ISSN 1443-850X

Biosshares

4 November 2011
Edition 432

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

In this edition...

Biotechs that don't pay attention to the First Rule of Biotech, which is to get, or have the capacity to get, the funds necessary to support commercialisation goals, become much riskier propositions for investors. Investors can forgive technical failure (i.e. that a technology simply doesn't work at the most basic medical level) but there is much less forgiveness for boards that fail to recognise the need to be properly funded. Accompanying our feature on financial execution risk is our regular analysis of quarterly cash flow reporting companies. The ASX rule covering quarterly cash flow reporting has been, in our opinion, a great aid for investors wanting to see which companies observe the First Rule of Biotech.

The Editors

Companies Covered:
Execution Risk, Cash Flow Analysis

	Bioshares Portfolio
Year 1 (May '01 - May '02)	21.2%
Year 2 (May '02 - May '03)	-9.4%
Year 3 (May '03 - May '04)	70.0%
Year 4 (May '04 - May '05)	-16.3%
Year 5 (May '05 - May '06)	77.8%
Year 6 (May '06 - May '07)	17.3%
Year 7 (May '07 - May '08)	-36%
Year 8 (May '08 - May '09)	-7.3%
Year 9 (May '09 - May '10)	49.2%
Year 10 (May '10 - May'11)	45.4%
Year 11 now commenced	-22.0%
Cumulative Gain	**229%**
Av. annual gain (10 yrs)	**21.2%**

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

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Individual Subscriptions (48 issues/year)
$375 (Inc.GST)
Edition Number 432 (4 November 2011)
ISSN 1443-850X

Financial Execution Risk for Biotechs – Can They Fund the Business Plan?

At a recent industry briefing, Graeme Kaufman from **Mesoblast** talked about execution risk, referring to the ability or inability of a company to fund its commercialisation objectives. With $255 million in the bank, that risk has largely diminished for Mesoblast, and this is one reason that explains Mesoblast's large market capitalisation of $2.2 billion.

However, for many other biotechs, the majority cannot fully fund their programs through to commercialisation. This explains the low market values for so many and the frustration of investors and management in undervalued stock. It's a very good point by Kaufman. Financial/funding risk, the global financial crisis has taught us, is one of the largest risks facing most biotech companies. The mantra the money comes first, then the technology, should be at the forefront of most biotech management teams.

Below we look at the financial execution risk profiles for some of the players in the Australian biotech sector.

Financial Execution Risk - Selected Companies

Less Exposed to Financial Execution Risk

Company	Cash at 30 Sept. ($M)
Mesoblast	$255.0
Biota Holdings*	$70.0
Prima Biomed	$51.1
QRxPharma	$32.0
Phosphagenics ***	$30.0
pSivida*	US$24.0
Bionomics	$18.9
Universal Biosensors	$18.8
Starpharma	$17.0
Clinuvel Pharmaceuticals	$14.6
Tissue Therapies	$13.5

More Exposed to Financial Execution Risk

Company	Cash at 30 Sept. ($M)
Pharmaxis	$33.7
Circadian Technologies	$22.4
Sunshine Heart	$10.5
Prana Biotechnology	$8.5
Patrys	$4.4
Alchemia**	$4.0
Biotron	$1.8
Antisense Therapeutics	$1.5

* At June 30
** Capital raising underway
*** At June 30, adjusted for subsequent $24 million placement

Alchemia

At the end of September, Alchemia had only $4.0 million left in the bank. A dwindling share price has followed the FDA approval of its generic drug fondaparinux (fonda), limiting the opportunity to raise funds. The company has a funding hole of about nine months before decent revenue streams start flowing in from fonda sales. On Thursday the company went into a trading halt with its share price languishing at around 28 cents.

The inability of the company to raise funds to complete its Phase III trial with HA-Irinotecan in colon cancer now sees no value at all being attributed to this asset, with the market placing very high execution risk on this program. The inability to initiate this program has seen a weakening of its intellectual property position with respect to time, and also the loss of leveraging of this technology platform for other cancer drugs.

Had Alchemia started its Phase III HA-Irinotecan study in 390 patients with colorectal cancer in 2009 or even early 2010, the trial would have been completed and the results would have been received by now. The delay in gaining fonda approval, and the commitment to fund the Phase III HA-Irinotecan trial from fonda revenue, which will cost around $20 million, has been the reason for the stagnation.

The problem for Alchemia is also likely due to a diversion of directions its shareholder base wants to take the company which has attributed to the stalled commercialization of its oncology assets.

Pharmaxis

Pharmaxis is, by various estimates, about $50 million short of the funds required to secure a market position for its lead drug, Bronchitol, for the treatment of cystic fibrosis. The unexpected delay in gaining European approval which triggered a crash in its share price has made funding options for the company more difficult. While the company should now receive European regulatory approval in January next year, the market perception is that the company will need to raise more funds and its volatile share price has caused many shareholders to exit.

This shortfall in funds has very likely been a factor of price weakness following the initial price surge after a positive CHMP view last month. Other options for the company include licensing regional rights to Bronchitol for CF in say Europe with potential upfront and milestone payments funding the commercialization in the US.

Sunshine Heart

Sunshine Heart is another company unhappy about its share price. The company has flagged that it will need to do a significant capital raising to fund its forthcoming pivotal study, which we expect will be in the order of $40 million. At a market capitalization of around $50 million, that may be difficult.

Patrys

Patrys has clearly articulated what it needs and where it expects to be by the end of 2012. What it needs is at least $5 million to expand the commercialization of its leading cancer antibody technologies. However with the market expecting a capital raising at a discounted price, there is some resistance on the company's share price.

Prana Biotechnology

Prana Biotechnology was down to $8.5 million in cash at the end of September. Late last year Prana was to receive a $15 million Victorian Government grant to fund a large Phase II study which would cost around $25 million. However with a change in government, that grant fell through. With limited funds, Prana is now seeking to gain more efficacy data from smaller trials, those being a small Phase II Alzheimer's disease trial in 40 people using the latest in imaging technology to measure effect on beta amyloid plaques. It will also conduct a 100 patient study in Huntington's disease.

Antisense Therapeutics

Antisense Therapeutics is expected to release some results in a Phase I trial in healthy volunteers with its current lead compound ATL1103. The trial is expected to provide early signs of impact on reducing circulating IGF-1 levels in the blood, with high IGF-1 levels associated with diabetic retinopathy and acromegaly.

However, with just under $1.5 million in cash at the end of September, the company will more than likely need to raise funds in coming months.

Cont'd over

Risks for Biotech Companies

Risks for biotech companies can be divided into three categories: financial execution risk, technology risk and commercial development risk.

Financial Execution Risk

As described earlier, this risk relates to ability of a company to fund its commercialization programs and is one of the key risks that investors should consider.

Technology Risk

This is an obvious risk. It relates to whether or not a technology will achieve the necessary endpoints, primary safety and efficacy.

Commercial Development Risks

This can be divided into at least six sub-categories: competition risk (including intellectual property), payment risk, market access risk, regulatory risk, product development risk and partnering risk.

Payment risk relates to whether a product will achieve a reimbursement price sufficiently in excess of the cost of goods and sunk development costs and that passes ROI objectives.

Competition risk relates to whether a product will achieve sufficient product advantages when it reaches the market and how long those advantages will be maintained from the threat of being superceded by a newer technology.

Market access risk is often ignored, and relates to whether a company will be able to compete, often against major corporations that largely define this industry. CathRx and Portland Orthopedics are two companies that stumbled over this factor.

Australian investors have become aware of the **risk the regulator** poses to biotech companies. In the last two years, at least three local companies - Chemgenex Pharmaceuticals, Pharmaxis and Psivida - have stumbled at the final hurdle before getting to market.

Partnering risk has also become a key issue to be wary of, particularly as partners are acquired by larger companies and a biotech company's program can become less important. Starpharma, Optiscan Imaging and Biodiem have all had to deal with this issue.

Product **development risk** includes, among other things, the risk that companies will not be able to complete recruitment into clinical studies. An example is Progen Pharmaceuticals.

Biotron

Biotron delivered some positive results in its Phase II Hepatitis C drug trial last month with BIT225. The trial in 24 patients showed an improvement over the standard of care treatment. However the company's cash balance may be impacting the share price, with just over $1.8 million in funds at the end of September.

Circadian Technologies

Circadian Technologies is well funded at the moment, however, with cash of $22.4 million at the end of June, it represents only around two years of funding for the company at its current spend. The point is that it is not always about the cash balance per se, but also whether the company has the funds to commercialise its assets.

Limited Financial Execution Risk

Although for many companies funding remains a significant challenge in the short and medium term, aside from the profitable businesses, there are several companies that have shown they have either largely eliminated or have shown they have the capacity to fund their programs when and as required.

On the top of this list is **Mesoblast**, which has indicated it intends to maintain a healthy cash balance and would appear to have the committed institutional shareholder base to ensure that occurs.

QRxPharma, **Bionomics**, **Starpharma** and **Phosphagenics** have shown they have the ability to clearly articulate their commercialisation objectives finding continued support for funding from investors. The risk of having insufficient funds to commercialise their assets is low, relative to many other biotechs.

In a similar fashion, **Prima Biomed** has been able to fund its CVac program, raising $41 million earlier this year. It's timing was almost perfect for this capital raising; at that time, the leading global cancer vaccine company had a market capitalisation of $6 billion. Since then, **Dendreon**'s share price has plummeted, with the company now valued at only $975 million. Prima now has sufficient funds to take its current programs through to 2014, at which point it should have results from its 800 patient Phase III ovarian cancer trial.

Tissue Therapies is well placed to fund its wound healing technology with $13.5 million in the bank at the end of September. It is currently in discussions with potential marketing partners and its product is expected to start selling in Europe in the first half of 2012.

Clinuvel Pharmaceuticals is similarly well placed. The company has indicated it is not looking to raise funds, having sufficient funds to get its lead product approved. It is expecting to file Scenesse for approval in Europe by year's end. The company has been very efficient with its cash usage. It last raised funds in 2007 and had $14.6 million in funds at the end of June.

pSivida has US$24 million in cash. Its lead drug candidate, Iluvien, of which it owns 20% of any future profits, is due to be assessed by the FDA in the next week. If that product is approved, pSivida will receive a US$25 million payment from its licensing partner, **Alimera Sciences**. If that occurs pSivida will be extremely well funded with an ongoing profit share from Iluvien sales. It should be noted, on Thursday Alimera announced the FDA may want to see data from a current 100 patient trial looking at delivery aspects of Iluvien before it considers it for approval.

Universal Biosensors had $18.8 million in cash at the end of September. Revenue from its first product, glucose test strips, as well as ongoing partnering revenue and its existing cash balance place that company in a comfortable financial position.

Biota Holdings had $70 million in funds at the end of June. It has ongoing revenue from royalties (4%) from Inavir (LANI) sales in Japan, global royalties from Relenza sales (7%), with those royalties ending in the US in December 2014 and in Japan in 2019. Future royalties we estimate to be between $100 million - $140 million. This assumes annual Relenza royalties of $35 million a year over the next three years (five year average) which will be driven be replenishment and rebalancing of global influenza drug stockpiles. We also believe seasonal usage will return to normal levels in the next three years following oversupply in FY2010 and low demand last year.

Biota also has a five year US$231 million US government contract to develop a long acting flu drug (LANI) for the US market. The US government holds about US$1.7 billion worth of flu drugs as a stockpile against any potential flu pandemic. The LANI drug, which is taken only once rather than twice daily for five days, has obvious benefits for this market. On completion of development of LANI in the US, Biota would be free to sell into the US$4 billion global stockpile market (which consists of around 20 government buyers) excluding Japan. It shares rights to LANI outside of Japan with **Daiichi Sankyo**, however, Biota will own any marketing rights. How profits are distributed with Daiichi Sankyo, after all costs are recovered by Biota, remains to be determined.

In our view, Biota Holdings is a clear takeover target. Biota's chairman, Jim Fox, was previously CEO of **Vision Systems**, which was acquired by **Danaher Corporation** for around $800 million. The push to open up value for Biota may also be coming from Fox, who after selling the fire detection assets at Vision Systems, opened up a three way bidding war for that company. Vision Systems was also a company that was poorly appreciated by the market and traded at a heavy discount to its final sale price.

We note a US-based hedge fund, **East Hill Holding Company**, has increased its stake to 9.2% in October, up from 6.0% in December last year. Biota is capitalised at only $140 million.

Bioshares

4.7B Reporting Companies – Cash Balances September 30, 2011

Sorted by Survival Index

	Code	Company	Cash Receipts ($M)	Nett Op. Cash Fl. ($M)	Cash End 30/9/11 ($M)		Survival Index	Comments/Events post reporting date
1	GTG	Genetic Technologies	$2.5	-$1.3	$14.9	A	**Not App**	
2	IMU	Imugene	$0.0	-$0.1	$2.0	A	**Not App**	
3	SOM	Somnomed	$3.1	-$0.1	$3.8	A	13.6	
4	PCC	Probiomics	$0.1	$0.0	$0.2	A	9.0	Completed $200K placement; to merger with Hunter Immunology
5	NEU	Neuren Pharmaceuticals	$0.0	-$1.0	$9.0	**CY**	7.0	
6	NDL	NeuroDiscovery	$0.0	-$0.2	$2.6	A	6.2	
7	HCT	Holista Colltech	$1.4	$0.2	$1.1	A	4.8	
8	RVA	Reva Medical	$0.0	-$11.7	$66.4	**CY**	4.3	
9	AVH	Avita Medical	$0.8	-$0.8	$11.8	A	3.9	
10	MSB	Mesoblast**	$0.1	-$16.4	$255.9	A	3.9	
11	UBI	Universal Biosensors	$14.3	-$3.7	$18.8	**CY**	3.9	
12	OBJ	OBJ	$0.0	-$0.6	$4.2	A	3.6	
13	PRR	Prima Biomed	$0.0	-$5.3	$51.1	A	3.5	
14	AVX	Avexa	$0.0	-$0.8	$16.1	A	3.4	
15	GID	GI Dynamics	$0.2	-$16.4	$72.6	**CY**	3.3	
16	ADO	Anteo Diagnostics	$0.0	-$0.6	$6.2	A	2.8	
17	TIS	Tissue Therapies	$0.0	-$1.9	$13.5	A	2.7	
18	BNO	Bionomics	$0.8	-$1.3	$18.9	A	2.4	
19	SPL	Starpharma	$0.5	-$2.1	$17.0	A	2.4	
20	BRC	Brain Resource Corp	$0.2	-$1.0	$6.7	A	2.2	Second tranche of Convertible Bonds issued ($5 million)
21	BLT	Benitec	$0.1	-$0.7	$6.2	A	2.0	
22	LBT	LBT Innovations	$0.0	-$0.2	$3.2	A	2.0	
23	MLA	Medical Australia	$2.5	-$0.4	$1.3	A	1.8	
24	RHT	Resonance Health	$0.5	-$0.3	$1.2	A	1.7	
25	PBT	Prana Biotechnology	$0.0	-$1.8	$8.5	A	1.6	
26	CBB	Cordlife	$1.8	-$1.5	$3.7	A	1.6	
27	ACU	Acuvax	$0.0	-$0.1	$1.1	A	1.5	
28	QRX	QRxPharma	$0.0	-$3.9	$32.0	A	1.5	
29	IPD	Impedimed	$0.8	-$3.3	$15.4	A	1.3	
30	VLA	Viralytics	$0.3	-$1.0	$4.0	A	1.2	
31	BDM	Biodiem	$0.6	-$0.1	$2.5	A	1.2	
32	CUV	Clinuvel Pharmaceuticals	$0.4	-$3.0	$11.5	A	1.1	
33	NAN	Nanosonics	$1.6	-$2.1	$10.3	A	1.1	
34	MGZ	Medigard	$0.0	$0.0	$0.6	A	1.1	
35	BIT	Biotron	$0.0	-$0.3	$1.9	A	1.0	
36	SHC	Sunshine Heart	$0.0	-$3.2	$10.6	A	1.0	
37	GBI	Genera Biosystems	$0.0	-$0.7	$1.8	A	**0.9**	
38	EMS	Eastland Medical Systems	$0.9	-$0.6	$2.8	A	**0.9**	
39	PYC	Phylogica	$0.0	-$2.0	$3.5	A	**0.9**	
40	PXS	Pharmaxis	$0.4	-$10.7	$33.7	A	**0.9**	
41	PAB	Patrys	$0.1	-$1.7	$4.4	A	**0.8**	
42	ACG	Atcor Medical	$1.9	-$0.3	$1.3	A	**0.7**	
43	UNS	Unilife	$1.5	-$7.8	$20.4	A	**0.7**	
45	ANP	Antisense Therap.	$0.0	-$0.9	$1.5	A	**0.7**	
44	AHZ	Allied Health	$1.6	-$0.6	$0.9	A	**0.6**	
46	ACW	Actinogen	$0.0	-$0.3	$0.6	A	**0.6**	
47	BCT	Bluechiip	$0.0	-$0.1	$0.9	A	**0.6**	
48	UCM	USCOM	$0.3	-$0.7	$1.4	A	**0.6**	
49	HCG	Helicon Group	$0.0	-$0.8	$0.9	A	**0.6**	
50	OMI	Occup.& Medical Innov.	$0.0	-$0.1	$0.4	A	**0.6**	
51	TDX	Tyrian Diagnostics	$0.3	-$1.0	$2.1	A	**0.6**	To license or sell core IP; considering strategic options
52	CDY	Cellmid	$0.0	-$0.6	$1.2	A	**0.5**	
53	LCT	Living Cell Technologies	$0.0	-$1.8	$2.9	A	**0.5**	Diabecell transferred to JV - $25M funds from Otsuka Pharm.
54	AGX	Agenix	$0.0	-$0.6	$1.2	A	**0.4**	
55	SIE	Scigen	$11.8	-$3.1	$1.8	**CY**	**0.4**	
56	CXD	CathRx	$0.0	-$2.0	$3.1	A	**0.4**	Conducting u/w rights issue to raise $2 million
57	ACL	Alchemia	$0.0	-$1.5	$4.0	A	**0.4**	Conducting capital raising
58	LER	Leaf Energy	$0.1	-$0.2	$0.6	A	**0.4**	
59	BNE	Bone Medical	$0.0	-$0.1	$0.1	A	**0.1**	US$6 M Convertibe note facility with La Jolla Cove Invest. Part.
60	HTX	Healthlinx	$0.0	-$0.7	$0.2	A	**0.1**	Entered into $3M funding agreement with US investor
61	IMI	IM Medical	$0.0	-$0.3	$0.1	A	**0.1**	Conducting rights issue to raise $2.8 to $3.3 million
62	SLA	Solagran	$0.2	-$2.1	$0.5	A	**0.1**	Finalising $2.9 million funding facility
63	AYX	Austofix	$0.4	-$0.2	$0.0	A	**0.0**	Accessing Con.Note; shares suspended pending capital raising
64	ISN	Isonea	$0.0	-$1.1	$0.2	A	**0.0**	Access to $10.6 million in US funding
65	ALT	Analytica	$0.0	$0.0	$0.0	A	**0.0**	Conducting rights issue to raise $2.7 to $2.9 million
66	CBZ	CBio				A		Did Not Report - Seeking to raise $M

*** SI - based on Q1 NOCF annualised*

Bioshares Model Portfolio (4 November 2011)

Company	Price (current)	Price added to portfolio	Date added
QRxPharma	$1.59	$1.66	October 2011
Mayne Pharma Group	$0.430	$0.435	September 2011
Genetic Technologies	$0.13	$0.18	August 2011
Acrux	$3.32	$3.37	June 2011
Psivida	$4.35	$3.95	May 2011
Bioniche	$0.69	$1.35	March 2011
Somnomed	$1.10	$0.94	January 2011
Phylogica	$0.056	$0.053	September 2010
Biota Holdings	$0.77	$1.09	May 2010
Tissue Therapies	$0.57	$0.21	January 2010
Atcor Medical	$0.08	$0.10	October 2008
Impedimed	$0.57	$0.70	August 2008
Bionomics	$0.40	$0.42	December 2007
Cogstate	$0.19	$0.13	November 2007
Sirtex Medical	$4.62	$3.90	October 2007
Clinuvel Pharmaceuticals	$1.48	$6.60	September 2007
Pharmaxis	$1.32	$3.15	August 2007
Universal Biosensors	$0.90	$1.23	June 2007
Alchemia	$0.28	$0.67	May 2004

Portfolio Changes – 4 November 2011

IN:
No changes.

OUT:
No changes

4.7B Reporting Companies – Cash Balances September 30, 2011 (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 last five quarters NOCF.

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

Commentary

At September 30, 2011, from a reporting pool of 66 companies, we calculated 29 companies to have a Survival Index of less than 1, with one company, CBio failing to report its cash position by the required date, while it conducts a capital raising. CBio recently announced its Phase II rheumatoid arthritis trial of Xtol did not meet its primary endpoint.

Acrux was released from its quarterly reporting obligations. Living Cell Technologies structured a joint venture with Otsuka Pharmaceutical Factory to house its diabetes implant therapy, Diabecell. Otsuka will provide $25 million in funding to the JV. And Tyrian Diagnostics is winding down activities and considering options, following the termination of a program with Bayer Crop Science.

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 average of net operational cash flows (NOCF) for the last five quarters ending September 30, 2011, into each company's cash assets as recorded at September 30, 2011. For companies that report on December 31 full year basis, the index is based on three quarters of net operational cash flows (NOCF) annualised. The NOCF is the net of receipts and outgoings incurred in support of operational activities.

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

Small cap life science companies that are not required to comply with the 4.7B Rule include: Acrux, Advanced Medical Design and Manufact., Immuron, Biota Holdings, Bioniche, Cogstate, Circadian Technologies, Clovercorp, Compumedics, Cryosite, Cyclopharm, Telesso Technologies, Ellex Medical Lasers, IDT Australia, ITL Corp, Calzada, Medical Developments Int., Novogen, Optiscan Imaging, Progen Pharm., Phosphagenics, Sirtex Medical and Virax Holdings.

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

Corporate Subscribers: Pharmaxis, Starpharma Holdings, Cogstate, Bionomics, Circadian Technologies, Biota Holdings, Impedimed, QRxPharma, Patrys, LBT Innovations, Hexima, Mesoblast, Atcor Medical, Tissue Therapies, Viralytics, Phosphagenics, Immuron, Phylogica, Bluechiip, pSivida, Antisense Therapeutics, Benitec, Allied Healthcare Group

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