

**In this edition...**

Financial discipline at Atcor Medical is continuing to yield results with that company posting its third consecutive quarter of positive cash flows. If the company maintains this positive trajectory, then Atcor should be set to post a welcome full year profit.

Many questions remain unanswered at Pharmaxis following the failure of its Phase III bronchiectasis trial and when doubt and uncertainty prevail, investors are often better placed to wait on the sidelines. Mesoblast continues with its spine program, with positive interim clinical data from its Phase II disc repair trial revealed. Prima Biomed faces big challenges in reducing its COGS for its CVac immunotherapy.

**Companies Covered: ACG, MSB, PRR, PXS**

	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 - current)	-8.0%
<b>Cumulative Gain</b>	<b>218%</b>
<b>Av. annual gain (11 yrs)</b>	<b>17.8%</b>

*Bioshares* is published by Blake Industry & Market Analysis Pty Ltd.

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Individual Subscriptions (48 issues/year)  
**\$400** (Inc.GST)  
Edition Number 501 (3 May 2013)

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# Bioshares

3 May 2013  
Edition 501

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

## **Atcor Medical Posts Third Consecutive Positive Cash Flow Quarter**

Atcor Medical (ACG: \$0.082) has posted its third consecutive positive cash flow quarter. The company sells the Sphygmocor device for measuring central blood pressure, which corresponds with the level of flexibility in the arteries or arterial stiffness.

In June last year the company reviewed its business and implemented a reduction in its cost base. This allows the company to be profitable when annual sales reach the \$8-\$9 million range. In this financial year, the company has signed three large pharmaceutical contracts, where those companies incorporate the company's test when trialing new drugs. This is where the majority of the income for Atcor comes from at this stage, and at least for the next 18 months is likely to be the main driver of overall sales.

### **Longer Term Driver**

The longer term driver of sales will be when this test is incorporated in regular healthcare checks, both at the specialist level and also in the GP clinics. At the moment the company has Category III reimbursement in the US, which started in January this year. Getting reimbursement upgraded in coming years to a Category I level, which will allow wider and more consistent coverage, is a major goal for the company.

### **Latest Results**

For the first three quarters of this financial year, the company has generated receipts of \$6.0 million with a net cash flow of \$1.15 million. However, this also includes a tax rebate of \$0.7 million and other income (grants) of \$433,000. The company is forecasting a positive cash flow in the current quarter as well.

The company continues to see a broadening of interest from its customers (pharmaceutical companies) to other disease areas outside of the core applications in hypertension, COPD and renal disease. This includes the area of cardio-oncology. COPD has become a bigger area of interest that two years ago. The company is also seeing customers move from using the product in a Phase II setting, then into Phase III and Phase IV trials. Atcor CFO Peter Manley said that many drugs in development can have an impact on the cardiovascular system (therefore a need to incorporate the Sphygmocor test).

*Cont'd over*

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Manley is hopeful that the company has moved through the most difficult phase (of the company's recent history) and that the company can maintain a positive cash flow, although the company is making no forecasts past the end of June.

### **Sphygmocor XCEL 'Being Well Received'**

In July last year the company filed the next generation Sphygmocor device, called the XCEL, for approval with the FDA and was granted marketing approval in November 2012. This product simplifies use of the test, involving a sleeve placed around the arm, rather than trying to pinpoint the artery in the wrist with a small probe. The device has now been used in one clinical trial. The new device should reduce operator training times in trials and potentially deliver more consistent results. The new product is being well received according to Manley. It is also approved in Europe and Australia.

### **Unknown Study Confirms Benefit of Sphygmocor Test**

Last month the company announced results that were published from a trial in South Africa involving 1,169 black South Africans. The trial was conducted without the knowledge of Atcor, with Atcor only having sold the system used for the trial.

The trial showed in subjects with marginally elevated blood pressure (120-139 mmHG systolic and 80-80 mmHG diastolic pressure), that measuring using the Sphygmocor device could predict those with target organ damage i.e. proximal organ damage in the heart, lung and kidneys, which are most affected by high blood pressure. By assessing those organs, there was a high correlation with high central blood pressure, but not very good correlation with the standard cuff pressure measurement. This confirms the increased arterial stiffness assessed in an American study involving 50 young adults. In that study, the African Americans were shown to have the cardiovascular age of 45 year olds.

There are a number of small technology players with central blood pressure tests, with Atcor being the leader in the field and having the most widely recognised test. It has been a long process for Atcor to change healthcare practise. As they should and will change, Atcor is in the leading position with arguably the most highly profiled and validated test on the market. The company has now positioned itself to start generating profits for its shareholders.

Atcor Medical is capitalised at \$12 million and had \$2.1 million in cash at the end of March.

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

## **Bioshares**

## **Pharmaxis Share Price Falls to Low Levels – What to Consider?**

Pharmaxis (PXS: \$0.15) has fallen to very low levels following the disappointing result from the company's Phase III study in bronchiectasis with its drug Bronchitol. This followed other disappointing news, primarily a knock back from the FDA to market the drug in the US for the treatment of cystic fibrosis, and the slower than expected take up of the drug in Germany and Australia.

The company, capitalised at \$46 million, is now trading well below its cash reserves, which stood at \$73 million at the end of March. However, a prime issue for the company and investors is that Pharmaxis is still spending around \$10 million a quarter (cash outflow of \$10.7 million in the March quarter).

There are a number of questions for investors that remain outstanding. These are:

1. By how much can the company reduce its spend rate?
2. What will be the course of action in the US and will the company be conducting further Phase III trials in cystic fibrosis following its meeting with the FDA?
3. How long will it take for the company to become cash flow positive from sales in existing markets of Bronchitol and the lung function test Aridol?
4. How long will it take to see traction in Europe from Bronchitol sales?
5. What are the commitments to conducting additional trials in CF in the US under the company's funding agreement with NovaQuest?

Product sales for the March quarter were \$853,000.

Pharmaxis has an earlier stage pipeline which it is now seeking partners to fund. This includes the company's ASM8 asthma treatment program, the new delivery device for Bronchitol which does not need multiple capsules, and three preclinical programs.

Although Pharmaxis had \$73 million in cash at the end of March, that will reduce to \$53 million by the end of September at current spend rates.

What investors need to monitor is for an improvement in Bronchitol's rate of market penetration and for growth in sales from entry into other markets.

The company needs to show that Bronchitol is a viable product that warrants continued investment. At the moment, the market is assigning negative value to this product.

The number of issues which require clarification or are unknown make Pharmaxis a stock about which to defer any entry decision until some, if not all, of these issues are resolved or better understood.

*Bioshares* recommendation: **Sell**

## **Bioshares**

## **Mesoblast Reports Positive Interim Phase II Results in Early Stage Disc Repair**

Mesoblast (MSB: \$5.82) has reported positive Phase II data in the first 50 patients in the company's Phase II trial in 100 patients requiring intervertebral disc repair. This is an earlier stage condition and it can progress to the more serious stage where spinal fusion is required. Being able to treat this condition early not only prevents more serious injuries, but for the company, greatly expands the potential market for such a therapy. Mesoblast is also assessing the use of its mesenchymal stem cells (MPCs) for the treatment of spinal fusion.

### **Results from First 50 patients**

Assessment of the first 50 patients was conducted at the six month point after treatment. There were two treatment doses, one consisting of 6 million MPCs with a hyaluronic acid (HA) carrier solution, and one with 18 million MPCs also with HA. This was compared against using HA alone, and also against a saline solution.

### **Safety**

Safety is one of the primary endpoints in this trial. In what is becoming a pattern now with the stem cell treatment, the lower dose is proving to be more effective than the higher dose. With the higher dose there was a higher level of adverse events, and with the lower dose, there were no cell-related serious adverse events.

### **Efficacy**

The low dose of MPCs delivered a statistically significant reduction ( $p=0.013$ ) in back pain of 69% compared to a 38% reduction in patients receiving HA alone.

The mean improvement in function was also statistically significant ( $p=0.038$ ) with an improvement of 51% in the lower dose group compared to only 19% increase in the HA arm.

A third measurement of overall treatment success incorporates the above two measures, along with no negative changes in neurological status, no negative changes in disc morphology, and no serious adverse events. Against the HA arm, the low dose MPCs delivered a statistically significant result ( $p=.036$ ) with 71% of patients considered a treatment success and 20% in the HA arm achieving overall treatment success. In patients receiving saline solution, 30% achieved treatment success and the low dose MPCs did not achieve statistical significance ( $p=.095$ ). [p-value needs to be less than 0.05 to be deemed statistically significant.]

In March, Mesoblast raised \$170 million which will allow it to fund Phase III trials in the area of degenerative spinal conditions (intervertebral disc repair and spinal fusion).

In January this year, Mesoblast reported results from a Phase II trial in spinal fusion. The trial looked at a low dose of MPCs (25 million cells), a high dose (75 million cells) and bone autograft. The low dose achieved spinal fusion in 85.7% of patients, compared to 75% of patients receiving a bone autograft achieving spinal fusion. The higher dose was less successful, with only 62.5% achieving spinal fusion.

The company stated that using its stem cells to achieve spinal fusion was effective as bone autograft and that it would proceed into Phase III trials in 2013. The company will also move the intervertebral disc repair program into Phase III trials if data from the full 100 patients matches the interim data.

Mesoblast has now achieved positive data in treating spine degeneration at two different stages of disease. The company also now has the financial capacity to execute its internally managed Phase III clinical programs. Advancing the company's technology into pivotal studies simultaneously in multiple applications helps reduce the risk profile of this stock. The company is also due to start a Phase III study this year in congestive heart failure with its partner Teva Pharmaceutical Industries.

At the end of March, Mesoblast had \$328 million in cash. Mesoblast is capitalised at \$1.83 billion.

### **Summary**

Clinical progress in the spinal fusion and disc repair areas notwithstanding, the Mesoblast market capitalisation continues to imply very high rates of success in all areas of activity. For some investors, entry into the stock should be timed to points when the risk/reward ratio of the stock achieves a more realistic tenor.

*Bioshares* recommendation: **Take Profits/ Reduce Exposure**

**Bioshares**

## **Prima Biomed's Cost of Goods Challenge**

Prima Biomed (PRR: \$0.072) is developing a cancer immunotherapeutic, termed CVac. This therapy involves the collection of dendritic cells (DCs) from a patient. These cells are then presented (ex vivo) to a fusion protein which contains sequences from the Mannin 1 protein (MUC1). This process trains the immune system to recognise the cancer cells which display MUC1, which then trigger a response that destroys the cancer cells.

The therapy uses a patient's own cells and is therefore categorised as autologous therapy. This approach means that the cells should not be rejected by the immune system of the patient. However, the approach imposes significant logistic and manufacturing costs that mean that Prima has major COGS challenges to solve.

### **Funding**

Prima is currently conducting an SPP to raise up to \$15 million. The company will also conduct a 1:4 options rights issue at 2 cents with an exercise price of 20 cents.

Prima held cash resources of \$28 million at March 31, 2013. However, the company is keen to improve its cash resources in order to initiate further Phase II trials of CVac in cancers other than ovarian cancer. The company has received a grant of €3.8 million to support three Phase II trials in new cancer indications from German state government sources.

### **Clinical Trials**

The company expects results from its 63 patient Phase IIb ovarian cancer trial to become available in the second half of 2013. From this trial, in 2013 Q3, the company expects to receive immune monitoring data and by 2013 Q4 receive progression free survival data and the first read-out of overall survival. This trial commenced in mid-2010.

The 1,000 patient Phase III CANVAS trial has been slow to recruit patients. In February, only three patients had been dosed. More recently as of April, seven patients had been dosed. In the background to this trial has been the need to establish collection centres and to improve the logistics related to the trial. As of January, 46 collection centres had been inspected and staff had been trained, with 28 declared ready to go. As of April, 31 centres were ready.

Prima has set 2015 as an approximate date for the receipt of data from the CANVAS trial. However, recruitment rates will play a significant role in determining whether this goal can be met.

### **COGS Challenge**

Putting the therapeutic potential of CVac to one side, the greater challenge for Prima is to improve the cost of supply of the treatment.

There are several areas in which the company must derive efficiencies, including quality control, logistics (both incoming and outgoing from collection and processing centres), and also in the design and operation of manufacturing facilities (clean rooms ect). The company must also scale-up production from current levels, where it can treat patients in the hundreds, to being able to treat patients in the thousands.

Achieving COGS which lie in 10%-30% range is likely to make Prima's technology more attractive to larger pharmaceutical partners. However, clinical success will also be needed to secure a partnership.

### **Summary**

Prima has very significant challenges ahead to improve its COGS margins and getting to commercially meaningful margins may be some years away. This aspect of the business, which is at the core of its business model, will make or break the company.

Prima is capitalised at \$77 million.

*Bioshares* recommendation: **Wait**

(Pending Positive Manufacturing Developments in Coming Months)

**Bioshares**

## 4.7B Reporting Companies – Cash Balances March 31, 2013

### Sorted by Survival Index

Code	Company	Cash Receipts (\$M)	Nett Op. Cash Fl. (\$M)	Cash End 31/03/13 (\$M)	Survival Index	Comments/Events post reporting date
ACG	Atcor Medical	\$6.00	\$1.15	\$2.17	A	Not App
HCT	Holista Colltech	\$4.28	\$0.14	\$1.75	A	Not App
LCT	Living Cell Technologies	\$8.23	\$1.74	\$4.96	A	Not App Received \$2.85 M option fee from Otsuka; also received service fees
SIE	Scigen	\$4.92	\$0.24	\$2.00	CY	Not App
NEU	Neuren Pharmaceuticals	\$0.00	-\$1.26	\$3.91	CY	7.1
AVX	Aveva	\$0.00	-\$1.57	\$12.96	A	6.2
MSB	Mesoblast	\$0.00	-\$42.86	\$327.99	A	5.7
NDL	NeuroDiscovery	\$0.00	-\$0.46	\$3.37	A	5.6 Acquired Enigma Therapeutics
NAN	Nanosonics	\$9.96	-\$4.10	\$24.92	A	4.6
OSP	Osprey Medical	\$0.00	-\$1.77	\$12.66	CY	4.4
UBI	Universal Biosensors	\$3.97	-\$3.95	\$20.23	CY	4.4
RVA	Reva Medical	\$0.00	-\$5.17	\$36.98	CY	4.2
SPL	Starpharma	\$5.81	-\$7.50	\$35.91	A	3.6
RHT	Resonance Health	\$1.29	-\$0.22	\$0.94	A	3.2
CDY	Cellmid	\$0.43	-\$0.78	\$3.21	A	3.1
SOM	Somnomed	\$12.47	-\$0.66	\$2.68	A	3.1
PAB	Patrys	\$0.00	-\$1.62	\$6.09	A	2.8
GID	GI Dynamics	\$0.34	-\$8.21	\$31.51	CY	2.6
PRR	Prima Biomed	\$0.00	-\$9.90	\$28.07	A	2.1 Conducting SPP to raise up to \$15M; also 1:4 Options Rights Issue
PXS	Pharmaxis	\$2.53	-\$26.71	\$73.00	A	2.0
OBJ	OBJ	\$0.07	-\$1.02	\$2.78	A	2.0
CBB	Cordlife	\$6.26	-\$2.34	\$6.25	A	2.0
ANP	Antisense Therap.	\$0.00	-\$2.03	\$4.78	A	1.8
AVH	Avita Medical	\$2.97	-\$5.58	\$12.33	A	1.7
VLA	Viralytics	\$0.00	-\$2.87	\$6.28	A	1.6
PYC	Phylogica	\$0.75	-\$1.37	\$2.88	A	1.6
PBT	Prana Biotechnology	\$0.00	-\$4.52	\$8.84	A	1.5 Received \$5.8 M R&D refund; SPP raised \$2 M
BRC	Brain Resource Corp	\$0.73	-\$2.31	\$4.28	A	1.4
BNO	Bionomics	\$2.58	-\$5.78	\$10.45	A	1.4 Rights Issue raised \$16.4 M
BIT	Biotron	\$0.00	-\$2.84	\$5.05	A	1.3
QRX	QRxPharma	\$0.00	-\$8.68	\$13.88	A	1.2
ACW	Actinogen	\$0.00	-\$0.10	\$0.15	A	1.2
CUV	Clinuvel Pharmaceuticals	\$1.14	-\$5.11	\$7.92	A	1.2 Susp. from trading pending completion of capital raising
AHZ	Allied Healthcare Group	\$5.29	-\$2.67	\$3.77	A	1.1
ACL	Alchemia	\$4.51	-\$10.04	\$13.81	A	1.0 SPP raised \$2.75 M (oversubscribed to \$9.5 M)
TIS	Tissue Therapies	\$0.00	-\$6.04	\$8.21	A	1.0
IPD	Impedimed	\$2.16	-\$6.11	\$8.06	A	1.0
BDM	Biodiem	\$0.08	-\$1.41	\$1.82	A	1.0
UCM	USCOM	\$0.52	-\$0.69	\$0.89	A	1.0
LBT	LBT Innovations	\$0.00	-\$1.33	\$1.59	A	0.9 Final agreement for APA system partn. with Hettich Ag due 15/5
BXN	Bioxyme	\$0.51	-\$0.53	\$0.64	A	0.9 Acquiring Vitality Devices
SUD	SUDA	\$3.42	-\$1.13	\$1.33	A	0.9 Reported 'outstanding' results of Phase III trial of Artimist
IVX	Invion	\$0.06	-\$2.13	\$2.07	A	0.7 Conducting SPP
ISN	Isonoa	\$0.02	-\$3.04	\$2.85	A	0.7
MGZ	Medigard	\$0.00	-\$0.16	\$0.15	A	0.7
IMI	IM Medical	\$0.00	-\$0.34	\$0.28	A	0.6
BCT	Bluechiip	\$0.10	-\$1.82	\$1.21	A	0.5
GBI	Genera Biosystems	\$0.04	-\$1.06	\$0.70	A	0.5
BLT	Benitec	\$0.36	-\$2.36	\$1.51	A	0.5
ACU	Acuvax	\$0.00	-\$0.37	\$0.22	A	0.4 Acquired Biolife, a cancer vaccine company
ADO	Anteo Diagnostics	\$0.01	-\$0.37	\$0.22	A	0.4
GTG	Genetic Technologies	\$6.51	-\$5.76	\$3.14	A	0.4
IMU	Imugene	\$0.00	-\$1.45	\$0.53	A	0.3 Conducting SPP
ALT	Analytica	\$0.00	-\$0.90	\$0.32	A	0.3
AGX	Agenix	\$0.01	-\$0.80	\$0.27	A	0.3 Accessing \$5M funding (Fortrend Securities); \$3M (Baycrest Capital)
UNS	Unilife	\$1.06	-\$29.67	\$9.32	A	0.2 Expects to finalise debt funding facility shortly
MLA	Medical Australia	\$7.13	-\$0.83	\$0.19	A	0.2
CGP	Consegna Group	\$0.00	-\$1.77	\$0.37	A	0.2
BNE	Bone Medical	\$0.00	-\$0.89	\$0.01	A	0.0 US\$6M Convertible note facility with La Jolla Cove Invest. Part.

Cont'd over

**Bioshares Model Portfolio (3 May 2013)**

Company	Price (current)	Price added to portfolio	Date added
Atcor Medical	\$0.082	\$0.082	May 2013
Circadian Technologies	\$0.250	\$0.270	March 2013
Tissue Therapies	\$0.135	\$0.255	March 2013
Allied Healthcare	\$0.029	\$0.026	February 2013
Psivida	\$2.45	\$1.550	November 2012
Benitec	\$0.013	\$0.016	November 2012
Nanosonics	\$0.405	\$0.495	June 2012
QRxPharma	\$1.22	\$1.66	October 2011
Somnomed	\$0.93	\$0.94	January 2011
Cogstate	\$0.370	\$0.13	November 2007
Clinuvel Pharmaceuticals	\$1.85	\$6.60	September 2007
Universal Biosensors	\$0.64	\$1.23	June 2007

**Portfolio Changes – 3 May 2013****IN:**

Atcor Medical has been added to the portfolio at 8.2 cents. See analysis on page 1.

**OUT:**

No changes.

**4.7B Reporting Companies – Cash Balances Mar 31 201s (Cont'd)****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 average of the last nine months of NOCF, annualised.

**CY:** The SI calculation for these companies is calculated on the average of the last five quarters of NOCF, annualised.

**Commentary**

There were 59 ASX listed life science companies (a year ago, 65) for which we tabulated cash flow receipts, net operational cash and for which we calculated Survival Index figures for the March quarter.

There were 20 companies which retained cash resources at March 31, 2013, sufficient to fund less than one year's worth of operational activities (based on previous spending patterns). There were 12 companies with less than six month's cash at hand. It should be noted that one of these companies, Medical Australia, has significant trading operations which means that other financial ratios are more appropriate to assessing its financial health.

Agenix and Bone Medical continued as companies which rely on dilutive funding facilities to remain operational. One company which is expecting to obtain debt funding is Unilife. It has also flagged that its situation should become more positive if a number of deals for its needle technology eventuate in the near future.

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 nine months ending March 31, 2013, annualised, into each company's cash assets as recorded at March 31, 2013. For companies that report on December 31 full year basis, the index is based on the last five quarters of net operational cash flows (NOCF). 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 than 0.5 may be in positions of funding stress and investors should investigate such stocks with a greater degree of concern.

*Small cap life science companies that are not required to comply with the 4.7B Rule include: Acrux, Advanced Medical Design and Manufact., Immuron, Bioniche, Cogstate, Circadian Technologies, Clovercorp, Compumedics, Cryosite, Cyclopharm, Ellex Medical Lasers, IDT, ITL Corp, Calzada, Medical Developments Int., Novogen, Optiscan Imaging, Progen Pharm. and Phosphagenics. Re-domiciled companies, pSivida and Heartware International no longer comply with the 4B Rule.*

**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**

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Name \_\_\_\_\_

Organisation \_\_\_\_\_

Ph ( ) \_\_\_\_\_

Emails \_\_\_\_\_

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