

**In this edition...**

In a break from our regular company analysis, we devote this edition to commentary provided by nine members of the biotech industry. The task was to discuss what biotechs need to do survive the very difficult times confronting the sector, with particular reference to where capital might be sourced. Not unexpectedly, more than one writer said that partnering would have increased significance for junior biotechs and the emerging rule of thumb is to have 3 years of cash at hand.

Greg Brown, the CEO of Impedimed, points out that the top ten pharma collectively hold US \$100 billion in cash. This puts them in a prime position as a source of capital.

And the resounding view is that biotech is not dead, given the long term demand for better drugs and medical technologies.

	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)	-38%
<b>Cumulative Gain</b>	<b>27%</b>
<b>Av Annual Gain (7 yrs)</b>	<b>17.8%</b>

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# Bioshares

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

## Special Edition

### **The Global Financial Crisis and the Future of Australian Biotech**

The global financial crisis has been a disruptive and challenging event for Australian biotech companies, emerging on the back of an eighteen month period of weakness, with the Opes Prime collapse in April an early and confounding factor in reducing biotech investment liquidity. The **Bioshares Index** has declined 56% from the March quarter, 2007, to September 30, 2008. A pivotal date for the sector was September 15, 2008, when US investment bank **Lehman Brothers** filed for bankruptcy.

The events that are symbolised by the disappearance of Lehman Brothers from the world of finance have played havoc for companies that were seeking to raise funds, with at least two Australian companies having their plans dashed. **Ventracor** had a term sheet in place in July with a US investor for a placement and rights issue of a convertible note. The chair of Ventracor, John Ward said that "as a result of exposure to Lehman Brothers, one of the cornerstone investors of our financing withdrew, leaving it virtually impossible to continue with this strategy." **Optiscan Imaging** was in the throes of a US directed capital raising, anticipating a placement of between US\$15 and \$20 million, with a US roadshow planned for October. Similarly, the events of September extinguished these plans.

While a number of companies are facing very uncertain futures, some companies have acted in timely fashion to preserve their businesses. **Alchemia** acted rapidly in response to the extreme deterioration in market conditions, announcing staff cutbacks at the end October. Foremost on investors minds is what should companies be doing in these extremely difficult times to survive. Is it really the end days for a number of companies?

*Bioshares* invited a number of CEOs and other industry figures to discuss these issues, addressing if possible the following questions:

1. What do businesses need to do survive the sea change that is occurring in global finance?
2. What will be the effects of a prolonged finance drought and what new sources of capital and approaches to funding do you think will emerge or dominate?
3. Is biotech dead?
4. What opportunities exist for small life science companies in the current biotech downturn?

We would like to thank Igor Gonda, Tom Wiggins, John Holaday, Deborah Rathjen, Josh Funder, Greg Brown, Richard Treagus, Leanna Read and Andrew Macdonald for kindly making the time to put their thoughts on paper for the readers of *Bioshares*.

**Bioshares**

## A Long Term Perspective

Igor Gonda

CEO Aradigm Corporation

*“While the next few years ahead of us are likely to be the worst our generation has experienced, the Darwinian rule will richly reward the most adaptable survivors...”*

Will the sun rise again for biotechs? Yes, but some companies may not live long enough to see it. Let's not kid ourselves – if you are a CEO of a company that is not making profits, it's time to get into the essential survival mode and preserve enough cash to be able to unlock the value of your intellectual property assets when funding becomes possible again. If you are lucky and have cash or shareholders with money who believe you can consolidate the assets of other companies, go for it, there have never been better bargains as many biotechs are trading well below their cash!

### The fundamentals

Long term, I believe the prospects for the "biotech" industry are very bright for the simple reason that it is as true today as before the financial meltdown. The fundamental value proposition in the search to prevent and treat diseases is the same; our society continues to be very interested to support biomedical research and pay for better healthcare products at a price that is commensurate with the socioeconomic value they provide.

So, somehow, we need to link more directly the long term socioeconomic value being generated in the R&D companies with the investment process on the way to generate this value. Traditionally, the focus of many biotech investors has been on the short term share price appreciation instead of the long term value generation. This needs to change in order for us to benefit from the long term appreciation of the value of health care industry. Here are some ways in which the long term success could be "engineered" and the taxpayers as well as the investors rewarded on appropriate time scales:

### Taxation structures

Long-term investments in Australian biotechs should be subject to attractive tax structures; conversely, speculative short term investment should be discouraged.

### Superannuation rules

Contributors to superannuation funds should have the option to allocate a certain portion of their contributions to long term investments in the "biotech asset class", with the tax benefits as proposed above for investments that support Australian R&D.

The investment of this money should be managed by specialised life science funds with perspective on the whole health care sector with sufficiently deep pockets to be able to invest broadly in this sector and reap the long term rewards of value generation in multiple investee companies. A naïve investor should not need to bet on one or two horses in the next race, but on the long term profitability of the whole industry.

### Resource sharing

There should be an increase in the effort, via various cooperative research centres sponsored jointly by the government and industry, to share resources in non-competitive premarketing research in areas in which Australian life sciences excel, such as immunology and respiratory medicine. These centres should have a much stronger industrial focus through Boards of directors, technical advisory boards as well as joint development committees for specific projects.

### Integration – an allout-effort

Healthcare is a global business in all of aspects – R&D, manufacturing, marketing and sales as well as investment in this business are truly international. To leverage the special strengths of Australia and to benefit maximally from the investments and markets in other parts of the world, we should make an all out effort to integrate ourselves into this global network through collaborations and import of experience in areas where we are lacking, especially for the strategic decision making.

The last decade has seen a very strong growth of Australian biotechs and while the next few years ahead of us are likely to be the worst our generation has experienced, the Darwinian rule will richly reward the most adaptable survivors, and their investors, when the next period of growth comes.

### Funding to Gravitate More to Late Stage Opportunities

Andrew Macdonald

CEO Cytopia

*“The most severe impact in the short term is likely to be on preclinical and clinical programs where considerable new capital is required.”*

There is little doubt that the global financial crisis is having a very significant impact on the Australian biotech sector, and will continue to do so for a considerable period. This is on top of fundamental change in this sector over the last couple of years as it slowly grows and matures. The hardest hit are probably the drug discovery and development companies, although no part of the broader biotech sector has been immune.

For biotech to be successful, it has to ultimately provide an acceptable return to investors. Economics dictate that the higher the risk, then the higher must be the return. Market distortions will occur for a time – sometimes for years – but eventually the market will correct.

### Re-discovering risk

We have been seeing a biotech correction for some eighteen months here in Australia – not just during 2008. Investors everywhere, but particularly in biotech, are both re-discovering risk and reassessing their risk tolerance. Specifically, investors have begun to recognise that regardless of the technology involved, the calibre of the people involved, or the amount of money committed, the chance of a drug candidate successfully making its way through the laboratory and clinic to market is still very low.

Other factors come into play. Late stage clinical trials are usually long and costly, and barren of news flow, and the market is realizing the challenge of a small biotech being able to navigate the complexities of taking a drug to market. This has been reinforced by recent drug candidate failures at a mid-to-late stage of development. Although disappointing, statistics strongly suggest that this should be no surprise.

#### ***Drought to last for most of 2009, if not longer***

The current financial drought is likely to extend for most of 2009 and possibly beyond. Two business models tend to dominate drug discovery and development and the implications for each in this climate will vary.

– Companies based largely on a single or key product. They are inevitably high risk and best sit in the hands of private equity, not public equity.

– Companies with a breadth of products that manage risk through pipeline and are usually seeking to build a sustainable business. These companies are more typically, but not always, funded by the public markets.

Some companies will weather the storm, particularly those with sufficient reserves, but many are faced with three broad choices. They can either try to raise money at unpalatable valuations, make adjustments to the business by reducing cost or conduct some sort of corporate activity from M&A through to out-licensing. Breadth of pipeline in the second model clearly provides flexibility that is not present in the first.

Funding will remain available but it will be rationed and gravitate more towards either late stage opportunities or opportunities close to significant milestones. In Australia, financing will be more from the private arena than public money and will probably favour the single product companies. Opportunities will abound but the risk proposition will be more carefully scrutinized.

As the financing bar is raised, some programs will simply not "pass muster" as attractive investments. In an ideal world, an eventual outcome would be tougher and data driven decisions on advancing compounds and drug candidates but these decisions are far more confronting when there is an absence of pipeline.

There has been remarkable resilience historically amongst early-to-mid stage biotech programs which are relatively inexpensive to fund. It will probably take at least another year or more of limited funding to have a very broad impact, and therefore the most severe impact in the short term is likely to be on preclinical and clinical programs where considerable new capital is required.

Many will look towards pharma for either an exit or dedicated funding. This might be an option for some, but global competition is fierce. This current economic predicament is not limited to Australia. Big pharma – and small – already have a queue of biotechs from around the world at their door seeking some, or any, sort of deal.

Cutting back cost is an obvious choice for many but unless funding improves in the short term, the cuts will in some cases need to be very deep and will significantly compromise the business. Reductions buy time but are usually in direct conflict with getting compounds to market.

#### ***Some excellent opportunities***

Some bolder companies will take more proactive steps to move their business model from a limited pipeline to a sustainable business. It is easy to be despondent in tough times, yet there are some excellent opportunities presenting themselves to bring together appropriate assets that will be ride the inevitable upturn in a far more robust fashion. It remains to be seen who will drive such change.

The extent of this crisis is without precedent in recent years but none of the above should be seen as a serious threat to the future of biotech. There will be casualties amongst the smaller, or poorly capitalised, companies, but there is also likely to be some positive change at the larger end of the biotech market where some clear market leaders will emerge. This bodes well for smaller companies as it will extend their growth and exit options.

What this should do overall is deliver a stronger biotech sector which is more structurally sound and ultimately more attractive to the private and public investors that will provide the long term development capital.

#### **Biotech or Bust?**

***Josh Funder***

***Investor, GBS Venture Partners***

*"Gone are the days when a good idea and a good stockbroker could list a preclinical biotech company on the ASX at boom valuations."*

The implications of the financial meltdown and economic recession for the Australian biotech sector are significant. Well managed, well financed companies with clear development objectives, however, will endure the storm and have a chance to flourish. But the bar is higher and weaker companies will fall away. There are some clear actions biotech companies should take in the current market.

#### ***New companies***

If you are thinking of starting a biotech start-up, it might be wise to keep thinking until the bad weather clears. Where possible, incubate a technology at the university or lab a little longer and come to the financial market with more mature data from animal disease models, prototype testing or studies in combination with existing therapies.

Explore ongoing grant funding locally such as NHMRC development grants as well as international sources such as NIH or philanthropic funds. Gone are the days when a good idea and a good stockbroker could list a preclinical biotech company on the ASX at boom valuations.

### **Existing companies**

For existing companies, the clear message is to plan to survive several years without significant additional capital and emerge with intellectual property intact, continued momentum and good prospects.

### **Core assets**

First, maintain the core assets of the company. Check the duration of the IP portfolio and budget to maintain key assets which will still command investment in 3 years time.

### **Cash for 2-3 years**

Second, cash is king. Financial reserves need to be secured for at least 2-3 years; in the past most companies were comfortable with a 1-2 year financial outlook. For all companies, this may mean reducing the number of development projects undertaken to the minimum value-adding studies. While this increases the risk of technical failure, it also reduces the clear risk of running out of money completely. Make sure out-of-cash dates are clear and any non-contingent liabilities accounted. With overhead reduced, companies can spend a little more time, not money positioning their products.

### **Review**

Third, review staff numbers to retain core expertise and operations only. Review external contracts for potential price reductions and more flexible tranching commitments. Biotech CEOs and boards will need to be quicker to act and more commercial in their approach to M&A terms, licensing and development. Australian biotechs have more experience than most in successfully operating virtual companies and lean operations.

There are some positives in the Australia sector. Many of the stronger listed companies raised significant amounts of money before the downturn and are well placed to continue prudent operations in the medium term. Some may be able to attract PIPES or follow-ons. Private companies which were able to attract broader syndicates of specialist, deep-pocketed investors are well positioned to continue developing products. While the IPO window may be firmly shut, the amount of angel, seed and venture funding in Australia has not fallen significantly and many funds are actively investing in the current market. High quality technologies and experienced business development teams will also be able to attract resources and expertise by partnering programs throughout a downturn.

Most importantly, the market for healthcare and biotech products is largely unaffected by the medium-term recession. Companies coming to market with global sales of biotech products will be well rewarded by the public markets. However, companies looking to exit in a trade sale may have to compete against a backlog of high quality, late-stage companies and so may face longer times to exit and lower prices on exit.

Biotech is a long-term business. Companies structured to meet short term or speculative objectives will be punished in the current climate. Companies set up for the long haul of developing a biotech product should actively respond to the current situation and emerge intact, if not better for it.

## **Financial Turmoil Calls for a Combination of Discipline and Disruptive Thinking**

**Richard Treagus**  
**CEO Acrux**

*"This is a time for management teams to be re-affirming their strategy, communicating clearly with all stakeholders, thinking expansively and seeking out new opportunities."*

These are without doubt extraordinary times in world financial markets and although the scale and extent of the pull back has many pundits equating it to the great downturn of the 1930's, what remains completely unprecedented, is the speed with which this correction has occurred and the unavoidable reality that all world economies and financial markets are inextricably linked. How can foreclosures on residential properties in California impact the viability and prospects of a biotech company down under, we ask? Welcome to the global reality.

A biotechnology company's *raison d'être* is to develop and commercialise novel technologies, with the objective of delivering benefits to patients and financial returns to its investors. The central challenge is one of proving the founding hypothesis, while at the same time managing timelines, cash burn and a variety of technology and business related risks. Given the events of the last 12 months, the narrow line separating success from failure has just got a whole lot thinner. The next few years in the biotech sector are likely to be very "Darwinian" in the sense that only the fittest will survive and those that were always destined to fail will likely fail faster.

### **Assumptions challenged**

It is not just the depressed share prices and the worst capital drought in recent times that are having an impact on start-up companies and their shareholders. The financial turmoil has altered many assumptions which require that even the best laid business plans be reviewed and adjusted.

One such factor is the dramatic swing in exchange rates. The depreciation in the Australian dollar has altered the financial projections for many companies. The value of future revenues is in many cases much greater, however in the short-term there is further pressure on cash utilisation for local companies incurring foreign currency expenditure. Companies may need to renegotiate contracts with service providers, narrow the scope of the work, or where possible, re-direct some of the development expenditure back to Australia; not only to lower costs, but also to benefit from local financial grants.

### **Staff retention**

Another consideration in this current climate is the challenge of staff retention. Success in a biotech company is heavily predicated on the ability to employ talented, committed and engaged people. Cash starved biotech companies rely heavily on long-term incentives to align and reward their key personnel. With stock options and performance rights out of the money, boards will have to remain carefully attuned to how they continue to attract and

retain the appropriate skills during these lean times. Non-financial incentives, individual staff development programs and flexible work arrangements are just some of the variables that should be considered.

It is an undeniable reality that new capital is extremely hard to access in the current climate and even when this can be done it is proving to be expensive. Companies are therefore forced to consider alternative means of boosting their cash reserves, and these may include any of the following:

#### *Deferring non-essential expenditure*

Management teams should identify expenditure that can be deferred without materially impacting either value or progress. Certain activities will need to be conducted sequentially rather than simultaneously. Ultimately however there is a cost to this given finite patent lives, but this may be an unavoidable consequence.

#### *Other sources of cash*

Seek out alternative sources of cash such as grants, research collaborations, sale of non-core assets, the partial sale of IP rights, or the monetisation of future royalty streams. With the latter approach, the revenue forecasts and the discount rate are the two variables that will be central in any negotiation.

#### *Costs*

Reduce fixed costs primarily related to facilities and staff numbers.

#### *Explore alternative partnering structures*

– Companies typically approach a partnering deal with the objective of maximising the value. It may be reasonable to accept a slightly lesser value, for a greater proportion of upfront cash payments.

– Renegotiate existing partner contracts to bring cash payments forward.

– Partner projects earlier than otherwise planned. It may be better to give up some portion of the value, rather than postpone or forgo the entire project completely due to cash restraints.

#### *A detailed health-check*

Companies that respond quickly and emphatically to these changed circumstances are likely to fair better and may even emerge in a stronger position once the financial turmoil has receded. In times such as these management teams and boards should be conducting a detailed health-check on their business. It is worth challenging the status quo, checking the validity of the business model, revisiting key assumptions, identifying risks and above all, thinking differently.

Despite the prevailing sentiment, this is not a time to stock up on candles, tinned food and bury the family silver in the backyard. In fact, quite the opposite, this is a time for management teams to be re-affirming their strategy, communicating clearly with all stakeholders, thinking expansively and seeking out new opportunities. It is without question very challenging to maintain forward momentum in these difficult times, but those management teams

that are able to effectively balance the need-to-survive with the need-to-succeed, will almost certainly fair better.

In short, cash is an essential raw material for all biotech companies and these times call for a high level of discipline and rigour, but perhaps somewhat paradoxically these are also times that call for disruptive and bold thinking at a strategic level.

### **A Time for Tough Decisions**

*Leanna Read*

*CEO TGR Biosciences*

*“Boards also need to put greater emphasis on refining their company's business model and route to market, rather than the science.”*

#### *1. What do businesses need to do to survive the next 6-12 months?*

The priority for the next 6-12 months is quite simple - conserve cash! And if you are a private company, don't even think about listing. This is a time for making some tough decisions and focusing on the key value-add parts of the business. **Alchemia** provides a good example. Even though their lead product, fondaparinux, is expected to secure regulatory approval by mid 2009, Alchemia still took the hard decision to reduce cash burn by curtailing early-stage projects through a 60% reduction in their R&D staff.

I would suggest that boards also need to put greater emphasis on refining their company's business model and route to market, rather than the science. Getting licence deals and products to market quickly should be the primary focus. Most life science companies should also be actively looking out for M&A opportunities and their boards should be prepared to give serious consideration to those that are genuine, even if the result would have a direct impact on members of the board and/or management.

#### *2. What will be the effect of a prolonged finance drought and what new sources of capital and funding approaches will emerge or dominate?*

As put bluntly by US-based **Sequoia Capital**: "If you are a start-up that is not cash-flow positive you are in a tough spot right now. If you haven't figured out your business model yet you are in trouble."

While the Australian venture capital industry still has funding, it will be required largely to support existing investee companies that will now have a delayed exit. Raising of new funds by the venture capital industry will be very difficult for the next few years. Companies will need to look more for private funding and to generate revenues.

One very positive development has been the growth of the Australian angel investment sector over the last couple of years, with the emergence of formal groups of angel investors and the possibility of syndicated investments. **The Australian Association of Angel Investors** (AAAI - [www.aaai.net.au](http://www.aaai.net.au)) estimates that about \$500 million was invested by active Australian angels in 2007, but this is just a small fraction of the capital that is potentially avail-

able from this sector. The importance of angel investors is that they focus on early stage companies and they contribute their expertise as well as funding.

### *3. Is biotech dead?*

No, but I expect a number of companies to go under. In future, the common biotech model of high-risk, long-term drug development will be severely growth retarded, particularly outside the USA. Instead, there will be more focus on other fields of biotechnology that are lower risk and offer much earlier cash flow, such as industrial biotechnology (e.g. optimizing enzymes for the mining industry applications), biomarkers, diagnostics and assay technologies. It is also encouraging that "big pharma" is increasingly looking to source new products and IP from biotechnology companies. This trend will almost certainly continue because it is both more cost effective and more productive than Big Pharma's own in-house R&D.

### *4. What opportunities exist for small life sciences companies in the current biotech downturn?*

When you consider that the average share price of the life sciences companies that have listed since 2004 is now only 40% of the list price, it is clear that the model of listing at an early stage is very high risk and generally not sustainable. I would hope that we see more consolidation of the Australian biotechnology industry through mergers and acquisitions – but I won't hold my breath!

Many early stage life sciences companies have their origins in public sector research organisations. In the current downturn, the parent organisations will need to consider incubating the technology for longer before seeking venture capital or "high net worth" investment.

The growth of the angel investment sector presents a very positive opportunity for small life science companies. By providing mentoring as well as funding, angels can provide an effective catalyst to turn start-ups into scalable, rapid-growth enterprises. However, they would not usually invest in drug development because the time and cost to market are too high. Hence the need for life sciences companies to focus on the business propositions that will get them to market quickly or get them to a compelling licensing situation.

## **Pharma and big biotech – both defensive and growth plays for investors**

**Deborah Rathjen**  
**CEO Bionomics**

*"We should remember that the Australian biotech sector has never been better placed with a growing number of companies with product in the market and/or close to the market."*

We are already seeing what biotech businesses need to do to survive the current cash crunch being enacted by firms locally. These include cutting costs to ensure sufficient runway, partnering programs (perhaps earlier than otherwise would be contemplated) to boost income and remove cost, raising capital as and when/if it

becomes available (sometimes at very significant discounts) and seeking M&A opportunities (although the capacity of Australian companies to access offshore opportunities is suffering from the currently poor exchange rate).

### **Focus**

The mantra is focus. This means that many companies will for a period of time become one shot plays as they execute dramatically streamlined business plans focusing on a key asset which is most likely to deliver value for shareholders.

### **Partnering**

Partnering programs will take on greater significance for small biotech companies. The current environment will, however, put pressure on cash-strapped companies in their partnering discussions so anything they can do to strengthen their balance sheets will help their cause.

### **Fewer companies with long term prospects**

The anticipated prolonged finance drought is likely to change the global biotech landscape significantly and the Australian scene will reflect those changes. Australian investors, with some notable exceptions, have continued to drip feed companies leaving them more vulnerable in the current environment. Looking forward 12 months we are likely to see fewer companies with viable, stand alone, long term prospects. Maintaining competitive scale will be a significant challenge for companies.

The players in the financing scene have completely changed. Exit the big investment banks - leaving the field to more nimble operators. A change in financing patterns is emerging with VC crossover funds and Pharma venture arms more active. We are likely to increasingly see equity investments as a component of Pharma licensing deals - even lines of credit. We are also likely to see an increase in financing structures around particular compounds or development programs - like the deals offered by Symphony Capital. Certainly companies will be investigating all avenues for financing.

### **The future of biotech**

Biotech is not dead - either as a business or an investment opportunity - just as Pharma is not dead. People still get sick and the development of new approaches to the diagnosis and treatment of disease will continue to be sought. Pharma and big biotech can be described as both defensive and growth plays for investors. They need to continue to grow their pipelines of product opportunities and small biotech has a vital role in feeding Pharma and big biotech pipelines to ensure their future growth and that's not going to change anytime soon. With patent expirations looming for many of Big Pharma's drugs, biotech represents a significant amount of capacity. Pharma has plenty of cash and hasn't overdosed on cheap debt with recent reports suggesting that Pharma is on the hunt for undervalued companies with promising technology. The food chain will be very much in evidence in 2009!

Every cloud has a silver lining right? For many companies the opportunity to do Pharma deals has never been more promising - whether licensing or acquisitions. And with the IPO window firmly

closed there will be more M&A which should, at current valuations, be favourable for building long-term shareholder value. We should remember that the Australian biotech sector has never been better placed with a growing number of companies with product in the market and/or close to the market. These companies demonstrate how far the sector has come with far less capital than our colleagues elsewhere. The Australian sector is well used to survival in a capital constrained environment - the current crisis will sharpen those survival skills.

### Plan on a three year drought

*John Holaday*

*CEO QRxPharma*

*“Try to find global relationships to extract the value of your company.”*

#### *1. What do businesses need to do survive the sea change that is occurring in global finance?*

The financial drought will be more than a year...plan on at least three. First and foremost, cut burn rate to an absolute minimum; make the hard decisions and emphasise any strategy that will bring early revenues. Look for strategic relationships, mergers and acquisitions. From a valuation perspective, if you think  $1+1=3$ , you are wrong; as you value your assets, remember that 10% of something is preferable to 100% of nothing. Strike early deals, you can't afford to add the value.

#### *2. What will be the effects of a prolonged finance drought and what new sources of capital and approaches to funding do you think will emerge or dominate?*

Many companies are not going to survive, but what differentiates those that will from those that won't isn't necessarily the quality of their technology, but the ability of the management to design an austerity program that will see the company through at least two years. Further, Australian and non-US biotech companies are disadvantaged due to a lack of liquidity and investor apathy. Try to find global relationships to extract the value of your company.

#### *3. Is biotech dead?*

Biotech isn't dead, but big pharma and "blockbuster mentality" is dead. Clearly, the historical spending in big pharma is not resulting in new drugs. Further, the FDA pendulum has swung more towards drug safety than drug effectiveness (read "Vioxx"), and for that reason away from "new chemical entities" and more towards repositioned drugs where history of use is known. Biotech companies will provide the future pipelines of Big Pharma, and they will buy Biotech companies instead of licensing their products. Look for either early deals (R&D) or late ones (Phase III). In between, there will be less interest.

#### *4. What opportunities exist for small life science companies in the current biotech downturn?*

What will be dead in 5-10 years is the practice of medicine as we know it. Medicine will depend on rapid diagnosis, genetic screening and a "Walmart" system of healthcare delivery. The emphasis on personalized medicine will increase, combining diagnosis and therapies in a rapidly emerging system where therapeutic compa-

nies make less money and diagnostic companies make more. Emphasise personalised medicine and preventive medicine to survive in the future healthcare environment. Research and Development is too expensive...leave that to the Academics.

### Biotech: Surviving in difficult times

*Tom Wiggans*

*CEO Peplin*

*“Every few years, US biotech industry analysts will observe “there is going to be a lot of consolidation this year”. It has never happened. This global financial crisis may be the catalyst that finally forces significant consolidation to occur.”*

We are facing the worst global economic crisis in eighty years. Because biotech is an industry that depends heavily on investment capital, how can it survive when capital is so constrained? To develop survival plans, we should first develop some assumptions on what our environment is going to look like over the planning period. Since most biotech companies plan financings and development milestones over a one to two year period, let's start there. I suggest that for planning purposes, we assume that during the next two years the availability of equity capital is going to be extremely limited. In fact it might be good to assume it is not available at all. Dark clouds hang over the global economy, and the global biotech industry, and I don't expect them to clear soon. Anyone who decides to hold out for a sunny day, and hope for better times, is taking a huge risk.

#### *Difficult questions, difficult decisions*

Within this environment CEO's and Boards of Directors must ask themselves difficult questions, and make extremely difficult decisions. Questions such as-

- How long will my cash last?
- What is the absolute longest I can make it last?
- Will I be able to achieve real value building milestones during this period?
- Will my current investors invest additional capital? If not, what are the realistic chances of finding new capital?

I believe the above questions should be asked, and answers developed, assuming the worst. While I am generally an optimist, I am afraid that this is no time for optimism when it comes to scenario planning. If a company cannot develop a viable survival plan for the next 2 years, it must consider its strategic options now. The longer this crisis lasts, and the less cash a company has, the more disadvantaged it will be in any strategic discussion.

Every few years, US biotech industry analysts will observe "there is going to be a lot of consolidation this year". It has never happened. This global financial crisis may be the catalyst that finally forces significant consolidation to occur. The sooner significant consolidation occurs, the stronger the industry will be now, and in the future. Consolidation requires making tough decisions such as reductions in force, or killing programs. However failing to aggressively consolidate will result in an industry full of companies that are gradually running out of cash, and which lack critical

mass to do any meaningful innovation or development. I know that many US venture capital groups are looking very aggressively at their portfolios, and making some hard decisions on which ones will be candidates for continued funding, and which ones won't. Some companies will cease to exist, but others may have an earlier, less than idea exit, but still one that leaves shareholders better off, and technology in stronger hands.

### ***The need for innovation***

In the face of such difficult and tumultuous conditions, one might ask the question "Can biotech survive?". My answer, despite the difficult and tumultuous conditions, is unequivocally yes. There will always be a huge need for innovation that can help cure disease. Biotech companies and their leaders must adapt to a changing environment, but they will never lose their entrepreneurship or their passion to improve lives.

### **Be ready for the new regulations on global finance**

**Greg Brown**

**CEO Impedimed**

*Quote – "Pharma has over US\$100 billion to invest and will emerge in the biotech area as a major source of funding"*

*1. What do businesses need to do survive the sea change that is occurring in global finance?*

**a.** Develop multiple business plans and the ability to change quickly if necessary – boards need to be able to move quickly to the environmental change by being flexible and ready for contingencies to be implemented quickly.

**b.** Rationalise – products close to market need to be focused on and all other costs on longer term projects mothballed or cut. Don't procrastinate, each month burns cash.

**c.** You can still look to raise capital:

**i.** Pharma companies - the top ten would have close to US\$100 billion in cash available for investment – they will be looking for bargains to stuff product pipelines and will want late stage developments, or early stage where it fits their business focus – be selective in who is approached and focus most efforts here.

**ii.** Remember that for every person who has lost money, generally someone has made money – yes the public markets are dead but there is still a lot of investment on the sidelines. Do the homework on other alternative funds and start targeting. Some major equity funds once in other fields will see healthcare as a good sector to be in going forward due to its strengths in downturns.

**iii.** Developing economies will continue to grow and could be good sources of funding. These countries can take the technology leap further, faster, by investing in internationally available high technology. Start looking to raise capital in different markets than the traditional targets.

**d.** Merge – with companies with similar product offerings, or different products to the same/similar target markets (e.g. medical devices to primary care), should consider merging.

**e.** Co-exist – Economies can be found in companies aligning costs - for instance the fixed costs for US operations can be significant and companies in similar fields could share the costs for quality, regulatory, operational, clinical, distribution, customer service and Selling & Marketing.

**f.** Partnering – development of strategic alliances with major partners.

**g.** For companies with products close to market - direct sales and marketing teams replaced by distributors maybe a necessary step.

**h.** Market focus – pick a market with the highest level of success and focus investments into this market. Consider not stretching funds across all markets and build a beachhead through focusing funds into a key targeted market. The US is often the fastest market to adopt new technology and the most rewarding if the health economics, clinical, regulatory and reimbursement strategies are well advanced.

*2. What will be the effects of a prolonged finance drought and what new sources of capital and approaches to funding do you think will emerge or dominate?*

**a.** The market will reduce significantly and a number of good companies will be lost.

**b.** Pharma has over US\$100 billion to invest and will emerge in the biotech area as a major source of funding.

**c.** Developing countries will have growing economies still and could emerge as a source of funding.

**d.** Investment funds could flow from other sectors looking for better recession resilience – Healthcare (biotech/medical device).

*3. Is biotech dead?*

**a.** No not at all - but the face of Australian biotech will change. It will be smaller, and companies will become far more focused and better funded. In return, more success will be seen, offering the risk/reward ratios that will bring investors into the market longer term and secure its future.

**b.** Investment markets will in future want more assurance on the risk/reward ratio, and investors will become more sophisticated in the basic requirements of a biotechnology opportunity. The more investors demand this, the more likely biotech businesses will meet the challenge and be better supported for success.

**c.** Biotech will come through this challenge and be far more recognised and sophisticated in its global commercialisation.

*Cont'd over*

4. What opportunities exist for small life science companies in the current biotech downturn?

a. Smaller number of targets able to better access appropriate funding – funds will start to go to well qualified targets.

b. Australia will be seen to offer value to key players (Pharma) with its quality and level of science. While there will be many opportunities undersold, these will go onto to make a return and Australian biotech successes will build further credibility behind our market. More companies will look to Australia for opportunities.

c. The world is changing and so are the markets. It is becoming more and more a global market thanks to IT/IS and we are players in this new global market. If one considers how we got to where we are, this crisis is indirectly due to lack of controls/regulations on global finance.

We should all be ready for the new regulations on global finance as this emerges. The benefit for Australia though is that it may help other countries more easily trade in our equity markets. One would hope this should add liquidity to biotech stocks which is often the limitation for foreign investment into Australian biotechnology/medical device. This could be an opportunity for companies, but with this comes higher expectations, than just a good idea.

For companies to take advantage of this, they will need to ensure all facets of the business are covered – clinical, health economics, regulatory (and its value proposition relevance), reimbursement, and commercialisation strategies will need to be benchmarked to other global companies challenging for the funding. The "make it, they will come syndrome" will no longer play well with key funds that focus in these markets.

**Bioshares**

**Bioshares Model Portfolio (28 November 2008)**

Company	Price (current)	Price added to portfolio	Date added
Hexima	\$0.39	\$0.60	October 2008
Atcor Medical	\$0.13	\$0.10	October 2008
CathRx	\$0.65	\$0.70	October 2008
Impedimed	\$0.65	\$0.70	Aug-08
Antisense Therapeutics	\$0.04	\$0.07	Aug-08
Mesoblast	\$0.88	\$1.25	Aug-08
Cellestis	\$1.88	\$2.27	April 2008
IDT	\$1.68	\$1.90	March 2008
Circadian Technologies	\$0.55	\$1.03	February 2008
Patrys	\$0.09	\$0.50	December 2007
Bionomics	\$0.24	\$0.42	December 2007
Cogstate	\$0.17	\$0.13	November 2007
Sirtex Medical	\$1.90	\$3.90	October 2007
Clinuvel Pharmaceuticals	\$0.21	\$0.66	September 2007
Starpharma Holdings	\$0.20	\$0.37	August 2007
Pharmaxis	\$1.20	\$3.15	August 2007
Universal Biosensors	\$0.53	\$1.23	June 2007
Biota Holdings	\$0.37	\$1.55	March 2007
Probiotec	\$1.31	\$1.12	February 2007
Peplin Inc	\$0.28	\$0.83	January 2007
Arana Therapeutics	\$0.80	\$1.31	October 2006
Chemgenex Pharma.	\$0.42	\$0.38	June 2006
Cytopia	\$0.17	\$0.46	June 2005
AcruX	\$0.47	\$0.83	November 2004
Alchemia	\$0.15	\$0.67	May 2004

**Portfolio Changes – 28 Nov 2008**

**IN:**  
No changes.

**OUT:**  
No changes.

**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**

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