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In this edition...
Our coverage of AGMs continues with reports on meetings held for Somnomed and Clinuvel Pharmaceuticals. Somnomed's chairman Peter Neustadt delivered blunt remarks about some previous failings, capital raisings and a desire to see disciplined growth. Clinuvel's AGM was marked with sadness at the passing of its CSO, Hank Agersborg. EU approval for Scenesse is nearing closer and the company will market the product itself. Neuren Pharmaceuticals is moving NNZ-2566 into a Phase II trial in Rhett Syndrome subjects. However, results from its TBI trial expected in 2013 Q1 may be a bump in the road. IDT Australia looks to be in need of recapitalisation. A litigation cloud sits over GI Dynamics. Is Probiotec an FY2014 earnings comeback story?
Companies Covered: CUV, GID, IMU, IDT, NEU, PBP, SOM

	Bioshares Portfolio
Year 1 (May '01 - May '02)	21.2%
Year 2 (May '02 - May '03)	-9.4%
Year 3 (May '03 - May '04)	70.6%
Year 4 (May '04 - May '05)	-16.3%
Year 5 (May '05 - May '06)	77.8%
Year 6 (May '06 - May '07)	17.4%
Year 7 (May '07 - May '08)	-36%
Year 8 (May '08 - May '09)	-7.4%
Year 9 (May '09 - May '10)	50.2%
Year 10 (May '10 - May'11)	45.4%
Year 11 (May '11 - May '12)	-18.0%
Year 12 (May '12 - current)	-9.4%
Cumulative Gain	**213%**
Av. annual gain (11 yrs)	**17.8%**

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Bioshares

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Somnomed AGM Report

Somnomed (SOM: 84 cents) Chairman Peter Neustadt said at this year's AGM that in 2010 and 2011 the company 'had dropped the ball a little'. However, the company was now in a far stronger position than it was 12- 18 months ago.

Sales in FY2012 increased 23% over the previous year, with unit sales of its snoring and sleep apnea treatment products also up 23% for the year. (For most companies this would be a good result. However this growth rate in unit sales is far lower that the 60% increase achieved in 2011 and the 75% increase in 2010.)

Neustadt said there is a growing acceptance of oral appliances by the medical community because CPAP (the gold standard) has significant compliance problems. Neustadt said that half of the patients with sleep apnea refuse CPAP treatment, and of the half that did take it up, 50% of patients stop using it.

There is also mounting clinical evidence of the co-morbidity associated with sleep apnea, particularly from the increased cardiovascular risk linked to sleep apnea, and there is also a link with diabetes. Neustadt said the medical world is ready to look at this approach.

Somnomed sells the Somnodent device, which is termed a mandibular advancement split that works by bringing the jaw forward to prevent airway closure during sleep. In FY2012, the company sold 31,878 devices, generating $15.2 million in revenue.

Management Changes During 2012

Somnomed earlier this year changed its management. Global CEO Ralf Barschow resigned and a CEO for the US market was appointed with a unanimous board approval. Neustadt, the company's Executive Chairman, currently has overall management responsibility. According to the company's annual report, a global CEO is expected to be appointed in the next financial year.

Since the change in management, Neustadt said that a great number of programs have been initiated that were not focused on before.

VP of Managed Care Position

The company has recently added a VP of Managed Care, to coordinate interactions with insurers in the US, to help patients get reimbursed. It is also hoping this appointment will open doors to other payors in the US.

The company is seeking to raise awareness of oral appliance therapy in the medical market. It is appointing a medical advisory board, a chief medical officer, and also a medical sales team with initially two people, one on the east coast and one of the west coast of the US. The impact from the company's drive into marketing/education of medical markets is not expected to be seen until towards the end of this financial year at earliest. (Previously Somnomed has focused on marketing through dental networks, and

Cont'd over

one of the company's key strengths is its dental networks, with dentists playing a major role in fitting the devices).

Somnomed is also employing people to assist with patient coordination from major healthcare groups. In one case, Kaiser Permanente had approved 200 patients to receive a Somnomed device, but because no one followed up, those patients did not receive a device. The CPAP suppliers are doing the same said Neustadt.

Europe Reimbursement Trends

In Europe, wherever reimbursement is secured, sales increase quickly said Neustadt. The company has been very successful in Holland with each of the nine insurers reimbursing the product, and eight of those insurers only reimbursing the Somnomed product. Sales in Holland are three times as big as Germany, where the product is not covered by public insurers (which represent about 90% of the market).

In January the company acquired a distributor in Holland, and in October the company acquired the second largest distributor of oral appliances in France. France currently has 10 staff. The acquisition will be completed on 30 November. It has already commenced integration of the French business into its own. The company will seek to take business away from Resmed's Narval (which originated in France) and has 70% market share. In France, the company should end up with 80%-100% reimbursement, with the company already having received registration for reimbursement in that country.

Capital Raising?

Neustadt said there are always rumours that the company is about to raise funds, which is possibly keeping the share price down. Somnomed will only raise funds if there is an acquisition that is outside of the company's normal business. 'Right now there is nothing on the table', according to Neustadt and it is not in the interests of shareholders to raise funds at current levels.

The expansion in the US will cost money. However this will be achieved from cash flow and from cash reserves ($3.7 million at the end of September). Additional sales people in the US will be funded from the increased sales they generate.

Neustadt said the company's share price is disappointing but will improve as the company delivers. The company has received an independent valuation which is significantly above the value represented by the current share price. The stock is gaining increased attention from investment funds, with institutional investors representing 10 of the top 20 shareholders.

'Sitting duck' for Acquisition?

Neusadt said the company is currently a 'sitting duck' for acquisition. Resmed came into the sector through its 2009 acquisition of Narval with that company's product only having come onto the market in the US this year. The company has not been approached (by suitors) yet, but no doubt it is on the radar said Neustadt. Big companies are not good at starting businesses from scratch believes Neustadt, which is what makes Somnomed a target. 'Sooner or later, someone knocks on your door', said Neustadt.

MATRx diagnostic

During the year the company received approval from the FDA for the MATRx diagnostic, which helps titrate the correct position of the Somnodent products.

Originally the Somnomed device was only for people with mild-to-moderate sleep apnea and where those patients had failed CPAP. For patients with severe sleep apnea whose life is at risk, doctors would not take the chance with oral appliances like Somnomed's.

However with a titration device like the MATRx, risk can be managed said Neustadt. This will lead to the Somnodent devices being used for mild, moderate and severe cases of sleep apnea, according to Neustadt. He also said the company's device has demonstrated a reduction in the apnea hypopnea index (number of apneas per hour) from 60 to less than four in some cases.

Neustadt said that two thirds of patients using the Somnodent products achieve a full (effective treatment) result.

Main Competition is from Resmed

Neustadt said Somnomed's products have become a mainstream solution. 'Somnomed is the only global company dealing with this in a global way'. The only (significant) competitor will be Resmed, although Neustadt believes it will take them a while. There may be two new competitors to emerge from the medical side. Existing competitors do not pose a major threat said Neusadt.

Market Opportunity

Neusadt said there are a few million people who have been diagnosed (with sleep apnea) but are not addressing their problem.

Second Generation Product

Each Somnodent appliance is expected to last five years. The company will start to roll out its next generation device, the Somnodent G2.

There is also sales potential from patients seeking a second, back-up device.

Outlook

Given the still somewhat unexplained departure of the Company's CEO earlier this year, it was interesting to hear Neustadt say there were no bad surprises on the horizon. Neustadt said sales for the current quarter should be in-line with the September quarter (where unit sales increased by 22% over the previous corresponding period).

Neustadt said the company is growing in a very disciplined and cost conscious manner. The company has set up its top corporate structure that could now operate a business 10 times as big. In response to questions, Neustadt said he does not want Somnomed to fall back and become a loss maker.

Somnomed is capitalised at $36 million.

Bioshares recommendation: **Speculative Buy Class A**

Clinuvel Pharmaceuticals AGM Report

At this year's AGM, Clinuvel Pharmaceuticals' Chairman, Stan McLiesh, acknowledged many long suffering shareholders, including himself, many who were asking when would it end (i.e. when would Scenesse gain broad regulatory approval). Quoting Michelangelo, McLiesh said "When it is finished".

McLiesh said Scenesse had now been accepted by the Italian Government and by Swiss Insurers at a price of €5,375 per implant, which was the initial price set in Italy. McLiesh asked shareholders to hold their nerve as some major milestones approached for the company, including Phase III trial results in the US and registration of Scenesse in Europe.

CEO Philippe Wolgen said that after eight years, he believed the end of the tunnel was in sight, as dictated by the EMA and FDA. The company has spent around $100 million on this drug since 2001, spending $80 million of that in the last six years.

Wolgen paid an emotional tribute to the company's CSO, Dr Hank Agersborg, who passed away recently. Dr Agersborg had been involved with afamelanotide (Scenesse) since 1995 and was a unique intellectual said Wolgen. Wolgen said there comes a time for each, but what was saddest was that Dr Agersborg did not live to see his dream to get this product onto the market. Dr Agersborg recently wrote “I think we have a great chance to write pharmaceutical history…in the next few months.”

Business Model

Clinuvel's model has been to keep outsourcing to a minimum, building and retaining its expertise in house. Over the last eight years the company has importantly kept its team together, with seven of its managers still with the company. This is something pharma can never do, said Wolgen, keep a whole team together for a decade.

In July the company raised $6 million. However there was no discount for this raise because the company believes it is undervalued.

Inflection Point Reached with Clinicians

Wolgen said that previously there were biases against the Scenesse treatment of EPP, which is characterised by a severe intolerance to sunlight. Clinuvel's solution is a product that increases the pigmentation density of the skin. However after two years of dealing with these skin specialists, it has reached an 'inflection point' where the biases disappeared. The program is going so well now that there is such strong demand from clinicians (to be involved) that it is difficult to know if these key clinicians are independent any more.

Expected Revenue from EPP

There are only a few thousand people in the world who are afflicted with EPP. And only seven universities focus on this area – six in the US, three in Europe and one in Queensland.

The market is very small. Clinuvel expects it can generate sales in Europe of $22 million a year, in the US $25 million of sales a year, and $3 million a year in Australia.

Advantages of a Niche Market

There are a several benefits from dealing in a small market. Firstly, the company can command a high price. Secondly, there are no competitors (in the case of EPP). Third, a small network of patients and physicians means a strong awareness of the potential new product is achievable, and that has already been demonstrated by Clinuvel.

For Clinuvel, it can market and sell directly by only adding six staff in Europe, operating from Switzerland, with marketing costing $1.2 million a year. The company will distribute the product through national porphyria experts in Europe, through many of the centres where the trials have been conducted.

Scenesse Safety – Positive Data from 2,300 Implants

Wolgen is satisfied with the safety and efficacy profile of Scenesse. To date almost 2300 injections of controlled release drug Scenesse have been given to more than 700 patients. In EPP alone, more than 230 patients have been involved in clinical studies and received 1,782 implants in total.

‘We believe there is no scientific bass to reject (Scenesse),'' said Wolgen. However, he was mindful of the uncertainties in bringing a product through the regulatory approval process.

Vitiligo Results Expected Shortly

Final results from the company's vitiligo (skin discoloration) trials are expected in the next few weeks. In that Phase IIa trial, 65 patients were enrolled and 54 patients completed the study. The next step will be a Phase IIb trial in Europe and Asia in 90–120 patients. Whilst the EPP market is only a few thousand patients worldwide, there are 45 million people with vitiligo.

EPP Approval in Europe

In February this year, Clinuvel filed Scenesse for regulatory approval in Europe. It has passed through the 80 and 120 day question and answer points and the company had an important meeting with the regulator in September that went very well.

In what is a very rare instance, the EMA requested to speak to physicians and patients to better understand the disease and the Scenesse treatment. Those interviews are now being conducted. Wolgen said there has not been one case of patient dissent from anyone who has taken the drug.

Summary

Clinuvel expects its spending to decrease as its clinical development slows down (following completion of EPP Phase III trials). Wolgen said the company is in preparation for the commercial launch of Scenesse in Europe.

Clinuvel is capitalised at $62 million and retained cash of $11.4 million at September 30, 2012.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

Five Stock Wrap

Company	Neuren Pharmaceuticals	**Code**	NEU	**CMP**	$0.04	**Cap'n ($M)**	$43.8	**Cash ($M)**	$7.1	**SI**	**4.3**

- Neuren is developing therapies to treat brain injury, neurodevelopmental and neurodegenerative disorders and cancer
- In December 2008, reported the failure of Phase III trial of Glypromate (a tri-peptide fraction of IGF-1) in CABG patients
- Developed an an analogue of Glypromate, NNZ-2566, which is orally bioavailable
- Completed Phase I of NNZ-2566 (oral formulation); 24 pts; 100mg twice daily for five days; was found to be safe and well-tolerated
- Submitted IND in support of Phase II trial of NNZ-2256 in Rett Syndrome subjects; trial will be partly funded by Rett Syndrome Found.
- Rett Syndrome Phase II will enroll 60 pts; study completion date Feb 2014; endpoints: safety, EEG and physiologcal changes
- Rett Syndrome is caused by mutations of the MECP2 gene and leads to loss of motor function; occurs mostly in females at 6-18 mths age
- Recently added VP Clinical Development and Medical Affairs (Dr Joe Horrigan - ex VP and Head of Medical Research at Autism Speaks)
- The completed Phase I study of NNZ-2566 (oral) enables start of the Phase II trial in concussion (IND is already in place)
- NNZ-2566 is in Phase II trial in pts with mod. to severe traumatic brain injury (260 pts); **study completion March 2013**

Comment: Shift to develop NNZ-2566 for Rett Syndrome has appeal in terms of validation and Orphan Drug commercialisation opportunity

Bioshares recommendation: **Sell** | Timing - Consider after TBI trial results are released

Company	IDT Australia	**Code**	IDT	**CMP**	$0.22	**Cap'n ($M)**	$9.5	**Cash ($M)**	$0.013	**PE**	**NA**

- IDT supplies specialised API contract manufacturing services, fee-for-service R&D and clinical trial services through its CMAX facility
- Revenue for FY2012 of $10M was 23% down from previous year; posted loss of $1.8M; trading at a 66% discount to net assets ($28M)
- Has embarked on revised strategy to include own product development and product ownership
- Appointed Kidder Williams to assist wth possible corporate opportunities
- Appointed Ashley Bates (ex-GSK) to identify new business opportunities - has reviewed 30 opportunities in recent months
- Commenced development of a generic anti-cancer drug; expects to file (with FDA) in early 2013 and start sales in 2014
- Recently requalified its Sterile Manufacturing facilities in Facility P in FY2012 (facility was funded by Pfizer but never used as intended)

Comment: IDT will likely require recapitalisation to support 'own' product development strategy; further board refreshment an issue

Bioshares recommendation: **Sell** | Timing - Consider after recapitalisation

Company	Imugene	**Code**	IMU	**CMP**	$0.012	**Cap'n ($M)**	$4.1	**Cash ($M)**	$1.7	**SI**	**1.7**

- Imugene was formerly commercialising vaccine technology from the CSIRO with lead applications in pigs and poultry
- Several collaborative partnerships failed to proceed beyond the earlier stages of technology validation by partners
- Most recently, Novartis terminated license agreement in September 2010
- Acquired Linguet drug delivery technology from Consegna Group in May; CGP now holds a 29% stake in IMU
- Consegna acquired the Linguet technology from OzPharma in August 2010 for $50,000, scrip and a 15% royalty
- At March 31, 2012 IMU retained $1.2M in cash; the company received $1M through a capital raising in support of the Linguet acq.
- First product targeted for development is a formulation of Vitamin D

Comment: Stewardship issues that have emerged at CGP have the potential to erode value at IMU

Bioshares recommendation: **Sell** | Timing -

Company	Probiotec	**Code**	PBP	**CMP**	$0.375	**Cap'n ($M)**	$19.8	**Cash ($M)**	$0.2	**PE**	**9.0**

- Probiotec manufactures and sells pharmaceuticals, foods and nutraceuticals; also supplies contract manufacturing services
- Sales from Continuing Operations (CO) fell by 8% in FY2012 (to $66M); Gross Margin fell to 44.7% from 47.3%; NPAT from CO was $2.6M
- PBP gearing ratio decreased from 45.7% for FY2011 to 41.2% for FY2012. Finance costs for FY2012 were $2M
- Reorganisation saw sale of Milton assets, various overseas activities scaled back, operations in Asia sold, Bundaberg plant closed
- Is investing ~$4.5M on dairy protein fractionation plant in South Aust. (growth in global lactoferrin prices a driver)
- Full benefits from new initiatives not expected until FY2014; debt expected to fall significantly in FY2014
- Company expended $1.5M on director and secretary compensation in FY2012

Comment: GFC related effects are steadily being addressed by Probiotec; scope for debt and margins to be improved further

Bioshares recommendation: **Hold** | Timing - HY results to illuminate progress

Company	GI Dynamics	**Code**	GID	**CMP**	$0.65	**Cap'n ($M)**	$186.4	**Cash ($M)**	$49.00	**SI**	**2.0**

- GID is commercialising the Endobarrier, a sleeve-like device which is implanted in the upper GI tract
- GID studies have shown that >80% of obese patients can reduce blood glucose to =< 7 and lose on ave 20% body weight in 1 yr
- Device is CE Marked (2010) and TGA approved (2011). Is available in Germany, Austria, Netherlands, Australia and Chile
- Pursuing reimbursement in Germany, Netherlands and France • Target market is obese patients with uncontrolled diabetes
- FDA recently approved pivotal trial in 500 pts over a 12 month treatment period; primary endpoint is improvement in blood glucose
- Larger than planned (300-400 pts) pivotal trial dispensed with need for pilot trial in 2013 in an estimated 78 pts
- IPO in Sept 2011 raised US$92M of which US$6M paid off debt and US$6.6 was for issue costs; has expended $16M over Q1-Q3 2012
- IPO Prospectus budgeted Pilot and Pivotal trials at US$26M; however, nett savings in time and money low in our view
- M&G Investments recently increased stake to 12% (M&G owns 11.2 of MSB; 9% of SPL)
- Company is in litigation with a supplier, Gore, which is claiming co-ownership of then-issued patents and applications as at 2010

Comment: Rather than focus on US pivotal trial, investors should focus on product acceptance and take up in current sales regions

Bioshares recommendation: **Speculative Hold Class B** | Timing -

Notes: PE - Price/Equity ratio SI - Survival Index (refer to Bioshares 480 for explanation)

Bioshares Model Portfolio (23 November 2012)

Company	Price (current)	Price added to portfolio	Date added
Psivida	$1.50	$1.550	November 2012
Benitec	$0.015	$0.016	November 2012
Nanosonics	$0.520	$0.495	June 2012
Osprey Medical	$0.41	$0.40	April 2012
QRxPharma	$0.82	$1.66	October 2011
Somnomed	$0.84	$0.94	January 2011
Cogstate	$0.350	$0.13	November 2007
Sirtex Medical	$11.46	$3.90	October 2007
Clinuvel Pharmaceuticals	$1.80	$6.60	September 2007
Pharmaxis	$1.18	$3.15	August 2007
Universal Biosensors	$1.01	$1.23	June 2007
Alchemia	$0.580	$0.67	May 2004

Portfolio Changes – 23 November 2012

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. For both groups, the rating "Take Profits" means that investors may re-weight their holding by selling between 25%-75% of a stock.

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: Pharmaxis, Starpharma Holdings, Cogstate, Bionomics, Biota Holdings, Impedimed, QRxPharma, LBT Innovations, Mesoblast, Tissue Therapies, Viralytics, Phosphagenics, Immuron, Phylogica, Bluechiip, pSivida, Antisense Therapeutics, Benitec BioPharma, Allied Healthcare Group, Genetic Technologies, Calzada, Bioniche, Atcor Medical, Invion