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In this edition...
Sleep apnea is a significant opportunity for oral appliance company Somnomed. Unit sales of its products rose 30% in the March quarter from the same quarter a year. Strong growth is expected to be maintained as dentists gravitate to a new product line to sell. The sector's newest heavy-weight, Mesoblast, continues to open up new treatment possibilities for its adult stem cell therapies, with metabolic syndrome, inflammatory lung diseases and rheumatoid arthritis areas to watch. The company has strong news flow ahead in the the next 12 months. Genetic Technologies is one stock clearly in a 'turn the corner' mode, with costs contained, profitability reached and a approval of its Melbourne labs gained from the US CMS, enabling sales of its Brevagen non-familial breast cancer test to commence.
The Editors
Companies Covered: GTG, MSB, SOM, Cash Analysis

	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)	45.1%
Year 11 now commenced	-
Cumulative Gain	**321%**
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 –

Mesoblast – Full Steam Ahead

There are no signs of things slowing down at Mesoblast (MSB: $8.15). As well as planning for its late stage clinical studies and preparing to get its commercial manufacturing facility on line in coming years, the company is also expanding its preclinical trials to investigate new uses for its world leading, adult stem cell technology. That includes the potential use as a systemic therapy for restoring an array of natural body functions.

Mesoblast's partner, Cephalon, is under attack from a hostile takeover bid from **Valeant Pharmaceuticals**. To date Valeant has been tight-lipped about Cephalon's stem cell deal with Mesoblast, while publicly denouncing a number of the Cephalon's smaller deals. This may indicate tacit endorsement of the Mesoblast deal by Valeant. But either way, if Valeant is successful in acquiring Cephalon, the future of the partnered programs with Cephalon will continue, with Mesoblast extremely well funded to maintain development. For Cephalon it has been a good investment, with its US$220 million stake in Mesoblast close to doubling.

Mesoblast continues to take full advantage of its fortunate position during recent and current economic downturns. During the biotech funding slump in Australia and through the global financial crisis, the company picked up many experienced local biotech managers. It is continuing that process in the US, where Big Pharma is going through major cost cutting, allowing Mesoblast to attract top quality people, some of whom will become involved with the company's clinical programs in the US.

The company's financial and corporate base will continue to be in Australia. CEO Silviu Itescu says that currently Australia provides better support for high risk ventures than the US, which is a surprising reversal of positions. The company had previously considered listing Angioblast in the US, but decided against it due to poor appetite for risk capital in the US.

Manufacturing

Mesoblast currently manufactures its product for clinical trials in Maryland in the US with a third party under contract. It is in the process of negotiating with third parties to build, own and operate commercial manufacturing facilities, and these discussions are at an advanced stage.

These three facilities would likely be built in the US, Europe and in another tax-effective jurisdiction. We expect the facilities will not be built and approved until 2016/17 at the earliest. However, the company may be able to manufacture sufficient material for commercial use at its current facility for the treatment of heart failure, which the company beleives can be on the market in 2015.

US Base

Mesoblast's base in New York will house its clinical, regulatory and manufacturing teams. The US office currently deploys 30 people and the company is actively recruiting staff.

– Cont'd over

Currently between 15%-17% of the company is held by UK funds. Mesoblast is making the most of its links to Cephalon investors, using the Cephalon link to educate those investors on the potential of its stem cell technology, and grooming those investors as potential future shareholders in Mesoblast. Those investors target companies valued between $2-$5 billion in size. Its US base is also in a handy location, literally being in walking distance of many of those investors.

Importance of Pre-Clinical Studies

One of the reasons the company believes that a competitor failed in late stage trials was because it did not conduct sufficient large animal preclinical studies. The company is currently using a natural diabetic primate group to investigate the systemic delivery of its stem cells. The company appears confident that its cells can be successfully applied for this use. An intravenous version of its cells could have multiple applications the company believes, including also metabolic syndrome, inflammatory lung diseases and rheumatoid arthritis. Itescu says it is because the stem cells secrete multiple (growth) factors that gives them such utility and activity, where the human genome work looked at one target and one drug, delivery few results.

Pivotal Studies

The company's bone marrow transplant cell expansion trial is due to commence Phase III studies in the third quarter of this year. The company is due to meet with the FDA in Q3 this year for its cardiovascular heart failure trial, with pivotal studies expected to begin in early 2012. The company is likely to use the smallest dose it used in the successful Phase II trial, with safety of the therapy one of the most important factors.

A Phase II disc repair trial is due to start shortly in around 100 patients, with a Phase III study planned for mid 2012. These trials are expected to be easy to recruit, reflecting the demand for such a therapy.

The company will also look to start Phase II studies in treating eye diseases (age related macular degeneration and diabetic retinopathy), diabetes and in heart attack patients receiving intra-coronary therapy such as stents.

Acquisitions

Mesoblast is very well placed to use its size to acquire other technologies or companies. However, the company says any acquisitions need to be carefully considered.

Summary

Mesoblast is a difficult company to value given the wide number of applications of the technology and the difficulty in judging the probability of this new generation technology getting through the regulatory pathway.

The biggest concern with commercialising this technology is not its efficacy, which has been consistently good, but if any serious side effects occur, which to date there have been none.

The data continues to look very good for all of the indications assessed to date, including bone repair, expansion of cells used in bone marrow transplant and in the treatment of congestive heart failure.

Mesoblast is extremely well funded and there is the opportunity for significant positive news flow over the next 12 months. Mesoblast is capitalised at $2.28 billion and retained cash of $272 million at March 31, 2011.

Major Milestones Ahead

- Primate studies in diabetes
- Disc repair Phase II study to begin shortly
- Results from Phase II orthopedic trials
- Phase II intra-coronary heart failure trial to begin
- 12 month Phase II data from CHF study, **Q3 2011**
- Start Phase III study in bone marrow transplant, **Q3 2011**
- Meeting with FDA for planned Phase III CHF study
- Congestive heart failure (CHF) trial to begin in **early 2012**
- Phase III disc repair study expected to begin **mid 2012**

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, ChemGenex Pharmaceuticals, Circadian Technologies, Biota Holdings, Mayne Pharma Group, Impedimed, QRxPharma, Patrys, LBT Innovations, Hexima, Mesoblast, Atcor Medical, BioMD, Tissue Therapies, Viralytics, Phosphagenics, Immuron, Phylogica, Bluechiip, Psivida