

In this edition...

A detailed understanding of the world of pain therapies and pain drug development is worth pursuing because, at first glance, this drug sector appears saturated by too many drugs. However, this is one area of drug development in which the introduction of modifications and improvements, and introduction of combination products, have made inroads into dealing with pain. And healthy revenues have flowed to a number of winners in this area of drug development. Our analysis of QRxPharma's combination drug, now called MoxDuoIR, sets out the challenges and the potential opportunity.

In the area of regenerative medicine, it appears that Big Pharma is starting to take a keen interest, and this has implications for two companies in the space, Mesoblast and Stem Cell Sciences.

Companies Covered: MSB, QRX, STC

	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 - current)	-39.0%
Cumulative Gain	26%
Av Annual Gain (7 yrs)	17.8%

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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* –

Regenerative Medicine Moves Ahead

The election of Barack Obama to the office of President of the United States of America is expected to see a positive shift in policy regarding stem cell research and medical therapies based on cell-based technologies. Such technologies and products are likely to benefit from more funding flowing to early stage research and latter stage product development is likely to benefit from a more conducive regulatory pathway.

So it was no surprise following the US elections on November 4, 2008, that **Pfizer** announced the establishment of a global regenerative medicine unit, **Pfizer Regenerative Medicine** on November 14, 2008. Regenerative medicine is a descriptor for therapies that are based on stem cell technologies. The unit is expected to function as one of four new small independent research outfits for Pfizer, organised to replicate the innovative culture typical of biotech start-ups. Pfizer Regenerative Medicine will have operations in Cambridge, UK and Cambridge, Massachusetts and will eventually employ 70 staff. The UK team will focus on neural and sensory disorders and the US team will focus on diabetes and cardiac diseases.

However, Pfizer is not the only major pharmaceutical company to initiate a regenerative medicine capability either directly through partnerships, with **Johnson & Johnson**, **GlaxoSmithKline**, **Roche** and **Novartis**. Pharmaceutical companies, while cautious, recognize that failure to embrace emerging technologies can be costly in terms missing competitive advantages from being on the 'technology' learning curve and the 'new therapy' learning curve early in the piece. The outstanding success of a number antibody drugs has gradually changed the willingness of large pharmaceutical marketing firms to adopt and develop technologies and products that often depend on different regulatory paths, reimbursement and marketing models, interventional techniques and changes to the views and opinions of physicians and patients. The real incentive however, comes from the creation of new intellectual property and domination of knowledge domains.

The regenerative medicine area received a stimulus when **Genzyme** and **Osiris Therapeutics** revealed in early November they created a partnership to develop two mesenchymal stem cell products, Prochymal (a Phase III stage product) and Chondrogen, developed initially by Osiris. Genzyme made an up-front payment to Osiris of US\$130 million. (see *Bioshares* 288)

A Recent Development...

A female patient, who had been suffering from tuberculosis induced dysphonia and cough, recently received a bio-engineered bronchial tube*. A human trachea donor scaffold was seeded with epithelial cells and mesenchymal-stem-cell derived chondrocytes. Four months after the operation, the patient has been observed to have a functional airway, no anti-donor antibodies have been detected and immune-suppressive drugs are no longer required.

* *The Lancet*, Nov. 19, 2008

Cont'd over

Positive clinical developments such as the one just mentioned are among some of the factors that are stimulating the interest of large pharmaceutical companies in regenerative medicine.

GlaxoSmithKline

In July, GlaxoSmithKline signed a five year, US\$25 million plus deal with Harvard Stem Cell Institute, to support stem cell research at Harvard University and several affiliated hospitals. The areas covered by the agreement include neuroscience, heart disease, cancer, diabetes, musculoskeletal diseases and obesity. What was interesting about the GSK announcement was the following statement: "We have carefully chose the Boston biomedical community to collaborate with on this important venture. It has the highest concentration of leading stem cell scientists and the Harvard Stem Cell Institute is the epicentre of that community."

Johnson & Johnson

Johnson & Johnson, through its venture capital unit has invested in **Tengion**, a company that is aiming to regenerate tissues and organs, using autologous uncommitted progenitor cells and tissue scaffolds. Tengion is conducting three Phase II clinical trials of its Neo-Bladder Augment in neurogenic bladder in spina bifida, neurogenic bladder following spinal cord injury and for treatment of urge incontinence.

On November 19, the company completed a Series C funding round, raising US\$21 million. The completion of a funding round in the midst of a major meltdown in global finance markets is possibly a sign of just how attractive cell therapy investments are becoming.

Novartis/Roche

Novartis and Roche, through their respective venture capital arms have invested in Spanish cell therapy company, **Cellerix**. Novartis Venture Fund and Roche Venture Fund invested in a Euro 27 million round in September 2007. Cellerix is developing a suite of products derived from expanded adipose tissues (fat cells). Its most advanced product, Ontaril FATT 1, is in a Phase III trial for patients with complex perianal fistulas with a cryptoglandular origin. Ontaril is an autologous cell product. However, Cellerix is developing allogeneic products targeting the same indications that Ontaril is directed at.

ASX Regenerative Medicine Company Briefs

Mesoblast

Developments at Mesoblast (MSB: 79 cents) were covered recently in *Bioshares* 288. However, several further items of interest emerged at the company's AGM held in late November. The company stated that to date, it had conducted over 400 large animal studies with no adverse events recorded.

The company also revealed that recruitment in the randomized Phase II congestive heart failure is proceeding very well with 17 out of 20 patients recruited, in a 3 x 20 cohort trial. Interim results will be available at three monthly intervals for the 12 month trial, which should see the first data appear around March 2009. The trial involves implantation by catheter of allogenic (single human donor) mesenchymal precursor stem cells (product name - Revascor).

Mesoblast also discussed its commercialisation options which includes the option of taking products to markets under its own efforts. However, such a strategy would require the highest capital commitments and the greatest execution risk. The second option is partnering of specific products. The third option is broad-based partnering of the platform technology, similar to the Genzyme-Osiris deal.

Mesoblast's view is that Osiris was about 18 months ahead when it signed up Genzyme. However, Mesoblast also believes that while there is growing interest from large pharmaceutical companies in cell therapy products and technologies, an attractive partnering deal will not occur until the technology has been sufficiently de-risked and that it works across multiple applications.

In our view, 2009 will be a pivotal year for Mesoblast, and the stock is a very attractive investment.

Mesoblast is capitalised at \$94 million.

Bioshares recommendation: **Speculative Buy 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.

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: Phylogica, Pharmaxis, Biotech Capital, Cytopia, Arana Therapeutics, Starpharma Holdings, Cogstate, Xceed Biotechnology, Optiscan Imaging, Bionomics, ChemGenex Pharmaceuticals, Circadian Technologies, Biota Holdings, Stem Cell Sciences, Halcygen Pharmaceuticals, Peplin, BioMD, Impedimed, QRxPharma, Patrys, Labtech Systems, Hexima, Tyrian Diagnostics, Mesoblast

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