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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

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

Extract from 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.

Taxotere (docetaxel)

Taxotere (docetaxel) has been a very successful drug product for **Sanofi**, running ten years of greater than €1 billion in global sales and three years of greater than €2 billion in global sales. The drug was initially developed by **Rhone-Poulenc Rorer,** which merged with **Hoechst** in 1999 to form **Aventis**, which was followed by Aventis merging with **Sanofi Synthelabo** in 2004.

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.

Cont'd over

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.

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.

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
1995	*$2*				
1996	*$89*				
1997	€ 225				
1998	€ 342	€ 170	€ 172		
1999	€ 500	€ 237	€ 263		
2000	€ 744	€ 367	€ 377		
2001	€ 1,003	€ 541	€ 462		
2002	€ 1,261	€ 701	€ 560		
2003	€ 1,359	€ 733	€ 626		
2004	€ 1,436	€ 725	€ 502	€ 209	
2005	€ 1,609	€ 695	€ 628	€ 286	$134
2006	€ 1,752	€ 708	€ 714	€ 330	$175
2007	€ 1,874	€ 691	€ 819	€ 364	$324
2008	€ 2,033	€ 737	€ 900	€ 396	$336
2009	€ 2,177	€ 827	€ 786	€ 564	$315
2010	€ 2,122	€ 786	€ 709	€ 627	$318
2011	€ 922	€ 243	€ 189	€ 490	$387
	Annual Change (%)				
1997					
1998	52%				
1999	46%	40%			
2000	49%	55%			
2001	35%	47%			
2002	26%	30%			
2003	8%	5%			
2004	6%	-1%			
2005	12%	-4%			
2006	9%	2%	14%	15%	31%
2007	7%	-2%	15%	10%	85%
2008	8%	7%	10%	9%	4%
2009	7%	12%	-13%	42%	-6%
2010	-3%	-5%	-10%	11%	1%
2011	-57%	-69%	-73%	-22%	22%

e - estimate

Source: Company filings

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**

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. 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, Circadian Technologies, Biota Holdings, Impedimed, QRxPharma, LBT Innovations, Mesoblast, Atcor Medical, Tissue Therapies, Viralytics, Phosphagenics, Immuron, Phylogica, Bluechiip, pSivida, Antisense Therapeutics, Benitec BioPharma, Allied Healthcare Group, Genetic Technologies