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Clinuvel remains an overlooked stock and is our feature this week. It expects to file Scenesse for approval next month. There is a very real unmet clinical need for this product in EPP, which should help it achieve market success.
Mesoblast is forging ahead aggressively, with at least 12 Phase II or Phase III trials underway or planned, and a clinical trial in diabetes expected to start next year.
Sunshine Heart released final results from its feasibility study, however whether those results will be good enough to fund a pivotal study remains to be seen.
And Bluechiip just signed an evaluation deal with Corning's life sciences division.
The Editors
Companies Covered: BCT, CUV, MSB, SHC

	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	-21.0%
Cumulative Gain	**232%**
Av. annual gain (10 yrs)	**21.2%**

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Blake Industry & Market Analysis Pty Ltd
ACN 085 334 292
PO Box 193
Richmond Vic 3121
AFS Licence
No. 258032

Enquiries for *Bioshares*
Ph: (03) 9326 5382
Fax: (03) 9329 3350
Email: info@bioshares.com.au

David Blake
Ph: (03) 9326 5382
Email: blake@bioshares.com.au
Mark Pachacz
Ph:03 9348 9317
Email: pachacz@bioshares.com.au

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Bioshares

11 November 2011
Edition 433

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

Clinuvel Pharmaceuticals – Prepares to File Scenesse for Approval

Clinuvel Pharmaceuticals (CUV: $1.55) is approaching its most significant milestone, that being the filing of its drug candidate, Scenesse, for European regulatory approval. The company is anticipating filing its drug for approval by the end of the year.

Clinuvel is an overlooked stock. After 20 years of R&D, it is on the cusp of filing its product for approval. The product is already being sold in Italy under a special exemption, which saw the company generate revenue from sales of Scenesse of $1 million last financial year.

What is deterring some investors is that its first market is a niche application, that being an obscure sun intolerance condition, called EPP. However the business plan for the company is excellent; that being, to bring the product to market the fastest and cheapest way possible, then to expand into larger indications such as the treatment of vitiligo (a skin discoloration) and in patients susceptible to skin cancers, initially organ transplant patients on immune suppression therapy.

What Clinuvel has done well is that it has proven the application of the product for EPP by getting into commercial use in Italy. The numbers of patients using the drug is low, with only 47 families on repeat usage of the drug. However, there are other benefits with the EPP market. Being an orphan drug indication, there is extended market exclusivity (10 years in Europe and seven years in the US). The company has been able to negotiate a high sale price at $7,500 per implant. Importantly, the EPP market is prepared for Clinuvel's product; there are patient forums through Facebook and similar communication channels that have facilitated the build up of knowledge about Scenesse. Patient groups and physicians are well aware of the pending arrival of Scenesse for the treatment of this unmet clinical need.

What has favoured Clinuvel in Italy is that there are two physicians with EPP who are brothers are on Scenesse treatment, plus an anaesthetist and a biochemist. This educated medical population in Italy has no doubt had significant influence in getting this treatment adopted in that country.

Clinuvel is now based in Baar, Switzerland. There are a number of reasons for this. The company is now 65% owned by international investors; it is close to its target market; and it is in the heartland of the European pharmaceutical industry, which is not a coincidence.

CEO Philippe Wolgen said the company's visibility has improved substantially with the international pharmaceutical industry, with the company playing without an audience when it was based in Melbourne (the company maintains its registered office in Melbourne). In terms of listings, the company believes the ASX is sufficient and saw no need to list on a US exchange.

Cont'd over

– Clinuvel cont'd

EPP Market Size

In Italy, the company says it has a market penetration of 22%. There are 47 families that are repeat users of the therapy, around 200 known patients in EPP in Italy and it's estimated that there are a further 200 undiagnosed people with the condition.

The company does not actively market the therapy in Italy. If the company could get a 40% penetration rate in Europe once the therapy is widely approved, with an annual sale price per user of $20,000, then sales of $32 million a year could be achieved. Assuming Europe makes up 40% of the global pharmaceutical market, then we reach potential future sales for EPP of $85 million a year.

Vitiligo and Skin Cancer Prevention

The treatment for vitiligo is relatively new. The first scientific paper describing the use of narrow band UVB to treat vitiligo first appeared in 2004 with more decisive papers emerging in 2008. It was previously thought that skin cells without pigmentation could not be repigmented. However it was discovered that activation by narrow band UVB encourages migration of melanocyte stem cells based in the hair follicles which causes restoration of natural pigmentation in the skin.

Clinuvel believes Scenesse can speed up the repigmentation process. It has treated 27 people to date for vitiligo, with a Phase II study underway in Europe and the US in 60 people. Interim results are expected in Q1 2012.

This is a large market with more than 45 million affected by the condition. There is strong interest to have the product developed for the US market, according to Wolgen.

The problem with narrow band UVB therapy is that it is very onerous and expensive, requiring treatment for 18 months, three times a week. The Phase II trial underway will investigate how this treatment timeframe can be reduced.

A treatment for vitiligo has been demanded for decades says Wolgen and narrow band UVB has unlocked this market. We believe it is potentially the jewel in Clinuvel's crown. However to bring it to market may involve testing in 1000-1500 people and may cost $50 million. It is for this reason EPP is the first target market.

Skin Cancer Prevention

The third target market for Clinuvel is skin cancer prevention for people at risk of developing skin cancers. This initially is targeted at people who have received an organ transplant, which is around 200,000 people. However this indication could be expanded to other high risk people, such as those who have developed numerous skin cancers. Ironically, the product was originally being developed for the prevention of melanomas.

Sales/Marketing Partner

Clinuvel has a number options with marketing its products. It can sell its product independently, which for EPP is a realistic possibility given it is a niche market, a large part of which already knows about Scenesse.

Cont'd over

EPP - A Patient's Perspective

At this year's AGM, shareholders heard from an Australian woman, Anne, who suffers from the condition EPP (Erythropoietic Protoporphyria). She has had the symptoms of EPP since birth, with doctors initially believing symptoms were due to an allergy to grass. Aside from having EPP, she has no other health issues and is completely normal in every other regard. She was finally diagnosed with EPP at the age of 30.

Anne gave a disturbing insight into living with EPP, which she said has brought absolute horror to her life. Anne's childhood and teenage years were a nightmare. The EPP reactions are caused by light, mainly sunlight, but all light can trigger a reaction. She needs to be careful to not sit next to a window or even under a skylight. Light from a computer, plasma TV or even a sowing machine can cause a painful reaction.

Severe reactions can last for six weeks after exposure to the light. There are no cures, and she has tried all potential therapies over 35 years, including regular blood transfusions. No pain killers take away or reduce the pain, which she likens to peeling off your skin, placing barbed wire underneath and then pouring boiling hot water over. Only continuous valium alleviates the pain which was described as absolutely excruciating, unbearable and unending, although you end up "living with the fairies" on valium. And this is a women who has three children. Surviving a severe reaction involves sitting in a dark room for six weeks dribbling cold water over the affected areas. For Anne, she is most affected with EPP on the hands and feet.

EPP is a familial disease. Her brother also has EPP, two of his children have EPP, and it is likely two of his grandchildren will have EPP. People with EPP seem to have formed a close group. Anne mentors a 22 year old women in how to live with this debilitating condition.

Also of interest, Anne described the treatment with Scenesse. Anne was in one of the EPP Clinuvel clinical trials. There was a placebo group in the trial. Anne said within two weeks she knew she was not in the placebo group. She could wear sandles for the first time without socks. She could walk to the supermarket and wait at bus stops. She could go to picnics and barbeques. She even went to the Melbourne Zoo on a hot day. "It was joyous".

For the first time in her life Anne could even enjoy the beach, sitting on Airley Beach with her granddaughters and going to Lorne beach in bathers.

On the overall effect of Scenesse, Anne said there were no negative side effects at all, only benefits. With Scenesee being available in Italy, Anne joked (maybe she was serious) that she would gladly become an Italian tomorrow if she could.

There is no treatment for this condition Anne said, and it has the possibility to change her life. “We are all desperate. Every person who has tried Scenesse wants it.”

Bioshares Model Portfolio (11 November 2011)

Company	Price (current)	Price added to portfolio	Date added
QRxPharma	$1.62	$1.66	October 2011
Mayne Pharma Group	$0.455	$0.435	September 2011
Genetic Technologies	$0.15	$0.18	August 2011
Acrux	$3.20	$3.37	June 2011
Bioniche	$0.69	$1.35	March 2011
Somnomed	$1.12	$0.94	January 2011
Phylogica	$0.057	$0.053	September 2010
Biota Holdings	$0.76	$1.09	May 2010
Tissue Therapies	$0.55	$0.21	January 2010
Atcor Medical	$0.08	$0.10	October 2008
Impedimed	$0.65	$0.70	August 2008
Bionomics	$0.40	$0.42	December 2007
Cogstate	$0.26	$0.13	November 2007
Sirtex Medical	$4.60	$3.90	October 2007
Clinuvel Pharmaceuticals	$1.55	$6.60	September 2007
Pharmaxis	$1.31	$3.15	August 2007
Universal Biosensors	$0.90	$1.23	June 2007
Alchemia	$0.29	$0.67	May 2004

Portfolio Changes – 11 November 2011

IN:
No changes

OUT:
pSivida has been removed from the portfolio at $2.03 following a Complete Response letter from the FDA being received by its licensee for Illuvien, Alimera Sciences.

– Clinuvel cont'd

The second option is to license the product, either globally (unlikely) or for regions (more likely) and for particular indications.

The third option is that the company could be acquired. This is also a realistic option.

Wolgen said there is moderate-to-strong interest in the technology from pharmaceutical companies.

Clinuvel has indicated that it will require additional funds next year. This can come from either a capital raising, from licensing income, or from debt finance. It is likely that the company will consider its funding options once European Phase III trial results for EPP have been released (trial CUV029), once Scenesse has been filed for regulatory approval in Europe and after results are released from the company's Phase II vitiligo trial.

Safety Data

Over 600 patients have been treated with Scenesse with no serious safety issues. Supporting the safety profile of the drug is that it has been in use in Italy since 2007, supporting longer term use of the drug.

The benefit of selling its drug now in Italy, is not only from confirming safety, but also ensuring manufacturing is ready. To date three commercial batches have been approved for use.

Potential Gain for Investors – The Surge Scenario

For whatever reasons, Clinuvel has shown to not be a stock that appreciates in market value with commercial and development progress. Gains in this stock will more likely be from one or two major share price surges that may occur from approval, licensing or acquisition of the company.

Regulatory Approval Timeline

In mid November Clinuvel will meet with the two rapporteurs in Europe that will be responsible for considering Scenesse for wider approval in Europe. It expects to file for approval in mid December. Then in mid June, it can be called to present its case to the CHMP in Europe, which Wolgen is in favour of doing. We expect a decision from European regulators in the second half of 2012.

Summary

Scenesse offers what appears to be an excellent treatment for a truly unmet clinical need. It has been a difficult commercialisation program, not least because its evaporating patent position in early days, and because of the incorrect positioning of the therapy as a tanning agent, which was never going to gain approval from regulators. The latter made the task of developing the product significantly more difficult.

While developing Scenesse, Clinuvel has been able to improve awareness of the disease and the potential of its product, not only with regulators, but also with patients and physicians. The company has a ready market for its drug, which is very rarely the case in drug development. Clinuvel has also made sure that its drug candidate is positioned as a first line therapy for EPP and vitiligo.

Clinuvel has indicated that it will need to raise funds. We view its funding risk as medium.

Clinuvel is capitalised at $47 million, holding cash of $11.5 million at September 30, 2011.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

Sunshine Heart – Too Little, Too Long, Too Hard

Sunshine Heart (SHC: 4.0 cents) has released the full results from its 20 patient feasibility study with its heart assist device, C-Pulse. The results were presented on Monday to the Transcatheter Cardiovascular Therapeutics symposium on Monday by the co-lead principal investigator to the study, Dr William Abraham.

Quality of Life iImprovement - Statistically Significant

On one the primary endpoints, and perhaps the most import measure of efficacy, quality of life, there was an improvement, from 64 (MLWHF quality of life score) to a MLWHF score of 49 (a decrease is considered an improvement).

Change in NYHA Ranking - Statistically Significant with 12/20 Improvement

There was a statistically significant improvement in classification of disease status, as defined by New York Heart Association ranking (with an overall reduction from 3.2 top 2.2). Of the patients in the trial, 18 were considered Class III and two Class IV.

Of the 20 patients, 12 improved in class ranking and eight remained the same. Of these, four improved to Class I.

Change in Six Minute Hall Walk (6MHW) - Not Statistically Significant

This test measures how far the patients could walk in six minutes, both before implant and after implant at three and six months. This result was not statistically significant, with only about a 20 meter improvement on average. Fourteen of the patients remained unchanged in this measure, five improved by more than 50 meters and one patient deteriorated by more than 50 meters.

Change in Left Ventricle Ejection Fraction - Statistically Significant

There was a statistically significant improvement in pump of the heart, as measured by left ventricular ejection fraction. However this result was disappointing, with only around a 10% improvement, from 28% to 31%. Normal ejection fractions are in the range of 55% to 70%.

Overall Improvements

Two patients (super responders) were removed from the therapy as a result of improvement in health, three were successfully bridged to a heart transplant, and two more patients are likely to be permanently discontinued as a result of improvement to a Class 1 NYHA status.

Summary

The feasibility study produced mixed results. On the most meaningful measure, quality of life, there was a clear improvement, and also in patients improving in heart disease class, patients being removed from therapy, and also a drop in pharmaceutical usage.

What was disappointing was the change in the six minute hall walk and the small improvement in ejection fraction.

Sunshine Heart will now need to raise around $40 million in our view to progress to a pivotal study, which will be difficult in current financial markets and given the company's market value. A sale of the business is also a possibility.

Sunshine Heart is capitalised at $48 million and had $10.5 million at the end of September.

Bioshares recommendation: **Sell**

Bioshares

Bluechiip – Evaluation Agreements to Drive Validation

Progress has been made at Bluechiip (BCT: $0.20), which announced it had signed an evaluation deal for its bio-storage tracking technology with the life sciences division of Corning, a US$24 billion company by capitalisation.

Corning reported sales of US$6.6 billion in 2010, with its Life Sciences Division posting sales of US$531 million.

The evaluation program is expected to take three months to complete. Bluechiip has developed a tracking button that Corning's LSD will place in vials, thus creating 'smart' tubes. If successful, then more decisions will have to be made by Bluechiip regarding a plastic-molding partner and distribution arrangements.

Corning's interest in Bluechiip's technology is based on a desire to ensure it can offer premium, innovative products to customers. In addition, Corning has a position in cryo-storage, which is a lead product opportunity area identified by Bluechiip.

The Corning deal is the third deal signed by Bluechiip in recent months. Also in November, the American Type Culture Collection (ATCC), a leading biological materials resource and standards organization, signed a collaborative evaluation and pilot agreement with Bluchiip. Acceptance of the Bluechiip tracking solution by a bio-storage organisation the size, calibre and reputation of the ATCC would provide important commercial validation for Bluechiip.

In September an unnamed bio-repository and bio-banking services provider also signed a collaborative evaluation and pilot agreement.

By the end of 2012 Q1and if all goes well with its evaluation programs, Bluechiip can then begin the task of executing commercial agreements. Bluechiip is capitalised at $11 million and retained cash of $0.9 million at September 30, 2011.

Bioshares recommendation: **Speculative Buy Class B**

Bioshares

Mesoblast Expands Clinical Development Opportunities

Mesoblast (MSB: $8.00) has delivered several announcements to the market in recent weeks which reveal the breadth of opportunities available to its novel adult stem cell technology.

The lead product opportunities for its mesenchymal pre-cursor stem cell (MPC) technologies are in treating bone and muscle related medical conditions, which are logical application areas given that mesenchymal stem cells give rise to bone, cartilage and are involved in muscle formation.

The company is currently managing six trials of Neofuse (MPCs from a single donor), examining the safety and efficacy of the product in treating degenerative disc disease, spondylolisthesis, spinal stenosis and cervical degenerative disc disease. A trial of Replicart, combined with Hyaluronan, for treating osteoarthritis following ACL reconstruction is underway. Two trials of its cardiovascular product Revascor are underway, with one completed and one in the LVAD setting terminated. (See table next page)

However, more treatment possibilities have emerged from pre-clinical research programs and no doubt supported by insights gained in human trials conducted to date. One hypothesis driving new research and clinical programs is that MPCs are multi-functional that induce complex cellular messaging activity, restoring a disease state to a normal state.

Mesoblast announced in October that it would commence a Phase II trial in patients with age-related macular degeneration, a condition in which leaky blood vessels cause blindness.

The 18 patient Singapore-based trial will compare the addition of Mesoblast's MPCs to the anti-VEGF agent Lucentis, to treatment with Lucentis alone. More trials are expected to follow in Asian and non-Asian population.

The trial is backed by several pre-clinical studies which showed in one study that a single injection of MPCs into the rats with induced excessive blood vessel at day 28, only 9% of blood vessels in treated eyes were leaking severely compared with 28% in control eyes. In a second study in non-human primates, it was shown that a single injection of MPCs along with the anti-VEGF agent Lucentis reduced severity of blood vessel leakage within two weeks, reduced the formation of new blood vessels within two weeks and prevented retinal detachment by day 42, compared to Lucentis alone.

Diabetes Pre-clinical Results

This week Mesoblast released results of a pre-clinical study of MPCs injected into 17 non-human primates with Type 2 diabetes. Four groups of treated subjects received different (escalating) doses of a single injection of MPCs against a control group which received saline. Over eight weeks every treatment group reported clinically meaningful reduced glucose levels. The trial reported a dose dependent effect, with highest doses of MPCs having a greater effect and the highest dose having a more sustained effect. The trial also reported a direct correlation between treatment and falling levels of C-reactive protein, a marker of inflammation.

Mesoblast plans to commence a randomised, placebo controlled trial of MPCs in Type 2 diabetes in 2012 Q1, once discussions with the FDA have taken place

Comment

Our comment on Mesoblast's continued expansion into new indication areas is that it could consider raising additional capital to fund the Phase III development of products in areas that have clinical and commercial merit.

Heart Failure Data Conference Presentation Ahead

Next week, clinical investigators will present the full results of the 60 patient Phase II trial of Revascor applied to the treatment of congestive heart failure. The results will be presented by Dr Emerson Perin at the Scientific Sessions of 2011 American Heart Association conference in Orlando, Florida

Some data from the trial is available for the 18 month follow-up point in the trial, including that there was a 50% decrease in serious adverse cardiac events and an 80% reduction in major adverse cardiac events. There was a 13% cardiac-related mortality in the control group compared to 0% in the treatment arm.

We would expect the full results to disclose more detail on the patients' response to the treatment. For investors, a key outcome of the presentation will be how the results are perceived by other cardiologists and cardiovascular surgeons.

Summary

Valuations of medical product development companies are subject to a greater range of probabilities and probability ranges than revenue-generating industrial companies. Within the framework of assessing speculative biotech investments, what is of importance to investors is how a company goes about mitigating and reducing risk and leveraging and locking in upside.

While there is clinical, long term safety, regulatory, pricing and market access risk outstanding for Mesoblast, it is worth noting that funding and manufacturing risks have been lessened considerably (though not entirely disposed of), both of which form a significant component of the company's current market-ascribed valuation. Manufacturing control and capital surety are the foundations for Mesoblast's objective of addressing many large market opportunities in the cardiovascular, orthopaedics, diabetes, inflammatory and opthalmic areas.

Mesoblast is capitalised at $2.2 billion and retained cash of $260 million at September 30, 2011

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

Mesoblast Clinical Trials Summary

ONGOING/PLANNED

Product	Indication	Phase	Start	Final Data Collection	Study Completion Date	Design	Pts	Primary Endpoints	Secondary Endpoints	Control or # Arms or Comparator
Neofuse Studies										
A Dose-escalation Study to Assess the Feasibility and Safety of 3 Different Doses of NeoFuse When Combined With MasterGraft Granules in Subjects Requiring Posterolateral Lumbar Fusion With Instrumentation.										
Neofuse	Posteraleteral Lumber Fusion	Phase I/II	Oct-07	Oct-11	Mar-12	Open Label, Randomized, Dose Escalation	40	Safety (30 days)	Overall fusion success (3 yrs)	6 arms
A Prospective, Multicenter, Randomized, Open-Label, Controlled Study Evaluating Safety and Preliminary Efficacy of NeoFuse When Combined With Mastergraft Granules in Subjects Undergoing Posterolateral Lumbar Fusion With Instrumentation										
Neofuse	Posteraleteral Lumber Fusion	Phase I/II	Nov-08	Nov-11	Nov-11	Randomized, Single Blind	24	Safety 24,26 months	Overall fusion success (3 yrs)	Compares autologous bone graft - 4 arms
A Prospective, Multicenter, Randomized, Open-Label, Controlled Study Evaluating Safety and Preliminary Efficacy of NeoFuse When Combined With MasterGraft Matrix in Subjects Undergoing Lumbar Interbody Fusion With Instrumentation										
Neofuse	Posteraleteral Lumber Fusion	Phase II	Sep-09	Jul-12	Jul-14	Randimized, Single Blind	24	Safety at 3 years	Efficacy of fusion at 3 yrs	Compares autologous bone graft - 3 arms
Phase 2 Study Evaluating Safety and Preliminary Efficacy of NeoFuse When Combined With MasterGraft Matrix in Subjects Undergoing Multi-Level Anterior Cervical Discectomy and Fusion With Anterior Cervical Plate Fixation										
Neofuse **[US Trial]**	Cervical Discectomy and fusion	Phase II	Jun-10	Dec-11	Dec-12	Randomized, Single Blind	24	Safety at 2 years	Fusion Success at 1 year	Compared to allograft spacer
Phase 2 Study Evaluating Safety and Preliminary Efficacy of NeoFuse When Combined With MasterGraft Matrix in Subjects Undergoing Multi-Level Anterior Cervical Discectomy and Fusion With Anterior Cervical Plate Fixation										
Neofuse **[Aust Trial]**	Cervical Discectomy and fusion	Phase II	Jun-10	Jun-12	Jun-13	Randomized, Single Blind	12	Safety at 2 years	Fusion Success at 1 year	Compared to allograft spacer
A Prospective, Double Blind, Controlled Study Evaluating Safety and Preliminary Efficacy of a Single Injection of Adult Mesenchymal Precursor Cells (MPCs) Combined With Hyaluronan in Subjects With Chronic Discogenic Lumbar Back Pain										
Neofuse	Degenerative Disc Disease	Phase II	Aug-11	Jul-13	Jul-15	Randomized, Double Blind	100	Safety at 3 years	Efficacy in pain reduction [1-36 mo]	4 Arms: HA soln, sham, Low dose MPCs & HA, High dose MPCs and HA
Replicart Studies										
Phase 2 Study to Assess Safety & Tolerability of a Single Injection Into the Knee Joint of Two Different Doses of MSB-CAR001 Combined With Hyaluronan Compared to Hyaluronan Alone in Patients Who Have Undergone an ACL Reconstruction										
Replicart	Anterior Ligament Reconstruction	Phase I	Mar-09	Jun-13	Jun-14	Double-blind, Randomized	24	Safety after 24 months	Efficacy at 2 yrs	
Revascor Studies										
A Phase 1b/2a Dose Escalation Study to Assess the Safety and Feasibility of Transendocardial Delivery of 3 Different Doses of Allogeneic Mesenchymal Precursor Cells (MPCs) in Subjects With Recent Acute Myocardial Infarction										
Revascor	Heart Attack (Damaged Heart)	Phase I/II	Mar-08	Dec-13	Dec-13	Randomized, Single Blind, Dose Escalation	25	Safety (30 days)	Cardiac function (090,180,360 d); Safety (360 days)	6 arms - 3 Revascor, 3 SOC
The **AMICI** trial (Allogeneic Mesenchymal precursor cell Infusion in Myocardial infarction)										
Revascor **[EU Trial]**	Heart failure after heart attack	Phase II	ANN: 2011 H2			Randomized, Single Blind	225	Safety and efficacy (6 months)	Durability of effect to 36 months	Placebo
Other Studies										
Adult Mesenchymal Precursor Stem Cells	Bone Marrow Transplantation	Phase III	N.A	N.A	N.A	N.A	N.A	N.A	N.A	N.A
Adult Mesenchymal Precursor Stem Cells	Cord blood expansion (hematological malignancies)	Phase III	ANN: 2011 H2			Randomized	240	N.A	N.A	N.A
A trial to evaluate the safety and effectiveness of a single intra-ocular injection of MPCs combined with the anti-VEGF agen Lucentis in newly diagnosed wet AMD patients										
Adult Mesenchymal Precursor Stem Cells	Eye disease (Wet AMD)	Phase II	ANN: 2011 H2			Placebo-controlled	18	N.A	Visual acuity and quality of life	Lucentis alone
TERMINATED										
The Effect of Intramyocardial Injection of Mesenchymal Precursor Cells on Myocardial Function in LVAD Bridge to Transplant Patients										
Revascor	Heart Failure - LVAD Implantation	Phase II								
COMPLETED										
A Phase II Dose-escalation Study to Assess the Feasibility and Safety of Transendocardial Delivery of Three Different Doses of Allogeneic Mesenchymal Precursor Cells (MPCs) in Subjects With Heart Failure										
Revascor	Heart Failure	Phase II	Aug-08	Jul-11	Jul-11	Single-blinded, dose-escalation, cohort study	60	Safety	Efficacy at 3,6 and 12 months	45 pts treatment group; 15 pts S.O.C

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, Patrys, LBT Innovations, Mesoblast, Atcor Medical, Tissue Therapies, Viralytics, Phosphagenics, Immuron, Phylogica, Bluechiip, pSivida, Antisense Therapeutics, Benitec, Allied Healthcare Group

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