ISSN 1443-850X

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Clinical trials are where the rubber hits the road for biotechs. Bionomics' clinical development of anti-anxiety drug BNC210 has gathered enough momentum to stimulate prospective partner interest in North America.
Patrys' antibody drug PAT-SM6 is progressing through a Phase I trial in non-metastatic melanoma patients, with an update on the trial expected next month and full results around mid year.
Antisense Therapeutics intends to start a single dose safety study in a Phase I trial of ATL1103 in Q3 2011.
Elsewhere we discuss Calzada's direction under new CEO Stewart Washer, the proposed merger of BioMD with Allied Medical and present analysis of our survey of life science CEO salaries for FY2010.
The Editors
Companies Covered: ANP, BNO, BOD, CZD, PAB, Salaries Survey

	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 - Current)	29.5%
Cumulative Gain	**275%**
Av Annual Gain (9 yrs)	**18.5%**

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

Blake Industry & Market Analysis Pty Ltd
ACN 085 334 292
PO Box 193
Richmond Vic 3121
AFS Licence
No. 258032

Enquiries for *Bioshares*
Ph: (03) 9326 5382
Fax: (03) 9329 3350
Email: info@bioshares.com.au

David Blake
Ph: (03) 9326 5382
Email: blake@bioshares.com.au
Mark Pachacz
Ph:03 9348 9317
Email: pachacz@bioshares.com.au

Individual Subscriptions (48 issues/year)
$350 (Inc.GST)
Edition Number 397 (25 February 2011)
ISSN 1443-850X

Bioshares

25 February 2011
Edition 397

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

Bionomics Builds Intense Interest in BNC210

Business development activities have been in full swing this year for Bionomics (BNO: $0.39) with the company conducting two partnering-directed trips to North America over January and February. CEO Deborah Rathjen firstly undertook 20 meetings structured around the JP Morgan Healthcare conference in San Francisco. This was followed by a an East coast partnering trip focussed solely on BNC210, which was supported by a contingent of key Bionomics personnel. There is intense interest building from potential partners in this program.

BNC210 is an anti-anxiety drug that at the end of the current Phase I program will have generated safety data from 120 human subjects together with some efficacy data as well. Common anxiety drugs include Valium, Buspar and Prozac, however, limitations of drugs in this class include sedation and withdrawal syndromes. BNC210 is a fast-acting, oral, once-a-day drug candidate that addresses these limitations.

Two Phase Ia trials of BNC210 have been completed with data from two Phase Ib trials expected to become available next month. The data is currently under lock and is being analysed.

One of these trials is comparing BNC210 to lorazepam, a drug similar to Valium (diazepam), with an endpoint comparing multiple-choice question reaction times. The second study is evaluating the effect on subjects who have been administered CCK-4 (cholecystokinin tetra peptide) in order to induce a panic attack. The endpoint is derived from panic symptom scale scores.

BNC210 attracted the interest of at least one potential partner that has been studying the same drug target that BNC210 modulates. This particular company had not been able to solve the problem of designing an anti-anxiety drug that wasn't sedative. The partnering roadshow has now opened up the possibility of a two-way dialogue for Bionomics and potential partners.

The Start-up Australia Tender

Start-up Australia has put its 27.8% stake in Bionomics up for tender, with a cut-off date of March 31, 2011. A successful tender would trigger a take-over bid for Bionomics. However, the process may have been slowed somewhat given that interim data from the Phase II kidney cancer trial has been put back to Q2 2011, due to several patients not completeing two full cycles of treatment.

Milestones

Q1 2011– BNC210: Report on two Phase Ib trials
Q2 2011 – BNC105: Interim data on mesothelioma and renal cancer Phase II trials

Bionomics is capitalised at $124 million and held cash resources of $8.5 million at December 31, 2011.

Bioshares recommendation: **Speculative Buy Class A**

Calzada Signals Commitment to Organic Growth of Business

Calzada (CZD: 4.3 cents) has signaled that it intends to build a broad-based biotech business, rather than being a serial investment vehicle that acquires biotech assets. Calazada was formerly Metabolic Pharmaceuticals. It acquired 100% of the Polynovo biomaterials business over the last two years.

Last year it took a strategic in **Avexa**, investing $4 million (at around 2.9 cents per share) for a 16% stake. The company attempted to spill the board, and very likely with the view to merge the businesses and gain access to Avexa's then $24 million in cash. In October last year Calzada exited Avexa at 2.8 cents a share.

Calzada has recently appointed an experienced biotech CEO, Stewart Washer, who will manage the commercialisation of the company. Washer, formerly CEO of **Phylogica**, has moved from Perth to Melbourne to head up operations. Under Washer investors should expect a lift in the company's profile and a more rigorous approach to business development.

Calzada is currently capitalised at $15 million with cash of around $8 million. Calazada has two core assets and each of those assets have commercialization programs underway.

Polynovo Assets

The Polonovo technology is based on a biodegradable polymer (polyurethane). The company can alter the properties of this polymer to accurately change the mechanical strength and degradation rates of the material when implanted into the body.

Novoskin – Burns

The first application is being developed in-house for the treatment of full thickness burns. Called Novoskin, the concept is that a 'bioresorbable matrix' will be placed on top of burns wounds immediately after the area has been cleaned. This will allow the wound to be sealed and protected from infection whilst the skin grafts are being prepared, and will also provide a base for the skin grafts. The graft will be placed over the matrix which will eventually degrade in the body as the skin regrows.

This program is being developed as a joint venture with Adelaide plastic surgeon, John Greenwood. Calzada owns 80% of the joint venture.

Calzada is seeking to start human trials with the program in Adelaide towards the end of this year or early next year. The company says that promising results from animal studies have been achieved with more underway.

Bone Putty

Calzada has a collaboration with **Smith & Nephew** which started three years ago. Smith & Nephew has US government funding to develop a bone putty to be used on the battlefield to treat major injuries. Smith & Nephew is also investigating use of the Polynovo Novosorb technology for fracture fixation.

Bone healing - undisclosed partner

In December 2009 Polynovo entered into a feasibility study with another (undisclosed) medical device firm to consider the same Novosorb technology for a different indication, potentially also in the bone healing/fixation area although not confirmed by the company. That collaboration was extended in January this year for a further 12 months with Calzada to receive $400,000 in milestone payments.

With two collaborators and an in-house program, the aim is to generate sufficient competitive tension to prompt one of the partners to commercialise the technology. The Polynovo team currently has five people producing its polymers in-house.

Metabolic Pharmaceutical Assets

Calzada has three areas it is seeking to commercialise the Metabolic Pharmaceutical asset, that is the drug candidate AOD9604 that had previously been tested as a weight loss treatment.

Cosmetic Cream

In September last year Phosphagenics licensed the rights to AOD9604 for use as topic cosmetic cream to reduce cellulite. This product is due to be launched by Phosphagenics in the next few months in Australia and then overseas. Calzada will receive a royalty from sales.

Dietary Supplement

Calazada is also investigating using AOD9604 as a dietary supplement. The compound has an excellent safety record. Calzada is talking to potential partners in the US to launch the product in that country.

Osteoporosis

Earlier this month Calzada reported more positive data on the potential benefit of using AOD9604 as a treatment for osteoporosis The laboratory study showed that AOD9604 can increase bone mineralisation in a stem cell assay. This adds to previous positive work in rat studies.

AOD9604 is a fragment of the human growth hormone and it is rational to suggest that it might have an effect on bone growth. Calzada will now seek to license the application of this drug candidate for the treatment of osteoporosis. It's likely the compound would have to be injected.

AOD9604 for weight loss?

In the area of weight loss, AOD9604 is currently being sold on the black market as an injectable product for reducing body fat, particularly in very enthusiastic body builders. This illegal use we would argue suggests that AOD9604 probably is effective in reducing fat levels, but it needs to be injected rather than being taken orally, which is the way Metabolic evaluated the drug.

It is unlikely the drug will be commercialised by Calzada as a weight loss treatment given the investment that would need to be made and the short patent life remaining (the core patent expires in 2018). As a treatment for osteoporosis there is potentially longer patent protection.

– Cont'd over

Patrys – Key Data for PAT-SM6 Expected in 2011

Patrys (PAB: 9.5 cents) is half way through the first stage of its Phase I safety study with its lead drug candidate, PAT-SM6. This first part of the trial will seek to enroll around 10 patients with melanomas that have yet to become metastatic. An update on the trial is likely next month with full results around mid year.

As part of this study, the patients have a biopsy taken before treatment, then an injection of PAT-SM6, followed by excision of the melanoma three days later and assessment of any effect on the melanoma from treatment. With many of these patients, the melanoma has been previously excised but continues to regrow. In practise, the likely aim would be to use PAT-SM6 and excision to stop the melanomas indefinitely.

In this trial, the company will look for presence of PAT-SM6 in the excised tumour. Patrys can also detect, using an assay, whether the drug candidate is causing cell death in the tumour. It will also look at the immune response to the drug candidate.

Tumour effect anticipated for PAT-SM6 in 2011

Following this study, the company is considering extending the study to look at higher doses of PAT-SM6 and to also look at the treatment of other solid tumours. By the end of 2011, the company will be looking to see an anti-tumour effect of PAT-SM6 either in the current study or from an extended safety study at higher doses.

PAT-SC1 manufacturing conversion underway

The PAT-SC1 drug candidate has already delivered positive results in a 35 patient Phase II gastric cancer study in Germany. Patrys regained the rights to this drug candidate last year. It is now converting the manufacturing of this product to its own proprietary method, with that work expected to be completed by April. Once the company shows the compound can be manufactured using its own technique, it is then in a position to produce product for clinical studies under GMP production.

It needs to be remembered that what has hampered the development of human cancer antibody drugs – that is the cancer antibodies found naturally occurring inside people protecting the general population against the daily threat of cancer, as opposed to genetically engineered antibodies that have been 'humanized' – is the ability to manufacture them on a commercial scale.

Patrys has now achieved that and is arguably the leader in this field. And it has surprised itself with its manufacturing capabilities, achieving much higher yields in the production of PAT-SM6 that it ever expected.

PAT-LM1 Ready and Waiting

The third drug candidate is PAT-LM1. This candidate is ready to progress into clinical development either through a partner or by Patrys. However the company is careful with is spending and until funding conditions improve, it's unlikely to progress in the short term. To produce sufficient material for early clinical studies and to conduct a Phase I study would cost between $3-$6 million.

Convertible Note Changes

Last year Patrys secured funding through a convertible note to access $15 million. Under the arrangement, Patrys had access to $5 million a year with a minimum draw down of $4 million in the first year. However, late last year the company raised $4.1 million through a placement and share purchase plan. So it negotiated to remove the guaranteed minimum it had to draw down from its convertible note facility.

To date the company has drawn only $1 million from the facility. About 80% of those funds that have been converted to shares have been sold by the convertible note supplier. A lower use of the convertible note will potentially allow better share price appreciation without the continuous sell down of the stock.

Access to the convertible note facility provides a source of funding for current activities, with placements and rights issues still the main funding option for expansion of activities into other clinical studies.

Summary

By year's end Patrys should be in a good position to provide information on whether on not the company's lead candidate, PAT-SM6, is having an effect on melanomas. Positive results from this trial will position the company better to fund further clinical studies with PAT-SM6 into other cancers, and also commence clinical work with PAT-SC1 and PAT-LM1, which may occur either independently or through a partner. Positive results will also provide major validation of the company's platform.

In other items to monitor, the company expects to report on its CSL collaboration in the first half of this year. Patrys is capitalised at $23 million and had $7.7 million in cash at the end of last year.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

– Calzada cont'd

Summary

Calzada is an investment worth considering. The company is trading just $7 million above cash with a capitalisation $15 million. Calzada has six shots on goal currently between the company's two technologies, The company's anticipated cash burn is only between $1.5-$2.0 million a year. With the addition of Stewart Washer as CEO and John Chiplin as a director, the company has signaled a commitment to focus on commercialising its core assets.

Bioshares recommendation: **Speculative Buy Class B**

Bioshares

Antisense Therapeutics to Move ATL1103 into Clinic

Funding constraints continue to exist for smaller Australian biotechs. However, some companies continuing to move drug candidates into clinical studies, albeit at a slower rate because of the continued difficulty in accessing capital. Antisense Therapeutics (ANP: 0.9 cents) has now raised sufficient funds to commence clinical studies with its current lead drug candidate, ATL1103.

The company plans to start a Phase I trial with ATL1103 in the third quarter of this year. The company will test the safety of the drug in healthy volunteers in a single ascending dose. Results from that study should be expected by the end of 2011.

The company is also looking to continue that study in a multiple ascending dose, however it will require a small amount of additional funds. Those funds may come from partnering one of its other programs, raising funds from its partner **Isis Pharmaceuticals**, grant funding or even through a convertible note.

The results from that study should be available in around March next year. Those studies should not just provide information about the safety of the drug, but there is the opportunity to quickly gain proof-of-concept evidence with this drug candidate.

The Appeal of ATL1103

ATL1103 has a number of particularly appealing aspects that make it worthwhile to pursue clinical studies. ATL1103 is an antisense drug that blocks the expression of the growth hormone receptor. This action thereby reduces the level of IGF-1 produced that circulates in the bloodstream. An excess level of IGF-1 is associated with diseases such as acromegaly, where abnormal growth of the hands, feet and organs occurs, and with diabetic retinopathy.

Reducing IGF-1 levels in the blood is a proven way to treat acromegaly and reduction of IGF-1 levels is an accepted primary endpoint by regulators. That the end point is reducing the levels of the primary biomarker, IGF-1, makes it straightforward to immediately detect whether the drug is having a positive effect.

In diabetic retinopathy, its been shown (by others) that a reduction in IGF-1 levels can slow progression of disease and improve vision.

Currently somatostatin agonists, such as **Novartis**' Octreotide, are effective in treating around 65% of patients with acromegaly. These somatostatin agonist drugs generate annual sales of around $1 billion. However around 35%-40% of people with acromegaly do not find effective treatment with these drugs, leaving a potential market of several hundred million dollars a year for an effective drug to reduce IGF-1 levels.

Another appealing aspect is that antisense drugs are known to accumulate in the liver and have shown to work well on diseases linked with the liver. That IGF-1 is produced in the liver works well in favour of an antisense drug approach.

The third positive factor is that Antisense Therapeutics has completed preclinical primate studies that showed that ATL1103 could reduce IGF-1 levels by 35% after only two weeks. So this drug should have a good chance of achieving early proof-of-concept data in people.

Antisense Therapeutics is capitalized at $8 million with $3 million in cash at the end of last year.

Bioshares recommendation: **Speculative Buy Class C**

Bioshares

Andrew Forrest's Allied Medical Continues to Build Presence With Planned BioMD Merger

BioMD/Allied Medical could be a company to watch out for in the future. On February 15, BioMD announced it would be merging with Allied Medical. There are synergies involved and a number of benefits for both companies from the planned merger.

BioMdD is commercialising a tissue engineering technology through its investee company Celxcel. The technology, called ADAPT, exploits a unique process that re-engineers animal tissue, producing a biologic soft tissue that significantly reduces calcification (hardness) of the implant. The process allows the tissue to be remodeled where the implant eventually resembles the surrounding tissue.

Allied Medical was spun out of **Fortescue Metals Group** in 2005. It has merged two medical distribution businesses that operate in Australia, one **Medevco**, that was acquired in August last year. That operation generates sales of around $5 million a year and last year recorded a small profit. The business sells medical and surgical products throughout Australia with a sales team of 15 people.

In August last year it also invested $3 million into Professor Ian Frazer's **Coridon** for a 38% stake. The company has an option to increase its stake to 55%. Coridon is developing a DNA-based vaccine to both prevent and treat infectious infections.

Allied Medical's strategy is quite simple. It plans to build its cashflow generating distribution business through acquisition. It is also making opportunistic investments in technologies developed by people with a proven track record, such as Ian Frazer, that can create products with global potential.

The third piece of the puzzle is funding. Allied Medical has 2200 shareholders with many also on the Fortescue register and Andrew Forrest owning 46% of Allied Medical. Presumably if the company has reached sufficient proof of concept with one of its technologies, then there is the opportunity to go to its shareholder base to bring those technologies to market.

Cont'd on page 6

CEO Salary Survey 2010

The median base salary for Australian life science CEOs in FY2010 was $282,000, 3.4% less then the median calculated from the same data pool of 54 companies for FY2009. This survey is based on data from companies in which the CEO was incumbent in both 2009 and 2010, so that a reasonable comparability between the two years can be maintained. Significant CEO turnover meant that many companies were excluded from this analysis.

The median SSOB (Salary, Superannuation, Other & Bonus) payment to CEOs was $356,000 for FY2010, 5.8% higher than the previous year.

The median base salary for CEOs of companies with capitalisations of less than $50 million increased by 6.8% over FY2010 (to $240,000), however the SSOB median for this same group fell 1% over FY2010 (to $306,000). This would seem to suggest that less bonus payments were made to this group.

In contrast, the median base salary for CEOs of companies with capitalisations of greater than $100 million decreased by 1.1% over FY2010 (to $350,000), however the SSOB median for this group increased 3.3% over that period (to $488,000).

The percentage difference between base salary and SSOB for companies with capitalisations of less than $50 million was 27%, whereas the same figure for companies with capitalisations of greater than $100 million was 39%.

In approximate terms, the CEOs of companies capitalised at greater than $100 million earned between 50%-60% more than the CEOs of companies capitalised at less than $50 million.

The median SSOB for the top five CEOs with significant shareholdings ($359,000) was 0.6% above the overall median SSOB ($356,000). At the same time , the median SSOB ($447,000) for the top five CEOs based on option holdings was 22.6% above the overall median SSOB.

CEOs - Top 5 Option Holdings

Company	CEO Options as % Shares Fully Diluted
Atcor Medical	3.9%
Austofix	4.5%
Probiotec	4.5%
Avita Medical	4.9%
Actinogen	15.8%
Median	
Base Salary	$342,571
SSOB	$446,477

CEOs - Top 5 Share Holdings

Company	CEO Shares as % Shares Fully Diluted
Probiotec	12.8%
ASDM	20.6%
Mesoblast	22.9%
SDI	45.4%
Compumedics	62.2%
Median	
Base Salary	$352,821
SSOB	$358,491
Overall Median (n=54)	
Base Salary	$281,882
SSOB	$356,411

Appendix A lists the remuneration data for the 54 companies analysed in this survey.

Median and Average Salaries - Selected Life Science CEOs 2009 & 2010
(n = 54 companies)

	Base Salary	Total SSOB	Abs. var.	% var.
2010				
Median	$281,882	$356,411	$74,529	26%
% ch - prev yr	*-3.4%*	*5.8%*		
Average	$287,245	$366,726	$79,480	28%
% ch - prev yr	*4.7%*	*3.8%*		
< $50 M cap	$240,295	$306,029	$65,734	27%
< $100 M cap	$265,417	$326,671	$61,254	23%
> $100 M cap	$350,390	$488,202	$137,812	39%
Var. >$100 cap to <$50 cap	*46%*	*60%*		
2009				
Median	$291,835	$336,782	$44,947	15%
% ch - prev yr	*23.1%*	*12.8%*		
Average	$274,461	$353,214	$78,753	29%
% ch - prev yr	*14.9%*	*15.8%*		
< $50 M cap	$225,000	$308,760	$83,760	37%
< $100 M cap	$252,859	$316,731	$63,872	25%
> $100 M cap	$354,456	$472,413	$117,958	33%
Var. >$100 cap to <$50 cap	*58%*	*53%*		

Methodology

We collected base salary, total remuneration, option and share holding data for more than 54 ASX-listed Life Science companies. The data was sourced from Annual Reports and other ASX filings.

We excluded companies that did not have a June 30 reporting date.

We excluded several companies domiciled overseas that did not report their accounts in Australian currency.

We excluded companies for which the CEO was not incumbent for both 2009 and 2010.

Capitalisations were calculated as of June 30 on a fully diluted basis.

Bioshares Model Portfolio (25 February 2011)

Company	Price (current)	Price added to portfolio	Date added
Somnomed	$1.01	$0.94	January 2011
Phylogica	$0.075	$0.053	September 2010
Sunshine Heart	$0.038	$0.036	June 2010
Biota Holdings	$1.07	$1.09	May 2010
Tissue Therapies	$0.67	$0.21	January 2010
QRxPharma	$1.45	$0.25	December 2008
Hexima	$0.30	$0.60	October 2008
Atcor Medical	$0.10	$0.10	October 2008
Impedimed	$0.77	$0.70	August 2008
Patrys	$0.10	$0.50	December 2007
Bionomics	$0.39	$0.42	December 2007
Cogstate	$0.20	$0.13	November 2007
Sirtex Medical	$5.63	$3.90	October 2007
Clinuvel Pharmaceuticals	$2.00	$6.60	September 2007
Starpharma Holdings	$1.06	$0.37	August 2007
Pharmaxis	$2.52	$3.15	August 2007
Universal Biosensors	$1.39	$1.23	June 2007
Acrux	$3.45	$0.83	November 2004
Alchemia	$0.72	$0.67	May 2004

Portfolio Changes – 25 February 2011

IN:
No changes

OUT:
No changes

– BioMD/Allied Medical continued

One of the impediments and failures of the biotech industry is an inability to access the end user, which is often controlled by multinational pharmaceutical or medical device companies. Allied Medical is potentially in a position to solve that distribution hurdle similar to what Fortescue had to achieve in building its rail link to ship its iron ore.

Synergies

There are synergies and benefits for both groups. Allied currently sells products to cardiologists with whom it has excellent relationships, according CEO Lee Rodne. BioMD's first product, the CardioCel patch, will be sold to cardiologists. BioMD will seek to list the product with the TGA this year that will allow it to launch that product.

For Allied, a merger with BioMD represents a way to gain a public listing on the ASX, and from there improved access to capital markets. Both groups will benefit from an increased size in attracting capital to fund programs.

Commercial terms & Structure

Under the terms, Allied shareholders will own 70% of the issued capital of the combined entity. This week **Avexa** agreed to sell its 19.9% stake in Allied to BioMD.

Three of the Allied team will join the BioMD board. They are Lee Rodney, the current Allied CEO, Chris Catlow, the first CFO of Fortescue, and current Fortescue Non-Executive director, Graeme Rowley. The current three BioMD directors will remain on the board.

Bioshares recommendation: **Under Review**

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, ChemGenex Pharmaceuticals, Circadian Technologies, Biota Holdings, Halcygen Pharmaceuticals, Impedimed, QRxPharma, Patrys, LBT Innovations, Hexima, Mesoblast, Atcor Medical, BioMD, Tissue Therapies, Viralytics, Phosphagenics, Immuron, Phylogica, Bluechiip

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