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In this edition...
Nearly all companies have filed their accounts for FY2008 with the ASX. We have trawled through the reports of some companies to bring readers a selection of notes and highlights, including notes regarding some less well known companies such as sleep apnea company SomnoMed and some old stayers such as Anadis and Clover Corp.

Antisense Therapeutics is also the subject of our attentions this week as we explore its IGF-1 program and explain why this is an attractive drug target. We also update readers on recent events at NeuroDiscovery and Arana Therapeutics.

Companies covered: ANP, AAH, NDL

	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)	-7.0%
Cumulative Gain	**94%**
Av Annual Gain (7 yrs)	**17.8%**

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Bioshares

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

Notes and Highlights from Selected 2008 Annual Reports

Today was the last day for ASX listed companies to file preliminary full year reports for the year ending June 30, 2008. Highlights drawn from annual reports for a selected number of companies follow.

Acrux

Drug delivery company Acrux reported a net loss of $5 million, but also posted revenues of $7 million. Acrux received a $3.5 million milestone payment from **Vivus** following the approval of Evamist by the US FDA.

Royalty revenues from US sales of Evamist look to be on the way, with the product receiving FDA approval in July 2007 and launched by marketing partner **KV Pharmaceuticals** in April 2008.

Advanced Surgical Design and Manufacture

ASDM listed on the ASX last year. The company undertook a small capital raising of $1.8 million, when it listed in December 2007. Funds were used to reduce debt, which stood at $3.5 million in 2007, but reduced to $0.76 million in 2008. The company's debut annual report (for 2007-08) is impressive, with growth of 21.5% for revenues of $7 million, albeit with a smaller net profit result of $0.2 million. The company also filed a patent infringement notice against **Portland Orthopaedics** in relation to ASDM's Hip Cup patent.

As of Friday, ASDM (AMT) shares at 45 cents were down 54% from their post listing high of 98 cents.

Agenix

This week, Agenix requested that its stock be suspended from trading. The company is unable to finalise its accounts while it waits for the ownership of certain Chinese entities to be clarified. The board of Agenix is not certain it has technically obtained control of these operations. Agenix initiated its acquisition of the **Shanghai Rui Guang Bio-Pharma Development Co, Ltd** and **Shanghai Yi Sheng Pharmaceutical Co, Ltd** in February 2007, paying $8.1 million in cash and $8.4 million shares, subject to milestones. Long-standing chairman Ravi Govindan resigned from the board on August 7, 2008. His replacement is Nicholas Weston, a Melbourne-based solicitor.

Agenix has also recently announced the completion of enrolment in its Phase II trial of Thromboview, an antibody based diagnostic technology. Fifty patients were enrolled in the pulmonary embolism trial, which compared Thromboview to Computed Tomography-Pulmonary Angiography. The company expects to develop an 'end of Phase II' package by Q1 2009.

Cont'd over

Anadis

Although Anadis has sold its functional foods contract manufacturing business, it continues to sell the travellers' diarrhoea product Travelan. Sales of this product totalled $237,800 for FY2008. The company's current focus is on developing therapeutic products using antibodies derived from immunised cattle. Anadis finished the year with approximately $1 million in cash, sufficient funds to cover the company's activities for about six months, based on recent spending patterns.

Apollo Life Sciences

Apollo Life Sciences has been in a restructure-cum-wind-up phase since March. The company finished the year with $237,000 in cash, but it remains to be seen how the company will advance to its next stage of its restructure, as it pursues a capital raising, licensing of core technologies, and possible sale or licensing of the OTC business. The company expects proceeds from these activities will enable it to continue as a going concern.

Avexa

Avexa's headline HIV drug program is better known to investors, with 100 sites now established for the Phase III trial of its compound, apricitabine (announced post-June 30). However, Avexa also reported that it had selected a compound from its earlier stage integrase inhibitor program (also HIV) to enter a formal pre-clinical program (which includes testing in animal models). The company expects to select another integrase inhibitor for pre-clinical studies in the near future.

Avexa's antibiotic program has delivered a compound into a pre-clinical program and human trials are expected to commence in 2009. Avexa reported a cash position of $43 million at June 30, 2008.

Biodiem

Biodiem's most advanced program is a live attenuated influenza vaccine partnered with Nobilon, a division of Organon. Manufacturing developments that have occurred over the last financial year include development of vaccine seeds, defining of the appropriate vehicle and delivery systems for cell culture manufacture, and identification of the device for nasal spray delivery.

Biodiem has also continued work on developing the peptide BDM-E, with pre-clinical studies ongoing at Monash University, despite unsatisfactory results from a Phase II study (in which a dose of 10 µg/day dose was administered) reported in October 2007. Biodiem has also commenced development of a chemistry, manufacturing and control package (CMC) in relation to BDM-E and has engaged **Genyzme Pharmaceuticals** as a manufacturer.

Biota

After concluding its litigation with **GlaxoSmithKline** by way of settlement, Biota recorded a loss of $6.5 million in FY2008. Biota spent $21.8 million on litigation in FY2008. The Biota chairman John Grant said that director Barbara Gibson would retire on December 31 2008 and that he would retire during FY2009. That leaves one director from 2004 associated with the decision to sue GSK still on the board (Ian Gust).

Clover Corp

Functional food ingredients company Clover Corp has delivered a surprising but very positive result, posting a net profit of $4.1 million, on the back of revenues of $21.6 million (up from $16.5 million in 2007). The company announced a 1 cent dividend. The company sells micro-encapsulated DHA powder. The company's 2008 performance was boosted by the acquisition of the 30% of **Nu-mega Ingredients** it did not already own in September 2007. After bottoming in June at 11.5 cents, Clover stock has increased strongly, finishing at 19.5 cents today (a 70% increase).

Ellex Medical Lasers

Ellex Medical Lasers managed to break the $50 million sales barrier for FY2008. Sales of $50.3 million increased by 13% from the previous year. However, after excluding one off items, net profit fell 40% for the year. In an obvious consideration of this poor performance, CEO Peter Falzon stepped down as CEO in late June, with COO Kevin McGuiness replacing him. Ellex Medical Lasers is one of a number of Australian medical device companies that have the ability grow sales but struggle to deliver commensurate growth in profits.

Novogen

Sydney-based Novogen manages both an OTC products business and a drug development program. For FY2008, sales of consumer health care products declined 12% to $9.4 million. The most significant weakness occurred in Europe where sales fell by 29%, in contrast to increases in Australasia and Canada. Novogen closed the year with $37.4 million in funds at hand. The company spent $18.8 million on R&D in 2008, compared to $16.1 million the previous year.

Novogen, through its subsidiary, Marshall Edwards Inc (MEI), is a conducting a Phase III trial of phenoxodiol in ovarian cancer patients. The company has reduced the panned patient enrolment in this trial from 470 patients to 340.

Other compounds being developed by Novogen (or through MEI) include triphendiol (NV-196) for pancreatic and bile duct cancers, NV-128 cancer (pre-clinical), NV-52 for inflammatory bowel dis-

Cont'd over

Peplin Postscript

Further to our article on Peplin last week, GBS Venture Partners has since contacted *Bioshares* and indicated that the object is not to sell the business but to build a pharmaceutical business focusing on dermatology. Whilst offers for businesses will always be considered, the aim at this stage is on building an integrated business.

Annual Reports. cont'd

ease, FAIMs, which is an anti-inflammatory compound, NV-27 for the reduction of restenosis following stenting (cardiovascular) and GLYC-101 for wound healing.

Sirtex Medical

Sales from Sirtex Medical novel liver cancer treatment technology (SirSpheres) increased by 14.3% to $38.1 million for FY2008. On a volume basis, sales rose 22.5%. The company stated in its preliminary final report that production of Sir-Spheres commenced at its Wilmington, USA facility in February and "is already supplying the majority if US treatment centres with locally produced doses". The company also reported that 132 sites in the USA offer the selective internal radiation therapy (SIRT) that uses Sirtex's SirSpheres.

Sirtex is also sponsoring or supporting 18 clinical trials of Sir-Spheres. The company's decision to increase its investment in research and clinical trials (FY2007 $2.312 million; FY2008 $3.795 million) has impacted on its profitability, with net profit for 2008 of $1.2 million down 23% from the previous year.

Somnomed

Somnomed delivered a 63% increase in revenues for FY2007 ($3.9 million). The company described 2007/08 as a 'turn-around year'. Somnomed markets the sleep apnea treatment device, the SomnoDent MAS, a splint which position the lower jaw slightly in front of the upper jaw in order to tighten the soft flesh at the back of the jaw.

Somnomed recorded a loss of $2.7 million for the year. However, fourth quarter growth may be an indicator of growth for FY2009, with quarter on quarter growth for the June quarter reaching 88%, and volume growth reaching 110%. Crossing the profitability threshold without the aid of further capital inflows may be a challenge for Somnomed, if business development costs need to increase to support marketing activities. The company held cash of $5.4 million at June 30.

Ventracor

A highlight from Ventracor's annual filings for 2007 was the income that the company has generated from sales of the VentraAssist heart assist device. Payments are received for the device when trials are conducted in the USA. Revenue for the year was just under $20 million. There were 166 patients implanted with the device during the year.

The company also restructured its R&D division during the financial year, displacing some Australian based operations with a new team based in New Jersey, staffed by former **St Jude Medical** employees with experience in developing fully implantable medical devices. Ventracor is developing a next generation heart assist device that does not require power leads to pass through the skin.

Ventracor employs 130 people in Australia, 25 people in the US and 13 staff in Europe. The company's cash reserves as of June 30 totalled $18 million.

Antisense Therapeutics' ATL1103 and the IGF-1 Target

Antisense Therapeutics (ATL) was partly created as an engine room to commercialise selected antisense compounds sourced from **Isis Pharmaceuticals**. The company's arrangement with ATL was that it had up to five targets it could select for which Isis would provide antisense drug candidates to inhibit. ATL had also licensed an antisense psoriasis program from the Murdoch Children's Research Institute.

ATL1102 program - Completed

The first program with the Isis compounds has been successfully completed by ATL, with Phase II trials yielding positive results in patients with multiple sclerosis and a licensing agreement signed with **Teva Pharmaceuticals,** which is responsible for bringing the ATL1102 drug candidate to market. Aside from involvement with program steering committee meetings, ATL's involvement with this project has ended. ATL will receive a net (after payment obligations to Isis) royalty which we estimate to be between 8%-10% with a total deal value of US$102 million. One third of all milestone and upfront payments go to Isis.

The results from this Phase II trial will be presented at a multiple sclerosis conference next month in Canada. A summary of the results revealed the drug reduced MS-related brain lesions by 54%, in line with the existing MS drug on the market, Tysabri, although the ATL1102 result delivered a better (lower) p-value.

Both drugs seek to inhibit the same target (VLA4) although through different mechanisms. Tysabri carries the risk of a PML brain infection (presumably as would ATL1102), however the risk is low - 1:1000 - and although there have been recent occurrences of this infection with Tysabri, the rate is currently much lower than the expected infection rate, with only a handful of cases after over 31,000 patients having been treated with the drug. For MS patients with relapsing-remitting MS, with few effective treatment options, this has become an accepted risk acknowledged by regulators.

As highlighted last year in *Bioshares*, ATL1103 is a particularly interesting program for ATL with strong potential. This program should have a higher chance of success for a number of reasons.

Firstly, ATL1103 targets the growth hormone receptor that resides in the liver that produces IGF-1. Blocking this receptor has applications in treating acromegaly (abnormal growth of the body and organs due to excessive growth hormone production) and diabetic retinopathy. Antisense drugs have recently shown to work extremely well in clinical trials in diseases where the target is based in the liver, because this is where antisense drugs have shown to accumulate.

The second reason why this program holds promise is that primate studies conducted by ATL have been shown to control IGF-1 levels in the blood, suggesting similar results could be achieved in people. The third factor swaying in ATL's favour is that the outcome, a reduction in IGF-1 levels in the blood, can be easily measured.

For ATL, the aim is to take subsequent development programs further through the clinical trials process. It should be noted, that this target was not supplied by Isis, unlike ATL1102, and as a result the royalty obligations to Isis are lower than for ATL1102. This program is expected to move into clinical trials in the late 2009. The market for the treatment of acromegaly is valued around US$800 million a year, with 20,000 people in major markets requiring drug therapy to treat this disorder.

ATL1101 program resurrected

ATL1101 was initially investigated as a topical treatment for psoriasis although early clinical trials indicated that was not going to be competitive against existing therapies. Late last year ATL resurrected this antisense inhibitor (of IGF-Ir) as a potential drug candidate against prostate cancer. There is renewed interest in this target for the treatment of various cancers, with at least seven major companies working on clinical programs. In July this year, ATL's program was listed in *Nature Biotechnology* as the only antisense approach to inhibiting this target.

ATL is collaborating with a US research group to assess this compound in mouse models, with results from that collaboration expected later this year.

Summary

Antisense Therapeutics is capitalised at $39 million with an estimated $9 million in cash. The company is developing a successful drug development track record. Its first which program has been licensed to Teva for MS has the potential to become a highly valuable asset should that drug make it to market within three to four years time. The company's focus moving forward is on ATL1103, which is expected to become a clinical drug candidate next year, will be well worth monitoring.

Bioshares

NeuroDiscovery - Update

NeuroDiscovery reported positive results in its second pain program. It has completed Phase IIa studies with NSL-101, a natural pain compound used in topical applications. Two trials were conducted, both in dental applications, following firstly wisdom tooth extraction, and following a second procedure to treat periodontitis (gum disease).

The compound was found to be as effective as a local anesthetic gel in the periodontitis trial. In the wisdom tooth extraction trial, the effect of NSL-101 could not be assessed because of the longer than expected action of the local anesthetic.

The advantage of the NSL-101 compound is that it is derived from herbal sources and could have applications in a variety of consumer products, including toothpastes and toothache pastes, ulcer gels and as a topical gel for stings and grazes. The company is in discussions to now out-license this product.

The company also reported operating results. Its pharmaceutical services business increased revenue by 18% to $2.2 million, generating a gross profit of $1.1 million. The company overall generated a net loss of $2.7 million and had $1.75 million in cash assets at the end of June. The company earlier reported the results from a Phase I trial with its lead pain treatment drug candidate, NSL-043, which is expected to move into Phase II studies in the first half of 2009.

Bioshares recommendation: **Speculative Buy Class B**

Arana Therapeutics - Phase II RA Trial Within Sight

Arana Therapeutics has completed enrollment of its Phase II psoriasis trial with its lead drug candidate, ART621. Results from this study will be made available in early 2009 and will be a significant milestone to monitor. The real importance of this trial is that if signs of efficacy can be established in psoriasis, then it will give some indication of the possible use in other inflammatory conditions, specifically in the massive rheumatoid arthritis market. The three leading drugs on the market currently generate sales of almost US$13 billion.

Arana's drug candidate is a smaller version of these leading antibody drugs and binds to the same target as two of these drugs, Humira and Remicade. Arana expects to file an IND for this program in the US towards the end of this year, with a Phase II rheumatoid arthritis trial expected to begin at the end of the year. Signs of efficacy in the psoriasis trial should stimulate considerable interest in this program.

Arana Therapeutics is capitalised at $264 million with $181 million in cash at the end of March this year and a further $70 - $80 million in royalties expected over the next three years.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

Bioshares Model Portfolio (29 August 2008)

Company	Price (current)	Price added to portfolio	Date added
Impedimed	$0.72	$0.70	Aug-08
Antisense Therapeutics	$0.07	$0.07	Aug-08
Mesoblast	$1.27	$1.25	Aug-08
Avexa	$0.29	$0.32	Jun-08
Cellestis	$2.21	$2.27	April 2008
IDT	$2.15	$1.90	March 2008
Circadian Technologies	$0.90	$1.03	February 2008
Patrys	$0.26	$0.50	December 2007
NeuroDiscovery	$0.09	$0.16	December 2007
Bionomics	$0.35	$0.42	December 2007
Cogstate	$0.14	$0.13	November 2007
Sirtex Medical	$2.40	$3.90	October 2007
Clinuvel Pharmaceuticals	$0.30	$0.66	September 2007
Starpharma Holdings	$0.25	$0.37	August 2007
Pharmaxis	$2.21	$3.15	August 2007
Universal Biosensors	$0.83	$1.23	June 2007
Biota Holdings	$0.75	$1.55	March 2007
Probiotec	$1.40	$1.12	February 2007
Peplin Inc	$0.50	$0.83	January 2007
Arana Therapeutics	$1.12	$1.31	October 2006
Chemgenex Pharma.	$0.99	$0.38	June 2006
Cytopia	$0.21	$0.46	June 2005
Optiscan Imaging	$0.21	$0.35	March 2005
Acrux	$1.15	$0.83	November 2004
Alchemia	$0.29	$0.67	May 2004

Portfolio Changes – 29 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

Corporate Subscribers: Phylogica, Pharmaxis, NeuroDiscovery, Biotech Capital, Cytopia,Arana Therapeutics, Starpharma Holdings, Cogstate, Xceed Biotechnology, Optiscan Imaging, Bionomics, ChemGenex Pharmaceuticals, Circadian Technologies, Biota Holdings, Stem Cell Sciences, Halcygen Pharmaceuticals, Peplin, BioMD, Impedimed, QRxPharma, Patrys, Labtech Systems, Hexima, Proteome Systems

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