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Companies covered: CIR, OBJ, PYC, RNO

	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 - May '13)	3.1%
Year 13 (May '13 - May '14)	26.6%
Year 14 (May '14 -)	-6.3%
Cumulative Gain	**322%**
Av. Annual gain (14 yrs)	**15.6%**

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Bioshares

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

OBJ Gains From P&G Product Licence But Bodyguard Product Is The One To Watch

Perth-based transdermal technology company OBJ (OBJ: $0.087) has had a strong share price run this year on the back of positive developments from its collaboration with global consumer goods group Proctor and Gamble (P&G).

The stock reached an all time high of $0.115 in April after OBJ announced it had signed a multi-product development agreement with P&G, as a well as a licensing agreement for a first product, the details of which were not disclosed. The agreement will fund three work plans, including the first licensed product. Another four products could eventually be funded and licensed under the agreement.

OBJ stands to receive royalties on products developed by P&G. OBJ also has collaborations with GlaxoSmithKline, exploring applications in the area of oral healthcare and analgesics, and with cosmetics company Coty.

Currently OBJ shares are up 691% both from a year ago and from when we discussed the stock last in *Bioshares* 507 (June 14, 2013).

OBJ has developed a technology which greatly improves the delivery of molecules, including large molecules across the skin. The technology does not use any external power source, instead harnesses magnetic forces, an induced charge effect (electric) and user movement to achieve penetration.

The technology has been expressed in three forms, including a magnetic micro-array patch in which active ingredients are pre-programmed to react in the desired way to penetrate the dermis, a field-in-motion magnetic array which can be integrated with brushes and applicators and which takes advantage of the consumer's use of motion. Finally a microprocessor controlled technology which delivers control where repeat delivery is required or delivery parameters need to be adjusted for special conditions (e.g. humidity or temperature).

Bodyguard

OBJ has retained control of its Bodyguard program, partly to offset risks associated with partnered product development programs. Bodyguard is a musculoskeletal patch designed to deliver chondroitin sulphate and glucosamine to joint areas. The product was approved by the TGA on March 28, 2014.

The product label says that Bodyguard contains nutritional ingredients (which) support the growth and maintenance of healthy cartilage, facilitates the accelerated delivery of ingredients to improve lubrication of the knee joint and overall cartilage function, helps improve joint stability and tracking, enhance recovery, reduce re-injury rates, increase pain-free mobility and reduce pain and joint deterioration.

– Cont'd over

Ophthotech Deal Confirms Interest in Circadian Pathway

This week eye drug developer Ophthotech Corporation signed up to a US$1 billion deal with Novartis for access toOphthotech's eye drug candidate, Fovista, which is currently in Phase III trials. Fovista is being trialed in combination with the eye drugs Lucentis and Eylea, which inhibit the VEGF-A proteins.

Fovista targets what is called the 'platelet derived growth factor'. Why this is important validation for Circadian Technologies (CIR: 0.22) is because next year Circadian also plans to start a combination trial with its drug candidate, now called OPT-302, with either Lucentis or Eylea, which are expected to generate over a $2 billion of sales each this year. But OPT-302 blocks different pathways, that of VEGF-C and VEGF-D. Blocking more than one of the pathways involved with unwanted blood vessel formation in the eye to treat wet AMD (age-related macular degeneration) is expected to make existing therapies more effective and potentially require less frequent injections into the eye, which at the moment are needed every one or two months.

In the Ophthotech-Novartis deal, Novartis has gained access to non-US rights only. Novartis has European marketing rights to Lucentis. (Roche has US marketing rights.) It paid US$200 million up front. The deal includes $800 million of milestone payments plus royalties from sales. Ophthotech currently has two Phase III trials underway of a combination therapy with Fovista and Lucentis, and plans a third trial with Eylea or Lucentis.

In the first half of next year, Circadian plans to conduct a Phase I/IIa trial in patients with wet AMD. The first part of that study will be the safety trial, involving around 20 patients with escalating doses, receiving one injection a month over three months. That trial will then likely be expanded to a further 15-20 patients to reach some efficacy endpoints at the highest tolerable dose in the Phase I section of the trial.

The first part of the trial is expected to take 12 months to complete, and about 18 months to get to the end of the Phase IIa part of the study. Efficacy endpoints will be measured including visual acuity, retinal thickness and the amount of fluid at the back of the eye.

In treating ophthalmic disorders, outcomes can be measured more rapidly than for instance in testing a cancer drug. Three months is generally sufficient time to see signs of efficacy in the treatment of AMD according to Circadian CEO Megan Baldwin. In mouse studies, OPT-302 has been shown to deliver similar efficacy to the drug Eylea, in inhibiting the lesion size and leaking in the eye. Lucentis did not show any efficacy in the mouse model.

Although the Phase I/IIa study will be expected to show signs of efficacy, the trial will not be powered to achieve statistical significance. Circadian will run the trial in the US under an IND.

At the end of this trial, Circadian will either move into a larger Phase II trial on its own or seek to partner the program. If OPT-302 is successful, it could either be used in combination with Lucentis or Eylea, and also potentially with a VEGF-A/Fovista combination product as Lucentis/Eylea, Fovista and OPT-302 all shut down different pathways in the eye.

Circadian is capitalised at $11 million. The company had $11.9 million in cash at the end of last year.

Bioshares recommendation: **Speculative Buy Class B**

Bioshares

– OBJ cont'd

The first expression of Bodyguard is designed as a 'wrap around' for the knees. However, more product versions could be made for use with rotator cuffs and hips. The company has also developed, in a prototype format, a 'Virtual Patch' formulation which would suit athletes or osteo-arthritis sufferers.

A first Bodyguard trial delivered a 14% improvement in joint function over two weeks, convincingly exceeding a minimum imposed of 5%.

The next step for OBJ is to complete a clinical study with the Australian Institute of Sport and then secure a distributor for the product. In addition, the company is developing a global regulatory strategy for the product.

Summary

OBJ is capitalised at $128 million. With 1.47 billion shares outstanding, it would be timely for the company to effect a share consolidation.

Bioshares recommendation: **Take Profits**

Bioshares

Rhinomed Achieves Positive Trial Data for Turbine

Rhinomed (RNO: $0.02) is commercializing the Turbine device which improves airflow through the nose. In a similar approach to the Breathe Right strips sold by GlaxoSmithKline that help dilate the nostrils, the Turbine is inserted into the nose and has shown to achieve 38% more airflow.

Although the Breathe Right strips are sold mainly for sleeping applications, Rhinomed's first market application is in sports, predominantly cycling. Rhinomed recently released results from a high performance sports study that delivered some positive results for the company.

An independent trial was conducted by former Olympic cycling gold medallist Rob Crowe in a sports clinic with nine cyclists. That trial was set up to investigate whether the Turbine device would provide professional cyclists any improvement in power and distance over the same period and at the same heart rate when using the Turbine compared to without.

It was an unblinded crossover study, so participants were tested both with and without the device. The trial showed that the Turbine was effective in six of the nine cyclists. In the six cyclists where there was an effect, the cyclists achieved an added 6.5% power when wearing the Turbine.

For the whole group during the 10 minute (around 12 km) high intensity trials, the riders achieved on average 143m more distance when wearing the Turbine.

Although Rhinomed had previously shown that its device delivers 38% more air through the nose, its effect on power, speed and endurance in cycling, the first target market, was unknown. CEO Michael Johnson said in a briefing this week that this data was the missing piece of the puzzle, allowing the company to now target sporting groups with this data.

Marketing approach

The Turbine product was launched in January this year officially. It can be purchased on line and is also sold through cycling shops in Australia. Australia is a test market, according to Johnson, and the company is seeking to have the product stocked at the 400 premium cycling stores. Johnson said the Turbine is a consumer product with pharmaceutical-type margins. There is a very healthy margin ($10) for retail operators to sell the product, which sells for $24.95 for a packet of three.

The other approach the company is taking is to promote the product to elite cyclists in the US and Europe. Trek Factory Racing Team rider Calvin Watson has been using the Turbine in the Tour of California and has been promoting its use in the US. In Europe, Tour de France green jersey winner Baden Cooke has been promoting the product to elite cyclists in the Giro D'italia underway at the moment and will be promoting it at the forthcoming Tour de France in July.

Rhinomed will also look to sell the product into cycle spin classes at sports training and exercise centres.

Sleep Market

The next market that the company will be looking to address is the sleep market, going head-to-head with the successful Breathe Right product. The company will be conducting trials, looking at how well partners of people who snore sleep when their partners use the Turbine. Rhinomed will sell the product into pharmacies through a distributor network.

The company is using the approach that gaining acceptance and building a profile in the sports market will help adoption in the sleep market. The company expects to start selling into the sleep market in the second half of this year.

Summary

Rhinomed is capitalised at $8 million and had $2.5 million in cash at the end of March. It's revenue for the March quarter was only $9,000, with the product officially launched in that quarter.

Rhinomed is building an experienced sports marketing team to build awareness of its Turbine product in the global cycling market.

The recent trial data provides important evidence to support the marketing and adoption of the product across high performance cyclists, which is potentially a very large market.

The sleep market, which is larger, has already been established with the competing product, and offers a second market opportunity.

The challenge for the company is gain sales traction for the Turbine over the next 12 months and to see increased adoption across elite cycling circles. The company has just over one year's cash at its current burn rate.

Bioshares recommendation: **Speculative Buy Class B**

Bioshares

Janssen Discontinues EET Collaboration With Phylogica

Shares in Phylogica (PYC: $0.015) fell 52% recently when a partner, Janssen, a subsidiary of Johnson & Johnson, decided to not proceed with a drug discovery collaboration. Janssen chose not to exercise an option it held to license outcomes from a program which had so far succeeded in validating Phylogica's Endosomal Escape Trap platform, according to Phylogica.

The decision by Janssen came as a 'complete shock' to Phylogica, which had made considerable progress towards tackling the problem of developing a platform which could deliver constructs – combinations of different peptides (or even antibodies or scaffolds) with different functions – to hit intracellular drug targets, a largely untapped area for drug discovery and development, outside of DNA or RNA approaches. An estimated 70% of drug targets lie inside the cell, and remain undeveloped as drug targets today.

According to Phylogica, the unit of Janssen which was managing the relationship with Phylogica is to be broken up. This unit had received an estimated US$40-US$50 million in funding by Janssen for the purpose of supporting discovery programs similar to the one conducted with Phylogica. Janssen, through this unit, invested $2.32 million into Phylogica's Endosomal Escape Trap platform

The Endosomal Escape Trap Platform

Most drugs work by engaging or binding with receptors on the outside of cells, with some small molecule drugs working by penetrating the cell wall.

The Endosomal Escape Trap platform circumvents a key problem for drugs that can penetrate cells but become trapped in endosomes (though it should noted that not every small molecule drug is trapped in the endosome). These intracellular vesicles first sort then direct material for degradation by the lysosome for recycling.

Phylogica has developed a platform technology which allows it to create drug constructs which can penetrate cells, escape from the endosome and the reach intracellular targets of druggable interest such as transcription factors.

The one thing Phylogica had to demonstrate was that it could deliver concentrations of its constructs which could deliver a therapeutic effect.

What's Next for Phylogica?

Phylogica will now proceed with a drug discovery program, building on the Janssen collaboration. It will aim to reduce the 30-40 constructs it developed for Janssen to one or two of the most potentially drug-like which demonstrate therapeutic activity at micro-molar concentrations. These are both key milestones for the company, even without the Janssen collaboration in place.

These drug candidates themselves could then out-licensed, including to Janssen, which Phylogica states it left a relationship with 'on good terms', or to other pharmaceutical companies.

The company's efforts going forward will most likely be focused on drug discovery in the oncology space, looking at intra-cellular targets associated with known pathways.

Competitive Advantage

One of the attractive features of Phylogica's Endosomal Escape Trap platform is that it is modular, or can be built on a plug-and-play basis. The platform has three components. The receptor binding domain (RBD) enables the peptide to cross into the cell, the cell membrane translocation domain (CMTD) facilities exit from the endosome, and the functional domain (or cargo) is the unit which holds the drug function.

The RBD could be made from a peptide (or Phylomer as they are termed by Phylogica), antibody or scaffold. The CMTD is the unique component that is exclusively a Phylomer. The cargo could include a Phylomer, antibody, scaffold, toxin, or siRNA.

On the one hand the platform has the potential to be extremely versatile yet on the other, it contains an exclusive element which stands to benefit Phylogica in the absence of any other validated technology that permits endosomal escape.

Summary

Leading Phylogica's share register is the Hockings family of Perth, with a 20% stake. This investment group has, following a board review of the company's programs and capability, indicated a willingness to continue to support the company.

Phylogica bears comparison with Benitec Biopharma as a company developing a broad-based and novel technology that could give rise to new therapeutics. When validation of the technology takes place first at technical proof-of-concept level, and then later at a clinical proof-of concept level, then the company could deliver a strong return on investment.

At the right time, Phylogica is a company which leading North American life science investors could be keenly interested in, if the company solves a set of key technical challenges.

Phylogica retained cash of $5.9 million at March 31, 2014. Phylogica is capitalised at $15 million.

Bioshares recommendation: **Speculative Buy Class B**

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Bioshares

Bioshares Model Portfolio (23 May 2014)

Company	Price (current)	Price added to portfolio	Date added
pSivida	$3.900	$4.000	May 14
Invion	$0.060	$0.089	February 14
Impedimed	$0.205	$0.245	December 13
Analytica	$0.036	$0.025	December 13
Imugene	$0.010	$0.022	November 13
Oncosil Medical	$0.105	$0.155	September 13
IDT Australia	$0.225	$0.260	August 13
Viralytics	$0.280	$0.300	August 13
Tissue Therapies	$0.330	$0.255	March 2013
Somnomed	$1.43	$0.94	January 2011
Cogstate	$0.240	$0.13	November 2007

Portfolio Changes – 23 May 2014

IN:

No changes

OUT:

No changes

Recommendations:

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: Cogstate, Bionomics, Impedimed, QRxPharma, LBT Innovations, Tissue Therapies, Viralytics, Phylogica, pSivida, Antisense Therapeutics, Benitec BioPharma, Admedus, Calzada, Invion, Circadian Technologies, Imugene, Analytica

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