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In this edition...
A bull run has been underway in the US, with the Nasdaq Biotech Index increasing 29% since mid-November. Will this trigger support for early stage biotechs is a key question. Somnomed sells the Somnodent appliance for sleep apnea. It has a tremendous opportunity because of CPAP non-compliance. The stock is trading at very attractive levels. Acrux has gained the first of possible three patent extensions in the US for Axiron. Sales of Alchemia's anticoagulant Fonda have now taken off in the USA. And Starpharma's dendrimer-docetaxel combo has delivered positive and suprising results in animal studies.
The Editors
Companies Covered: ACR, ACL, SOM, SPL, Nasdaq Biotech Index

	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 - May'11)	45.4%
Year 11 now commenced	-24.6%
Cumulative Gain	**217%**
Av. annual gain (10 yrs)	**21.2%**

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Bioshares

10 February 2012
Edition 442

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

Somnomed – Very Attractive Buying

Somnomed's (SOM:$0.97) business is heading in the opposite direction to its share price. The stock has fallen 35% in recent months yet over the last year the company has increased its employee count from 80 to 125. Unit sales in the last quarter were up 24% over the previous corresponding period, profit margins are expanding and the company has sufficient funds to build its global oral appliances business.

Somnomed makes the Somnodent MAS oral appliance which is used to treat sleep apnea and also offers a treatment for snoring and teeth grinding. The product looks similar to a mouth guard and works by bringing the lower jaw forward, thereby keeping the airways open during sleep.

To date Somnomed has sold more than 70,000 of its oral appliances, from which Somnomed makes between $500-$600 per system. The systems are sold to the end user at between $1500-$2000.

In the US there is wide reimbursement for the systems which is helping drive growth. In the third quarter of last year US unit sales increased by 24% over the previous corresponding period (pcp). In Europe unit sales increased 45% in the same September quarter over the pcp, and by 44% over the pcp in the December quarter.

Currency Negatives

However, working against the company is the strengthening Australian dollar, with sales in the third quarter of last year increasing only 13% over the pcp and 15% over the pcp in the last quarter. The strong growth in Europe means that region now contributes to 35%-40%, up from 10%-15%.

One helpful measure to monitor has been the dentists who measure and fit the Somnodent systems. They form an important part of the chain and make a tidy revenue from this business. They are important in the same way that interventional radiologists are to the delivery of Sirtex Medical's Sir-Spheres.

Qualified Dentists Numbers Increase

The number of qualified dentists who fit the Somnomed systems in the US has increased from 1500 to 1800 in the last year. In Australia this number has largely stayed level ar around 400 dentists. And in Europe, where the dentists become certified in fitting these devices, the number has increased from 700 to 1000.

Somnomed recently acquired a small distributor in Holland, which helps the company secure its position in that market. In Holland, the Somnodent system is fully reimbursed if the patient is diagnosed with sleep apnea. The company paid €1 million for 50% of the business, with the reminder to be acquired over the next five years in half scrip and half cash, depending on net profits. The upfront payment involved 250,000 Euro cash payment and the rest in Somnomed shares.

Cont'd over

Acrux – 1st of Three Patent Extensions Granted in the US

Acrux (ACR: $3.56) has been issued a Notice of Allowance in the US for one of its three patent applications covereing its testosterone product Axiron. This patent is on the applicator used to deliver Axiron. It extends patent protection out to 2029. Its second (pending) patent extension is around its formulation of testosterone. But its most important patent extension the company is waiting on is one around delivering the drug under the arm. We expect news on the remaining two patents should not be far away with the process well advanced.

Acrux's core patent, which is based on the skin penetrating properties of the additive to its drug formulations, runs until 2017. So an extension through a series of patents of up to 12 years market exclusivity adds a lot of value to the Axiron asset. Competitors will be able to bypass the applicator patent, but only by developing their own applicator system and then run clinical trials. This should give, as an estimate, around five years protection out past 2017.

The delivery of drug under the arm is an ideal location as it prevents transfer of the testosterone hormone to others, such as children or women. This has been an issue with other testosterone products. The 'armpit' patent was filed in 2006, so will give patent protection out to at least 2026, and more likely out to 2028 with a patent term adjustment (due to delays in prosecution of patents by the US Patent Office). The applicator patent recently allowed received an 863 day patent term adjustment (extension). A positive ruling from the US Patent Office on these remaining patent applications may trigger a takeover offer from Eli Lilly for Acrux.

Direct-to-Consumer Marketing Begins

On 16 January Eli Lilly started its TV ads for Axiron. The advertising campaign will run for a number of months across 10 major US cities. Eli Lilly's competitor in this market, Abbott Laboratories with Androgel, is also running TV campaigns. This battle between two pharmaceutical majors over what will very likely become a multi billion dollar market is the reason the testosterone market is accelerating.

The testosterone market grew at an annual compound growth rate of 19% over the last five years. Last year Eli Lilly thought that growth rate was not sustainable. However, the market currently is growing at 20% a year. In 2011, the transdermal testosterone market was worth US$1.46 billion. A market size in excess of US$2 billion a year looks likely in the next two years as Eli Lilly and Abbott fight it out.

Eli Lilly recently indicated it had 10% of the US market and that it was gaining 20% of all new scripts. Our estimate is that a 40%-60% market position is a realistic target for Eli Lilly. By mid year we expect the discounting to users will be largely reduced, when payment from insurers should be largely in place across the board. This will see a significant step up in royalties to Acrux as the sales of Axiron increase due to significantly less discounting, more market share, and we expect Acrux's percentage royalty will also increase as sales of Axiron reach higher levels. There will also be sales-based milestone payments.

Acrux has indicated that its royalty expectation is $7-$8 million for this financial year, and $40 million in FY2013. The company will update the FY2013 forecast later this year.

Acrux is capitalised at $593 million.

Bioshares recommendation: **Buy**

Bioshares

– Somnomed cont'd

The CEO of Somnomed, Ralf Barschow, said that the company will now concentrate on utilization rates across dentists. Some dentists may only install one or two units every quarter and others are installing between 30-50 every month.

The market is still very large for Somnomed's appliances. There are two million new CPAP (the device developed by Resmed to treat sleep apnea) patients each year annually but around half discontinue treatment in two years. The number of people who have been diagnosed and are untreated is in the millions according to Barschow.

Summary

Somnomed's annual unit sales are tracking at just under 31,000 systems and annualised sales are tracking at $14.4 million, based on the latest quarter results. The company had $3.2 million in cash at the end of last year.

We expect the company to make a small loss in this financial year (net cash out outflow for the first half was $0.7 million) with any surplus funds we expect will be used to fund the growth in the business.

Somnomed is capitalised at only $41 million. It is currently trading on a price-to-sales ratio (market cap/sales) of 2.9 times which is low for this type of company. Gross margins have increased from 58% in the first quarter of 2010 and are currently 69%. Barschow is aiming to increase gross margins to over 70%.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

A Liquidity Event for The Nasdaq Biotech Index

The Nasdaq Biotech Index, the seminal index of biotech activity, recently reached a new three year, or post-GFC, high closing at 1266 points on February 6, 2012. The market value of the 116 stocks that make up the Nasdaq Biotech Index at February 10 was US$375.5 billion.

The index had sustained a period over the 1100 point mark in June and July 2011, but slumped in August in line with weakness with most other indices as global economic fears re-emerged.

Since August, but more particularly November 18, the Nasdaq Biotech Index has been on a bull run, increasing 39% from the August low and 29% from its November 18, 2011 level.

Roughly a third (39 out of 116) of the stocks that comprise the Nasdaq Biotech Index have posted gains of greater than 30% since November 18.

What have been the Out-performers?

The top performing stocks since November have been Affymax (112%), Regeneron Pharmaceuticals (105%), ISTA Pharmaceuticals (99%), Micromet (93%), GTx (90%), Santarus (74%), Amylin (72%), Lexicon Pharmaceuticals (71%), Achillon Pharmaceuticals (70%) and Alnylam Pharmaceuticals (69%).

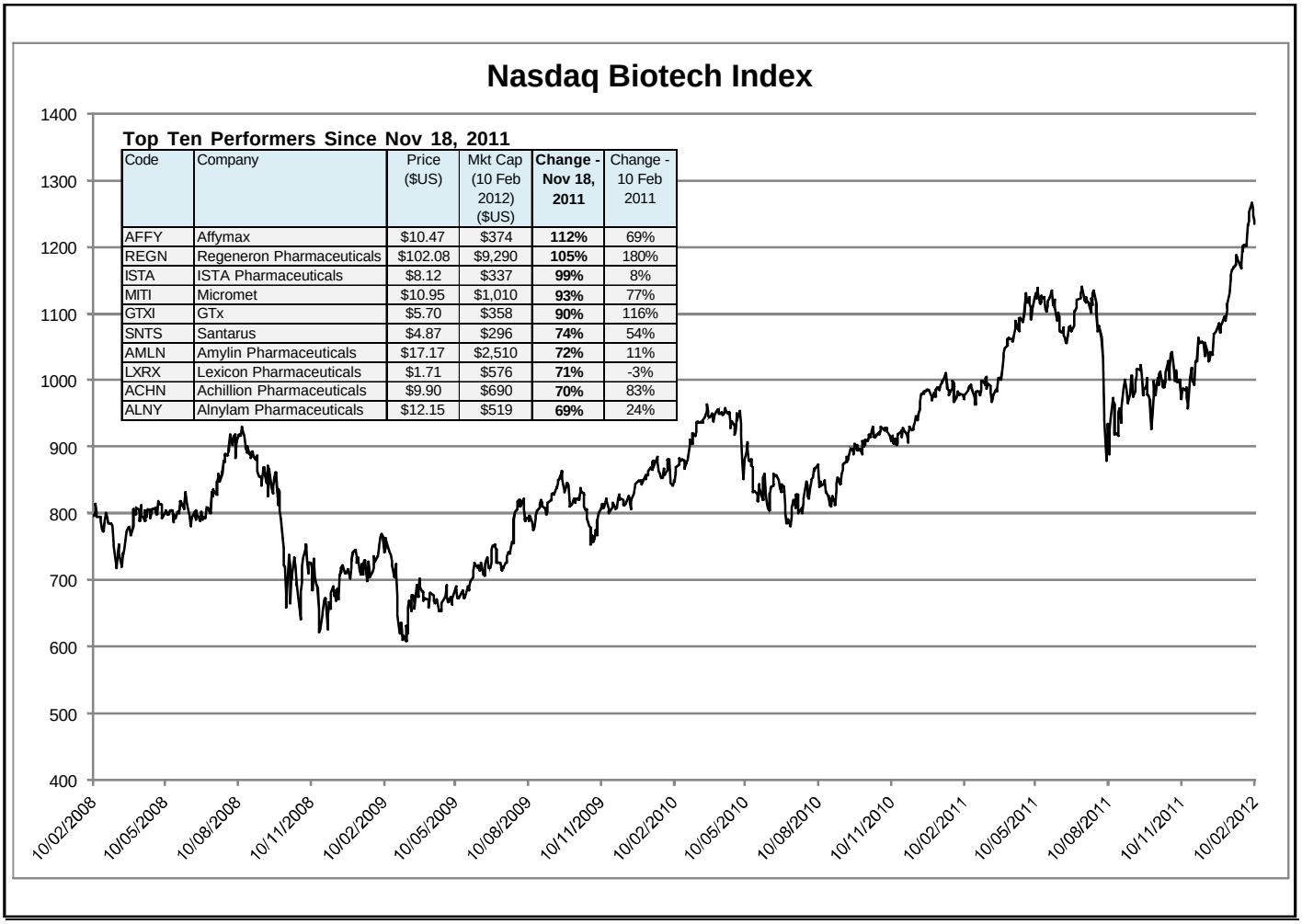
Affymax's stock increased as the company's anemia drug peginesatide successfully passed through an FDA advisory committee. Regeneron's share price was boosted following the settlement of a dispute with Genentech for the eye drug Elyea. ISTA Pharmaceuticals was subject to a hostile bid (withdrawn in January) by Valeant Pharmaceuticals. In January Amgen announced it would acquire Micromet for US$1.16 billion, a company whose main product has yet to complete a Phase II trial.

The top ten stocks by capitalisation, and which have more influence by weight in the index, have also generally performed strongly. From November 18, Amgen (US$53 billion) has increased by 21%; Gilead Sciences (US$40 billion), 35%; Teva Pharmaceuticals (US$39 billion), 11%; Celgene (US$31 billion), 14%; Biogen Idec (US$28 billion), 10%; Shire Pharmaceuticals (US$19 billion), 10%; Alexion Pharmaceuticals (US$15.5 billion), 30%; Mylan (US$9.7 billion), 28%; Regeneron Pharmaceuticals (US$9.3 billion), 105%; and Life Technologies (US$8.8 billion), 32%.

Summary

As a substantial number of US biotech stocks appreciate in price, a flow-on effect is that liquidity and investment returns improve. If investment sentiment remains positive and excess cash is returned to pockets of dedicated biotech investors, then the opportunities for financing both private and public earlier stage companies may also improve.

Bioshares



Top Ten Performers Since Nov 18, 2011

Code	Company	Price ($US)	Mkt Cap (10 Feb 2012) ($US)	**Change - Nov 18, 2011**	Change - 10 Feb 2011
AFFY	Affymax	$10.47	$374	**112%**	69%
REGN	Regeneron Pharmaceuticals	$102.08	$9,290	**105%**	180%
ISTA	ISTA Pharmaceuticals	$8.12	$337	**99%**	8%
MITI	Micromet	$10.95	$1,010	**93%**	77%
GTXI	GTx	$5.70	$358	**90%**	116%
SNTS	Santarus	$4.87	$296	**74%**	54%
AMLN	Amylin Pharmaceuticals	$17.17	$2,510	**72%**	11%
LXRX	Lexicon Pharmaceuticals	$1.71	$576	**71%**	-3%
ACHN	Achillion Pharmaceuticals	$9.90	$690	**70%**	83%
ALNY	Alnylam Pharmaceuticals	$12.15	$519	**69%**	24%

Alchemia's Fonda Sales Take Off

Sales of Alchemia's (ACL: 37.5 cents) generic synthetic heparin, fondaparinux (fonda) have finally started to take off. Alchemia's partner, **Dr Reddy's**, has been able to ramp up production of fonda which now places it in a position to deliver as much of the drug to the US market as its sales team can sell.

Dr Reddy's launched the drug in the US at the start of August last year. By the end of October it was only achieving sales of around US$350,000 a week. In the last three months those sales have accelerated and Dr Reddy's is now selling just under US$1.5 million a week. This should translate to a profit split of around $25 million a year for Alchemia at current sales.

Dr Reddy's strength is in its retail sales (to pharmacies) and has now gained more than a 30% market share (by total market value). What has been surprising to all is that the retail market value has stayed somewhat constant, even though the prices have fallen from the entry of generic players (the other generic player being **GlaxoSmithKline's** authorized generic distributor, **Apotex**). The lower price appears to have increased the usage of the drug among patients.

The retail market is the higher margin sector, with lower prices paid by hospitals because of their bulk purchasing of drugs. Once the retail sector has been fully penetrated Dr Reddy's will then likely concentrate on securing the hospitals market, although it does not have a large presence in that market.

Alchemia to Split Oncology and Fonda Businesses

Late last year Alchemia raised $20 million when its cash balance was running dangerously low. Those funds will now be sufficient to fund the Phase III trials off its lead oncology program HA-Irinotecan.

At the same time, the company announced it would spin off its oncology business into a separate entity by the end of this year. What is driving this decision is that the company wants to return fonda revenue as dividends to shareholders and to run the oncology business as a separate entity, potentially listed on the ASX or in the US.

The company has indicated the planned demerger is subject to further evaluation and market conditions. Timing is the key issue. From one perspective it's a peculiar decision as the company now has the funds to get the lead oncology program to a major inflexion point, that being results from its Phase III trial. An unambiguously positive result would place the company in a position file HA-Irinotecan for approval in Europe and the US. The company would also be in a position to then leverage its HyACT oncology platform (combining hyaluronic acid with cancer drugs) with a range of existing cancer drugs.

Another factor driving the decision is that management believes that investors will now only value the company on its future fonda revenue and ignore the oncology assets in development. This argument has some merit.

Capital markets remain tentative so that will be important factor. The HA-Irinotecan program will still need some of the fonda revenue to complete Phase III trial. That trial is expected to cost $20 million and Alchemia had $21.4 million in cash at the end of last year.

By mid year, Alchemia should start to see some of the fonda revenue, with around $8-$10 million, by our estimates, needing to be recouped by Dr Reddy's for setting up the manufacturing plant for fonda.

DRP Option

A different option for Alchemia to explore would be to keep the two businesses together until the major inflexion point is reached in about 18-24 months time. In the meantime the company could commit to distributing 90% of the fonda revenue to shareholders as dividends, and give shareholders the option as to whether they want to reinvest that money into the oncology programs, through a dividend re-investment plan (DRP).

Phase III Trial Commences

In January the first patient was recruited into the Phase III HA-Irinotecan study in patients with colorectal cancer. At last record 27 sites were ready to start recruiting patients out of 55 sites that will be involved with the trial. Alchemia CEO, Pete Smith, said the data emerging from numerous researchers around the CD44 pathway, that its HyACT platform hits, is really good. This is very promising for Alchemia's Phase III trial, which on historical averages, being in Phase III, has around a 50% chance of success.

Alchemia is capitalised at $105 million.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

Starpharma Takes Aim at Docetaxel

Starpharma (SPL: $1.37) recently announced the results of animal studies of a dendrimer-docetaxel formulation. The formulation was applied to mice with breast cancer tumour grafts. The formulation was compared to stand-alone docetaxel and saline.

In the case of the active arms, tumour volume decreased up until day 60, when grafted tumours on the docetaxel treated arm began increasing in volume. However, in the dendrimer-docetaxel arm, tumour re-growth did not occur until day 94, or well beyond the expected time for completion of such animal studies.

The results are positive and surprising. If such efficacy benefits can be repeated in further animal studies as well as in human studies then the company potentially may have a valuable asset on its hands.

Starpharma has so far been evaluating dendrimer-docetaxel formulations with a view to improving water solubility of docetaxel. There could well be sufficient merit to simply bring an improved version of docetaxel to market through improvements to its solubility, leading further to reductions in injection site reactions. One in five patients are likely to experience (injection site) hypersensitivity to docetaxel.

Docetaxel is a taxane-class drug which work by inhibiting tubulin in cells and interfere with cell division. Dendrimers are precisely constructed, uniform large molecules that can be engineered to contain smaller active chemical groups, or for those groups to be bound to the surface of the dendrimer.

Sales History - Two Taxane Class Drugs

	Taxotere (docetaxel)				Abraxane (albumin-paclitaxel)	
Company	Sanofi				Celgene	
Year (CY)	(€ M) *($US)* Total	(€ M) US	(€ M) W-Eu	(€ M) EM/Oth	($US M) Total	
€ 1,995	*$2*					
€ 1,996	*$89*					
€ 1,997	€ 225					
€ 1,998	€ 342	€ 170	€ 172			
€ 1,999	€ 500	€ 237	€ 263			
€ 2,000	€ 744	€ 367	€ 377			
€ 2,001	€ 1,003	€ 541	€ 462			
€ 2,002	€ 1,261	€ 701	€ 560			
€ 2,003	€ 1,359	€ 733	€ 626			
€ 2,004	€ 1,436	€ 725	€ 502	€ 209		
€ 2,005	€ 1,609	€ 695	€ 628	€ 286	$134	
€ 2,006	€ 1,752	€ 708	€ 714	€ 330	$175	
€ 2,007	€ 1,874	€ 691	€ 819	€ 364	$324	
€ 2,008	€ 2,033	€ 737	€ 900	€ 396	$336	
€ 2,009	€ 2,177	€ 827	€ 786	€ 564	$315	
€ 2,010	€ 2,122	€ 786	€ 709	€ 627	$318	e
€ 2,011	€ 922	€ 243	€ 189	€ 490	$387	
	Annual Change (%)					
€ 1,997						
€ 1,998	52%					
€ 1,999	46%	40%				
€ 2,000	49%	55%				
€ 2,001	35%	47%				
€ 2,002	26%	30%				
€ 2,003	8%	5%				
€ 2,004	6%	-1%				
€ 2,005	12%	-4%				
€ 2,006	9%	2%	14%	15%	31%	
€ 2,007	7%	-2%	15%	10%	85%	
€ 2,008	8%	7%	10%	9%	4%	
€ 2,009	7%	12%	-13%	42%	-6%	
€ 2,010	-3%	-5%	-10%	11%	1%	
€ 2,011	-57%	-69%	-73%	-22%	22%	

e - estimate

Source: Company filings

Ironically, in late 1994 Taxotere was at first rejected by the FDA's Oncologic Drugs Advisory Committee. Taxotere was developed in the wake of Taxol (paclitaxel) (Bristol Myers Squibb), which was approved by the FDA in 1992. Taxotere has several chemical differences to Taxol, with the design intent to improve the solubility of the compound.

Taxotere has received FDA approvals for the treatment of breast, non-small cell lung, prostate, gastric and head and neck cancers, often in combination with agents. Sales have grown over the years as the number of indications expanded.

Taxotere was shown to be superior to Taxol in one open label Phase III head-to-head study. Neuropathies are less with Taxotere use than with Taxol.

The patents covering docetaxel expired in Europe in 2010 and in the US in 2011. Consequently, global sales fell 57% in 2011 with a 69% fall in the US and a 73% decrease in Europe. Sanofi launched a taxol derivative Jevtana (cabazitaxel) for prostate cancer in 2010, garnering sales of €82 million in that year and €188 million for 2011.

The Development Proposition?

The development proposition for a dendrimer-docetaxel formulation is that as a technology enabled, or 'super' generic, it would follow the 505 (b) (2) pathway through the FDA. This means a dendrimer-docetaxel drug candidate would only need a single Phase III trial (presumably comparing dendrimer-docetaxel to docetaxel) for registration purposes. However, the complexities of multi-drug cancer treatment regimes would more than likely mean that a suite of trials would continue as the drug proceeds through an initial indication approval process.

A useful comparison for development purposes is **Celgene**'s Abraxane, obtained through the $3.2 billion merger with **Abraxis Biosciences** in June 2010. Abraxane is a formulation of paclitaxel with albumin nano-particulate. This formulation eliminates the need to use cremaphor as a solvent, which is the source of severe sensitivity problems associated with both Taxol and Taxotere.

Cont'd over

Bioshares Model Portfolio (10 February 2012)

Company	Price (current)	Price added to portfolio	Date added
QRxPharma	$1.60	$1.66	October 2011
Mayne Pharma Group	$0.320	$0.435	September 2011
Genetic Technologies	$0.13	$0.18	August 2011
Acrux	$3.56	$3.37	June 2011
Bioniche	$0.72	$1.35	March 2011
Somnomed	$0.97	$0.94	January 2011
Phylogica	$0.037	$0.053	September 2010
Biota Holdings	$0.79	$1.09	May 2010
Tissue Therapies	$0.39	$0.21	January 2010
Atcor Medical	$0.09	$0.10	October 2008
Impedimed	$0.55	$0.70	August 2008
Bionomics	$0.45	$0.42	December 2007
Cogstate	$0.25	$0.13	November 2007
Sirtex Medical	$4.80	$3.90	October 2007
Clinuvel Pharmaceuticals	$1.93	$6.60	September 2007
Pharmaxis	$1.01	$3.15	August 2007
Universal Biosensors	$0.75	$1.23	June 2007
Alchemia	$0.375	$0.67	May 2004

Portfolio Changes – 10 February 2011

IN:
No changes

OUT:
No Changes

– *Starpharma cont'd*

Abraxane was approved in January 2005 for the treatment of metastatic breast cancer, with a submission in process for non-small cell lung cancer. It is also being trialled in patients with metastatic malignant melanoma and pancreatic cancer.

Sales of Abraxane for its first approved indication have been strong, with US$134 million in revenues in its launch year of 2005, climbing to US$387 million in 2011. In the same way that Sanofi and its predecessors built sales for Taxotere by adding indications in cancers with large numbers of patients, then one could expect that Abraxane sales have the potential to reach the billion dollar mark over time.

Summary

A potentially valuable new product looks to have emerged from the Starpharma drug discovery engine. The value lies in the development of a greatly improved, and patent protected, active drug compound which , in its current approved form, is well entrenched as a standard of care in oncology around the world.

Starpharma now faces important development decisions regarding how to proceed with the development of its dendrimer-docetaxel drug candidate before it presumably licences the product to a marketing partner. A 505 (b)(2) pathway gives the company the option, because of lower costs, of managing all development activity through to Phase III.

The key risk for the dendrimer-docetaxel program will primarily lie with current and emerging competitors for the treatment of breast, lung and prostate cancers.

Starpharma is capitalised at $383 million with $49 million in cash at the end of 2011.

Bioshares recommendation: **Speculative Hold Class A**

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

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