the year (\$8.8 million). Biota expended \$11.2 million on product development costs in FY2010, however \$3.9 million was refunded by the NIH. The company recently commenced a Phase II trial of BTA798 for the treatment of Human Rhinovirus infection in asthma patients. The two year program is expected to cost \$25 million.

Biota retained cash of \$104.9 million at June 30, 2010.

**Bioshares** 

<b>Bioshares</b>	Model	Portfolio	(20	August 2010)

Company	Price	Price added	Date added
	(current)	to portfolio	
Sunshine Heart	\$0.032	\$0.036	June 2010
Biota Holdings	\$0.93	\$1.09	May 2010
Tissue Therapies	\$0.20	\$0.21	January 2010
QRxPharma	\$0.95	\$0.25	December 2008
Hexima	\$0.25	\$0.60	October 2008
Atcor Medical	\$0.14	\$0.10	October 2008
CathRx	\$0.16	\$0.70	October 2008
Impedimed	\$0.67	\$0.70	August 2008
Mesoblast	\$1.95	\$1.25	August 2008
Circadian Technologies	\$0.65	\$1.03	February 2008
Patrys	\$0.10	\$0.50	December 2007
Bionomics	\$0.30	\$0.42	December 2007
Cogstate	\$0.24	\$0.13	November 2007
Sirtex Medical	\$5.14	\$3.90	October 2007
Clinuvel Pharmaceuticals	\$0.23	\$0.66	September 2007
Starpharma Holdings	\$0.52	\$0.37	August 2007
Pharmaxis	\$2.10	\$3.15	August 2007
Universal Biosensors	\$1.50	\$1.23	June 2007
Probiotec	\$1.27	\$1.12	February 2007
Acrux	\$2.00	\$0.83	November 2004
Alchemia	\$0.49	\$0.67	May 2004

# Portfolio Changes - 20 August 2010

## IN:

No changes.

#### OUT:

No changes.

# - Phylogica cont'd from page 1

Each research collaboration lasts for around 12 months. Phylogica says it currently has the capacity to screen for six different partners at the one time and it is investing in robotics capabilities to increase this capacity to handle 12 parallel collaborations.

For Phylogica this model allows early revenue streams to make the company profitable, and the flow through from collaborations that progress into clinical studies (further milestones) and potentially to marketed products, from which Phylogica would stand to receive a single digit royalty.

Phylogica has a further two potential drug discovery deals with major pharmaceutical companies which it says are currently in late stage discussions and believes it may close by year's end. If the company could engage four significant drug discovery collaborations over 12 months, including the two already signed, and progress its Roche collaboration to the second stage, it will be well on the way to building a sustainable business and joining its peers listed above.

# **Summary**

At 30 June, the company had \$1.2 million in cash. Adding the funding from the AstraZeneca collaboration, we estimate the company has around \$2.4 million in funds to support the business. We believe there is a very good chance the company will continue to build its revenue from discovery collaborations. The company also has a supportive shareholder base to access should it need to raise further funding.

Bioshares recommendation: Speculative Buy Class B

# **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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