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In this edition...
Cytopia's decision to merge with YM Biosciences is a watershed moment for drug development companies in Australia.
Cytopia had gone down the path of *de novo* small molecule drug discovery, which in the fragmented world of cancer drug development, is arguably more costly and more difficult than the strategies adopted by other firms to improve or re-purpose known drugs.
In contrast, new technology approaches, such as antibody drugs or cellular therapies, have the potential to offer new levels of therapeutic performance. We highlight recent local and global trends in the world of cell therapies and suggest that a new commercial phase of this therapeutic approach is imminent.
We also discuss recent trends in debt financing obtained by local biotechs.
The Editors
Companies Covered: CYT, Cellular Therapies, Debt Financing

	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 - Current)	54.0%
Cumulative Gain	**187%**
Av Annual Gain (9 yrs)	**19.1%**

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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) 9671 3222
Email: pachacz@bioshares.com.au

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Bioshares

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

Cytopia to Merge with YM Biosciences

Cytopia (CYT: $0.105) has announced that it intends to merge with Toronto-based **YM Biosciences**. Assuming the proposal is approved by 75% of shareholders under a scheme of arrangement and court approval is obtained, Cytopia will merge with YM Biosciences in February 2010 and be de-listed from the ASX. Shareholders will then hold shares in a Canadian company listed on the New York Stock Exchange and the Toronto Stock Exchange. Under the merger proposal, Cytopia shareholders will be offered 1 YM Biosciences shares for every 11.737 Cytopia shares.

The deal means that the two main clinical assets of Cytopia, CYT997 and CYT387 will continue to be funded. More importantly the deal should allow CYT997 to be progressed into combination therapy trials. The lead attraction of a merger with YM Biosciences is that it is developing an antibody drug, nimotuzumab, that is making its mark as a superior version of other EGFR binding antibodies such as Erbitux. This drug has been evaluated in 5,000 patients and is approved for use in a number of countries. The Cuban origin of this antibody has hampered its development in the USA, which subjects Cuban technologies and products to strict import controls and limits. Only recently did YM Biosciences receive approval to conduct clinical trials in the USA

As of June 30, Cytopia had $4 million in cash at hand. For quite some time, Cytopia's management has sought to access cash resources through M&A strategies, but failed in a hard-fought attempt to merge with **Progen Pharmaceuticals** earlier this year. Cytopia pursued the M&A path because of difficult funding conditions and, in our analysis, several of the company's significant shareholders were no longer willing to continue to fund the company, but would accept dilution through a merger. The discontinuation of the funding through a research collaboration with **Novartis** in June added further financing challenges for the company, culminating in 18 redundancies at the time.

Cytopia's funding challenge has been that the development of CYT997, a small molecule vascular disruption agent, is predicated on the requirement *for this drug class* to conduct multiple randomised combination therapy trials, which in our estimate could mean the enrolment of 75-100 patients in each of at least three trials, the cost of which could range from $17 million to $22 million.

It is a disappointing outcome for a company that had access to such promising technologies. The outcome through this acquisition allows survival of existing programs.

Companies such as **Bionomics** and **Chemgenex Pharmaceuticals** recognised early on that drug development through drug discovery from first principles would take too long, cost too much and be too risky for a small biotech. The *de novo* approach to small molecule drug discovery and development, which Cytopia has attempted, is extremely difficult and costly. The successful companies in Australian biotech, from **Pharmaxis** to **Peplin**, have selected programs where the molecule risk is lower and where proof of

Cont'd on page 6

A Wave Of Cell Therapy Products Approaching Market

Over the next 18 months cellular therapies, including stem cell therapies, will arrive on a commercial basis in western healthcare markets. This will be the beginning of a new era in modern medicine, which takes it cue from when many of the opportunities in small molecule drug development have been exhausted or are becoming increasingly difficult to capture (as highlighted by falling small molecule drug approvals), when the antibody therapeutics field looks to have reached a plateau, as antisense technologies are still seeking clinical and commercial success, and RNAi technologies remain in their clinical infancy.

All Eyes on Dendreon

In the next nine months, **Dendreon** is expected to launch its cancer treatment Provenge product, an autologous therapeutic prostate cancer immunotherapy/vaccine. The therapy harnesses a patient's own immune system to fight the cancer using reprocessed or 'supercharged' dendritic cells that are specific to the cancer cells. These immune cells are expected to remain active in the body to continue fighting the cancer cells. Dendreon is expecting to submit an amendment to its regulatory submission for approval with the FDA (BLA submission) in mid November and the company is anticipating product launch in mid 2010.

Dendreon currently has 25% of its future expected manufacturing capacity at its New Jersey facility, in the heartland of US pharmaceutical manufacturing territory. This facility will increase to 48 work stations in the first half of 2011, and in the second half of 2011 two additional facilities, in Los Angeles and Atlanta, are expected to come on line. Each of these facilities will have 36 work stations.

Dendreon will then seek to expand the applications of Provenge by conducting clinical trials in breast cancer (late 2010/early 2011), metastatic renal cell carcinoma (2011) and colon cancer in 2012. The company's aim is to start one new cancer cellular immunotherapy trial every year. Those that said an autologous cell therapy product could not be profitable look to be in the minority with Dendreon now capitalised at US$3.1 billion.

In Australia, Prima Biomed has seen its share price surge with its activities in therapeutic cancer vaccines. The company has received clearance to begin its Phase II trial in 60 women with ovarian cancer with its own therapeutic cancer vaccine, called CVac.

Current Cell Therapy Products

There has been little progress (in western markets) in cellular therapy products. One of the most successful to date is a product called Carticel, sold and processed by **Genzyme**. This product is used to repair cartilage damage. The product was approved for use in the US in 1995 and to date over 13,000 patients in the US have been treated with this therapy.

The treatment involves taking a biopsy of chrondrocyte cells from a patient's own healthy cartilage, having those cells grown in a laboratory by Genzyme Tissue Repair, and then implanted to repair the cartilage. The current cost for this autologous cell therapy product is on average US$26,000.

Adult Stem Cell therapies - Osiris Therapeutics Receives Major Setback

The leader in commercialising adult stem cell technologies has been **Osiris Therapeutics.** Using its mesenchymal stem cells, the company was well advanced in Phase II and Phase III trials in several applications. In November last year it struck a major partnering/licensing deal with Genzyme Corporation. The deal involved a US$130 million up-front payment to Osiris with a potential total deal value worth US$1.4 billion for Genzyme to access ex-North American rights alone.

However, last month Osiris reported disappointing results from its two Phase III trials where its lead product candidate, Prochymal, failed to reach primary endpoints in graft versus host disease involving around 450 patients. Osiris believes its stem cells have anti-inflammatory properties and with the ability to prevent scar tissue formation and regenerate specific tissue structures. This was the first phase III adult stem cell trial *ever* completed.

In a subset of the patients, those with liver and gastrointestinal GvHD, statistically significant positive results were achieved (in the steroid refractory group). This mirrored earlier pilot data. However for some reason in the Phase III trials the company broadened its patient group, including skin GvHD, which is linked to 80% of cases, and preliminary results showed the trials failed to meet primary endpoints. The company is now seeking to focus on severe GvHD of the liver.

In another setback in March this year, Osiris stopped a 210 patient Phase III trial with Prochymal in Crohn's disease after a trial flaw was revealed showing a higher than expected placebo response rate.

Osiris is also conducting clinical trials with Prochymal in lung tissue repair (COPD), type 1 diabetes (protection of islet cells) and in patients following heart attack. The company has also completed enrolment in Phase I/II with Chondrogen, a similar stem cell therapy to improve regeneration of the meniscus following knee surgery.

As with many highly successful technologies, including Avastin and SSRI drugs (that now includes antidepressants such as Prozac) which generate billions of dollars in annual revenue, late stage clinical setbacks have needed to be overcome to find suitable applications for the technologies.

Opportunity for Mesoblast to become Dominant Adult Stem Cell Group

Osiris stumbling presents an opportunity for Mesoblast to become the dominant adult stem cell company. Where Osiris uses mesenchymal stem cells, Mesoblast is using the precursor to these cells, called mesenchymal precursor stem cells (MPCs). It argues it has a purer and more potent population of adult stem cells than Osiris.

Cont'd over

Mesoblast is developing orthopedic applications of these stem cells. It is conducting two Phase II trials in the US in spinal fusion, one trial in Melbourne in knee osteoarthritis, and it is planning to introduce a product in Australia for the treatment of non-union long bone fractures. The company is also seeking to file an IND in the US for the repair of intervertebral discs, with positive preclinical results recently achieved.

The company's CEO, Silviu Itescu, argues that Mesoblast has conducted more thorough preclinical studies in large animal models before it has embarked on clinical trials, which should reduce the chance of disappointing clinical outcomes with its cells. So far that has proven to be the case.

Its sister company, Angioblast Inc, in which Mesoblast owns a 38% interest, is currently recruiting for three Phase II trials in the US – two in heart disease and one in bone marrow therapy (expansion of hematopoietic stem cells used in bone marrow transplants) – and in conjunction with LVAD (heart pump) implants in a Phase II trial which is not yet recruiting. One of the advantages of working in cardiovascular disease is that any improvements in disease can be measured quickly and accurately.

Mesoblast has decided to file one of its products for regulatory approval in Australia. This is a strategic decision that looks to be well founded because it should result in the generation of revenue for the company, and will also increase the profile of the product (and technology) through clinical use. This product will be an autologous stem cell therapy for the treatment of non-union long bone fractures.

This product could generate a niche income stream of $5 million - $10 million a year in Australia from only 200 procedures, even if the procedure was not reimbursed. Patients who have fractures that are not healing can face amputation of the limbs. And high performance sports people may seek the technology to reduce healing times, allowing them to return to their sports sooner and stronger than without stem cell-assisted bone repair.

Cell Therapies in Melbourne will reprocess the cells. Cell Therapies is positioning itself to capitalise from this accelerated introduction of new cell therapy products that is anticipated.

Progress in the global stem cell arena

According to a summary prepared by Robin Young covering the Stem Cell Summit held in January in New York this year, the stem cell field looks set to break out in the next few years. "There is no doubt whatsoever we that clinicians are standing at the dawn of the cellular phase in therapeutic history."

In China autologous stem cell therapies are now generating in excess of US$50 million a year. In the US around 30,000 patients have been treated with allogeneic stem cell therapies in the last four years and over 2,000 people with autologous stem cell treatments. Most of the controversy over stem cell use has related to embryonic stem cells. Ironically, any therapies derived from these stem cells remain a very long way from clinical use and most of the therapies will involve adult stem cells. Adult stem cells are being derived from many new sources including human testes, skin and placenta.

And some of the breakthroughs may occur in less regulated markets which is also a risk for the technology. Hospitals in China are currently claiming to provide autologous stem cell therapies for over 25 different diseases or disorders. At the controversial **Xcell-Center** in Cologne, Germany, they are using autologous stem cells to treat patients for at least 12 different applications, including treatment of spinal injuries, stroke and Alzheimer's disease. Cases of stem cell therapies in India to treat spinal cord injury, with some success, are also being cited.

Stem cell therapy lends itself to niche market applications in some cases, where for up to $50 million a viable commercial operation can be built. Locally developed and processed stem cells that are delivered in stem cell hospitals may be the way some of these treatments are introduced. This is distinct from a pharmaceutical development model, where several hundreds of millions of dollars are required to bring a new therapeutic to market.

These niche businesses will offer unique therapies that will be taken up with or without reimbursement in cases. One example cited at the Stem Cell Summit was of Australian Graham Barnell who travelled to the US and paid $1.3 million for a life saving stem cell transplant to treat his leukemia.

Future Stem Cell Treatments?

HIV is another area that may benefit from stem cell research. One theory being pursued (at the City of Hope Medical Center in California) is to deliver replacement stem cells into the bone marrow that can produce white blood cells that are resistant to attack from the virus.

ReNeuron in the UK has received regulatory and conditional ethics approval to trial its allogeneic stem cells (derived from adult tissue) for the treatment of disabled stroke patients via a direct injection into the brain. The first patients will receive two million stem cells and this will be scaled up to 20 million cells as the trial progresses.

Stem Cell Therapy Market

Mesoblast and Angioblast have certainly selected the right markets for which to develop its products. By 2018, it is expected that stem cell products will be generating revenue in the order of US$8 billion a year in the US, in 2 million annual procedures, from $65 million revenue in 2008. Almost half of that revenue is expected to come from orthopedic applications (US$1.5 billion) and cardiovascular therapy uses ($2.3 billion).

Summary

The appeal with cellular therapies is that they seek to enhance the natural processes of the body; the most powerful system in the body, immune system cells, or the multifunctional stem cells that are distributed throughout the body and curiously perform their set tasks as and when required. It does appear that an exciting new dawn involving cellular therapy is approaching.

Cont'd on page 6

Trends in Financing – Convertible Notes and Draw-downs

The financing window for biotechs opened in the September quarter, with $165 million in capital flowing into the sector. The bulk of these funds has been provided by way of placements, right issues and share purchase plans. A much smaller proportion of funds were obtained through hybrid debt facilities, such as convertible notes (loans), or equity draw down facilities. Although there has been no discernible increase in the use of these funding mechanisms over the last few years, the appearance of new finance providers is noteworthy.

In the week gone by, **Healthlinx** announced it had arranged a $7.2 million convertible note line of finance with US based **Springtree Special Opportunities Fund LP**. In July, Prima Biomed secured a $25.5 million convertible note with Springtree and in June, **Viralytics** arranged four US$1.5 million note facilities with **La Jolla Cove Investors**.

These groups appear to be looking to compete with the **Fortrend Securities Pty Ltd**, the Australian subsidiary of Fortrend Securities Inc. This firm has provided at least $42 million worth of equity draw down facilities to Australian biotech companies in the last few years, including this year Prima Biomed ($12 million) and more recently Avita Medical ($5 million).

On the following page we have set out, on a sample basis, a comparison of the five of these financings, including a listed convertible note raising that was conducted by Virax Holdings in early 2008. The information is incomplete due to companies not reporting all the terms of these financings on a consistent basis. In general prospectus governed and deed managed Australian originated convertible note offerings provide the most disclosure.

For example, whereas the Healthlinx arrangement is reported as setting a limit of Spingtree not obtaining a holding of greater than 19.99%, such a provision is not reported for Prima Biomed. Interestingly, Fortrend Securities, under the equity draw down arrangement with Avita Medical, can hold no greater than 4.9% of the company. This is in fact not that beneficial a provision to Avita Medical as it compels Fortrend to dispose of stock that it acquires as Avita taps the facility and also means that share disposals are not tracked through the substantial shareholder rule.

One provision that appears to not get a mention is that these providers of convertible note finance or equity draw down finance appear to be at liberty to sell stock that they accumulate as the recipients access the funding facilities. Thus the potential for downward pressure on the stock price exists as does an increasing desire of companies to drive their stock price higher to decrease the amount of stock issued to the note provider.

Our expectation is that apart from Virax Holdings, these four companies will pursue high intensity communication strategies with the market over the medium term.

One feature common to the debt or drawdown funding arrangements for Healthlinx, Viralytics and Avita Medical is that optionality is structured into these arrangements, with each company, to varying degrees in a position to elect to discontinue its access to the funding mechanism should it see fit to do so. (We assume this is also the case for Prima Biomed.)

Zero Coupon

One way Springtree appears to be setting a point of difference is through offering a zero rate coupon (interest rate) on its note offerings. It could well be compensated by extracting more options, such as the one option for five shares issued deal it has structured, for example, with Prima Biomed.

Virax Holdings

The Virax Holdings convertible notes offering is quite different to those in place for Prima Biomed, Healthlinx and Viralytics. Although it too has a zero coupon, these notes are listed on the ASX. These notes can be exchanged for 2 shares in Virax any time between January 1, 2009 and December 31, 2009. However, due to the decreasing likelihood of certain milestone funds being received by the company by December 31, 2009, which would be used to pay back the redemption balance, Virax is seeking to restructure the terms of the note.

So instead of converting 1 note into 2 shares, it is proposed that 2 notes convert to 5 shares, that the maturity dateis extended to December 2011, and a redemption premium of 40% is paid (in contrast to the existing 20% premium).

Summary

Convertible note funding is often seen as a last resort for biotechs. There is some credence to this point since at least three companies that have used such facilities, being **Avastra**, **Polartechnics** and Portland Orthopeadics, have gone into administration. These mechanisms can be very dilutionary, which is another way of saying very expensive. However, they are an option, sometimes the *only* option, when other investors are neither willing or able to provide funding.

The main challenge, as suggested above, is that any company that takes on convertible note finance, in an arrangement that freely allows the provider to sell stock, is for the recipient company to be in a position to sustain high value announcements to the market or penetrate new investment audiences to maintain a particular strength in its share price.

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A Sample Comparison of Convertible Note and Draw-down Facility Financings

Company	Healthlinx	Prima Biomed	Viralytics	Avita Medical	Virax Holdings
Code	HTX	PRR	VLA	AVH	VHL
Share Price					
31/12/2008	$0.063	$0.005	$0.040	$0.036	$0.029
9/10/2009	$0.115	$0.220	$0.030	$0.160	$0.066
Shares on Issue (Latest) (M)	112.5	532.4	319.1	96.6	130.7
Options (Listed and Unlisted)	10.3	154.6	109.0	8.9	13.5
Capitalisation (Shares on Issue)	$12.9	$117.1	$9.6	$15.5	$8.6
Date - Financing Announced	5/10/2009	21/07/2009	12/06/2009	20/07/2009	18/02/2008
Finance Provider	Springtree Special Opportunities Fund LP	Springtree Special Opportunities Fund LP	La Jolla Cove Investors, Inc	Fortrend Securities Pty Ltd (Subsid. Fortrend Securities Inc)	Various Investors through Placement
Country of Origin	USA	USA	USA	USA	
Type	Convertible Note	Convertible Loan	Convertible Note (Facility)	Equity draw down facility	Listed Convertible Notes
ASX Code					VHLG
Total Funds that can be Accessed ($M) (or raised)	$7.2	$25.5	Up to (4) US$1.5 M, each of two year duration	$5.0	$1.4
Funds Accessed to Date (estimated) ($M)	$0.23	$1.7	US$750,000	$1.0	$1.4
Notes on Issue (M)					13.67
Interest Rate/Coupon	0.0%	0.0%	4.75%		0.0%
Issue Price		The lesser of:	The lesser of:	90% of VWAP of 5 trading days prior	$0.10
		130% of ave closing price for 20 day prior date of agreement	$0.50		
		90% of ave VWAP for 5 days prior to repayment period	18% discount to VWAP		
Conversion rights					1 Note for 2 shares any time between 1/1/09 and 31/12/2009
				Min issue price not be less than $0.04	
Maximum holding financier can obtain	19.99%			4.9%	
Additional Comments	Subsequent tranches >$60K, but <$200K	15 M options granted at 11% of ave VWAP for 20 days prior to date of agreement. Also for 1 option for every five shares issued through loan.	Can be drawn down at $250,000 per month	25% of shares allotted will be taken as 3 yr unlisted options at issue price	Unsecured

– Cytopia cont'd

principle can be established early on with limited budgets. Cytopia gave it a good shot but in the end was just too hard and took too long.

Options for Investors

We believe investors have two options. It would make sense for shareholders not wishing to own shares in a foreign entity to dispose of their Cytopia shares. However, liquidity may be an issue in this case as Cytopia shares have historically been thinly traded. Alternatively, investors could follow through and take up YM Biosciences stock, and potentially take advantage of any price gains that occur as a result of the successful progress of nimotuzumab.

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– Cell Therapies cont'd

Dendreon's anticipated launch of Provenge next year will draw much attention to the field. And stem cell therapies are making very strong progress with local company Mesoblast on track to become one of the leading global adult stem cell companies, if clinical advances are an accurate measure. There will be setbacks in the process with Dendreon (having previously knocked back by the FDA for approval of its Provenge product) and Osiris Therapeutics examples to note.

The success in the future will depend of the right business model being chosen, forming strategic partnerships where required, and having the capacity, both financial and in management, to effect the commercialisation of the technologies. But it would seem that investors and the broader population have much to look forward to from the introduction of these novel therapies.

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Correction:
Ascent Pharmahealth: In our table of stocks that comprise the Bioshares Index, as published in Bioshares 331, the share price and capitalisation figures for Ascent Pharmahealth were incorrect.

Ascent PharmaHealth's capitalisation at September 30, 2009 was $59 million, its share price was 24 cents, which was 81% higher for the quarter and 18% higher from a year ago.

Bioshares Model Portfolio (9 October 2009)

Company	Price (current)	Price added to portfolio	Date added
Biodiem	$0.23	$0.15	October 2009
QRxPharma	$0.95	$0.25	December 2008
Hexima	$0.60	$0.60	October 2008
Atcor Medical	$0.16	$0.10	October 2008
CathRx	$0.36	$0.70	October 2008
Impedimed	$0.64	$0.70	August 2008
Mesoblast	$1.03	$1.25	August 2008
Circadian Technologies	$0.72	$1.03	February 2008
Patrys	$0.14	$0.50	December 2007
Bionomics	$0.29	$0.42	December 2007
Cogstate	$0.25	$0.13	November 2007
Sirtex Medical	$5.05	$3.90	October 2007
Clinuvel Pharmaceuticals	$0.33	$0.66	September 2007
Starpharma Holdings	$0.57	$0.37	August 2007
Pharmaxis	$2.28	$3.15	August 2007
Universal Biosensors	$1.45	$1.23	June 2007
Probiotec	$2.51	$1.12	February 2007
Chemgenex Pharma.	$0.73	$0.38	June 2006
Acrux	$1.77	$0.83	November 2004
Alchemia	$0.53	$0.67	May 2004

Portfolio Changes – 9 October 2009

IN:
No changes.

OUT:
No changes.

How Bioshares Rates Stocks

For the purpose of valuation, *Bioshares* divides biotech stocks into two categories. The first group are stocks with existing positive cash flows or close to producing positive cash flows. The second group are stocks without near term positive cash flows, history of losses, or at early stages of commercialisation. In this second group, which are essentially speculative propositions, *Bioshares* grades them according to relative risk within that group, to better reflect the very large spread of risk within those stocks.

Group A

Stocks with existing positive cash flows or close to producing positive cash flows.

Buy	CMP is 20% < Fair Value
Accumulate	CMP is 10% < Fair Value
Hold	Value = CMP
Lighten	CMP is 10% > Fair Value
Sell	CMP is 20% > Fair Value

(CMP–Current Market Price)

Group B

Stocks without near term positive cash flows, history of losses, or at early stages commercialisation.

Speculative Buy – Class A
These stocks will have more than one technology, product or investment in development, with perhaps those same technologies offering multiple opportunities. These features, coupled to the presence of alliances, partnerships and scientific advisory boards, indicate the stock is relative less risky than other biotech stocks.

Speculative Buy – Class B
These stocks may have more than one product or opportunity, and may even be close to market. However, they are likely to be lacking in several key areas. For example, their cash position is weak, or management or board may need strengthening.

Speculative Buy – Class C
These stocks generally have one product in development and lack many external validation features.

Speculative Hold – Class A or B or C

Sell

Corporate Subscribers: Phylogica, Pharmaxis, Cytopia, Arana Therapeutics, Starpharma Holdings, Cogstate, Bionomics, ChemGenex Pharmaceuticals, Circadian Technologies, Biota Holdings, Halcygen Pharmaceuticals, Peplin, BioMD, Impedimed, QRxPharma, Patrys, Labtech Systems, Hexima, Tyrian Diagnostics, Mesoblast, Atcor Medical, CathRx

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