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In this edition...
We take a look at the half yearly results for the established revenue generating businesses in the sector. We compare the performance of 12 companies and look at which companies look particularly attractive using a standardised investment measure.

And we take a closer look at the US$11 billion acquisition of Pharmasset by Gilead, and the implications that has for the HCV space and for locally listed Biotron

The Editors
Companies Covered: ANP, BIT, CGS, SOM, SRX, UBI

	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	-25.3%
Cumulative Gain	**214%**
Av. annual gain (10 yrs)	**21.2%**

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Bioshares

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FY2012 Half Year Results Analysis

At the end of mid year reporting season for FY2012, we take a look some established and emerging life science companies in the sector. As a visual aid, when have prepared a chart (see next page) for 12 companies. Some of these companies are not profitable, or are operating at break even, investing surplus cash flow to growing their businesses. So a Price-Earnings ratio is not suitable for all.

As an alternative measure, we have used Price-Sales ratio (capitalisation/annualised sales) and have plotted this against the compounded sales growth for the last three years, based on annualised half year results.

The lower the Price-Sales ratio (PSR) means the business is being valued more cheaply by the market. More established and mature businesses will trade at a PSR of around 1.0, and higher growth and higher margin businesses may trade at a PSR of between 3.0-4.0.

Looking at the chart, five companies (Cochlear, CSL, ResMed, Sirtex Medical and Medical Developments) are all in the same region on the chart, with less than 10% annual growth in sales for the last three years, and a PSR of between 3.0-4.3.

The market looks to be factoring in sustained high growth for these businesses. Looking at the EBIT margins then for these businesses is necessary and very informative. Cochlear has the highest margin of 28.3% (before product recall costs), then CSL at 27.3%, and Resmed's margin is significantly lower at 19.8%. Cochlear's position as having the highest PSR is suitable, given its high margin and arguably very sustainable and strong long term growth profile.

Another observation with this batch of companies is that their growth in sales over the last three years has been very low, at less than 10% per year for each. A major factor has been the strengthening Australian dollar, which has increased by around 23% against the US dollar over three years, or at a compounded growth rate of 7% a year over this time. Resmed's sales are recorded in US dollars.

Sirtex Medical

Sirtex Medical fits comfortably in this group of companies. Its PSR is 3.8 and its compounded annual sales growth for the last three years has been 7.8%. In the latest half year, the company's sales increased by 8.1% although this was dampened by the rise in the dollar, with units unit sales increasing by 16%.

Sirtex offers an investment opportunity based not only on the premise that should sales continue to increase at around 15% or more a year, but that there could be a step change increase in usage if the therapy gains approval for use as a first line therapy (rather than as salvage therapy where the product is currently being used), and also the product is firmly adopted as a treatment for not just secondary liver cancer, but for primary liver cancer. (See last week's *Bioshares*)

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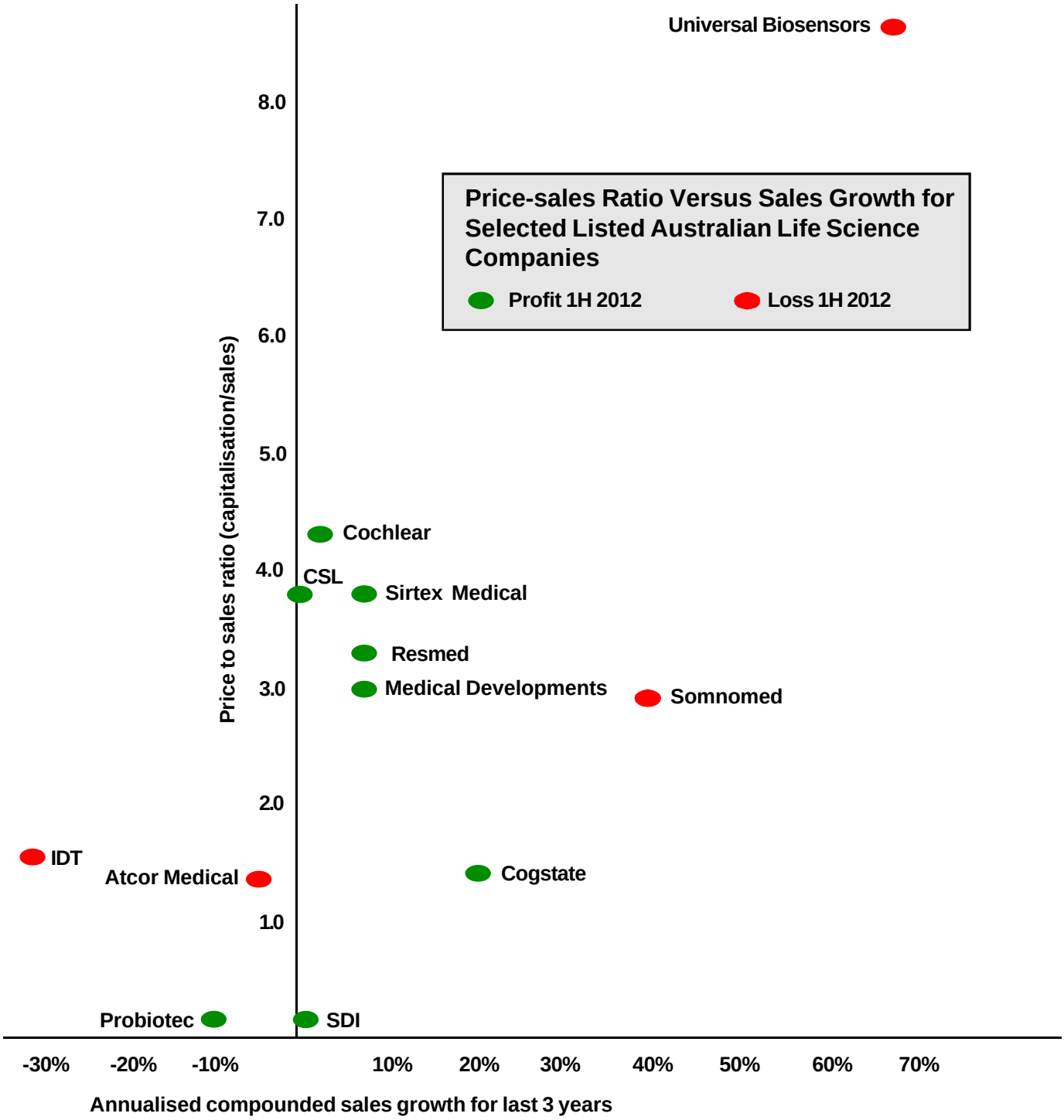

To make this happen, the company is conducting at least five trials which will recruit just short of 3,000 patients. The company is investing $60 million over five years in these trials, with the company already 18 months into this program. Results from the studies will start to emerge in late 2014, the first being a 450 patient study looking at using its Sir-Spheres as a first line therapy with chemotherapy and against chemotherapy alone.

Sirtex is not only investing for the future, but is also paying an annual dividend of 7 cents per share, equating to $3.9 million. It generated a net profit of $6.1 in the first half of this financial year.

Its results for the US were very strong, with a 25% growth in unit sales. The Asia Pacific region was also very strong, growing at 27.7% although off low volumes. The disappointing region was Europe, where unit sales volumes fell by 2.9%, largely due to the difficult economic conditions there. The company also experiencing some price cutting competition in Turkey from Nordion. Turkey has previously been highlighted as a strong performing market for Sirtex.

Nordion makes glass beads containing the same radioisotope,Yttrium-90. Nordion has a much smaller presence in this market, supplying product to around 150 centres compared to 588 for Sirtex's Sir-Spheres. Sirtex CEO Gilman Wong said a competitor is healthy for this space, helping validate this treatment approach.

Cont'd over

– Half Year Analysis cont'd

The difference between the two however is that Sirtex is investing in clinical trials and Nordion has been planning to invest in a large study for the last 12 months although it has yet to commence.

Sirtex Medical is now focusing on 2020, ensuring the company has the necessary capabilities to manage the growth over the next eight years. A large part of this is making sure it has highly experienced managers in its major regions. It replaced its US manager at the end of 2009 with that change now delivering an excellent result.

Last year it hired a new manager for the Asia region, a very experienced pharmaceutical executive who previously worked for Bayer and launched the liver cancer drug Sorafenib. Sirtex's Sir-Spheres will both compete with and potentially can be used in combination with Sorafenib.

Somnomed

Somnomed has grown its sales at a compounded annual growth rate of 40% for the last three years, albeit off a low base. Sales in the first half if this financial year were $6.85 million, up 14.6% on the previous corresponding period, also negatively impacted the strong Australian dollar. However unit sales were considerably stronger, growing at 26% over the previous corresponding half.

Somnomed is trading at a PSR of 2.9 times. The company made a small loss for the half ($3,682), reinvesting all of its operating cash flow into growing the business. Looking at Somnomed's position in the chart provided, Somnomed is one of the standout investment options. Somnomed is capitalised at $40 million.

Cogstate

Cogstate has had its best first half on record, with sales increasing by 75% to $6.9 million. The company has grown sales at a compounded annual rate of 21.5% over the last three years and is trading at a PSR of only 1.4.

Its results have also been negatively impacted by the appreciating local currency. However the company has acknowledged and responded to those conditions by lowering is cost base considerably over the last 18 months. As a result, the company generated an operating profit of $2.6 million for the half (a $3.4 million net profit, which includes revaluation of assets).

Similar to Sirtex, Cogstate is also investing in long term growth of the business which cold translate into future step changes in revenues. The first is using its cognition testing platform to manage concussion in sport, which is becoming a big issue in the USA. It is also seeking to introduce its product as a population dementia screening test. It is currently in discussions with potential partners. Should a disease modifying drug treatment reach the market for Alzheimer's disease – and they are getting close, particularly Johnson & Johnson's bapineuzumab – then there will be very large market for the Cogstate test.

Cogstate is capitalised at $19 million with just under $3.5 million in cash and a further $3.6 million in receivables (and payables of $1.2 million).

Universal Biosensors

Looking at the chart provided, Universal Biosensors (UBI) looks expensive, trading on a PSR of 8.6 times. However it has delivered compounded annual growth in sales of 67% for the last three years. And strong grow is expected to continue, as the glucose strips it makes for its partner, Lifescan (Johnson & Johnson), continue their global rollout, most recently in the US.

Lifescan has a 27% global market share in a market where more than 16 billion strips were sold in 2010. UBI expects higher production volumes this year, with a current capacity of 750 million strips a year. And Lifescan has also started making its own strips in Scotland as well. UBI receives US 1 cent for each strip Lifescan sells, regardless of who makes them. That equates to US$43 million a year in potential revenue for UBI if Lifescan was to transition its entire product range to the UBI designed diagnostic system. Blood glucose testing is a massive market that continues to grow at around 10% a year.

UBI has become Lifescan's innovation partner in the area of glucose monitoring. It is currently working on novel glucose testing product. That feasibility program is on track to be completed this year. The work will bring in US$4.5 million to UBI this year.

UBI is also investing in future growth, with a second product in development and partnered with Siemens Healthcare Diagnostics. This potential product, called PT-INR, is for use by patients and healthcare workers to titrate correct chronic warfarin dosage. The company is also working on a platform to apply its technology for use in antibody-based diagnostic tests. This is a very challenging application but can have very high rewards for the company.

Recommendations

Sirtex Medical: **Buy**
Somnomed: **Speculative Buy Class A**
Cogstate: **Buy**
Universal Biosensors: **Speculative Buy Class A**

Bioshares

Understanding Gilead's US$11 Billion Price Tag for Pharmasset

On November 11, 2011, **Gilead Sciences**, a US pharmaceutical firm with a strong focus on infectious diseases, announced it would acquire **Pharmasset**, a company developing several products to treat Hepatitis C (HCV) infection for US$11 billion, or US$137 per share. Formal discussions began in June 2011, but informal discussions may have commenced up to two years before the announcement. The cash deal was structured with Gilead securing $6.2 billion in debt to fund the acquisition.

The deal was the surprising because Pharmasset's lead compound, PSI-7977, had only recently been advanced into two Phase III programs, which at a less superficial level, set the deal as a Phase II deal. However, the deal was pitched to the investment community as one which could see an approval of a new first-to-market "all oral" therapy for HCV as soon as 2014, backed by "compelling Phase II data".

Why did Gilead pay out one of the largest sums in the history of biotech for a Phase II grade company? To understand the deal logic it is helpful to consider the evolution of treatment regimes for HCV.

History of HCV Treatment

From the early 1990s, HCV infection has been treated with non-specific anti-viral cytokine interferon, when in 1991 the FDA approved **Schering**'s Intron A (recombinant interferon-alpha). The Sustained Virological Response (negative viral load at six months post-treatment; also SVR24) with this treatment was 9%.

The next breakthrough came in 1998 when ribavarin (a small molecule compound that works in the nucleus of the Hepatitis C cell to interfere with RNA replication) was added to the treatment regime. This moved the SVR to 29% for HCV genotype 1.

When **Genentech** introduced pegylated interferon-alpha (PEG-Intron) in 2002, together with that company's version of ribavarin (Copegus), the SVR for HCV genotype 1 improved to 44-51%.

Yet only quite recently, in May 2011, two molecules, boceprivir (Victrelis - **Merck**) and telaprivir (Incivek - **Johnson & Johnson/ Vertex Pharmaceuticals**), with different mechanisms of action, were approved by the FDA, which have lifted the SVR to the 66-79% range. It is important to note that these two drugs have been approved in combination with pegylated interferon and ribavarin, illustrating the dominant position these two agents have as standard of care. Boceprevir and telaprivir are protease inhibitors, which stop viral replication by inhibiting the protease machinery which is used to cut or divide proteins prior to their assembly as virions.

However, these new therapies do not come with improvements to dosing or to the acceptability profile of the drugs. Boceprivir must be taken three times a day, in four capsules for a total of 800 mg each time i.e. 12 capsules a day. Telaprivir must be taken three times a day, in two capsules for a total of 750 mg each time i.e six capsules day. The management of patients with HCV infection has become quite complex because the regimes require different combinations of drug to be administered at different times for different periods of the 48 week treatment period. On top of that interferon is an injected drug, and is poorly tolerated by many patients.

Pharmasset – History

Pharmasset was founded in 1998 by noted anti-viral drug company founders Raymond Schinazi and Dennis Liotta, both from **Emory University**. It listed on the Nasdaq in 2007. Its backers up to the IPO included MPM Capital (5.349 million shares), Burrill and Company (2.156 million shares), TVM Capital (2.369 million shares) and MDS Capital (1.586 million shares). The company has raised capital every year since its IPO, raising a total of US$384 million.

Up until its listing Pharmasset had raised approximately US$60 million (net of costs). At September 30, 2011 the company employed 82 people.

Schinazi and Liotta also founded **Triangle Pharmaceuticals** which they sold to Gilead in 2003 for US$464 million.

Shareholders at the time of Pharmasset's February 2011 proxy filing were Fidelity Management and Research (4.376 million shares; 12.8% holding), T Row Price (2.574 million shares; 7.6% holding), Burrill & Company (1.96 million shares, 5.7% holding), Blackrock Advisors (1.95 million shares, 5.7% holding) and Wellington Management (1.754 million shares; 5.1%).

Although Burrill and Company sold shares into a capital raising in 2011, their final stake (assuming it was held until the acquisition) was worth $268 million.

In 2004, Pharmasset struck a collaborative licensing deal covering PSI-6130 and its pro-drugs with Roche, Roche paid an up-front licensing fee of US$8 million, with a total of US$105 million in milestone payments possible.

Pharmasset had accumulated project costs since 2008 of US$62 million on PSI-7977 and US$23 million on PSI-938.

The Holy Grail for HCV Treatment

The Holy Grail for HCV treatment is one that combines one or more active pharmaceutical agents into the one pill for single daily administration and which addresses most of the different strains of HCV. (HCV genotype 1 accounts for ~70% of infections in the US and Japan.) In addition, such a drug would not require responses guided therapy, acts quickly, has a very manageable side effect profile, has a high cure rate and would be suitable for all populations (i.e. white, black, Asian), with interferon ultimately eliminated from the regime.

Enter PSI-7977

Pharmasset's PSI-7977 (a polymerase inhibitor) demonstrated a 3.6 log reduction in viral load following dosing of 400mg once a day after three days of administration, indicating its potential for fast action. Its next-in-line compound, PSI-938, also achieved a 3.6 log reduction in viral load with 300 mg once a day over three days.

Cont'd over

– Giliead/Pharmasset cont'd

At the time of Gilead's acquisition of Pharmasset, the Phase II trial (the ELECTRON study) had not been completed with data for SVR at 12 weeks for the peg-interferon free and ribavarin free arm not available for genotype 2/3 patients. Post merger, Gilead announced data from four weeks of treatment for genotype 1 patients, showing that patients treated with PSI-7977 (now GS-7977) and ribavarin achieved undetectable viral load at four weeks.

More recently (Feb. 17), Gilead released data from another arm of the ELECTRON trial, which showed that six of eight patients from the arm of the trial that enrolled genotype 1 patients who were non-responders to interferon, had relapsed four weeks after the end of twelve weeks of treatment on GS-7977 and ribavarin. Gilead's share price lost 14% on the day of that announcement. From a share price peak at Feb. 6 at US$56.03 to its most recent low on Feb. 22 at US$44.53, Gilead has seen US$8.7 billion carved off its market capitalisation of $33.72 billion.

Deal Rationale?

Gilead's reasoning behind its acquisition of Pharmasset would have also included the potential for the two unpartnered Pharmasset compounds to be combined with one or more compounds from its own HCV portfolio, such its own protease inhibitor candidate GS 9451, its NS5A inhibitor GS5885 or its non-nucleoside candidates GS 9190 and GS 9669, with an oral formulation ideally excluding ribavarin.

However, the most important thesis as advanced by Gilead is that the HCV market is very poorly served by the interferon-dominated standard of care which it argues turns people away from treatment due to its unpalatable side effect profile. On top of that the market is also only weakly penetrated. Gilead estimates that there are 12 million people in major pharmaceutical markets infected with HCV with 4.5 million diagnosed but less than 200,000 patients treated each year.

Pharmasset management put together revenue and free cash flow forecasts for PSI-7977 (see table). What makes the forecasts interesting is that they assume a strong annual growth rate for the diagnosis of HCV of 10%, a base price of US$36,000 for each course of treatment, and peak market shares ranging from 60% to 90% for the main HCV treatment sub-markets. Within a field that has numerous competitor products in development, including more than 20 at the Phase II and Phase III stages of development, the Pharmasset assumptions of market dominance are audacious.

Pharmasset Updated Sales Forecasts for PSI-7977

Fiscal Year	Total Revenue (US$M)	Free Cash Flow (US$M)
2012	$15	-$136
2013	$0	-$250
2014	$526	$78
2015	$4,029	$1,436
2016	$8,126	$2,578
2017	$8,218	$2,502
2018	$7,458	$2,209
2019	$6,965	$1,936
2020	$6,726	$1,709
2021	$6,326	$1,515
2022	$5,843	$1,342
2023	$5,323	$1,189
2024	$4,891	$1,052
2025	$4,494	$922
2026	$4,494	$901
2027	$4,494	$901
2028	$4,494	$901
2029	$4,494	$901
2030	$4,494	$901
Total	*$91,410*	*$22,587*

Source: SEC filing (SCHEDULE 14D-9)

By way of example of competitor drugs in development, a study that enrolled 21 patients who had not previously responded to interferon or ribavarin and published in the NEJM in January 2012 showed that a combination of daclatasvir (60 mg daily) with asunaprevir (600 mg twice daily) achieved a SVR for 36% of patients at 12 and 24 weeks without the co-administration of ribavarin and peg-interferon alpha -2a. In administration with ribavarin and peg-interferon, the SVR was 90% at 24 weeks.

Gilead also acquired in the form of Pharmasset a company founded by scientists with a track record in anti-viral drug development. (see box previous page).

Discussion & Implications for Biotron

The Gilead acquisition of Pharmasset raises several questions for investors in the field, including the obvious one of whether it paid too much. Time will tell in that regard. However another question is, is it worth other companies with HCV development programs continuing their programs in the face of what seems like a bold declaration of guaranteed market success?

The short answer is yes, with local company Biotron (BIT: $0.145) placed in an even stronger position. One feature of Gilead's newly acquired compounds that has yet to be fully characterised is the degree and the rate that resistance (from mutations) that occurs. HCV is a virus that is prone to copy errors and is hence very successful in developing drug resistance.

Biotron's advantage for BIT225 is that its mechanism of action is different to the polymerase and protease inhibitors. BIT225 could potentially be combined with drugs with alternative mechanisms of action to better address the problem of HCV mutation.

BIT225 is an assembly inhibitor whereas protease inhibitors stop proteins being made. Polymerase inhibitors stop the HCV genome from being reproduced.

It also appears that BIT225 delivers a more gradual response, in contrast to GS-7977's relatively fast ability to suppress HCV.

BIT225 has completed a Phase II 28 day study in combination with interferon and ribavarin (SOC) which showed a complete early virological response (EVR) after 12 weeks in 86% of patients taking the 400mg dose of BIT225 and SOC, 88% for patients taking the 200mg dose at 12 weeks versus a 63% complete EVR. EVR is defined as below detectable levels of virus. However, the stronger 400 mg dose delivered the highest median log reduction of -4.957 at 35 days compared to -4.351 for the 200 mg dose.

Biotron's next steps for the development of BIT225 will be to plan and initiate a 90 day trial with ribavarin alone or potentially one with boceprivir. However, the company must first complete 90 day toxicology studies.

Cont'd over

Company	Price (current)	Price added to portfolio	Date added
QRxPharma	$1.80	$1.66	October 2011
Mayne Pharma Group	$0.295	$0.435	September 2011
Acrux	$3.74	$3.37	June 2011
Bioniche	$0.51	$1.35	March 2011
Somnomed	$0.95	$0.94	January 2011
Phylogica	$0.041	$0.053	September 2010
Biota Holdings	$0.78	$1.09	May 2010
Tissue Therapies	$0.37	$0.21	January 2010
Atcor Medical	$0.08	$0.10	October 2008
Impedimed	$0.50	$0.70	August 2008
Bionomics	$0.45	$0.42	December 2007
Cogstate	$0.26	$0.13	November 2007
Sirtex Medical	$5.00	$3.90	October 2007
Clinuvel Pharmaceuticals	$1.78	$6.60	September 2007
Pharmaxis	$1.00	$3.15	August 2007
Universal Biosensors	$0.80	$1.23	June 2007
Alchemia	$0.435	$0.67	May 2004

Portfolio Changes – 2 March 2011

IN:
No changes

OUT:
No changes

– Giliead/Pharmasset cont'd

Biotron is reasonably well funded following the conversion of listed options which raised $8 million, with 80% of options exercised. As of December 31, 2011, Biotron held $9.1 million in cash.

The Pharmasset acquisition is a reminder of the time it takes, the dedicated focus required and scale of capital required to build a successful company. From company formation in 1998 to a projected market launch in 2014 is a period of 16 years. The capital raised by Pharmasset up to acquisition was US$450 million.

The Pharmasset acquisition is finally a reminder that the availability of a drug or treatment regime does not mean that a patient population is well served, in fact the opposite could be true in that an existing standard of care remains very much sub par.

Biotron is capitalised at $33 million.

Bioshares recommendation: **Speculative Buy Class B**

Bioshares

Antisense Therapeutics Looks to Set Up JV for ATL1102

Antisense Therapeutics is resurrecting its ATL1102 program. It has a term sheet agreement with the TJAB group in China to set up a fully funded joint venture to commercialise ATL1102. Antisense previously completed a successful Phase II trial with ATL1102 in patients with multiple sclerosis. It partnered the drug program with TEVA which then returned the program to Antisense two years ago.

The reason Teva stopped development on the program was because of the need to conduct further preclinical toxicology work on the compound. TJAB, which was formed in 2009 with $162 million in Chinese Government funding, will conduct all of the necessary toxicology work. If the drug profile is safe, it will move the drug into Phase II testing for the treatment of MS and also for the treatment of asthma.

TJAB will also conduct a Phase I/II trial in looking at the role ATL1102 might play in the mobilisation of stem cells. This aspect of the drug candidate was discovered in Antisense's Phase II MS trial result and also in animal studies, after another compound that inhibits the same pathway, Tysabri, was also shown to have an effect on stem cell mobilisation. Tysabri generated sales of just over $1 billion last year.

Under the terms of the agreement, Antisense will be providing its intellectual property, its guidance, but no financial assistance. TJAB will commercialise the compound for the Chinese market and Antisense will commercialise the program in other regions, with a revenue split depending on level of investments made.

Antisense had $1.5 million in cash at the end of last year. It has potentially a further $1.4 million of funds that may sourced from the exercise of options by July this year which are currently in the money. To fund its lead program, ATL1103, for which the company recently generated positive Phase I results, the company will likely need to raise additional funds.

Bioshares recommendation: **Speculative Buy Class C**

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, Calzada

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