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In this edition...
We have prepared our annual clinical trials survey. There are currently 11 Phase III trials underway or in the planning by Australian biotechs, an impressive result. However perhaps not surprisingly, the number of clinical trials underway or in the planning was well down on last year's figure, now 55 compared to 82 in 2008.

We also provide a major update on CathRx, which has recently secured some funding, although at quite a price. And Cytopia has announced its second clinical program to proceed.

The Editors

Companies Covered: CYT,CXD, Clinical Trials 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 - Current)	7.4%
Cumulative Gain	**108%**
Av Annual Gain (8 yrs)	**14.7%**

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Bioshares

26 June 2009
Edition 317

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

CathRx To Raise Funds, At A Price

Funding conditions for biotech companies may have improved marginally, judging by the $47 million capital raising by Pharmaxis earlier this month, the $18 million raised by Chemgenex or the $15 million raised by Impedimed recently. However for most companies in the sector, access to funding remains very challenging, particularly for earlier stage or smaller companies.

CathRx is an example of the level of difficulty involved in raising a seemingly modest level of funds. At the beginning of this month the company announced a capital raising through a private placement and a rights issue totalling $6.9 million. The issue is underwritten by Wilson HTM. However the issue is being conducted at 25 cents a share, which is a 50% discount to the closing price before the issue was announced.

Founders and board members have also been required to step up to the plate, through a sub-underwriting agreement with Wilson HTM to take up to $3.2 million in any shortfall if requested to do so by Wilson HTM. The new shares are expected to commence trading on 13 July.

It is a crucial funding round for CathRx, perhaps being the final funding round before the business becomes firmly established and is cash flow positive. The company is forecasting a breakeven position within 18 months when annualised sales of $5 million are expected to be achieved.

CathRx manufactures and sells catheters used in cardiac procedures to diagnose and treat cardiac arrhythmias. Pharmaceuticals have traditionally been used to treat such disorders, however not very successfully. Catheters are placed inside the heart (via an artery in the groin) to map the electrical malfunction (diagnosis) then to treat this electrical imbalance through ablation (treatment).

The adoption of this technology has been occurring for the last decade, however it has been hampered by the technical difficulty and the lack of expertise in cardiac specialists to perform the procedure. The field has also lacked the technical advances to enable these procedures to be conducted more simply and quickly. CathRx sees itself as part of the solution, and at a time when this field could break out and become the next multi-billion dollar, cardiac stent market for the medical devices industry.

Advantages of the CathRx Catheters

The CathRx catheter design provides the next generation design of cardiac catheters. The stylet inside the catheter can be withdrawn at any time without removing the catheter

5th Thredbo Biotech Summit
****** 28–29 August, 2009 ******
Final early bird offer expires 30 June

from the artery, allowing the deflection curve size (how much the catheter bends to access different parts inside the heart for diagnosis or ablation) to be varied. The novel design of the catheters also provides a high quality signal for the operator to read the results.

Market Progress

CathRx has three of its diagnostic catheters on the market in Europe. By the end of March next year, the company expects to have three diagnostic catheters on the market and its treatment catheter (irrigation ablation catheter).

Sales Network in Europe

The CathRx catheters are manufactured in an impressive facility in Sydney which has received European approval to manufacture medical devices. The facility has the capacity to manufacture 2000 units a month at present. The catheters are sold into Europe and the UK through a number of distributors. This month the company announced the appointment of a German distributor for the largest market in Europe, being Germany, Austria and Switzerland. It is also selling its catheters through its UK distributor and with an additional distributor for France and Italy. A year ago the company made a high profile appointment to head up its global marketing activities, Ged Wallace. Wallace was previously President of **Boston Scientific** for Europe, Middle East and Africa. Prior to that he was President of **Baxter Healthcare** for Asia/China.

CathRx started selling its catheters into Europe in September last year. Receipts from customers for the first nine months of this financial year were only $40,000.

In the second half of 2009, CathRx will start clinical trials with its irrigation ablation catheter. The trial will recruit 15 patients with Atrial Flutter and will be conducted at the Monash Medical Centre in Melbourne. It is expected the trial will be completed by the end of September this year and the company will then immediately file the catheter for approval with European regulators.

One of the difficulties the company faces when marketing its products is that it currently does not have the full suite of diagnostic and treatment catheters. The company is anticipating this device will receive regulatory approval in the first quarter of 2010, which will complement its suite (four) of diagnostic and therapeutic catheters available in Europe, and thereby allow it to compete on a more equal footing with competitors.

The European market is more accessible for CathRx, being more fragmented and less dominated by global medical device firms, as is more the case in the US.

M&A Transactions in the Cardiac Catheter Space

Medtronic is positioning itself as one of the leading players in the cardiac catheter market. In September last year it acquired **CryoCath** Technologies in Canada for US$380 million. At the time of the acquisition, CryoCath had annual sales of $40 million, with its cryotherapy balloon catheter, called Artic Front. The catheter had been on sale in Europe at the time of the acquisition and in the US was undergoing clinical trials. The cryoballoon type catheters represent a significant advance in the treatment time for ablation pro-

Cont'd over

The 5th Bioshares Thredbo Biotech Summit

28-29 August, 2009

Current Speakers, Chairs & Panelists List

Pete Cook (CEO, Biota Holdings)
Jackie Fairley (CEO, Starpharma Holdings)
Lusia Guthrie (CEO, Labtech Systems)
Mike Hirshorn (Four Hats Capital)
Professor Silviu Itescu (Founder, Mesoblast)
Michael Johnson (Cogentum)
Phil Kearney (Merck Sharp & Dohme)
Robert Klupacs (CEO, Circadian Technologies)
Warwick Lamb (CEO, Imugene Ltd)
Alan Liddle (Immune System Therapeutics)
Rosanne Dunn (Immune System Therapeutics)
Jeremy Curnock Cook (Intersuisse Bioscience Managers)
Mark Morrisson (CEO, Universal Biosensors)
Tony Radford (CEO, Cellestis),
Deborah Rathjen (CEO, Bionomics)
Alan Robertson (CEO, Pharmaxis)
Brigitte Smith (Partner, GBS Venture Partners)
Tanya Solomon (Analyst, ABN AMRO Morgans)
Richard Treagus (CEO, Acrux)
Lisa Springer (Independent Consultant)
Ray Wood (CEO, Cell Therapies Pty Ltd)
Shane Storey (Senior Analyst, Wilson HTM)
David Blake (Bioshares)
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cedures, reducing procedure times from three hours to around one hour.

In January this year, Medtronic acquired another cardiac catheter business, purchasing **Ablation Frontiers** for an initial payment of US$225 million. Ablation Frontiers' catheters use radiofrequency energy for ablation of heart tissue, the same as the CathRx energy source. Ablation Frontiers catheter was first approved in Europe in 2006 and at the time of the acquisition was conducting clinical studies with its ablation catheters in the US.

In May 2008, **Boston Scientific** acquired **CryoCor** for an aggregate price of US$20 million. CryoCor's cryoablation catheter has been on the market in Europe since 2002 and at the time of the acquisition was in clinical trials in the US. Cryocor and Boston Scientific had been collaborating since 2007 combining Cryocor's cryo energy with Boston's cryo balloon catheter.

Rapidly Evolving Field and Market

The frenetic level of M&A activity in the cardiac catheter field highlights the dynamic nature and accelerating interest in this area. The probability of curing atrial fibrillation with the single procedure is now about 75% - 80%, which is making it an attractive and superior alternative to chronic drug treatment where the end result is poor (only a 21% reduction in recurring arrhythmia). That two million people are affected by atrial fibrillation in the US, it represents a potential multi-billion dollar annual market once the suite of ablation catheters are approved for use in the US (with many already on the market in Europe). It is estimated that over US$9 billion a year is spent on healthcare costs associated with atrial fibrillation. Between 3%-4% of the population over the age of 65 suffer from atrial fibrillation, which is poorly treated with chronic warfarin therapy.

The challenge for CathRx is whether it can stay with the head of the pack in product development. For the diagnostic catheters, CathRx's opportunities are unhindered. For ablation catheters, CathRx needs to compete against the emerging cryoballoon catheters which are offering significant user benefits with a marked reduction in procedure times.

Market for Cardiac Catheters

By October 2010, CathRx is aiming for 5.5% of the European market with its then range of diagnostic and ablation catheters, which represents a target market size of $90 million in Europe for those catheters. Its advanced ablation catheter, of which few details have been revealed, is expected to be approved in Europe in 2011. The catheter ablation market is roughly the same size as the diagnostic catheter market.

The overall European market for cardiac catheters is estimated at between $300 - $400 million a year. The global market has the potential to become a multibillion dollar market, once widespread adoption of cardiac catheters occurs, including in the US.

Summary

There are some strong positive features about CathRx. Its board is prepared to continue to financially support commercialisation of the company's technologies. The company is involved in a highly dynamic field where significant M&A transactions have occurred over the last two years. The US market is about to break open for cardiac catheters, potentially creating a multibillion dollar global market. CathRx has its first three catheters approved and on the market in Europe. Its catheters provide unique functionality with high quality signalling. It is confident in its product rollout to forecast revenue numbers with profitability in sight. And the board/ founders have an excellent track record with technology development, with previous involvement with Memtec and current involvement with leading, emerging biotechs Pharmaxis and Universal Biosensors.

Risks for the company include funding, although the current capital raising, which is underwritten, is expected to be sufficient to bring the company to profitability. The reliance on third party distributors is a risk. And perhaps the greatest risk is keeping pace with the rapidly evolving technologies in the cardiac catheter field.

CathRx is capitalised at $32 million, including the current capital raising underway to raise $6.9 million which is fully underwritten. The company had $6.8 million in cash at the end of March.

Bioshares recommendation: **Speculative Buy Class B**

Bioshares

Cytopia to Move CYT337 into Clinic

Cytopia is broadening its clinical pipeline with its second clinical program expected to start in the second half of 2009. The lead candidate, CYT387, will be trialed in around 30 patients with myelofibrosis. The trial will be conducted at the prestigious Mayo Clinic under the study chair Dr Ayalew Tefferi, who is a key opinion leader in this field.

CYT387 inhibits the JAK2 signalling pathway in cells. This pathway is linked with various cancers and inflammatory disorders. The JAK2 inhibitors are the backbone of the company, with the company founded on the proprietary position around inhibition or modulation of this biological pathway in cells.

The disease Cytopia is tackling in this clinical trial fits into a broader category of myeloproliferative disorders. The estimated market size for these disorders is around US$500 million with no currently effective treatments on the market.

The Phase I/II trial will be an open label trial, likely in around 30 patients. Trial results should start to become available in the first quarter of 2010, with results expected to be seen within four weeks of treatment. The Phase I and Phase II part of the trial should be completed by the end of 2010. The company estimates the trial will cost only $1 million to conduct. Costs of the trial are reduced because the candidate is an oral formulation, and that the trial can be conducted at the one centre in the US, which treats a large number of patients with this disease.

Cont'd on page6

Clinical Trials Survey 2009 – Summary

Company	DrugCode / Name [Trial Code]	Phase	Expected qtr - results announced	Disease or Medical Condition
		2009 H1		
Clinuvel Pharmaceuticals (CUV)	CUV1647	Phase II	2009 H1	Photosensitivity associated with cancer treatment
		2009 Q2		
BioMD (BOD)	CardioCel	Phase II	2009 Q2	Congenital heart disease
		2009 Q3		
Biotron (BIT)	BIT225 [003]	Phase Ib/IIa	2009 Q3	Hepatitis C virus infection
Clinuvel Pharmaceuticals (CUV)	CUV1647	Phase II	2009 Q3	Acute anaphylactic reaction to sun
Phosphagenics (POH)	Oxycodone/TPM [POH019-09]	Phase I	2009 Q3	Healthy volunteers
Tissue Therapies (TIS)	VitroGro	Safety & efficacy	2009 Q3	Diabetic, venous & pressure ulcers of the skin
QRxPharma (QRX)	Q8003 (MoxDuo)	Phase II	2009 Q3	Moderate to severe acute pain
Acrux (ACR)	AXIRON	Phase III	2009 Q3	Hypogonadism (testosterone deficiency in men)
ChemGenex Pharmaceuticals (CX	Omacetaxine [CML-202]	Phase II/III	2009 Q3	CML pts, failed imatinib, with T315I mutation
		2009 Q4		
Bionomics (BNO)	BNC105P [001]	Phase I	2009 Q4	Cancer
Bionomics (BNO)	BNC210 [001]	Phase I	2009 Q4	Anxiety
Clinuvel Pharmaceuticals (CUV)	CUV1647	Phase III	2009 Q4	Absolute sun intolerance
Peplin (PLI)	PEP005 Gel [REGION-IIa][On head]	Phase III	2009 Q4	Non-cancer skin lesions
Peplin (PLI)	PEP005 Gel [REGION-IIb][on head]	Phase III	2009 Q4	Non-cancer skin lesions
Peplin (PLI)	PEP005 Gel [REGION-Ib][Non-head]	Phase III	2009 Q4	Non-cancer skin lesions
Peplin (PLI)	PEP005 Gel [Non-head]	Phase II	2009 Q4	Non-cancer skin lesions
Phosphagenics (POH)	Diclofenac/TMP [POH020-09]	Phase I	2009 Q4	Healthy volunteers
Pharmaxis (PXS)	PXS25	Phase I	2009 Q4	Healthy volunteers
		2010 Q1		
Pharmaxis (PXS)	Bronchitol [CF302]	Phase III	2010 Q1	Cystic fibrosis
BioMD (BOD)	GyneCel	Phase II - Pilot	2010 Q1	Pelvic floor prolapse
ChemGenex Pharmaceuticals (CX	Omacetaxine [CML-203]	Phase II/III	2010 Q1	CML pts, failed multiple TKIs
Phosphagenics (POH)	Oxycodone/TPM [POH015-09]	Phase I	2010 Q1	Healthy volunteers
Pharmaxis (PXS)	Bronchitol [ICU201]	Phase II	2010 Q1	Ventilator associated pneumonia
Viralytics (VLA)	CAVATAK [X-03]	Phase I	2010 Q1	Cancer
		2010 Q2		
Sunshine Heart (SHC)	C-Pulse	Feasibility	2010 Q2	Heart Failure
		2010 Q23		
Biota (BTA)	CS8958 [Elderly Subjects]	Phase I	2010 Q3	Influenza infection
Biota (BTA)	CS8958 [Multiple Dose]	Phase I	2010 Q3	Influenza infection
Biota (BTA)	CS-8958	Phase III	2010 Q3	Influenza infection
ChemGenex Pharmaceuticals (CX	CGX-635-AML-204	Phase II	2010 Q3	AML patients who have failed prior chemotherapy
Halcygen Pharmaceuticals (HGN)	SUBA-itraconozole [HGN06]	Phase II	2010 Q3	Onycho-mycosis of toenail
Viralytics (VLA)	CAVATAK [X-04]	Phase I	2010 Q3	Cancer
Viralytics (VLA)	CAVATAK [X-06]	Phase I	2010 Q3	Cancer
		2010 Q4		
Clinuvel Pharmaceuticals (CUV)	CUV1647	Phase II	2010 Q4	Precursor to skin cancer
Mesoblast (MSB)	Neofuse [SF0106] [with PEEK OPTIMA Cage]	Phase I/II	2010 Q4	Degenerative disk disease with spondylolisthesis
Biota (BTA)	BTA798	Phase IIa	2010 Q4	Human rhinovirus infection

Note, table is sorted by quarter of expected result.

Comments

Our survey of clinical trials being planned or conducted by Australian listed biotech firms shows 55 trials are planned or underway as of June 2009. A number of these trials have been paused or are suspended, pending the availability of funds.

This latest survey figure is significantly less than the 82 clinical trials underway or planned that we reported a year ago, and still less than the 72 from the previous year.

The number of clinical trials conducted by ASX biotechs could be expected to fall further in the next few years as a consequence of the reduced flow of investment into the sector.

According to the survey there were 11 Phase III trials, 22 Phase II trials, 9 Phase I/II and 11 Phase I trials underway or in planning.

The results from at least 18 clinical trials, including several prelimi-

Cont'd over

Clinical Trials Survey 2009 – Summary

Company	DrugCode / Name [Trial Code]	Phase	Expected qtr - results announced	Disease or Medical Condition
2011 - and beyond				
HealthLinx (HTX)	OvPlex	Phase II	2011 Q1	Ovarian Cancer
Cytopia (CYT)	CYT387 [CCL09101]	Phase I/II	2011 Q1	Myeloproliferative disorders
Cytopia (CYT)	CYT997 [CCL08001]	Phase Ib/II	2011 Q2	Glioblastoma multiforme (glioma)
Mesoblast (MSB)	Revascor [AB002}	Phase II	2011 Q3	Heart Failure
Mesoblast (MSB)	Revascor	Phase II	2011 Q3	Heart Failure
Avexa (AVX)	Apricitabine [301 & 302]	Phase III	2011 Q3	HIV
Neuren Pharmaceuticals (NEU)	NNZ-2566	Phase II	2011 Q3	Traumatic brain injury
Mesoblast (MSB)	Neofuse [SF002]	Phase I/II	2011 Q4	Degenerative disk disease with spondylolisthesis
Pharmaxis (PXS)	Bronchitol [B305]	Phase III	2011 Q4	Bronchiectasis
Mesoblast (MSB)	Revascor [AB001]	Phase I/II	2013 Q4	Recent Acute Myocardial Infarct
Quarter not stated/not available				
Biotron (BIT)	BIT225 [004]	Phase Ib/IIa		HIV infected patients
Clinuvel Pharmaceuticals (CUV)	CUV1647	Phase III		Severe sun poisoning
Cytopia (CYT)	CYT997 [CCL07001]	Phase II	TBD	Multiple myeloma
Living Cell Technologies (LCT)	Diabecell	Phase I/IIa		Insulin dependent diabetes
Mesoblast (MSB)	Allogeneic MPCs	Phase I/II		Haematologic malignancies
Mesoblast (MSB)	Allogeneic MPCs	Phase II		Acute Traumatic Knee Injury
Novogen (NRT)	NV06 [0039]	Phase III		Ovarian carcinoma
Novogen (NRT)	NV06 [Yale 27640]	Phase II		Ovarian carcinoma
Novogen (NRT)	NV06 [Yale 0703002467]	Phase II		Prostate cancer
Prima Biomed (PRR)	Cvac [CAN-003]	Phase IIb		Epithelial Ovarian Cancer (EOC)

nary results, are expected to be announced over the remainder of 2009. A similar number of results (17) are expected to become available during 2010.

There were 22 companies surveyed (25 in the 2008 update), with data supplied by survey respondents or sourced from company publications, announcements and other public clinical trial databases. Activity figures obtained from this survey understate the actual number of trials underway or planned as the survey excludes companies conducting post-marketing trials. Some companies also elected to not include all clinical trial activity in their survey responses.

A more complete survey report can found in **Appendix A**.

Bioshares

Cytopia cont'd

If positive results emerge, the company will look to expand into other myeloproliferative disorders and look to move into a Phase II/III trial for myelofibrosis. With no effective therapies on the market, this program has the potential to move rapidly through the clinical trial process. There are currently three other companies with clinical programs working on the same target.

Incyte Pharmaceuticals is trailing its JAK inhibitor on a number of myeloproliferative disorders and inflammatory conditions (included rheumatoid arthritis). Its myelofibrosis trial is currently at the Phase II/III stage of development. SBio from Singapore started its Phase I/II trial in myelofibrosis in Australia at the end of last year with its JAK2 inhibitor. And Targegen Inc is currently conducting its Phase I/II trial in myelofibrosis in six centres in the US.

Myeloproliferative disorders are a nascent market and are eligible for orphan drug status. Cytopia's expertise developed over the last decade in developing JAK2 drug candidates places this Phase I/II program is the company's sweet spot.

Glioma trial update

Cytopia is currently conducting a Phase I/II trial in patients with Glioma with its lead, CYT997. Three sites in Australia are recruiting patients, with additional two Australian sites and one international site expected to be added. Around 30 patients are to be enrolled. Some efficacy results from this trial are expected to be reported by the company in the first half of 2010.

Funding requirements

Over the next five months the company will need to address its funding requirements, with sufficient funds at the moment to take the company to the end of March 2010. Funding options include a partnering deal or an equity raising.

Recommendation

Cytopia's share price has fallen by over 90% from its high three years ago. Whilst many of the leading biotech company share prices have bounced back this year, Cytopia and many smaller biotechs have ongoing funding challenges recognised by investors which has caused the sell-off in such stocks. Cytopia is now capitalised at only $6.4 million. At some stage this stock has the potential to generate a multiple fold return, once funding issues subside, equity markets stabilise and certainly when and if a clinical breakthrough is achieved. Adding a second clinical program to its pipeline significantly increases the possibility of the latter occurring.

Bioshares recommendation: **Speculative Buy Class B**

Bioshares

Bioshares Model Portfolio (26 June 2009)

Company	Price (current)	Price added to portfolio	Date added
ASDM	$0.33	$0.30	December 2008
QRxPharma	$0.38	$0.25	December 2008
Hexima	$0.35	$0.60	October 2008
Atcor Medical	$0.19	$0.10	October 2008
CathRx	$0.45	$0.70	October 2008
Impedimed	$0.61	$0.70	August 2008
Mesoblast	$0.79	$1.25	August 2008
Cellestis	$3.01	$2.27	April 2008
IDT	$1.45	$1.90	March 2008
Circadian Technologies	$0.75	$1.03	February 2008
Patrys	$0.10	$0.50	December 2007
Bionomics	$0.22	$0.42	December 2007
Cogstate	$0.24	$0.13	November 2007
Sirtex Medical	$3.51	$3.90	October 2007
Clinuvel Pharmaceuticals	$0.29	$0.66	September 2007
Starpharma Holdings	$0.33	$0.37	August 2007
Pharmaxis	$2.47	$3.15	August 2007
Universal Biosensors	$0.95	$1.23	June 2007
Biota Holdings	$1.29	$1.55	March 2007
Probiotec	$1.92	$1.12	February 2007
Peplin Inc	$0.59	$0.83	January 2007
Arana Therapeutics	$1.40	$1.31	October 2006
Chemgenex Pharma.	$0.64	$0.38	June 2006
Cytopia	$0.08	$0.46	June 2005
Acrux	$1.15	$0.83	November 2004
Alchemia	$0.36	$0.67	May 2004

Portfolio Changes – 26 June 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, Optiscan Imaging, Bionomics, ChemGenex Pharmaceuticals, Circadian Technologies, Biota Holdings, Halcygen Pharmaceuticals, Peplin, BioMD, Impedimed, QRxPharma, Patrys, Labtech Systems, Hexima, Tyrian Diagnostics, Mesoblast, Atcor Medical

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