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In this edition...
Business is a matter of steady progress towards clear commercial goals. QRxPharma continues to complete studies of its novel pain drug. Pharmaxis continues to drive Bronchitol towards the market, with a European approval anticipated this year. Pharmaxis has adapted its strategy over the years, but the main focus has been on commercialising Bronchitol under its own steam. In the case of CathRx, a wholesale change in strategy has been adopted with a shift to a partnership and new market access model. Genetic Technologies' new strategy is to cement a place as an provider of oncocology diagnostics. Also confronting the issue of how to generate growth is Resonance Health, which is developing a non-invasive test for liver fibrosis.

The Editors
Companies Covered: CXD, GTG, PXS, QRX, RHT

	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)	67.1%
Cumulative Gain	**214%**
Av Annual Gain (9 yrs)	**20.5%**

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Bioshares

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Edition 355

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

Bronchitol on Track for EU Approval

Pharmaxis (PXS: $3.03) continues the path to market for its cystic fibrosis drug candidate, Bronchitol, which is on track for regulatory approval by the end of this year in Europe. For the US, results from the second pivotal CF study are expected next month.

The main goal and primary endpoint is an improvement in lung function (FEV1). The first trial, on which the European submission is based, achieved an improvement in lung function of 7%. This compares favourably to the highly successful CF drug Pulmozyme, which was approved on a lung function improvement of 5.8%. Improvement in FEV1 is accepted as a surrogate measure for extension of life.

In that first CF trial (in 295 patients), Bronchitol even achieved a 5% improvement in patients taking Pulmozyme as well as a baseline therapy. A sustained 5% improvement in lung function will modify the course of disease said CEO Alan Robertson in a briefing to investors this week, and will increase life expectancy. At 12 months, overall lung function had improved by 8% and 18 month data from patients in the first Phase III extended treatment trial should be available next month.

Another highly important measure, according to Alan Robertson, is a reduction in exacerbations. Exacerbations in CF patients are often life threatening, in most cases resulting in hospital admission and high dose antibiotic treatment.

The first CF trial achieved a 26% reduction in exacerbations. Pulmozyme achieved a 27% reduction in exacerbations in its pivotal studies. A reduction of greater than 20% in exacerbations is considered as a very significant achievement by CF physicians, according to Robertson.

Pulmozyme currently generates sales of around $500 million a year. The drug is taken by 55% of people with CF in Europe and 75% of people with CF in the US. Robertson believes Bronchitol could meet those penetration rates. He stressed that Bronchitol is not a competing drug to Pulmozyme, with both agents expected to be used together. He does not expected people to stop taking Pulmozyme and change over to Bronchitol. The overall drug costs for CF to health care budgets is very small relative to global pharmaceutical expenditure.

Pulmozyme sells for $13,000 per year of treatment per patient in Europe. Reimbursement does not need to be negotiated in the UK and Germany, although does in France, Spain and Italy. In the UK however, and presumably in other regions, CF groups, such as the UK CF Trust, need to be agreeable regarding pricing, presumably to support the product. Pharmaxis is also working with NICE (National Institute for Health and Clinical Excellence) in the UK regarding the health economics of payment for Bronchitol. Robertson believes Bronchitol is extremely well positioned, being a product that has generated strong data and which outperforms the incumbent product (Pulmozyme). An outcome between NICE and Pharmaxis regarding support of pricing for Bronchitol in the UK is expected to be announced around October this year.

– Cont'd on page 4

CathRx's New Strategy Built on Mandated Recycling in Germany

Catheter products company CathRx (CXD: $0.18) is completing a 1:1 rights issue at 16 cents to raise up to $11 million. The rights issue is not underwritten and closed on Friday. The capital raising is aligned with the appointment in March of a new CEO, board member Jeff Goodman, and also with the launch of a new strategy to commercialise the company's suite of unique modular catheters that have been developed primarily for use in the cardio-electrophysiology. The uniqueness of the catheters relates to a modular design, whereby fixed and steerable curves can be swapped without the need to remove the catheter from a patient.

The company's products marketed and in development include catheters that can diagnose and treat heart conditions such as atrial fibrillation and atrial flutter. Two products have gained European market approval; a decapolar catheter and a duodecapolar catheter for atrial flutter.

The Old Strategy

The company's old strategy was based on selling its range of catheters, through distributors, in direct competition with large market-dominating competitors, such as **Medtronic**, **Biosense Webster** and **St Jude**.

We ascribe the failure of the strategy to the incomplete development of a complete suite of catheters (the staged rollout strategy), both diagnostic and therapeutic, coupled to vastly inferior sales and marketing resources relative to its competitors. Other factors such as weakened economic condition would also have worked against the company.

The New Strategy

The company's new strategy is built on a still-to-formalised partnership with a Berlin-based German catheter products and reprocessing firm, **Pioneer Medical Devices**. This business takes used catheters and cleans, sterilises and packages equipment for reuse. Replacement of components can also form part of the service. One of the features of the service is that products in the hands of hospital, for which they a disposal responsibility for, with the reprocessor delivering a 'door to door ' service that includes the device, its re-processing and disposal. Disposal is a not an insignificant cost, representing 30% of the upfront cost per catheter procedure in Europe, according to CathRx.

Germany is arguably a whole-of-world test site for the viability of the recycling model that the German Government has now mandated. If Pioneer Medical can capture revenues in this market, then the likelihood of the model being successful elsewhere should increase.

In March 2010 CathRx signed a Heads of Agreement with Pioneer Medical, with a formalisation anticipated in the next few months. This remains an outstanding investment risk relating to an investment in CathRx.

Under the agreement, CathRx would supply Pioneer with its products for Europe on an exclusive basis over a five year period.

Re-branding

Pioneer Medical would re-brand CathRx products with its Master2cout label. Currently, Pioneer Medical is working with CathRx to gain CE mark approval for reprocessing for CathRx European approved products. Although some components of CathRx's catheters are already approved for reprocessing, such as the stylet, we understand additional CE marking is being assisted by Pioneer Medical.

The strategy is not confined to Europe, with CathRx looking to build similar partnerships with other companies for other regions within a twelve month period.

One element of the old strategy retained in the new strategy is to control and manage manufacturing of catheter products at the CathRx's facility at Homebush, Sydney. The company also will continue its development of its advanced atrial fibrillation catheter.

The key to the strategy for both CathRx and Pioneer Medical (and potentially others) is that CathRx catheters are modular. CathRx estimates that so called single use catheters are being re-processed between 3.1 and 3.6 times in Europe, reflecting for the most part the useable lifespan of the electrode components. However, using the modular CathRx catheters, it is possible to take advantage of 20 re-uses for the stylet and extension cable and for the sheath five to six times.

The CathRx catheter technology is primarily applied to cardiology. However, the same principles of modular design can be applied to, for example, urinary and neurological catheters.

Revenue Model

Pioneer Medical's revenue model depends on converting single users into repeat service based users. We understand CathRx would share in profits and collect a transaction benefit each time a device was re-processed. Access to a transaction-based, service model income stream is an attractive feature of the potential arrangement.

Competition Risk

The threat from the large single-use catheter companies remains a concern, despite the German government laws that stipulate the use of recyclable products. The threat is that these companies would lobby against a trend towards re-processed products.

Summary

CathRx has an opportunity to work its way out of an exceedingly difficult financial situation, holding less than six months cash at December 31, 2009. It may have only once chance, through the current rights issue, to do this since this 'Plan B' provided by the re-processing tie up is more of an emerging and unproven opportunity and at this stage really confined to one country.

– Cont'd on page 4

Genetic Technologies – Dialling Up an Oncology DX Strategy

Genetic Technologies (GTG: 3.5 cents) is, like CathRx, in the midst of building a new business strategy. The company is a supplier of genetic testing services in to public authorities such as the NSW Police Service, paternity testing services and animal genetic testing. However, the greater part of the company's revenues has over the last five years has come in the form of licensing income. For the period 2005-2009 the company generated $41 million in licence income in relation to its non-coding DNA patents (which have now expired) compared with $17.4 million from testing services. [The non-coding DNA patents have generated in total more than $50 million in revenue to date.]

With the decline in licensing revenue set in, although it is being slightly offset by some retrospective claims for infringement, the company has been compelled to seek new growth opportunities. It has elected to build capabilities in the field of oncology diagnostics, building on its position as the Australian licensee of the BRCA 1 and BRCA 2 breast cancer susceptibility gene tests, which it licensed in 2002 from **Myriad Genetics**.

In October 2009, Genetic Technologies licensed a micro-RNA based Cancer of Unknown Primaries (CUP) diagnostic from **Rosetta Genomics**.

In January 2010, the company signed on as a distributor for **Response Genetics**'s PCR based ResponseDX range of tests that aid the treatment of patients with lung, colon and gastric cancer.

Perlegen Assets

Last week the company has now finalised the acquisition of assets from the defunct US-based **Perlegen**. The assets encompass the Brevagen breast cancer risk test and a suite of patents that complement Genetic Technologies non-coding DNA patents, with a patent life extending to 2022.

The Brevagen test is a validated product that is market ready. The test offers women an assessment of the sporadic risk of breast cancer (as opposed to familial breast cancer). The test combines population risk factors with genetic risk factors. The market opportunity resides in improving the classification of women who obtain an indeterminate result from a breast biopsy.

Genetic Technologies has paid approximately US$1.2 million for the Perlegen assets, benefiting from a company that has been wound down following a failed IPO in 2006, a Series E investment form Pfizer ventures and a subsequent failed Series F round in 2009. Perlegen began filing patents covering the test in 2006.

Context

The context for Genetic Technologies' portfolio development objective is that cancer diagnostics can be segmented into a continuum of information requirements, ranging from risk assessment, screening, differential diagnosis, staging of disease, prognosis, therapy selection, therapy monitoring and surveillance. This continuum can be cast against various cancers to create a matrix of product opportunities.

Product opportunity analysis conducted by Genetic Technologies shows that as much as 50% of the opportunities in the matrix remain unmet.

Using breast cancer as an example, Genetic Technologies is the provider of risk tests (BRCA 1 and 2), with Combimatrix and Ipsogen offering staging tests, Agendia and Siemens providing prognosis tests, Diagnocure, Agendia and Genomic Health offering therapy selection tools, Genomic Health providing therapy monitoring and Combimatrix offering a surveillance product.

While breast cancer is replete with a range of tests across a spectrum, many other cancers, such as bladder, melanoma, mesothelioma, head and neck, are without equivalent products. This represents the market opportunity for Genetic Technologies.

The Clarient Model

Genetic Technologies is looking to emulate **Clarient**, a US oncology diagnostic testing and services company. This company recorded sales of US$92 million in 2009, (US$74 million in 2008; $43 million in 2007) and employs 58 sales staff out of a total of 361 (Dec 31, 2009), as well as several hundred lab staff . The company sells to community pathology practices and hospitals. Although the company has recorded strong sales growth in the last three years, it has not posted a profit. However, the strong sales growth is a sign of the potential for players in the sector.

Clarient offers more than 350 tests. In 2009, Clarient launched the Insight Dx Breast Cancer profile tests (a prognostic test), an EGFR mutation test, which aids the selection of therapies for lung cancer patients and a BRAF mutation test (a predictive biomarker for colorectal cancer, which aids in the selection of therapies for colorectal cancer patients). Clarient is capitalised at US$229 million.

Funding an Issue

To progress its strategy Genetic Technologies must find additional capital. It recently completed a small capital raising of $1 million from a boutique US investor, the company's first fund raising since 2003. Other funds could stem from business rationalisation, with the company looking to divest or partner the RareCellect non-invasive pre-natal testing platform (as flagged in the company's 2009 Annual Report).

Key Investment Risks

The influential position of foundation shareholder Dr Mervyn Jacobsen, who is a significant shareholder with at least a 40% direct interest, is a potential concern for investors looking to invest in the company. In 2008, he removed 5 directors from the board. A general risk is that existing shareholders are unwilling to support capital raisings needed to grow the oncology diagnostics business.

Another risk for the company is that the objective of building an oncology diagnostic business focused on the US will under-realised if sufficient and competent sales staff and supervisory management cannot be found and retained.

– Cont'd on page 4

Bioshares Model Portfolio (16 April 2010)

Company	Price (current)	Price added to portfolio	Date added
Tissue Therapies	$0.23	$0.21	January 2010
Biodiem	$0.18	$0.15	October 2009
QRxPharma	$1.18	$0.25	December 2008
Hexima	$0.39	$0.60	October 2008
Atcor Medical	$0.14	$0.10	October 2008
CathRx	$0.18	$0.70	October 2008
Impedimed	$0.69	$0.70	August 2008
Mesoblast	$2.08	$1.25	August 2008
Circadian Technologies	$0.74	$1.03	February 2008
Patrys	$0.15	$0.50	December 2007
Bionomics	$0.33	$0.42	December 2007
Cogstate	$0.29	$0.13	November 2007
Sirtex Medical	$5.88	$3.90	October 2007
Clinuvel Pharmaceuticals	$0.24	$0.66	September 2007
Starpharma Holdings	$0.68	$0.37	August 2007
Pharmaxis	$3.03	$3.15	August 2007
Universal Biosensors	$1.70	$1.23	June 2007
Probiotec	$1.76	$1.12	February 2007
Acrux	$2.30	$0.83	November 2004
Alchemia	$0.60	$0.67	May 2004

Portfolio Changes – 16 April 2010

IN:
No changes.

OUT:
No changes.

– Pharmaxis...from page 1

If a positive decision is received by European regulators regarding Bronchitol for the treatment of CF (in late 2010), the company will then receive a marketing license one month later, at which point the company will be ready to begin selling the drug immediately, firstly in the UK and Germany. Pharmaxis has maintained a close and sometimes intimate dialogue with European regulators.

With other programs, a second Phase III trial, using the same Bronchitol drug candidate, for the treatment of bronchiectasis, is expected to complete recruitment by year's end in 400 patients. Patients will be treated for 12 months, with results expected in early 2012. Bronchiectasis affects eight times as many people as those with CF.

In February this year, Pharmaxis completed the acquisition of **Topigen Pharmaceuticals**. The key asset acquired is a Phase II asthma drug candidate, ASM8. In a recently completed Phase II study, patients' breathing was improved by 32-49%, which was an excellent result although only tested for a short treatment period (four days). A second Phase II trial should be completed this year involving a longer course of treatment. The potential appeal of this program is that ASM8 has a patient friendly delivery system through inhalation compared to other products on the market that require injection, and could treat those patients who do not respond to corticosteroids.

There are several major milestones for Pharmaxis this year that if achieved, should see continued strengthening in the company's share price. Pharmaxis is capitalised at $683 million. It had $95.9 million in cash at the end of March and is spending around $36 million a year currently.

Bioshares recommendation: **Speculative Buy Class A**

– CathRx...from page 2

First time investors in CathRx could be in a position to reap considerable returns if CathRx's strategy is successful, even only confined to European markets. Including the rights issue, on a fully diluted basis, the company is capitalised at $25 million. Cash at the end of February was $3.2 million with up to $11 million being raised.

We suspect that the board will position the company for sale, provided the new strategy can be shown to work. The horizon for such an event could be within 18-24 months.

Bioshares recommendation: **Speculative Hold Class B** (To be reviewed when the deal with Pioneer Medical is completed, and manufacturing recommences).

Bioshares

– Genetic Technologies...from page 3

Summary

We expect Genetic Technologies to continue to add to its portfolio of cancer diagnostic offerings. The oncology diagnostics strategy is still being rolled out and in our opinion it will be at least 24 months before investors can gauge the success of the strategy.

However, the company is now emerging as a stock to watch, although implementation risk is an issue that will accompany the new growth strategy. With a capitalisation of $13 million, we place a **Speculative Hold Class C** on Genetic Technology shares. Demonstration of strong cost management, coupled to increased efficiencies from genetic testing businesses and the sourcing of fresh capital needed to pursue the growth strategy would improve our risk rating of this stock.

Bioshares

QRxPharma – Full Steam Ahead

Developments at QRxPharma are falling into line with the three applications of the company's core pain therapy technology progressing well. QRxPharma's core technology relates to the discovery that if certain proportions of morphine and oxycodone are combined, the same therapeutic benefit can be achieved if a similar therapeutic dose of morphine or oxycodone alone is taken, but with a considerably better side effect profile.

QRxPharma is commercialising three versions of the opioid combination. The first is an immediate release version, the second a sustained release, and the third an intravenous version.

First Application

The immediate release version, MoxDuoIR, has just completed the first of two pivotal studies the company needs to file that drug product for approval in the US. That study involved 522 patients who underwent a bunionectomy procedure. The results from the trial were positive, however the bar was set quite low by the FDA, with the company needing only to compare the efficacy of the combination treatment against the individual parts. The trial looked at a combination dose of 12mg of morphine with 8mg of oxycodone.

The second trial underway needs to show that the combination of opioids is effective at relieving pain in a second indication, that being after knee replacement surgery. This trial will involve 140 patients and is expected to be completed by July. The primary endpoint is to compare the pain differences between higher and lower doses of the combination therapy (arm one will start at a 12mg/8mg morphine/oxycodone dose and arm two will start at 6mg/4mg then move to 3mg/2mg). Once again the hurdle here set by the FDA is low.

QRxPharma expects to file its drug for approval by the end of this year, with approval anticipated by the end of 2011 if successful and product launch in 2012. The current market in the US alone for these drugs is valued at between US$1.8 billion –US$2.0 billion.

Second Application

The second application of this technology is for use in a sustained or controlled release format. That drug candidate is called MoxDuoCR. This product will also include a tamper-resistant feature with a proprietary sustained release technology.

Last month the company initiated a Phase I pharmacokinetic study to look at how the drug is absorbed, metabolised and eliminated from the body. It will be compared against sustained release versions of morphine (MS Contin 30mg) and a sustained release version of oxycodone (Oxycontin 20mg). The market in the US alone for these drugs is valued at US$5.6 billion a year. The Oxycontin product, which generates sales each year of US$2.9 billion for **Purdue Pharma**, comes off patent at the end of 2013 which will open up this market. MoxDuoCR is anticipated to get to market, if all goes well, by 2014/2015.

There should be an even stronger demand for the sustained release version of QrxPharma's opioid combination because the sustained release versions are prescribed for chronic pain treatment. Side effects in chronic opioid use are an even larger issue than in an acute use setting. One of the major side effects with opioid use is constipation. (See marketing study 1 below).

Third Application

The third application of the technology is for delivery in an intravenous form. In February this year the company formed a collaboration with a Chinese company, **China Aoxing Pharmaceutical Company**. China Aoxing will develop the opioid IV combination product for China, from which QrxPharma will receive a royalty. The other benefit for QrxPharma is that it can use any data developed by China Aoxing to use in registration of the product in other regions. QRxPharma will also license the MoxDuoIR version to China Aoxing from which it will also receive a royalty from sales in China.

The IV version could reach the US market in 2013/2014. It is a highly generic market in the US valued at between US$220 million – US$250 million. However, like most pain therapeutic markets, success is dependent on delivering distinct product advantages with the right marketing strategy that services existing product shortfalls. This could potentially be a very important application for QRxPharma.

Program Delay

As the global financial crisis hit in 2008 and 2009, access to future funding became uncertain. Not wanting to start its pivotal studies and finish with very little in cash, the company delayed the start of its pivotal programs. This time allowed the company to conduct two important marketing studies, and also liase with the FDA to design its pivotal/registration trial. Initially this was under a Special Protocol Assessment arrangement.

However as the GFC eased, funding once again became available and QRxPharma raised $21.6 million at 80 cents a share in November last year (underwritten by RBS Morgans). It started its first pivotal study that month, not waiting for the final SPA agreement. The company says the important discussions with the FDA had allowed the trial to be designed with dialogue from the regulator.

The pivotal Phase III studies are designed such that they provide little detail on the real advantage of the company's opioid combination concept. The studies compare the combination against the individual components separately (following a bunionectomy procedure), and also compares one dose of the opioid combination against another in a different indication (total knee replacement).

Marketing Studies

Marketing studies highlight the real benefit of this QRxPharma drug combination concept.

Marketing study 1

In 197 patients following a bunionectomy procedure, the company looked at two different doses of its opioid combination – 12mg/8mg (morphine/oxycodone) and 6mg/4mg (morphine/oxycodone) – and compared the treatment against the individual parts. However there was a reason for the selection for these dosages.

– Cont'd over

As measured by equivalent opioid dosage, it is generally accepted that 6mg of morphine is equivalent to 4mg of oxycodone. So the 6mg/4mg (morphine/oxycodone) dose is therefore the equivalent opioid dose of 12 mg of morphine or 8mg of oxycodone.

The structure of this marketing study therefore allowed the company to compare the equal therapeutic doses of 6mg/4mg (morphine/oxycodone) against 12mg of morphine and separately against 8mg of oxycodone.

The results confirmed the similar therapeutic effect of these opioid doses. There was a stark positive difference in the combination 6mg/4mg arm against the morphine equivalent dose and the oxycodone equivalent dose as measured by reductions in nausea, vomiting and dizziness. There was an increase in the number of patients who had headaches in the 6mg/4mg combination arm (9% versus only 3% for 12mg morphine and 0% for 8mg oxycodone). Patients were also two to four times more likely to discontinue treatment early when not on the combination dose. (See corporate presentation released 26 August 2009).

Marketing Study 2

In a 29 patient study reported in August 2009, QrxPharma compared equal therapeutic quantities (as decided by each patient) of its immediate release opioid combination with the very successful Percocet (oxycodone and paracetamol) product from Endo Pharmaceuticals in patients following total knee replacement. The trial found that patients had half the rate of constipation with MoxDuoIR (7% versus 13%) and a very clear benefit in gastrointestinal side effects (14% versus 47% for Percocet) and vomiting (0% versus 20% for Percocet).

Summary

The dual opioid technology of QrxPharma is now progressing well on all three applications. The company should file its first product for approval by year's end with three product launches slated for between 2012-2015. The pain therapeutic space QrxPharma will be competing in is worth around US$7 billion in the US alone. If the company can successfully carve out a part of the market, it has the potential to become a highly successful business. Its technology offers clear patient benefits in a space where small product improvements with the right marketing strategy have yielded multi-billion dollar products (see cutout below).

QRxPharma is capitalised at $121 million with $27 million in cash at the end of last year.

Bioshares recommendation: **Speculative Buy Class A**

Blockbuster Pain Products

- Oxycontin, sustained release oxycodone, Purdue Pharma, US$2.9 billion sales (comes off patent in 2013).
- Duragesic fentanyl patch, Johnson & Johnson, US$2.1 billion peak sales (2004)
- Lyrica, Pfizer, improved gabapentin for neuropathic pain, US$2.7 billion in 2008
- Lidoderm, lidocaine patch, Endo Pharmaceuticals, US$776 million

Resonance Health – New Imaging Modality Gains Acceptance

Resonance Health has developed a novel way to detect iron overload in the liver. The traditional way has been, and still largely is, to inject a 16 gauge needle into the liver several times to take samples that are analysed by a pathologist.

Resonance Health has developed an impressive new, non-invasive method that uses standard Magnetic Resonance Imaging, called Ferriscan. The company has characterised the magnetic effect the MRI has on the iron in the liver through a software program. It is gaining acceptance as a very accurate, if not more accurate method, to measure iron levels in the liver.

The MRI images are sent to Resonance Health's Perth processing facility from around the world via the internet. The company's technicians process the image, which takes about one hour to process each test. The company charges US$300 per test in the USA.

Resonance Health has reached a position where the test has become very well accepted by physicians around the world, particularly in the paediatric setting. More than 8,000 tests have now been conducted worldwide with the Ferriscan technology. The company has reached a level where it operates at a breakeven point, generating around $2 million a year in revenue. However that revenue figure has plateaued in the last 12 months. The challenge for the company, now that the test has become established and widely validated, is to progress the company to the next stage, where accelerated strong top and bottom line growth can be achieved.

One of the factors that will facilitate this growth is reimbursement in the US and other countries. At the moment the company processes tests for users from 20 countries around the world, in 150 centres by around 500 physicians.

Previously the test was largely used in a number of clinical trials of pharmaceutical drugs to treat liver iron overload, with Novartis using the test in six global studies. Now 60% of the tests are from daily clinical community use.

Asia is a large market for Resonance Health due to the high prevalence of liver disease, although reimbursement is not anticipated there. Some paediatricians, including those at the Children's Hospital in Philadelphia, will not biopsy children and now only use the Ferriscan test.

Next Test – Liver Fibrosis

The company is looking to apply the test in detecting liver fibrosis. In a standard MRI scan of the liver, iron dominates the con-

– Cont'd over

– Resonance Health cont'd

trast. However, iron does not move into fibrotic part of the liver. The company is looking to use the same iron level imaging processing technology to develop a system for non-invasive diagnosis of liver fibrosis. It is a substantial market with the disease arising from a number of reasons, including Hepatitis C infection and Fatty Liver Disease, with the latter affecting one third of the US population according to the company.

The company is close to achieving proof-of-principle with this test. It is conducting a 50 patient study at two Perth hospitals with results expected at the end of the month. There are blood tests and an ultrasound test available for liver fibrosis, however these modalities are not good at detecting mild and moderate disease.

Marketing of the test would be less difficult, with the same physicians using the test as those who use the iron overload test.

Challenges and Opportunities

Resonance Health has achieved global penetration of the test into 500 centres without any significant marketing of its iron liver test. It should now be in a position to invest in wider marketing of the test. The test is very well received by users, taking only 48 hours to process, rather than up to three weeks for a blood test or biopsy. The Ferriscan test is arguably even more accurate that taking a biopsy because it assesses the whole liver rather than taking random biopsies.

Testing using Ferriscan has also some unexpected benefits. The company has in some cases diagnosed MRI hardware faults, and remote analysis of images adds a layer of qualitative control for radiologists ensuring they have done their job correctly.

Resonance Health believes that clinicians will support reimbursement of the test. This and the wide adoption of the test to date should position the company well to negotiate reimbursement with payors around the world.

Summary

The Ferriscan technology is unique, now established and its accuracy widely accepted in measuring liver iron levels. The company is in a position to accelerate adoption from greater marketing of the test and through gaining effective reimbursement. Resources are a constraint for the company, with only $2.5 million in funds at the end of last year. Resonance Health is capitalised at $10 million.

Bioshares recommendation: **Speculative Buy Class B**

Bioshares

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: Pharmaxis, Starpharma Holdings, Cogstate, Bionomics, ChemGenex Pharmaceuticals, Circadian Technologies, Biota Holdings, Halcygen Pharmaceuticals, Peplin, Impedimed, QRxPharma, Patrys, Labtech Systems, Hexima, Tyrian Diagnostics, Mesoblast, Atcor Medical, CathRx, BioMd, Tissue Therapies, Viralytics

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