ISSN 1443-850X

In this edition...
After a stellar run last financial year, the country's leading drug developers have seen their share prices take a breather and in some cases, fall considerably. Some continue to power ahead and others may face dire times ahead.

One stock that continues to offer great value is Arana Therapeutics, formerly Peptech and Evogenix. And we look at the Biotech Capital, a listed biotech fund that continues its transition to investing in revenue generating businesses.

The editors
Companies covered: AAAH, AVX, BTC, CUV, CXS, PEP, PGL, PXS

	Bioshares Portfolio
Year 1 (May '01 - May '02)	21.2%
Year 2 (May '02 - May '03)	-9.4%
Year 3 (May '03 - May '04)	70.0%
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 (from 4 May '07)	-11.5%
Cumulative Gain	**189%**
Av Annual Gain (6 yrs)	**26.8%**

Bioshares is published by Blake Industry & Market Analysis Pty Ltd. The company also provides market and company analysis of the Australian pharmaceutical and biotech industries for local and international funds management institutions, venture capital funds and other related industry groups. For further details contact David Blake (see details below).

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Individual Subscriptions (48 issues/year)
$320 (Inc.GST)
Edition Number 242 (23 November 2007)
ISSN 1443-850X

Bioshares

23 November 2007
Edition 242

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

Biotech's Phase III Leaders...Taking Stock

Over the 2007 financial year, the leading Australian biotech companies that were conducting Phase II and Phase III trials performed exceptionally well. The six stocks in the table below increased on average by 112% over that period. However it looks like investors are taking a breather from the euphoria surrounding the success of later stage clinical trials in some of these companies.

Phase III Leaders Performance

Company	Share price (30 June 2007)	Gain in FY2007	Change since June 30
Avexa	$0.64	176%	1.6%
Chemgenex Pharm.	$1.12	167%	-2.0%
Clinuvel Pharm.	$0.92	149%	-53%
Progen Pharm.	$4.60	70%	-43%
Pharmaxis	$3.30	60%	26%
Peplin	$0.86	50%	-12%
	Av.	**112%**	**-14%**

Progen Pharmaceuticals

Progen Pharmaceuticals (PGL: $2.63) has been one of the most disappointing Phase III group stocks since the company raised approximately $70 million to fund its Phase III trial of PI-88 for liver cancer. The stock climbed as high as $9.66, and the company raised $73.7 million at $5.74. The stock has since fallen over 50% from the price at which the funds were raised.

The company is on track with its Phase III trial to begin before year's end. The company recently announced it was abandoning its Special Protocol Assessment (SPA) with the FDA to speed up the development process. The company was recently granted a Fast Track Approval status from the FDA. The upshot of this is that the company will have its trial endpoint assessed though a surrogate marker (so a faster approval). The marker/measure is 'disease free survival', which is quicker to establish than overall survival, which is the standard measure for cancer drugs. That this has now been agreed to by the FDA explains why Progen no longer requires the SPA.

Other advantages of Fast Track Approval status are the ability to submit the New Drug Application in parts. It does not mean the company gets priority review. Fast Track Approval status is awarded to companies developing drugs to meet unmet clinical need, which for liver cancer, there are no pharmaceutical treatment options.

Bioshares recommendation: **Speculative Buy Class A**
Market Capitalisation: $155 million
Cash (30/6/07): $100 million

Cont'd over

Avexa

Warning signs are emerging with this stock. Avexa (AVX: 64.5 cents) recently announced that its Phase III trials will need to be considerably larger than originally expected, with two Phase III trials involving 900 patients each in 165 sites around the world, up from earlier estimates of 800 patients in total.

Avexa will now need to find a partner to complete the Phase III trials. The increased patient numbers have blown out the endpoint for the trials (second half of 2010 to file an NDA) and also the costs, which is why a partner will be required. The company will however begin the Phase III trials this year.

The reason for the increased patient numbers is due to the lack of clarity regarding an optimum dose in the Phase IIb trial, which involved a 600mg and 800mg dose. The Phase III trial will include an additional 1200mg dose arm, hence the bigger trial size.

In conducting the Phase IIb study, Avexa had difficulty in recruiting sufficient patient numbers. Recruiting 1800 patients will be an enormously difficult task. This is because there are fewer HIV resistant cases occurring due to the better compliance from patients as a result of advances in medication delivery, such as once a day tablets. Better compliance helps keep the virus load down and prevent the onset of drug resistance.

Phase III Leader Board

Company	Market Cap ($M)	Comments
Pharmaxis	809	Solid progress continues
Avexa	262	Funding & timeline blowout
Chemgenex Pharm.	206	Solid progress continues
Progen Pharm.	155	Oversold, longer term investment
Peplin	155	Core portfolio stock, excellent value
Clinuvel Pharm.	131	Oversold, good buying opportunity

Many investors will be disappointed that the timelines have blown out which reduces the potential value of this drug, with core patents to expire in 2013. (The company will receive a five year market exclusivity if the drug reaches the market and patent extensions are likely increase the company's proprietary position out to 2018 at least). On the current timeline, we expect the drug will reach the market in 2012 if there are no further delays.

Investors may also be disappointed by Avexa not having the capacity to complete its Phase III trials independently. And remembering that a royalty of 12-15% of any future sales is payable to Shire Pharmaceuticals, the outlook is dimming on this program.

We recommend readers take this opportunity to exit this stock. Our three month price target is 40 cents.

Bioshares recommendation: **Sell**
Market Capitalisation: $262 million
Cash (30/9/07): $71 million

Pharmaxis

Pharmaxis (PXS: $4.15) has moved into conducting a series of Phase III trials in cystic fibrosis and bronchiectasis. The first Phase III trial result, in bronchiectasis, delivered overwhelmingly positive data. A second Phase III trial in bronchiectasis is planned for early 2008. A Phase III trial in cystic fibrosis is underway outside of the US with another US Phase III trial expected to begin shortly following the receipt of an important Special Protocol Assessment from the FDA for its trial design.

Aridol sales (a lung function test) are expected to gain traction in 2008 as individual country approvals are received in Europe. These types of tests are more established outside of Australia and represent a reasonable market for Pharmaxis.

Pharmaxis is a quality company with strong commercial prospects. It continues to get strong support from investors. A more detailed update on the company will be provided next week.

Bioshares recommendation: **Speculative Hold Class A**
Market Capitalisation: $809 million
Cash (30/9/07): $129 million including recent capital raisings

Clinuvel Pharmaceuticals

Clinuvel Pharmaceuticals' (CUV: 43.5 cents) share price has fallen sharply with concerns that its major shareholder may exit the stock. The company is currently conducting two Phase III trials in sun-exposure disorders. The company's drug, CUV1647, is on track to be submitted for regulatory approval in Europe in early 2009. It is an attractive investment proposition into a well managed company.

Bioshares recommendation: **Speculative Buy Class A**
Market Capitalisation: $131 million
Cash (30/9/07): $60 million

Peplin

Peplin (PLI: 75 cents) is a very solid biotech company with Phase III trials of its drug candidate PEP005 in actinic keratosis due to begin. The company is very well managed and owns the compound outright. It will seek to build its own marketing team in the USA. It is an excellent long term holding. Of interest will be to see how the stock fares once it begins trading the Nasdaq stock market in coming months. When the stock breaks the $1.00 price, it may see accelerated appreciation. Its recent price weakness presents a good opportunity to investors.

Bioshares recommendation: **Speculative Buy Class A**
Market Capitalisation: $155 million
Cash (30/9/07): $30 million with additional funds to be raised through a listing in the USA.

Chemgenex Pharmaceuticals

ChemGenex Pharmaceuticals' (CXS: $1.10) lead drug, renamed omacetaxine mepesuccinate, is currently in a registration trial (Phase II/III) for the treatment of chronic myeloid leukemia in patients resistant to the very successful drug Gleevec. The company anticipates filing for regulatory approval of omacetaxine in early 2009

in the US and Europe. It's a well managed and solid company with strong commercial prospects.

Bioshares recommendation: **Speculative Buy Class A**
Market Capitalisation: $206 million
Cash (30/6/07): $25 million

Summary

The lead drug development companies present some good opportunities for investors. Pharmaxis and Chemgenex continue to be solid performers. Progen and Clinuvel have fallen considerably and present good buying opportunities. Peplin remains an excellent core portfolio stock. Recent developments at Avexa present some serious concerns for that company. However, with three companies expected to file for regulatory approval in early 2009, there is reason to be optimistic for the success of this sector in proving it can take therapeutic products through registration and beyond.

Bioshares

Arana Therapeutics – A superb investment opportunity

With the selection of a new corporate identity and name of Arana Therapeutics (AAH: $1.14), the merged entity of Peptech and Evogenix has now signalled a break with the past for both companies. The Peptech name was arguably the corporate identity in great need of an overhaul, with an eleven-year history that represented a mixed bag in terms of success and failure. Peptech was founded in June 1985 as Peptide Technologies and changed its name to Peptech in 1996.

The Arana share price has performed poorly in recent months. Price weakness has engulfed many biotechs as the US sub-prime credit crisis has washed over global financial markets. Arana shares would have also suffered some weakness as various investors attracted to the former Peptech story and the former Evogenix story departed.

What has now eventuated is that Arana Therapeutics is sitting as an extraordinary investment opportunity. Arana is capitalised at $267 million. While on the surface this may seem a market value that befits a clinical stage biotech company, in fact after deducting cash ($169 million) and a conservative estimate of prospective royalty income estimated at $80 million to follow, Arana Therapeutics is trading at a technology value of $18 million.

The market is currently ascribing US$16 million technology value to the following assets:

- an IP position covering the binding of ligands, such as monoclonal antibodies or antibody fragments to the TNF-alpha protein, that lasts to 2011
- an IP position covering super-humanisation, optimisation and syn-humanisation technologies
- a domain antibody (dab) (ART621) set to enter a Phase II trial in 2008
- a protein therapeutic (ART010) targeting bone metastasis sent to enter the clinic in 2008
- five other protein/antibody candidates and one small molecule drug candidate with reasonable prospects of two advancing into clinical development in 2009, and the right to two dab targets under agreement with GSK
- commercial agreements generating upfront, milestone and royalty payments for projects with **GlaxoSmithKline**, **CSL**, **Vegenics** and recently with **Aveo Pharmaceuticals**
- antibody engineering know-how and expertise

Leaving all other assets aside, it is difficult ascribe as a minimum value US$16 million to the drug candidate, ART621, which is a domain antibody or fragment that is much smaller in size than full antibodies. Rights to dab technology in the area of TNF-alpha binding were licensed from Domantis, which was sold to GSK in late 2006 for $575 million.

There are several factors that investors should keep in mind with respect to this program. Firstly, the anti TNF-alpha antibody drug space has proved to be very successful, clinically and financially. Sales of the three Anti- TNF-alpha drugs, (Remicade, Humira, and Enbrel) totalled US$7.9 billion in 2006, and for the nine months ending September 2007, US$5.9 billion (see table). Sales of these drugs are driven by the expansion in the number of indications for which the drugs are approved as well as underlying growth in patients with chronic inflammatory diseases such as rheumatoid arthritis, and the fact that they have delivered significant patient benefit.

Cont'd over

Marketed Anti TNF-alpha drugs
(rheumatoid arthritis (RA), psoriatic arthritis, ankylosing spondylitis (AS) and Crohn's disease)

Company	Brand name	Name/code	Description	Route of Admin.	Sales 2005 $US (B)	Sales 2006 $US (B)	Sales 2007 $US (B) (9mo)
Centocor	Remicade	infliximab	chimeric IgG antibody	Injected s.c (every 2 weeks)	$2.5	$3.0	$2.4
Abbott Laboratories	Humira	adalimumab	humanised IgG antibody	Injected at GPs (very 8 weeks)	$1.5	$2.0	$1.1
Amgen	Enbrel	Eternacept	fusion protein (decoy receptor)	Injected (twice weekly)	$2.6	$2.9	$2.4
				Total	**$6.6**	**$7.9**	**$5.9**

Arana, with ART621, is in a superior position with respect to many other potential rivals in having unencumbered freedom to operate in the TNF-alpha space. Although Arana's blocking patents will expire in 2011, it is well placed in the meantime as an exclusive developer of a new technology that acts on TNF-alpha.

What is worth noting is that the application of biologic medicines to TNF-alpha targets has yet to be overtaken by rival approaches, which include the targeting of other cytokines (such as Il-6, Il-1, Il-23, Il-15, Il-17) or other components of the inflammatory cascade. Outside of the TNF-alpha space, there are between 25-30 drugs in development to treat rheumatoid arthritis and similar conditions. It is also worth noting that the development of small molecule drugs to treat inflammatory diseases has proved very difficult, regardless of the 'cascade' pathway chosen.

In Arana's favour there a few competitors in the TNF-alpha drug development space (see table below). The two leading 'next generation' drugs are UCB Celltech's Cimzia and Centocor's (a unit of Johnson & Johnson) golimumab. Cimzia, a pegylated antibody fragment, is to be submitted to the US FDA for a biologics license towards the end of this year. However, it has also recently been rejected by the EMEA in Europe (the company has placed an appeal). Centocor's golimumab , which might called 'Son of Remicade', is a fully human antibody, whereas Remicade is a chimeric, or part murine antibody. While golimumab may be not too different from Remicade, it may offer dosing advantages over Enbrel and Humira. Golimumab may be administered by subcutaneous injection once every four weeks or infusion once every three months, compared to Enbrel's twice weekly injections and Humira's injections every eight weeks in a doctor's surgery.

Competitive advantages of ART621

Arana's ART621 potential competitive advantages should stem from reduced immunogenicity, lower cost of goods, and an improved efficacy derived from a possible ability to better penetrate joints and tissues. However, insights in efficacy can only be properly gained from randomised Phase II and Phase III trials.

Comparison with Ablynx

A company that offers some useful comparisons to Arana Therapeutics is **Ablynx**, from Belgium. Ablynx is developing products, including a rheumatoid arthritis candidate, based on antibody constructs derived from camelids (camels and llamas). Ablynx recently listed (November 6, 2007) on the NYSE Euronext Brussels exchange, raising $146 million. With Ablynx further behind Arana in clinical development of an antibody fragment drug, let alone a TNF-alpha targeted drug, and with a yet to be confirmed IP position, its capitalisation following listing of $413 million implies a technology valuation of $266 million. It could be argued, that by comparison with Ablynx, Arana with a technology valuation of $18 million is significantly undervalued.

Summary

Arana's shareholder register problems, which in our view are major source of its stock price weakness, are slowly being resolved. The company now has several committed biotech investors behind the company. More may follow as the Arana investment proposition is re-stated in overseas investment markets. At current prices, Arana represents a superb investment opportunity.

Bioshares

Anti TNF-alpha drugs in development

Company	Brand name	Name/code	Status	Description	Route of Admin.
Centocor (J&J); Schering Plough - EU Rights		golimumab (CNTO 148)	4 X Phase III (US); 4 X Phase III (EU)	antibody	s.c and i.v
UCB Celltech	Cimzia	certolizumab pegol	Apply for US BLA end 07; appealing EMEA	pegylated Fab antibody fragment	s.c
AranaTherapeutics		ART621	To enter Phase II (early 2008)	domain antibody	s.c
Ablynx (partnered with Wyeth)		Nanobody (class name)	Pre-clinical	VhH camelid domain antibody	
Celgene	apremilast	CC-10004	Phase II	small mol (460d) TNF antagonist	oral
Isis Pharmaceuticals		ISIS 104838	Phase II (completed)	antisense oligonucleotide	s.c
Targeted Genetics		tgAAC94	Phase II (suspended)	AAV vector delivery of TNFR:Fc gene	

Biotech Capital – Continues with New Investment Approach

Several months ago Biotech Capital (BTC: 30 cents) made a decision to change its investment approach. The listed life science venture capital fund started out as an investment vehicle to give investors an exposure to a portfolio of early development stage biotech businesses. The fund is now realigning its investment focus on revenue generating businesses, where exit opportunities are better and investment horizons are shorter for its shareholders.

Generic Health

This week Biotech Capital announced it had made a $2.2 million investment in a generic pharmaceutical business, Generic Health. The generic pharmaceutical area can be highly successful if the business plan is smart and the execution is very solid, which it needs to be in this industry. **Arrow Pharmaceuticals** set the benchmark in performance and generated wealth of $800 million for its investors in just six years, after it sold its business to Sigma in 2005. Others such as **PharmAust** and **Genepharm Australasia** have found the going a lot more difficult.

Generic Health was formed in 2004 and is based in Melbourne. Its competitive advantage that underpins its business is the international low cost manufacturing contracts it has formed overseas to make generic pharmaceuticals for the Australian market. Low cost manufacturers entered the local market about one year ago with Ranbaxy from India gaining a presence in Australia with its own field force. Generic Health believes it can match any overseas low cost drug makers and is seeking to be competitive to gain a slice of the $550 million generic pharmaceutical business in Australia.

The market has been splintered from when **Alphapharm** had over 80% of the business in Australia in the 1990s and made the market difficult for new entrants to gain a significant presence. **Hexal** and **Douglas Pharmaceuticals** struggled to gain over 5% market share each and it was Arrow Pharmaceuticals the that led the charge very successfully to break the Alphapharm dominance.

Genepharm Australasia, which listed on the ASX in June 2004, had a higher cost supply agreement with its Greek affiliate company that made it less competitive in the Australian market. It has since acquired Douglas Pharmaceuticals to beef up its business. Alphapharm and Sigma now have only an estimated 60% of the Australian generics market.

Generic Health's approach is to sell the top 30 generic drugs on the Australian market (from a total of over 200) which represents around 75% of the market. It does not have complicated discount systems, but seeks to offer the lowest price on any of the pharmaceuticals it sells, which can be purchased as a single product line. The simplicity and clarity of its service together with what it believes will represent the most competitive prices underpins its current approach.

The company's CEO, Gavin Upiter, has pharmaceutical manufacturing experience from working with **Bristol Myers Squibb** for 12 years in South Africa, Australia and Europe and this experience assists the company in selecting high quality and low cost manufacturers in India and China. According to Upiter, the generics market is in a state of flux in Australia and is ready to adopt the simplified low cost pricing model that Generic Health is offering.

Generic Health runs a low overhead structure with its distribution outsourced to Sigma and API. It has a modest sales team that services 1500 pharmacies at the present. It current sells 12 pharmaceuticals which represents about 40%-50%. A further 12 are expected to be released in Australia over the coming year.

The company is close to approaching a breakeven position. Growth will come from adding to its product line and participating in a high growth market over the next five years from the raft of patent expiries occurring over this time.

Sensear

In June this year Biotech Capital made an investment ($2 million) in a hearing technology company Sensear (see edition #222 of Bioshares). In January/ February next year, Sensear will begin selling its industrial earmuffs, with orders expected to immediately come in from groups such as Qantas. The ear muff does not block all noises, but has a microphone system in built that allows normal conversation to be heard.

The company is also developing a retail model that will be ideal for people with frequency loss or for people exposed to noisy working environments such as night clubs. The retail version looks more like an iPod and would not carry any of the social stigmas that might be associated with other hearing devices.

Manufacturing of the devices is conducted in China although assembly is completed in Perth, where some in-house knowledge is applied to complete manufacture of the device. Progress in Sensear will be worth monitoring in 2008.

NeuroDiscovery

In May this year Biotech Capital invested $1.5 million in NeuroDiscovery, a listed biotech company that also has a profitable pharmaceutical services business, NeuroSolutions, as a subsidiary. NeuroSolutions is expected to generate revenue of $2.5 million this financial year and make a gross profit of around $1.5 million. There is also good upside with this investment, with three Phase II trials in pain (with two different compounds) expected to be underway by mid 2008.

Continence Control Systems

Biotech Capital made a $2 million investment in Continence Control Systems in 2004. CCS is developing a bionic implant system for treating urinary incontinence. Last month, CCS announced a merger with Colocare, a company that expects to begin selling its colostomy management device next year in the USA. The merged entity will have near term revenue with the possibility of adding further revenue streams from an acquisition in the continence control space ahead of possible IPO in 2008.

Cont'd over

Other revenue generating investments

Biotech Capital has invested in listed companies Stem Cell Sciences and Starpharma, which have established revenue streams from research and industrial product sales , although the development of therapeutics are the main business objectives of those companies.

XRT is another investee company of Biotech Capital. The company has developed a phase imaging x-ray system used in a variety of applications including the silicon chip industry, and it is currently generating sales of its systems. One of the fund's earlier investments, Pacific Knowledge Systems, sells its proprietary software for use in the pathology industry and has reached a breakeven position in its business.

Only three companies from the 11 investments Biotech Capital has made (including Generic Health) are not generating revenue. These are Alchemia, Phylogica and Biocomm, with Alchemia slated to begin generating revenue in 2009.

Summary

The transition for Biotech Capital to investing in revenue generating businesses has moved into full swing. If the investments perform well, it should translate into more immediate reflection in value in the Biotech Capital share price.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares Model Portfolio (23 November 2007)

Company	Price (current)	Price added to portfolio	Date added
Cogstate	0.13	0.13	November 2007
Ventracor	$0.65	$0.625	October 2007
Sirtex Medical	$4.75	$3.90	October 2007
Clinuvel Pharmaceuticals	$0.44	$0.66	September 2007
Progen Pharmaceuticals	$2.63	$3.52	September 2007
Starpharma Holdings	$0.39	$0.37	August 2007
Pharmaxis	$4.15	$3.15	August 2007
Universal Biosensors	$1.57	$1.23	June 2007
Biota Holdings	$1.38	$1.55	March 2007
Tissue Therapies	$0.45	$0.58	February 2007
Probiotec	$1.42	$1.12	February 2007
Phylogica	$0.18	$0.42	January 2007
Peplin Inc	$0.75	$0.83	January 2007
Arana Therapeutics	$1.14	$1.31	October 2006
Sunshine Heart	$0.15	$0.19	September 2006
Chemgenex Pharma.	$1.10	$0.38	June 2006
Cytopia	$0.60	$0.46	June 2005
Optiscan Imaging	$0.29	$0.35	March 2005
Acrux	$1.57	$0.83	November 2004
Alchemia	$0.63	$0.67	May 2004

Portfolio Changes – 23 Nov 2007

IN:

Cogstate has been added to the portfolio at 13 cents. The company appears to be a passing a pivotal point for its cognitive testing business. It has just secured a major contract for a Phase II schizophrenia trial in over 80 sites valued at $0.7 and won four contracts in the last month worth $1.16 million. Our expected sales for the company are $4 million for this financial year. At a three times sales multiple, our price target for the company at the end of this financial year is 23 cents a share. The company had $1.5 million cash at the end of September.

OUT:

Circadian Technologies has been removed with some possible price weakness due to the company's investment in Avexa. At June 30 it owned 13.6 million shares in Avexa.

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, Pharmaxis, NeuroDiscovery, Biotech Capital, Cygenics, Cytopia, Biodiem, Arana Therapeutics, Starpharma Holdings, Cogstate, Xceed Biotechnology, Incitive, Optiscan Imaging, Bionomics, ChemGenex Pharmaceuticals, Medical Therapies, Circadian Technologies, Biota Holdings, Stem Cell Sciences, Halcygen Pharmaceuticals, Peplin, BioMD, Impedimed

Subscription Rates (inc. GST)

48 issues per year (electronic distribution): **$320**

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