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**In this edition...**
What does it take to make a pharmaceutical business? An ability to access the necessary funding is one major factor, something ably demonstrated by Pharmaxis. This company continues its march towards commercialisation of Bronchitol, with the launch of this therapy for cystic fibrosis patients in Europe expected in 2011.

In our analysis of quarterly cash balances we observe an increase in the number of companies experiencing financial stress. Some companies continue to survive on a quarter by quarter basis, although we have seen an increase in the number of companies being re-capitalised and used for new non-biotech busines activities this year.
**The Editors**
**Companies Covered: PXS, 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 - Current) | 23.5% |
| **Cumulative Gain** | **140%** |
| **Av Annual Gain (8 yrs)** | **14.7%** |

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# Bioshares

**7 August 2009**
**Edition 323**

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

## *Pharmaxis – Still On Track To Become Australia's Most Successful Drug Development Business*

Pharmaxis is an example for the broader Australian investment community of the true potential of investment in Australia's biotechnology sector. Its lead product, Bronchitol for the treatment of cystic fibrosis, is due to be filed with UK regulators for European approval by the end of next month. If all goes to plan, and it has so far, the drug should be on the market in Europe at the beginning of 2011, and later that year for sale in the US.

Pharmaxis is now capitalised at $530 million. The reason for the high value being placed on the company is that it is seeking to enter a market in which it could generate revenues of at least US$200 million, and as high as US$400 million. The leading product on the market, Pulmozyme, sold by **Genentech/Roche**, generated sales last year of US$476 million. Sales increased by over 50% from 2005 to 2008.

Pharmaxis' Bronchitol generates a similar improvement in lung function to Pulmozyme. It can be used in conjunction with Pulmozyme, which gives patients and a further benefit of 5.2% improvement in lung function. However, the advantage that Bronchitol has over Pulmozyme is that it takes only 3-4 minutes to administer, in a portable hand held device, compared to 20 minutes for Pulmozyme, which needs to be delivered by a nebulizer.

Pharmaxis is working from a position of strength, with limited reliance on third parties. It is keeping the option open of selling the product direct, which the company believes can be successfully conducted globally with a sales force of only 40 people. This is because of the narrow distribution channels in place through the cystic fibrosis treatment centres. In the US there are only 110 CF centres, with Europe more fragmented but still reachable with 350 centres.

The company currently has an office and a marketing team in the UK for its Aridol lung function test. This base will likely be used to build its European Bronchitol marketing team, with the company estimating 25 people being required to service the top five markets in Europe (UK, Germany, France, Spain and Italy). However a decision has not been made yet as to what mix of direct or distributor sales teams will be used.

Pharmaxis has built a manufacturing plant that has sufficient capacity to produce product for 40,000 patients a year. The US and Europe each have around 30,000 people afflicted with CF. Pulmozyme is used by about 50% of people with CF in the US and by about 40% in Europe. The plant is expected to be ready for production by mid next year.

### Sales Expectations

Pharmaxis has expectations that its product will generate sales of Bronchitol in the CF market on par with Roche's Pulmozyme, which is currently generating sales of close to

*Cont'd over*

US$500 million. Pulmozyme generates an improvement in lung function of 5.6%. In the Phase III study reported in May, Bronchitol generated an improvement in lung function of 6.5%. The key factor in favour of Bronchitol is in its delivery, a hand-held puffer. A common complaint from people with CF is the high daily treatment burden of therapies, both drug and physical lung percussion. There is also an added benefit of 5.2% in lung function if Pulmozyme and Bronchitol are used together, with the drugs working through different mechanisms.

This Phase III data suggests that a reasonable percentage of people using Pulmozyme should switch to Bronchitol, as well as many patients using both drugs. There will be some people for whom Pulmozyme will work better, and in some patients the benefit from Bronchitol will far exceed 6.5%. With these drugs, unlike an antidepressant or a blood pressure drug, the patient almost immediately notices whether the drug is helping the clearance of mucous from the lungs.

Given the high usage of Pulmozyme, that there is an existing market, the narrow distribution channels through CF centers, and the active and vigilant approach to new drug therapies by CF communities – about 30% of all people with CF have been in some form of clinical trial – we expect that the adoption of Bronchitol, should it be approved, to be reasonably rapid once reimbursement is achieved. We are anticipating sales of US$200 million a year to be achieved within three years of market launch in Europe, and could subsequently reach US$400 million a year. There is also the potential for the lung function test Aridol to make a more meaningful contribution to sales ($595,000 last financial year) and for Bronchitol to be used in the treatment of bronchiectasis, a broader degenerated lung condition which predominantly affects people above the age of 55. The first approval for Bronchitol is expected to be in Australia this year for the treatment of bronchiectasis.

### Development Risk & Regulatory Approval

For Europe, there is the final regulatory risk, with Bronchitol to be filed for approval in Europe by the end of next month. For the US, a second Phase III trial in 300 people is being conducted. Over 200 have now been enrolled with results expected in the first quarter of next year. To date all trial results for Bronchitol have been clearly positive. This will be the last major technical hurdle for the company.

Bronchitol is expected to reach the market for treatment of bronchiectasis next year in Australia, in early 2011 in Europe for CF and late 2011 for CF in the US. The drug has orphan drug status in Europe (up to 12 years market exclusivity) and the US (seven years market exclusivity). We anticipate the regulatory process will be accelerated due to the severity of this disease, which causes fatalities in children and where the average life expectancy is less than 40 years of age.

In Europe the drug will be released first in Germany and the UK, where there is free pricing and reimbursement does not need to be negotiated. France, Italy and Spain, where reimbursement will need to be negotiated, will follow. By year's end the company expects to have a comprehensive dossier on the health-economic benefit of its drug, which will be used to negotiate pricing.

Pulmozyme sells for US$13,000 in Europe and US$22,000 in the US. The company will seek to match the 'sensible price' that has been negotiated in these regions for Pulmozyme, although healthcare reform issues in the US may provide some challenges in achieving the Pulmozyme price in that region.

### Future Value of Pharmaxis

**Cochlear** currently trades on a price-to-sales multiple (capitalisation/annual sales) of 4.7 times. **Resmed** trades a multiple of 3.7 times. **Sirtex Medical**, which we believe to remain considerably undervalued given its potential to continue with very strong sales growth, trades on a price-to-sales multiple of 3.7 times. Pharmaxis should have a considerably higher gross margin on its product than Cochlear (gross margin 72%) and ResMed (gross margin 59%), at close to 90%. Sirtex Medical currently generates a gross margin of 80%. We would expect Pharmaxis could trade on a multiple of between 5-7 times sales.

If Pharmaxis could generate sales of between US$200 – US$400 million, then the company could potentially be worth between A$1.2 billion – A$3.3 billion when these sales are achieved.

### Summary

Pharmaxis currently has 110 employees. At the end of June the company had $125 million in cash to fund the rollout of its product. To date close to $130 million has been spent on development of its products, which combined, these two sums represent around 50% of the company's current market value.

With one final technical hurdle to go for the US in the form of the second Phase III trial, Pharmaxis continues to edge closer to become Australia's most successful drug development business.

*Bioshares* recommendation: **Speculative Buy Class A**

**Bioshares**

# *4.7B Reporting Companies – Cash Balances June 30, 2009*

## *Sorted by Survival Index*

| | Code | Company | Cash Receipts ($M) | Cash End 30/06/09 ($M) | | Survival Index | Events since June 30; other comments |
|---|---|---|---|---|---|---|---|
| 1 | AVS | Avastra | $52.6 | $0.7 | A | **Not App** | |
| 2 | UNI | Unilife | $33.3 | $4.7 | A | **Not App** | |
| 3 | CTE | Cryosite | $6.8 | $1.3 | A | **Not App** | |
| 4 | BPH | Biopharmica | $0.0 | $0.4 | A | **Not App** | |
| 5 | IMU | Imugene | $0.0 | $2.5 | A | **Not App** | |
| 6 | CGS | Cogstate | $7.1 | $3.0 | A | **Not App** | |
| 7 | LBT | Labtech Systems | $1.8 | $3.2 | A | **Not App** | |
| 8 | RHT | Resonance Health | $2.0 | $2.6 | A | **Not App** | |
| 9 | CBB | Cordlife | $20.2 | $7.1 | A | **Not App** | |
| 10 | BRC | Brain Resource Corp | $4.6 | $16.8 | A | **Not App** | |
| 11 | SIE | Scigen | $8.1 | $6.1 | CY | 44.1 | |
| 12 | NDL | NeuroDiscovery | $2.3 | $1.4 | A | 13.4 | |
| 13 | ACG | Atcor | $11.3 | $3.4 | A | 5.4 | |
| 14 | PAA | Pharmaust | $1.7 | $3.8 | A | 4.9 | |
| 15 | PXS | Pharmaxis | $1.0 | $125.0 | A | 4.7 | |
| 16 | HXL | Hexima | $0.2 | $30.2 | A | 4.2 | |
| 17 | CUV | Clinuvel Pharmaceuticals | $0.0 | $37.7 | A | 3.4 | |
| 18 | ACW | Actinogen | $0.0 | $1.9 | A | 3.4 | |
| 19 | SOM | Somnomed | $7.4 | $4.0 | A | 3.1 | |
| 20 | SPL | Starpharma | $8.8 | $11.6 | A | 2.8 | |
| 21 | UBI | Universal Biosensors | $3.8 | $22.3 | CY | 2.7 | |
| 22 | BDM | Biodiem | $3.0 | $4.0 | A | 2.5 | |
| 23 | ATW | Atos Wellness | $26.6 | $2.6 | A | 2.1 | |
| 24 | NAL | Norwood Abbey | $0.1 | $0.4 | A | 2.1 | |
| 25 | MSB | Mesoblast | $0.2 | $16.5 | A | 2.0 | |
| 26 | UCM | USCOM | $1.6 | $1.9 | A | 1.9 | |
| 27 | EMS | Eastland Medical Systems | $13.0 | $2.8 | A | 1.9 | |
| 28 | HGN | Halcygen | $0.0 | $7.9 | A | 1.9 | |
| 29 | GTG | Genetic Technologies | $9.8 | $7.8 | A | 1.6 | |
| 30 | NAN | Nanosonics | $0.1 | $13.9 | A | 1.5 | |
| 31 | ACR | Acrux | $1.2 | $14.8 | A | 1.5 | |
| 32 | OBJ | OBJ | $0.5 | $1.5 | A | 1.5 | |
| 33 | BPO | BioProspect | $0.1 | $2.4 | A | 1.4 | |
| 34 | PAB | Patrys | $1.0 | $9.6 | A | 1.2 | Undertaking $6.8 M Rights Issue ($5 M u/w) |
| 35 | BOD | BioMD | $0.0 | $1.2 | A | 1.2 | |
| 36 | ACL | Alchemia | $0.0 | $8.3 | A | 1.2 | |
| 37 | QRX | QRxPharma | $0.0 | $17.8 | A | 1.0 | |
| 38 | XCD | Xceed Capital | $4.9 | $1.0 | A | 1.0 | |
| 39 | BNO | Bionomics | $5.5 | $4.8 | A | 1.0 | |
| 40 | GBI | Genera Biosystems | $0.0 | $3.3 | A | 1.0 | |
| 41 | ANP | Antisense Therap. | $3.5 | $3.1 | A | 0.9 | |
| 42 | HCG | Helicon Group | $0.0 | $0.8 | A | 0.9 | |
| 43 | AVH | Avita Medical | $2.4 | $4.1 | A | 0.9 | Secured $5 M facility from Fortrend |
| 44 | BLT | Benitec | $0.2 | $1.9 | A | 0.9 | |
| 45 | PYC | Phylogica | $0.0 | $3.1 | A | 0.8 | |
| 46 | KSX | KarmelSonix | $0.1 | $3.0 | A | 0.8 | |
| 47 | CXD | CathRx | $0.1 | $7.3 | A | 0.7 | Completed $5.3 Rights Issue and $1.6 M placement |
| 48 | MGZ | Medigard | $0.0 | $0.3 | A | 0.7 | |
| 49 | MVH | Medic Vision | $1.8 | $0.7 | A | 0.6 | |
| 50 | PBT | Prana Biotechnology | $0.0 | $4.3 | A | 0.6 | |
| 51 | IPD | Impedimed | $3.4 | $6.6 | A | 0.6 | Rights issue net proceeds of $6.6 M expected |
| 52 | LCT | Living Cell Technologies | $0.2 | $2.9 | A | 0.5 | Placement raised $4.2 M |
| 53 | BIT | Biotron | $0.0 | $1.0 | A | 0.5 | |
| 54 | PRR | Prima Biomed | $0.0 | $0.9 | A | 0.5 | Access to $25.5 M Convertible Loan facility |
| 55 | ADO | Anteo Diagnostics | $0.7 | $1.0 | A | 0.5 | |
| 56 | TDX | Tyrian Diagnostics | $1.5 | $3.4 | A | 0.5 | Ann. rights Issue to raise $5M |
| 57 | ALT | Analytica | $0.0 | $0.5 | A | 0.5 | Conducting SPP |
| 58 | AVX | Avexa | $0.0 | $18.8 | A | 0.5 | Has access $2M in CSIRO funding |
| 59 | STI | Stirling Products | $0.4 | $0.9 | A | 0.4 | |
| 60 | VLA | Viralytics | $0.0 | $1.3 | A | 0.4 | Raised $0.9 M in options rigght issue; acces to US$6 M convertible notes |
| 61 | ICV | Incitive | $0.0 | $0.4 | A | 0.4 | Change of business - has acq. V-Patch Medical Systems |
| 62 | FER | Fermiscan | $2.4 | $3.2 | CY | 0.4 | |
| 63 | AYX | Austofix | $1.8 | $0.6 | A | 0.4 | Still to access $1.2 M under IFSA program |

# *4.7B Reporting Companies – Cash Balances June 30, 2009*

## *Sorted by Survival Index*

| Code | Company | Cash Receipts ($M) | Cash End 30/06/09 ($M) | | Survival Index | Events since June 30; other comments |
|---|---|---|---|---|---|---|
| 64 PLI | Peplin | $0.7 | $22.1 | CY | 0.3 | |
| 65 TIS | Tissue Therapies | $0.0 | $0.8 | A | 0.3 | |
| 66 SHC | Sunshine Heart | $0.0 | $2.0 | A | 0.3 | Raising up to $8 M |
| 67 NEU | Neuren Pharmaceuticals | $0.0 | $0.6 | CY | 0.2 | Conducting SPP |
| 68 SLT | Select Vaccines | $0.0 | $0.1 | CY | 0.2 | |
| 69 FYI | Freedom Eye | $0.0 | $0.2 | A | 0.2 | Raising $575 K |
| 70 ACU | Acuvax | $0.0 | $0.2 | A | 0.2 | |
| 71 FLS | Fluorotechnics | $3.3 | $0.7 | A | 0.2 | Ann. Rights Issue to raise $1 M |
| 72 RBY | Rockeby Biomed | $1.2 | $0.2 | A | 0.2 | Can access $500K in credit facility |
| 73 PCC | Probiomics | $0.9 | $0.1 | A | 0.2 | |
| 74 SLA | Solagran | $0.2 | $0.5 | A | 0.2 | Ann. Placement for $5.54 M |
| 75 MTY | Medical Therapies | $0.0 | $0.2 | A | 0.1 | Raised $550 K in placement |
| 76 IMI | IM Medical | $0.5 | $0.3 | A | 0.1 | Balance of drawdown facility is $4.4M |
| 77 HTX | Healthlinx | $0.1 | $0.2 | A | 0.1 | |
| 78 OMI | Occup.& Medical Innov. | $1.8 | $0.2 | A | 0.1 | Conducting fundraising |
| 79 BOS | Biosignal | $0.2 | $0.1 | A | 0.1 | IP sold; is acquiring assets of RGM Entertainment |
| 80 GIA | Giaconda | $0.0 | $0.03 | A | 0.1 | Has access to loan facility |
| 81 BNE | Bone Medical | $0.0 | $0.01 | A | 0.0 | Undertaking a placement to raise up to $1 M |

**Legend:**

**Not App.** : The SI calculation for these companies is not calculated due to the companies reporting positive operational cash flows, or in some cases marginally negative operational cash flows.

**A**: The SI calculation for these companies is based on the last four quarters' figures, annualised.

**CY**: The SI calculation for these companies is based on the average of the latest two quarters' figures, annualised.

*Advanced Medical Design and Manufact., Agenix, Imuron, Arana Therapeutics, Biota Holdings, Cellestis, Circadian Technologies, Clovercorp, Compumedics, ChemGenex Pharm., Cyclopharm, Cytopia, Telesso Technologies, Ellex Medical Lasers, Ascent PharmaHealth, IDT Australia, ITL Corp, Life Therapeutics, Metabolic Pharmaceuticals, Medical Developments Int., Novogen, Optiscan Imaging, Progen Pharm., Polartechnics, Phosphagenics, Sirtex Medical and Virax Holdings – (26 companies).*

*Re-domiciled companies, Psvida and Heartware International no longer comply with the 4B Rule, although Peplin Inc elects to report.*

## *June Quarter Survival Index Analysis*

Each quarter, the majority of ASX listed biotech companies are required to report their cash positions. In turn, a key analytical measure we present each quarter is the 'Survival Index' (SI). The index measures how many years those cash reserves will last, based on a company's recent spending patterns. It is limited because it does not account for companies that may increase spending in the next period of activity.

The index is derived for this quarter by dividing the net operational cash flows (NOCF) for the twelve months into each company's cash assets as recorded at June 30, 2009. For companies that report on Dec 31 full year basis, the index is based on average last two quarters of NOCF, annualised. The NOCF is the net of receipts and outgoings incurred in support of operational activities.

As a rule of thumb, companies that present with an SI of less than one are likely to be raising funds to support their activities, or are in the process of doing so. A healthy SI is either two or more. Companies with SIs of less then 0.5 may be in positions of funding stress and investors should investigate such stocks with a greater degree of concern.

### Commentary

For the June quarter 2009, for 41 of 81 reporting companies we calculated SIs of less than 1.0 and for 30 companies we calculated SIs of less than 0.5, or less than six months cash. A year ago we calculated 34 out of 93 companies with an SI of less than 1.0 and 21 with an SI of less than 0.5 .

Although many companies continue to raise funds, or are seeking to raise funds, the growth in the number of companies with tenous or difficult financial prospects is consistent with the selective interest investors have exhibited in the last six months towards biotech stocks.

The overall number of cash balance reporting companies continues to fall as companies de-list (e.g. **Stem Cell Sciences**) or are recapitalised with the business focus applied to new activities outside of biotech, or a placed into administration.

One company that from the latest survey looks like it will be raising funds in the not too distant future is **Peplin**. This company held $22.1 million cash as of June, but with several pivotal trials to be completed prior to the submission of PEP005 to the FDA for

*Cont'd over*

**Bioshares Model Portfolio (7 August 2009)**

| Company | Price (current) | Price added to portfolio | Date added |
|---|---|---|---|
| ASDM | $0.32 | $0.30 | December 2008 |
| QRxPharma | $0.62 | $0.25 | December 2008 |
| Hexima | $0.60 | $0.60 | October 2008 |
| Atcor Medical | $0.19 | $0.10 | October 2008 |
| CathRx | $0.36 | $0.70 | October 2008 |
| Impedimed | $0.60 | $0.70 | August 2008 |
| Mesoblast | $1.24 | $1.25 | August 2008 |
| Cellestis | $3.66 | $2.27 | April 2008 |
| IDT | $1.68 | $1.90 | March 2008 |
| Circadian Technologies | $0.75 | $1.03 | February 2008 |
| Patrys | $0.09 | $0.50 | December 2007 |
| Bionomics | $0.23 | $0.42 | December 2007 |
| Cogstate | $0.26 | $0.13 | November 2007 |
| Sirtex Medical | $4.49 | $3.90 | October 2007 |
| Clinuvel Pharmaceuticals | $0.33 | $0.66 | September 2007 |
| Starpharma Holdings | $0.40 | $0.37 | August 2007 |
| Pharmaxis | $2.38 | $3.15 | August 2007 |
| Universal Biosensors | $0.90 | $1.23 | June 2007 |
| Biota Holdings | $2.06 | $1.55 | March 2007 |
| Probiotec | $2.14 | $1.12 | February 2007 |
| Peplin Inc | $0.58 | $0.83 | January 2007 |
| Chemgenex Pharma. | $0.58 | $0.38 | June 2006 |
| Cytopia | $0.08 | $0.46 | June 2005 |
| Acrux | $1.23 | $0.83 | November 2004 |
| Alchemia | $0.41 | $0.67 | May 2004 |

## *Portfolio Changes – 7 August 2009*

**IN:**
No changes

**OUT:**
No changes

approval, it is likely more funds will be sought. However, given that late stage of development and the body of knowledge built up about the drug, a capital raising should be relatively easy to accomplish.

**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, Cytopia, Arana Therapeutics, Starpharma Holdings, Cogstate, Bionomics, ChemGenex Pharmaceuticals, Circadian Technologies, Biota Holdings, Halcygen Pharmaceuticals, Peplin, BioMD, Impedimed, QRxPharma, Patrys, Labtech Systems, Hexima, Tyrian Diagnostics, Mesoblast, Atcor Medical, CathRx



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| | | |
|---|---|---|
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| | $750 | 4-5 email addresses |
| | $950 | 6-10 email addresses |

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