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In this edition...
Reporting season is underway creating an opportunity for Bioshares to discuss some profitable companies in the life sciences space, including CSL and IDT Australia. CSL has recorded a very strong full year profit, helped in no small part by sales of the cervical cancer vaccine Gardasil that was invented at the University of Queensland. And IDT Australia is benefiting from the desire of Big Pharma companies to out-source work to high quality specialised providers.

We also provide readers with an extensive update on Antisense Therapeutics and progress in the antisense drug development arena.

The editors
Companies covered: ANP, CSL, IDT

	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 (from 4 May '07)	-9.1%
Cumulative Gain	**197%**
Av Annual Gain (6 yrs)	**26.8%**

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Bioshares

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

Gardasil Boosts CSL's Bottom Line; Long-term Strategy Needs Action

CSL (CSL: $95.30) is Australia's largest life sciences company, capitalised at $17.4 billion. The company has enjoyed very strong support, registering a 96% growth in its share price over the last twelve months.

CSL is a manufacturer of products sourced from plasma. Plasma is what remains from blood after the removal of red cells, leukocytes and platelets. The components of plasma are salts, water, enzymes, antibodies and other proteins. Some of these antibodies and proteins can be transformed into medical treatments for conditions such as hemophilia and other bleeding disorders and various immune deficiency disorders.

CSL is organised into three businesses including CSL Behring (the international plasma products business excluding Australia, New Zealand and Asia), CSL Bioplasma (the ANZ and Asian plasma products business) and CSL Biotherapies, which is a manufacturer and marketer of vaccines, and acts as a regional distributor for a range of pharmaceutical products.

Full-year Results

CSL recorded a net profit of $539 million for the year ended June 30, 2007, a 360% increase from the previous year. When adjusted for a contingent payment in FY2006 made in respect of the Aventis Behring acquisition, the increase was 54%. If a settlement payment made to Sanofi Aventis in FY2007 is also factored out, then the increase in profit was 48%. Group revenues for the FY2007 were $3.3 billion

CSL Behring recorded sales of $2.6 billion for FY2007, an increase of 8% from the previous year. In US dollar terms (the currency in which a significant portion of the CSL Behring business is conducted) growth was 13% following a 10% increase the previous year.

CSL Bioplasma sales increased by 10% to $211 million for the same period. CSL Biotherapies posted very strong sales growth of 49% ($317 million) for FY2007, powered by $100 million in sales of Gardasil, the human papillomavirus (cervical cancer) vaccine in Australia.

The Gardasil Effect

CSL has delivered a very strong result for the fiscal year ending June 30, 2007, due to sales of Gardasil in Australia ($100 million), and royalty income from the sale of Gardasil elsewhere ($86 million). The company significantly exceeded its guidance provided a year earlier for royalty income, when it stated that Gardasil royalty income would be in the order of $40-$50 million for FY2007.

CSL has issued guidance suggesting that total revenue growth will be between 12% and 14% for FY2008, with net earnings (NPAT) to lie between $670 million and $700 million. Gardasil royalties are anticipated by CSL to be $155 million for FY2008. These company

forecasts exclude interest costs associated with a proposed share buyback, and are subject to price movements in prices of core plasma products, tax rates and currency.

Number two ranking

CSL ranks as the number two plasma fractionator in the world, second to Baxter International. Baxter International's Bioscience plasma product division generated sales for the equivalent FY2007 period of US$4.3 billion, an increase of 20% from the previous corresponding period. This may be compared to sales aggregated from CSL Behring and CSL Biotherapies of US$2.2 billion for FY2007, which represented an increase of 13% from FY2006.

Growth in Baxter Bioscience' sales would appear to have been aided considerably by growth in sales of ADVATE (rAHF-PFM), a recombinant, not plasma derived, Factor VIII product. Baxter stated that it expected sales of ADVATE to approach US$1.1 billion for CY2007, up from US$850 million for CY2006 (an approximate 30% increase).

ADVATE is also manufactured without using human albumin or plasma. Recombinant Factor VIII outsells plasma derived Factor VIII by a ratio of 3 to 1 in the USA. CSL does not manufacture any coagulation factors using recombinant technologies. CSL does sell two products, Helixate FS and Helixate NexGen, which are manufactured by Bayer (and branded by Bayer as Kogenate FS). This arrangement is a legacy from CSL's acquisition of Aventis Behring acquisition in March 2004. CSL's manufacturing contract with Bayer was extended from 2009 to 2017 in February of this year.

The global recombinant coagulation factors market (Factors VIIa, VIII, IX) was estimated at US$4.7 billion for 2006, of which CSL's share was approximately 7%. CSL stated that sales of Helixate were US$340 million in FY2006 and were at a similar level for FY2007. Helixate accounted for approximately 17% of CSL Behring's sales in FY2007.

CSL's strategy…

While CSL appears to be on a very strong footing, several elements of the company's strategy could be best described as ultra-conservative to the point of denying the company the opportunity of even greater business expansion and capital growth. The strategy may also be flawed in that it does not sufficiently account for several long-term threats to the company. These threats include the competitive pressures from recombinantly manufactured biopharmaceutical products, (eg from Baxter's ADVATE product).

CSL and Baxter Bioscience Plasma Product Sales (Fract. & recom.)
($US '000)

Period	CSL Bioplasma + CSL Behring	Baxter Bioscience*	Total	Change
Yr end 30/6/07	$2,232	$4,271	$6,503	18%
Share	*34%*	*66%*		
Yr end 30/6/06	$1,969	$3,557	$5,526	
Share	*36%*	*64%*		

*excludes Transfusion Products Business

Capitalisations of Selected Pharma and Biotech Companies*

	Company	Market Cap ($US B)
1	Johnson & Johnson	$179
2	Pfizer	$171
3	Glaxosmithkline	$145
4	Novartis	$123
5	Merck	$110
6	Sanofi-Aventis	$110
7	Abbott Laboratories	$81
8	Genentech	$77
9	AstraZeneca	$74
10	Eli Lilly	$64
11	Wyeth	$63
12	Bayer	$60
13	Bristol-Myers Squibb	$58
14	Amgen	$55
15	Novo Nordisk	$35
16	Gilead Sciences	$35
17	Baxter International	$34
18	Allergan	$18
19	Biogen Idec	$18
20	Genzyme	$16
21	**CSL**	**$14**
22	Shire Pharmaceuticals	$14
23	Elan	$9.2
24	UCB	$5.6
25	Cephalon	$4.9
26	Vertex Pharmaceuticals	$4.8
27	Medarex	$2.2
28	Crucell	$1.3

* this is not a complete list

Several benefits of third generation recombinantly manufactured products in the immune-deficiencies and antihemophilic factors markets are security, quality and control of supply, with dependency on plasma collection through blood collection centres made redundant. Another benefit is safety. This was inferred by the FDA when it commented on the ADVATE approval that an antihemophilic human factor VIII product that does not use additives derived from human or animal blood in its manufacture "provides added reassurance against any theoretical infectious risks that may arise from the use of blood-derived additives in the manufacturing of factor VIII."

Share buy-back?

The decision by CSL to seek to undertake a share buy-back is shortsighted. The approximate sum of $750 million allocated to the buyback could be put to much better use to fill and expand the company's product pipeline and expand and develop the companies cell-based (ie recombinant) manufacturing capabilities for protein drugs and vaccines.

Cont'd over

– CSL cont'd

The company has outlined for several years that it intends grow its business through the development of novel biotech products and novel plasma products. CSL appears to be meeting its objective of developing novel plasma products, as demonstrated by the recent FDA approval of Privigen and the clinical development of a reconstituted high density lipoprotein product. However, CSL's progress, in the area of biologic or protein based medicines has been slow to take off. The company has only one antibody in development for therapeutic areas outside its traditional core area of immunotherapies and under its own control and management. This product, CSL360, is being developed for acute myeloid leukemia and CSL recently announced that CSL360 has commenced a Phase I study.

CSL's acquisition of **Zenyth Therapeutics** in 2006 would have added valuable protein drug development skills to the company. However, a weakness with CSL is that it appears to lack a well-developed 'new business' function that is capable of identifying and executing M&A and product in-licensing opportunities as well as new business integration, *outside* its traditional core business areas of plasma-based products and vaccines.

An argument can be made for CSL's expansions into protein and monoclonal drug development because these products, which are manufactured using recombinant technologies, potentially offer both high growth and sizeable revenues because they can offer significant patient benefits. They also offer logical diversification for CSL away from its reliance on plasma-derived therapies, which are not without commercial risk.

Acquisition and merger opportunities

CSL should be well placed to in-license new product opportunities from Australian research bodies and biotech companies. However, acquisition of international firms that have products in development as well as on the market and a focus on one or two biologic product franchises, could be equally suitable strategic considerations for CSL (cap'n US$14 billion). *Examples* of these acquisition targets include the Belgian company **UCB** (cap'n, US$5.6 billion), **Medarex** (US$2.2 billion) and Seattle-based **Zymogenetics** (US$830 million)

Summary

Over the short-to-medium term CSL's prospects appear to be remarkably good, with revenues from Gardasil set to play a 'good news' element in the company's next few reporting periods. Advances on the vaccine front may also boost the company's overall sales if CSL is permitted to sell influenza vaccine in the USA. However, the long term future of CSL's main business is subject to some uncertainties and threats and the company would do well to establish a broader base for new growth opportunities sooner rather than later.

CSL is trading on a prospective PE ratio of 25 based on the upper end of the company's profit forecast of $700 million for FY2008.

Bioshares Recommendation: **Hold**

Bioshares

What is the Outlook for Antisense Therapeutics?

Antisense Therapeutics (ANP: 3.3cents) has experienced difficult times over the last two-and-a-half years. In March 2005, the company's Phase II trial of its lead compound, ATL1102, for the treatment of multiple sclerosis, was halted because of the dangerous side effects from an existing therapeutic, Tysabri, that inhibits the same target to that of ATL1102. The field of antisense technology as a therapeutic approach has yet to be commercially validated after 20 years of research. Antisense Therapeutics' also halted its psoriasis program with ALT1101 due to poor efficacy from the antisense compound. With the tide turning possibly in favour of the company in recent months, it's worth looking at the developments with this company.

The delay in bringing an economically viable antisense drug to market - on which we are still waiting - and the emergence of a more powerful technology to silence messenger RNA in the cell (which in turn prevents unwanted protein production in the body) has increased the skepticism of investors regarding the relevance of antisense technology.

The new technology on the block, RNA interference (RNAi), has many advantages over antisense technology. RNAi compounds work at much lower concentrations than antisense drugs and are not destroyed in the cell by serum nucleases. RNAi compounds also have the capability to move between the cells.

The downside of both technologies is the difficulty of getting these drugs into the actual cells. With antisense, Antisense Therapeutic's partner, Isis Pharmaceuticals, has spent almost 20 years in altering the chemistry on the antisense compounds to deliver the drug candidates into the cell. It is now onto its third generation chemistry.

With RNAi, viral vectors are the most popular method for getting those candidates into the cell. The delivery issue is the reason why the first and only antisense drug on the market is used for the treatment of eye diseases, injected directly into the eye. Similarly the most advanced RNAi clinical candidates are targeting eye diseases.

However the RNAi drug molecules, called small interfering RNA (siRNA), can be so effective once in the cells that they may become toxic and turn on unwanted genes. Antisense compounds are more mellow in their action, which in some situations, where more careful or modest manipulation of cellular function, could be advantageous. Whilst there is likely to be a place for both technologies, RNAi seems likely to generate more commercial success.

What is antisense and RNAi?

Both approaches seek to silence the messenger RNA in the cell to stop the production of the protein outside of the cell. Antisense uses a single matching oligonucleotide sequence to bind with the mRNA. RNAi uses a short double stranded RNA to bind to the mRNA and inactivate it. Both techmologies need to get into the cell to work, different to most current drugs that work outside of the cell.

Isis finally looks set to deliver

This year **Isis Pharmaceuticals** has delivered exceptional Phase II study results from three Phase II trials testing its cholesterol lowering antisense drug candidate, ISIS 301012. Tested in patients with high cholesterol, in patients with familial hypercholesterolemia, and also in patients on existing statin medication, the drug candidate reduced LDL cholesterol levels by around 50% from initial levels or from baseline levels following statin treatment. Further Phase II trial results are expected to be released in 2007. If subsequent Phase III trials are successful, the drug could become an extremely successful product for Isis and also renew some faith in the antisense technology field.

Delivery the issue for antisense drugs

Antisense drugs are believed to accumulate in the liver, the same organ which produces and helps breaks down cholesterol. This 'co-location' effect may be what makes cholesterol an ideal candidate for an antisense drug and may explain the success Isis is having with its cholesterol lowering antisense drug.

Antisense compounds are also known to accumulate in bone marrow, the spleen and in lymph nodes. This is important for the Antisense multiple sclerosis program which is targeting the production of lymphocytes, specifically, preventing the formation of the VLA-4 protein on the lymphocytes. Lymphocytes are produced in bone marrow and also reside in lymph nodes and in the spleen, all organs that are known to accumulate antisense-type drugs.

ANP's lead program - Multiple Sclerosis, ATL1102

Antisense Therapeutics is looking to block the same target as the current drug on the market, Tysabri. Tysabri is a monoclonal antibody with blocks the VLA-4 protein on the outside of lymphocytes in the blood. The VLA-4 protein attaches to the blood vessel wall and allows migration of these immune system cells to central nervous system. The results in the autoimmune disease known as multiple sclerosis. The action of ATL1102 is slightly different to Tysabri, in that it works earlier in the process, attempting to prevent the production of these VLA-4 proteins on the surface of the white blood cells (lymphocytes).

Current trial

Antisense Therapeutics is conducting a Phase II trial in multiple sclerosis in Europe in 80 patients. The trial is more than 50% enrolled. It has been slowed firstly by Tysabri being taken off the market, then by the availability of Tysabri, with patients electing to take Tysabri than an experimental medicine that works on the same target, particularly where Tysabri was reimbursed by health bodies. Trials were initially being conducted in Germany and have since moved to Poland, the Slovak Republic, the Czech Republic, Romania and Bulgaria. Results from the trial are anticipated by year's end, although this may move to early 2008.

Tysabri sales build

Tysabri was taken off the market in 2005 after two patients taking Tysabri and interferon died from a viral infection of the brain (pro-

Cont'd over

– Antisense Therapeutics cont'd

gressive multifocal leukoencephalopathy). It results from a latent virus infection in the liver which is somewhat common but became fatally active in two cases. Currently there are 13,000 MS patients using Tysabri in the US and Europe. The drug is very effective, reducing the relapse rate in MS patients by 68%. A further 1,000 patients are taking the drug in clinical trials and no new fatalities have been recorded. The drug was reintroduced in the US and Europe in June 2006. It sold US$47.5 million in the June quarter, up 56% on the March quarter this year.

Comments

Although Tysabri and ATL1102 both seek to achieve the same goal, of stopping the function of VLA-4, the two approaches are very different. Tysabri operates in a very direct approach. It's a monoclonal antibody that is delivered once a month by infusion directly into the blood stream. It then binds to the VLA-4 protein.

Quite differently, ATL1102 needs to make its way into lymphocyte cells and then prevent the protein production of VLA-4 by binding to the mRNA within the lymphocyte cells. Technically, this is a much more difficult task. However, if the antisense compounds can enter the right cells without being destroyed, then the approach is very efficient, cleaner and less expensive.

One consideration to note is that ATL1102 may not need to show that it is as effective as Tysabri. An immune modulating drug that is more modest in its effect on VLA-4 and therefore the overall immune system could be more appealing to a wider population of less advanced patients with multiple sclerosis, given the residing safety concerns with Tysabri. As with all immune modulating drugs, incapacitating the immune system in an aspect is likely to result in increased vulnerability to other invading pathogens, which may explain the earlier patient deaths from Tysabri.

Other projects

The company has ceased developed on an antisense psoriasis program. Its antisense asthma program is not being advanced as the company considers its options. It is continuing with ATL1103 for inhibiting IGF-1 in the blood stream by attempting to block growth hormone receptor expression (GHr). Potential applications are for treating excessive growth hormone action, and in treating diabetic retinopathy, which is associated with excessive IGF-1 levels. Reducing IGF-1 levels has been shown in the clinic to slow the progression of this disease.

Of particular interest with this program is that the tissue target is the liver, the same tissue target that is showing excellent results for Isis's cholesterol program. The company is undertaking toxicology studies. Importantly, in April last year, the company showed that it could suppress IGF-1 hormone levels in primates. The program is in toxicology testing and is expected to move into the clinic towards the end of 2008.

Summary

There is a belief by many that antisense technology does not work and attention should be focused on the potentially more powerful technology of RNAi. RNAi has few critics at present and there is a lot of commercial interest in RNAi as shown by large licensing and M&A deals in the space. Although antisense technology has not delivered commercial success, RNAi has not yet had the opportunity to fail in the clinic. However, the interest in antisense technology may be renewed if the promising results from Isis's cholesterol program translate into successful revenue generating products.

Antisense Therapeutics is moving towards a potentially large value creation milestone with the release of Phase II data, which ex-

Cont'd over

Bioshares Model Portfolio (24 August 2007)

Company	Price (current)	Price added to portfolio
Acrux	$1.30	$0.83
Alchemia	$0.73	$0.67
Biodiem	$0.29	$0.29
Biota Holdings	$1.68	$1.55
Circadian Technologies	$1.21	$1.45
Clinuvel Pharmaceuticals	$0.66	$0.66
Cytopia	$0.63	$0.46
Chemgenex Pharma.	$0.80	$0.38
Optiscan Imaging	$0.42	$0.35
Peplin	$0.82	$0.83
Peptech	$1.25	$1.31
Pharmaxis	$3.40	$3.15
Phylogica	$0.27	$0.42
Probiotec	$1.13	$1.12
Progen Pharmaceuticals	$3.52	$3.52
Starpharma Holdings	$0.36	$0.37
Sunshine Heart	$0.18	$0.19
Tissue Therapies	$0.50	$0.58
Universal Biosensors	$1.27	$1.23

Portfolio Changes – 24 August 2007

IN:

Progen Pharmaceuticals has fallen to very attractive levels, with a Phase III liver cancer trial to start soon. The company has an estimated $100 million in cash and is capitalised at $209 million.

Clinuvel Pharmaceuticals has dropped to attractive levels. With two Phase III trials underway with its lead compound in people with sun intolerance disorders, it's a good entry point for this stock. CUV had $62 million in cash and investments at June 30. It is capitalised at $199 million.

OUT:

No changes.

IDT Australia Posts Very Strong Profit Growth

IDT Australia (IDT: $2.12) delivered a strong full year result for shareholders. Its net profit soared by 51% to $5.5 million. The stock is now paying a 4.7% fully franked dividend yield, is trading on a PE of 16.7, and strong double digit growth is forecast by the management for the current year.

IDT Australia has been a difficult business to assess. The company does not report on its individual business units and more often than not does not reveal the drugs it is manufacturing for other parties. And results have been patchy as the company has rebuilt parts of its business over the last three years following difficult trading circumstances.

IDT Australia has four main business:

- Fee-for-service work, which involves the formulation of new experimental drugs for clinical trials
- Manufacture of active pharmaceutical ingredients (API), which is the bulk manufacture of the core pharmaceutical product component
- Manufacture of finished product (where the API) is often manufactured by others but not always
- A Phase I clinical trial centre in Adelaide, called CMAX, acquired in 2002

Over the last three years, IDT Australia suffered a large blow to its core business, losing the majority of its generic API business to lower cost competitors in Asia. Over the last four years, revenues have been steady, at between $25 - $27 million a year. However, in the last three years, IDT Australia has had to replace an estimated $10 million in lost revenue from the manufacture of generic APIs with other business. Raw materials and consumables used is a good measure of changes in this business. Between FY2003 - FY2007, this input decreased from $4.8 million in 2003 to $4.5 million, $2.5 million, $2.0 million and $450,000 in the last financial year. The company continues to manufacture APIs, but only for branded products and not generic products. This year it was awarded a long term contract to manufacture an API for a recently approved oncology drug, which will start in this financial year.

The company generated total revenue of $26.7 million. An estimated $7 million of that is generated by the CMAX facility. The dominant business unit for the company is its fee-for-service work, with about a dozen drugs being manufactured for mainly US pharmaceutical companies for clinical trials. The upturn in net profit in the last financial year was likely to be significantly influenced by the company's expansion of its business with Pfizer, announced in January of this year, for the manufacture of an experimental antibiotic. Given that the company rarely reports new contracts, this was evidently a significant deal which sees Pfizer contribute to costs for expansion of the facilities at IDT.

Key risks

IDT's business remains diversified through its related-businesses model. A major global shift in the pharmaceutical industry can have a serious medium term impact on the company's business, but its diversified structure has allowed IDT to recover from such changes. Main risks going forward are that the industry may move away from outsourcing, which is unlikely, that fee-for-service work declines as small biotech companies run out of cash, and that fee-for-service work for larger pharma customers does not convert into long term manufacturing contracts on approved pharmaceuticals.

Summary

IDT has successfully weathered a large disturbance to its business over the last three years. The company has improved profitability, with its EBIT margin increasing from 24% in 2005 and 2004 to 29% last year. With another strong year forecast by the company and with the loss of the generics API business behind them, IDT is trading at very attractive levels as an income stock paying close to a 5% fully franked dividend yield.

Bioshares recommendation: **Buy**

Bioshares

– Antisense Therapeutics cont'd

pected in the next six months. The results should be clear as to whether this drug candidate is having any impact on the disease. However given the failure rate of antisense drugs globally, which can be attributed to the level of difficulty involved with the technology's approach, we view this stock as extremely speculative and recommend investors reconsider this stock following the release of the MS trial results. If the result is positive, the technology risk will reduce considerably. If the results are negative, it will provide a better entry point into the stock which will be driven by the ATL1103 program. This program should have a higher chance of success than the MS trial.

Antisense Technologies is capitalised at $17.6 million with $7.6 million in cash at the end of June. Circadian Technologies owns just under 27% of Antisense Technologies.

Bioshares recommendation: **Wait for MS data to determine investment position**

Bioshares

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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