

**In this edition...**

The outbreak of influenza in Mexico, caused by a strain of swine influenza has spread rapidly amongst humans, with nearly 900 cases reported to date. This strain, A-H1N1, was found to contain genes from human, pigs and birds. A global influenza pandemic has threatened. In turn, this has raised questions about defence against pandemic threats. In response to previous arguments about just such a threat, governments have been stockpiling the anti-influenza drugs Tamiflu and Relenza. The likelihood that stockpiling policies will be revisited by governments is high with orders for GlaxoSmithKline's/Biota's Relenza likely to increase. Biota is also well placed with its next generation flu drug, a long acting version, being readied for the market in Japan, with a Phase III trial recently completed.

**The Editors****Companies Covered: BTA**

	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)	-7%
<b>Cumulative Gain</b>	<b>93%</b>
<b>Av Annual Gain (7 yrs)</b>	<b>17.8%</b>

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# Bioshares

1 May 2009  
Edition 309

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

## **How Many Millions Of Lives Will These Three Australians Save?**



*Graeme Laver*



*Peter Colman*



*Mark von Itzstein*

As governments around the world, including in Australia, argue and procrastinate about whether to support biotechnology investment during the current global financial crisis in favour of propping up aging car industries, perhaps one of the most significant contributions to global health in recent decades from biotech research is currently being recognised and utilised.

The outbreak of the 'swine flu' that originated in Mexico has spread across the globe with over 700 confirmed cases and 20 deaths. The alarming aspect of this influenza strain is the efficiency at which this virus is transmitted that has now spread to 16 countries in a number of weeks. A global pandemic outbreak is very real, with the World Health Organisation moving the threat to a Stage 5 threat. A Phase 5 alert means that a "strong signal that a pandemic is imminent". There are some signs that the outbreak may be stabilising. However a more serious second wave of infection may occur in the northern hemisphere winter towards the end of this year.

Some positive news about this threat is that the more densely populated northern hemisphere is moving towards its summer, which will help limit the transmission of the virus. Good news for the northern hemisphere but not for Australia although there are no confirmed cases in Australia yet. The morbidity rate is lower than first thought and than seen in Mexico, with only one death outside of Mexico.

And significantly, there are now two influenza drugs that are effective against this potentially deadly strain of the virus. Those two drugs are Tamiflu, developed by **Gilead Sciences** and sold by **Roche**, and Relenza, developed by **Biota Holdings** and sold by **GlaxoSmithKline**. It is possible that the global stockpiling and availability of these drugs is helping limit the death rate from this virus outbreak, with an estimated 300 million treatment courses of Relenza and Tamiflu currently stocked by government health authorities that have started to be dispensed to control and treat infection. Each person

*Cont'd over*

infected with the virus and all those who have come into close contact with carriers are being given one of these two antiviral drugs.

### Flu drugs pioneered in Australia

Most of the pioneering work on developing these drugs was conducted in Australia by three scientists: Graeme Laver, Peter Colman and Mark von Itzstein and their scientific teams.

Relenza is an exquisitely designed drug and one of the few drugs globally that has been developed through a 'rational design process', where the exact mechanism of action is observed, a three-dimensional image of the solid crystal structure of the point of interest is created, and a compound is built to sit inside a specific region inside that three-dimensional structure.

Graeme Laver and his team from the **John Curtin School of Medical Research** purified and crystallized the influenza protein neuraminidase. Peter Colman and his team from **CSIRO** then, through a painstakingly manual procedure, generated a three dimensional map of the influenza protein molecule using X-rays and layers of plastic transparencies (this was before the days of powerful computer software and hardware available to anyone today). Colman made the brilliant presumption that a pocket on the neuraminidase protein of the influenza molecule must have been an integral part of this virus because it was present on every strain of the influenza virus and therefore a necessary part of virus replication. And he was right.

A chemist Mark von Itzstein (and his team at the **Victorian College of Pharmacy**) was then brought in to build a chemical structure that would fit into the pocket on the neuraminidase protein. He was successful in constructing zanamavir (Relenza). However Gilead Sciences, riding on the coattails of the Relenza progress, which lacked sufficient patent protection over the research, soon followed and came up with their own compound, called oseltamivir (Tamiflu) to sit in the same pocket, and gave it an enteric coating to allow it to be taken as a tablet.

Ironically, it is Tamiflu that has achieved 90% of the commercial success to date with its tablet delivery format being preferred to the inhaled version of Relenza. This in itself is an irony, as the Relenza compound is targeted directly to the point of infection in the lungs rather than delivered systemically.

Graeme Laver, who died last year, was a firm believer that another influenza pandemic was inevitable. His prediction is now being taken a lot more seriously with a pandemic recently considered imminent by the WHO although there are some views that its impact may be less severe than was initially thought

Although Gilead and Roche have been the main beneficiaries from the demand for influenza drugs in the past, capturing around 85% of the global demand for stockpiling and most of the seasonal flu drug market, that can be expected to change as a result of the emerging resistance to Tamiflu in seasonal flu in the USA. However it should be noted that both drugs are currently effective against the current swine flu.

There is now a very strong argument that governments stockpiling these drugs can not afford to favour one drug over the other because of relative ease of delivery for one of these drugs, Tamiflu. Governments with existing stockpiles and governments looking to increase their stockpile levels should be looking to balance their stockpiles evenly of the only two antiviral drugs effective against the current swine flu virus.

The very real pandemic threat and the effectiveness of these two flu drugs in limiting mortality will almost certainly see global stockpile levels increase, perhaps double, as the arguments for stockpiling these drugs no longer having to be made by government health authorities.

### Governments order more Relenza & Tamiflu

This week the Finnish Government announced it will acquire 880,000 doses of Relenza as a stockpile, along with only 90,000 treatment courses of Tamiflu in addition to the 90,000 course of Tamiflu stockpiled to date.

The Danish Government will order 40,000 treatment courses of Relenza, with the country's head of disease prevention stating there was no guarantee the swine flu would respond to Tamiflu in the months ahead (with resistance issues surfacing in the USA to Tamiflu).

Apparently the US and UK Governments will continue to build their flu drug stockpiles, predominantly with Relenza. The UK Government is looking to increase its Relenza stockpile proportion to 50% from 33%. The US is also likely to increase its proportion of Relenza weighting in its 73 million course, flu drug stockpile from 20% Relenza. To date 25% of the US stockpile has been released for use by healthcare workers. Currently as estimated that US\$6.5 billion worth of Relenza and Tamiflu have been stocked by governments around the world.

### Forward royalty estimates

Biota is currently due to receive \$36 million in June for Relenza sales made to the end of April this year. We understand GlaxoSmithKline has a manufacturing capacity for 66 million treatment units of Relenza a year. Relenza is sold to governments for stockpiling at around US\$20 per treatment course. At a capacity of 66 million units, that represents a potential royalty to Biota of \$125 million a year at maximum current capacity (or \$250 million over the next two years). Biota's Relenza patents start to expire in mid 2011 although in the US are extended out to mid 2013. From 2011 - 2013 royalties we estimate will fall by around 50% from the previous years due to patent expirations.

Biota is currently capitalised at \$242 million. It has \$55 million in cash with \$36 million due in Relenza royalties due in June. There is further upside in the future cash flow equation if GSK can increase its production from outsourcing manufacture. There is also upside for Biota as it is (in conjunction with Daiichi Sanjyo) the only company that has a long acting flu drug program (a prodrug of Relenza) which is currently in Phase III trials in Japan. This drug

*Cont'd over*

candidate needs to be dosed only once every five days, as opposed to twice daily administration for Tamiflu and Relenza, and there may be significant value in this future product for Biota. This drug could be available for stockpiling within two years.

Daiichi Sankyo will commercialise the drug in Japan where Biota will receive a royalty, and will share the rights outside of Japan. No doubt finding a partner to complete development of this drug outside of Japan will have become much easier for the companies and with the potential terms more favourable in light of the current demand for this class of drugs.

This level of protection with government stockpiles also remains low given the quoted figure is only for one week's treatment per person.

### Summary

Biota Holdings has shown that investment in biotechnology can not only pay off for investors, but provide life saving technologies for millions of people. It is a salient point that the world is a much safer place to be in at the moment thanks to three Australian researchers, Graeme Laver, Peter Colman and Mark von Itzstein and their research teams. Unfortunately for Graeme Laver he didn't live to see the biggest benefit that his contribution to global health is making with the world battling the threat from a global influenza pandemic.

In the current climate of government budget cuts, this Australian science success story should serve as a reminder to governments not just in Australia but throughout the world of their obligation to continue funding and supporting medical research that can deliver life saving medicines that also confer important economic benefits.

### Recommendation

With regards to Biota, we expect there may be further to go with Biota's share price, as governments continue to stockpile Relenza in favour of Tamiflu, and as consumer awareness and demand for these drugs accelerates. Whether a pandemic eventuates or not, the world has at least come close to a global influenza pandemic and has witnessed the life saving benefit these drugs have provided, with no virus mutation yet to occur that exhibits inbuilt resistance to these drugs. However, the argument could be made that this class of drugs should be used for stockpiling and with high risk patient groups only to prevent drug-resistant influenza strains developing.

How many lives around the world are saved by these Australian scientists this time or when an influenza pandemic does occur will be difficult to count but it could be very easily be number in the millions. The world is certainly far better off with these drugs within its armoury of defensive pharmaceutical products.

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

#### Bioshares Model Portfolio (1 May 2009)

Company	Price (current)	Price added to portfolio	Date added
ASDM	\$0.30	\$0.30	December 2008
QRxPharma	\$0.47	\$0.25	December 2008
Hexima	\$0.45	\$0.60	October 2008
Atcor Medical	\$0.23	\$0.10	October 2008
CathRx	\$0.68	\$0.70	October 2008
Impedimed	\$0.75	\$0.70	August 2008
Mesoblast	\$0.78	\$1.25	August 2008
Cellestis	\$2.71	\$2.27	April 2008
IDT	\$1.78	\$1.90	March 2008
Circadian Technologies	\$0.84	\$1.03	February 2008
Patrys	\$0.05	\$0.50	December 2007
Bionomics	\$0.22	\$0.42	December 2007
Cogstate	\$0.20	\$0.13	November 2007
Sirtex Medical	\$3.00	\$3.90	October 2007
Clinuvel Pharmaceuticals	\$0.31	\$0.66	September 2007
Starpharma Holdings	\$0.27	\$0.37	August 2007
Pharmaxis	\$2.28	\$3.15	August 2007
Universal Biosensors	\$0.80	\$1.23	June 2007
Biota Holdings	\$1.38	\$1.55	March 2007
Probiotec	\$1.76	\$1.12	February 2007
Peplin Inc	\$0.64	\$0.83	January 2007
Arana Therapeutics	\$1.38	\$1.31	October 2006
Chemgenex Pharma.	\$0.42	\$0.38	June 2006
Cytopia	\$0.12	\$0.46	June 2005
Acrux	\$0.58	\$0.83	November 2004
Alchemia	\$0.35	\$0.67	May 2004

#### Portfolio Changes – 1 May 2009

**IN:**  
No changes

**OUT:**  
No changes

### 4.7B Reporting Companies – Cash Balances Mar. 31, 2009 Sorted by Adj. Survival Index

Code	Company	Cash End 31/03/09 (\$M)	Survival Index	Post 31/3 Cash Inflow	Survival Index - Adj.	Comments/Events post March 31
1 SRX	Sirtex Medical	\$21.0	A	Not App	Not App	
2 BRC	Brain Resource Corp	\$20.9	A	Not App	Not App	
3 UNI	Unilife	\$7.2	A	Not App	Not App	
4 BDM	Biodiem	\$5.6	A	Not App	Not App	
5 LBT	Labtech Systems	\$3.5	A	Not App	Not App	
6 AOS	Advanced Ocular Systems	\$2.9	A	Not App	Not App	
7 IMU	Imugene	\$2.8	A	Not App	Not App	
8 CGS	Cogstate	\$2.7	A	Not App	Not App	
9 RHT	Resonance Health	\$2.6	A	Not App	Not App	
10 NDL	NeuroDiscovery	\$1.5	A	Not App	Not App	
11 CTE	Cryosite	\$1.0	A	Not App	Not App	
12 AVS	Avastra	\$0.9	A	Not App	Not App	
13 BPH	Biopharmica	\$0.5	A	Not App	Not App	
14 ACG	Atcor	\$3.9	A	12.5	12.5	
15 CBB	Cordlife	\$6.5	A	8.4	8.4	
16 PAA	Pharmaust	\$3.9	A	5.5	5.5	
17 HXL	Hexima	\$31.8	A	4.2	4.2	
18 PXS	Pharmaxis	\$85.8	A	3.9	3.9	
19 CUV	Clinuvel Pharmaceuticals	\$39.4	A	3.9	3.9	
20 UBI	Universal Biosensors	\$28.0	CY	3.4	3.4	
21 ACW	Actinogen	\$1.9	A	2.7	2.7	
22 SIE	Scigen	\$8.9	CY	2.6	2.6	
23 FER	Fermiscan	\$5.6	CY	0.7	2.4	
24 SPL	Starpharma	\$5.9	A	1.5	2.2	Rec'd \$3.1M in placement 7/4; \$1.2-\$1.5M to follow; SPP to follow
25 ACR	Acrux	\$19.6	A	2.2	2.2	
26 SOM	Somnomed	\$4.0	A	2.1	2.1	
27 MSB	Mesoblast	\$7.9	A	0.9	2.1	Completed \$10.8 M placement in Mar Q; Funds rec'd post 31/3
28 HGN	Halcygen	\$8.8	A	1.9	1.9	
29 GTG	Genetic Technologies	\$9.4	A	1.9	1.9	
30 BPO	BioProspect	\$2.7	A	1.7	1.7	
31 NAN	Nanosonics	\$16.1	A	1.7	1.7	
32 QRX	QRxPharma	\$25.4	A	1.5	1.5	
33 PAB	Patrys	\$11.6	A	1.3	1.3	
34 BNO	Bionomics	\$6.1	A	1.3	1.3	
35 MGZ	Medigard	\$0.1	A	0.3	1.3	SPP funds of \$360K rec'd post 31/3
36 OBJ	OBJ	\$1.2	A	1.2	1.2	
37 ANP	Antisense Therap.	\$3.9	A	1.2	1.2	
38 ACL	Alchemia	\$9.5	A	1.2	1.2	
39 AVH	Avita Medical	\$5.1	A	1.1	1.1	
40 BOD	BioMD	\$0.7	A	0.7	1.1	Closed rights issue 27/3 -raised \$421K ; shortfall placement raised \$437K
41 HCG	Helicon Group	\$1.0	A	1.1	1.1	
42 PLI	Peplin	\$38.2	A	0.9	0.9	
43 ADO	Anteo Diagnostics	\$1.6	A	0.9	0.9	
44 ALT	Analytica	\$1.2	A	0.9	0.9	
45 LCT	Living Cell Technologies	\$5.3	A	0.8	0.8	
46 PBT	Prana Biotechnology	\$5.8	A	0.8	0.8	
47 UCM	USCOM	\$1.4	A	0.7	0.7	
48 TDY	Tyrian Diagnostics	\$4.8	A	0.6	0.6	
49 CXD	CathRx	\$6.9	A	0.6	0.6	
50 SLA	Solagran	\$1.8	A	0.6	0.6	
51 BLT	Benitec	\$1.2	A	0.6	0.6	Conducting rights issue
52 NEU	Neuren Pharmaceuticals	\$0.5	CY	0.1	0.5	
53 XCD	Xceed Capital	\$0.9	A	0.5	0.5	
54 ATW	Atos Wellness	\$1.2	A	0.5	0.5	
55 SHC	Sunshine Heart	\$3.9	A	0.5	0.5	
56 TIS	Tissue Therapies	\$1.4	A	0.5	0.5	
57 FYI	Freedom Eye	\$0.4	A	0.5	0.5	
58 AYX	Austofix	\$0.9	A	0.4	0.4	
59 FLS	Fluorotechnics	\$1.2	A	0.3	0.4	Conducted rights issue; \$0.7M rec'd pre 31/3; \$0.49M rec'd post 31/3
60 GBI	Genera Biosystems	\$1.2	A	0.3	0.3	
61 KSX	KarmelSonix	\$1.4	A	0.3	0.3	
62 BIT	Biotron	\$0.6	A	0.3	0.3	14/4 closed SPP - raised \$800K
63 AVX	Avexa	\$12.8	A	0.3	0.3	Closed \$16.68M rights issue and placement 30/4
64 VLA	Viralytics	\$1.0	A	0.3	0.3	Conducting options right issue to raise \$3M
65 IPD	Impedimed	\$4.0	A	0.3	0.3	
66 SLT	Select Vaccines	\$0.5	CY	0.2	0.3	
67 CAU	Colltech	\$0.3	A	0.3	0.3	
68 MVH	Medic Vision	\$0.3	A	0.3	0.3	
69 GBL	Genesis Biomedical	\$0.3	A	0.2	0.2	
70 RBY	Rockeby Biomed	\$0.4	A	0.2	0.2	
71 EMS	Eastland Medical Systems	\$0.3	A	0.2	0.2	

## 4.7B Reporting Companies – Cash Balances Mar. 31, 2009 Sorted by Adj. Survival Index

Code	Company	Cash End 31/03/09 (\$M)	Survival Index	Post 31/3 Cash Inflow	Survival Index - Adj.	Comments/Events post March 31
72 PRR	Prima Biomed	\$0.3	A	0.2	0.2	Has access to \$12M equity draw down facility
73 ACU	Acuvax	\$0.2	A	0.2	0.2	Sold stake in drug asset; cash to improve by more than \$750K
74 HTX	Healthlinx	\$0.4	A	0.2	0.2	
75 PYC	Phylogica	\$0.6	A	0.2	0.2	22/4: Placement \$1.2 M and Con notes \$1.24M; placement of \$1.4M to follow
76 BOS	Biosignal	\$0.2	A	0.1	0.1	Raised \$120K through placement
77 GIA	Giaconda	\$0.005	A	0.0	0.1	Rec'd \$60K loan; has undrawn facilities of \$200K
78 DIA	Dia-B Tech	\$0.2	A	0.1	0.1	
79 OMI	Occup. & Medical Innov.	\$0.2	A	0.1	0.1	
80 ICV	Incitive	\$0.1	A	0.1	0.1	16/4 Rights issue raised \$783K
81 IMI	IM Medical	\$0.2	A	0.1	0.1	
82 MTY	Medical Therapies	\$0.1	A	0.1	0.1	Completed \$700K placement 17/4; requires shareholder app.
83 BNE	Bone Medical	\$0.1	A	0.1	0.1	
84 STI	Stirling Products	\$0.1	A	0.1	0.1	
85 PCC	Probiomics	\$0.038	A	0.1	0.1	
86 NAL	Norwood Abbey	\$0.021	A	0.0	0.0	Rec'd sh. term funding of \$250K; to receive div. from Norwood Im. ~\$972K.

### 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 three quarters' figures, annualised.

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

*Small cap life science companies that are not required to comply with the 4.7B Rule include:*

*Advanced Medical Design and Manufact., Agenix, Imuron, Arana Therapeutics, Biota Holdings, Cellestis, Circadian Technologies, Clovercorp, Compumedics, ChemGenex Pharm., Cyclopharm, Cytopia, Teleso Technologies, Ellex Medical Lasers, Ascent PharmaHealth, IDT Australia, ITL Corp, Life Therapeutics, Metabolic Pharmaceuticals, Medical Developments Int., Novogen, Optiscan Imaging, Progen Pharm., Polartech, Phosphagenics, Sirtex Medical\*, Ventracor and Virax Holdings – (27 companies).*

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

*\* This company elects to report.*

## March 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.

We have adjusted the SIs of companies where companies have received committed funds, or similar, not long after the close of the quarter.

The index is derived for this quarter by dividing the annualised average of net operational cash flows (NOCF) for the last three quarters into each company's cash assets as recorded at December 31, 2008. For companies that report on Dec 31 full year basis, index is based on average last five 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 than 0.5 may be in positions of funding stress and investors should investigate such stocks with a greater degree of concern.

### Commentary

For the March quarter 2009, 45 of the 86 reporting companies reported SIs of less than 1.0 and 29 companies reported SIs of less than 0.5, or less than six month's cash. In comparison, in the December quarter, 27 companies reported SIs of less than 0.5.

Although the number of companies in distress appears to be about the same from quarter to quarter, what must be noted is the flow of companies removed from the analysis. We have removed **Brainz** and **Stem Cell Sciences** as these companies have gone through a divestment process and exist in a state of operational hibernation. **Narhex Life Sciences** has also been removed from the analysis as it is suspended from trading and can best be described as moribund. Previously **Apollo Life Sciences**, **Ambri** and **Portland Orthopaedics** have been removed. And two companies that appear to be set for a degree of business re-purposing are Biosignal and Incitive.

The Survival Index analysis shows that the viability of a substantial number of biotech companies remains in doubt. However, what is also evident is that some companies have achieved some success in gaining small amounts of funding, which would appear to enable them to survive for several more months. Some companies generating clinical interest and success, e.g. **Mesoblast**, have managed to raise reasonable tranches of funds to secure ongoing clinical trial requirements.

**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 (note, accidentally omitted from this list from Eds 297 onwards), Pharmaxis, Cytopia, Arana Therapeutics, Starpharma Holdings, Cogstate, Optiscan Imaging, Bionomics, ChemGenex Pharmaceuticals, Circadian Technologies, Biota Holdings, Stem Cell Sciences, Halcygen Pharmaceuticals, Peplin, BioMD, Impedimed, QRxPharma, Patrys, Labtech Systems, Hexima, Tyrian Diagnostics, Mesoblast, Atcor Medical

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