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Companies covered: ANP, CGS, Fitgenes

	Bioshares Portfolio
Year 1 (May '01 - May '02)	21.2%
Year 2 (May '02 - May '03)	-9.4%
Year 3 (May '03 - May '04)	70.6%
Year 4 (May '04 - May '05)	-16.3%
Year 5 (May '05 - May '06)	77.8%
Year 6 (May '06 - May '07)	17.4%
Year 7 (May '07 - May '08)	-36%
Year 8 (May '08 - May '09)	-7.4%
Year 9 (May '09 - May '10)	50.2%
Year 10 (May '10 - May'11)	45.4%
Year 11 (May '11 - May '12)	-18.0%
Year 12 (May '12 - May '13)	3.1%
Year 13 (May '13 - May '14)	26.6%
Year 14 (May '14 -)	10.5%
Cumulative Gain	**398%**
Av. Annual gain (14 yrs)	**16.8%**

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Bioshares

15 August 2014
Edition 564

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

FitGenes IPO Profile

Fitgenes, a health and wellness business which combines personal genetic information with pathology and other data, is seeking to raise a maximum of $3.6 million (minimum, $3 million) from the issue of 12 million shares at 30 cents. Of the funds, $2 million will be used to expand its network of clinics as well as its distributor channel of independent healthcare practitioners. Some funds will be applied to research and to new product development and towards the acquisitions of clinics or practices that can be integrated into the Fitgenes group of branded clinics.

The indicative capitalisation of the Fitgenes, based on 41.9 millions shares, which includes 4.1 million shares issued for the acquisition of Gordiantec, is $12.6 million. The Gordiantec acquisition will be completed once the capital raising is finalised. Gordiantec is a spinout of technologies developed at the University of Western Australia and the Western Australian Institute for Medical Research. Gordiantec has developed mathematical rules (algorithms) for identifying the variations of genes which are associated with disease, with a particular focus on diabetes and cancer.

Investors can apply for shares using the application form contained in the offer document. In addition, the company is using the ASX's book build facility to allocate shares under this capital raising. The book build facility allows investors to place bids on stock sought.

Fitgenes was founded in 2009 by Dr Paul Beaver, the company's Chief Science Officer, and Leigh Beaver. The chair of the company is Dr Carrie Hillyard. Other members of the board, post-listing, will be Conrad Crisafulli, Liddy McCall, Dr John Hurrell and CEO Robert Mair.

The company recorded revenues of $0.9 million for FY2013.

Bluemount Capital is the lead manager of the offer.

While the offer is described as an IPO, Fitgenes is using the shell of ATW Holdings to list, with the ASX code changing to 'FIT'.

The Fitgenes Business

The Fitgenes business can be seen as a major departure from genetic testing and genome profiling businesses that have come into being over the last decade or more.

The testing for specific gene markers or mutations that give rise to, or are associated with various diseases or illnesses is well established. A substantial body of literature has been established that confirms the role of many of these mutations and markers in disease.

These developments, alongside decreases in the cost of genome sequencing, led to the establishment of companies in the USA such as 23andme, a company backed by Google

Cont'd on page 3

Comparison of Selected Genetic / Personalised Genomics Information Companies

Company	Status	Products	Goal	Testing Capability	Model	Comments
USA						
23and Me	Private (Investors - Yuri Milner, J&J, MPM Capital, Google Ventures)	Personal Genome Service (200+ traits)	Provide inherited traits and ancestry-related genetic reports	Uses CLIA certified labs	Direct to Consumer (**DTC**); Online kit orders, results available online, no counselling	FDA closed company's offering of reports to new customers in Nov 2013
DeCode	Acquired by Amgen in 2012 for US$415M	DecodeMe (47 conditions and traits)				Product discontinued by Amgen - focus reverted to discovery tasks
Interlukin Genetics	ILIU - OTCQB (Cap: US$29 M) (Testing Rev 2013: US$2.2M, 2012: US$2.2M)	**PerioPredict** (periodontal disease) plus tests under the **Inherent Health** brand for weight management,bone health,nutrition, hearth health and wellness	Genetic susceptibility testing	Operates its own CLIA lab, certified 2005	Works with healthcare provider to make decisions regarding nutrition, exercise and lifestyle	PerioPredict distributed by Renaissance Health Services; markets Inherent Health through Amway as well as online
Navigenics	Acquired by Life Technologies				Exited DTC	
Pathway Genomics	Private (founded 2008)	Genetic tests covering cancer, cardiac, medication, weight management, general health, carrier status	To provide actionable and accurate genetic information to improve or maintain health and wellness	Operates its own CLIA lab, certified 2013	Physician directed	
Coriell Life Sciences	Private	GeneVault, GeneExchange, GeneDose	Delivers access to genomic interpretation		Physician-guided, clinical care focus	
Basehealth	Private (US$6.3 M of angel investor funding)	**Genophen** (40 disease conditions)	Integrate genomic with medical and lifestyle data		Initial visit to doctor; uses comprehensive health assessment,	Calculates relative lifetime risk, and achievable risk; builds pharmacogenomic and nutrigenomic profiles
Australia						
Genecare	Private - has links to Brighthope Health, Nutrition Care Pharmaceuticals, Nutrigenomics Australasia	Sydney based Integrated Health refers to tests/panels for 83 diseases branded by GeneCare				Website not active
MyGene						Under administration
Nimble Diagnostics	Private (Syd)	Ancestry, Paternity & Prenatal Testing, Cancer Nutraceuticals		Outsourced labs?	DTC	Global focus
Smart DNA	Private (est 2009) (Melb)	SmartDNAWellness (covers 100 DNA changes)	Assist patients achieve wellness objectives		Accessed via registered practitioner	
Fitgenes	IPO	Offers personalised health and wellness programs, based on panels of genetic and pathology tests, and other information	To provide healthcare and wellness services based on an individual's genetic, medical and nutrional profile	Preference for outsourced facilities	Practitioner-directed, using independent and internal clinics	Building international business
Genomics for Life	Private (Qld)	Various panels for cancer, also paternity testing	To aid in determining most effective treatment	Operates lab	Counselling referred to Genesis Genetics	
EU						
GenePlanet	Private	Personal genetic analysis; Nutrifit (35 analyses, 110 genetic variations)		Labs in Slovenia and Ohio	Direct to Consumer (DTC); Online kit orders, results and advice returned by mail	

Ventures, and GenePlanet in Europe, to offer direct-to-consumer, gene profiling or risk assessment services.

The US FDA halted 23andme's direct to consumer activities in November 2013, stating that the company's product was a device that had not been cleared by the FDA, being a product "intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or function of the body."

A general concern with the DTC approach is that information is provided without interpretation or counsel from trained healthcare professionals.

Industry pioneer Decode, which originated in Iceland, offered the DecodeMe panel of gene tests, prior to its acquisition by Amgen in 2012, but that has been discontinued.

In contrast to the direct-to-consumer model, the Fitgenes business is based on healthcare practitioners working alongside clients (or patients, depending on where they sit in the illness-wellness spectrum) to achieve wellness goals.

These healthcare practitioners could be integrated medicine doctors, physiotherapists, traditional Chinese medicine practitioners, osteopaths, naturopaths, nutritionists or even dentists and pharmacists.

Revenue Model

Fitgenes aims to generate revenues through the license of its PracwarePro software, which is a 'turnkey' business system which can be rapidly and easily deployed from the cloud, to independent practioners or to new Fitgenes clinics. The software creates and manages personalised health programs, linking genetic and pathology information to diagnostic tools. PracwarePro also includes marketing and website materials, a support centre, business management processes and standard operating procedures.

Fitgenes charges license fees of $1200 per annum for PracwarePro. It also generates income from training practitioners in nutrigenomics, with other revenue derived from diagnostic and pathology services. It should be noted that Fitgenes does not cast itself as a laboratory services operator and would outsource testing for the most part.

The key to the revenue model is the uplift for practitioners, which comes from the sale of high margin nutritional supplements. This uplift also applies to Fitgenes' own clinics and is one of the drivers for Fitgenes to expand its own clinics.

Competition

An analysis of the competitive landscape for Fitgenes indicates a stronger rather than weaker position for the company. The table on the previous page shows that there are very few companies that integrate genetic information with pathology derived health data and other lifestyle or medical information, and which then offer structured diet and exercise programs in response.

In the USA, only one company, Interlukin Genetics, has a suite of tests which are used by doctors to help customers make decisions about nutrition, exercise and lifestyle. A recent market entrant, Basehealth is interested in combining genomic, medical and lifestyle data, with responses to analyses seemingly left in the hands of the physician.

Fitgenes' closest competitor in Australia is Melbourne-based SmartDNA (also founded in 2009), which aims to help patients achieve their wellness objectives. As with Fitgenes, it operates a practitioner-directed model rather than a DTC approach, with nutrition management included in the post-analysis response. SmartDNA offers accreditation programs to practitioners. The number of SmartDNA practitioners could not be ascertained from that company's website. Fitgenes has trained more than 400 people to become accredited Fitgenes practitioners.

The presence of SmartDNA in the competitor landscape is a positive sign for investors in the emerging field of integrated medicine or wellness management, because it shows that other entrepreneurs have also identified the market opportunity in DNA-informed wellness management, and are also similarly cognisant of the need to find the right business model.

Attributes of a Franchise

What is very interesting about Fitgenes is that it is exhibiting the signs of a franchise master in its early days. Franchises are successful once the parent and its group of stores have achieved some scale and market presence, have proved it has a quality product or service offering, have figured out how to scale the business further, begun to entrench the brand, and have established the rules, operating procedures and principles necessary for running a successful franchise and proved that the franchisees can generate attractive returns. As these things come into place, a metric to monitor will be the number and rate at which new practitioners sign onto Pracware and become Fitgenes Certified Practitioners.

Diagnostic or personal biological information is often not worth much at all unless it can be acted upon. It is highly likely that the Fitgenes business model will be copied because it seeks to give clients (or patients) interested in wellness a plan of action, and one in which they are supported by a trained adviser and motivated to complete by their personal expense on the program.

Fitgenes' advantage is that is one of the first movers with a business model that has structured incentives for practitioners alongside the needs of clients who need a number of coaching style consultations to meet their wellness objectives.

Key Dates

Offer Opens: August 4, 2014
Offer Closes: September 30, 2014
Expected date for requotation of shares: October 13, 2014

Investors are required to read a copy of the prospectus which can be downloaded from www.fitgenes.com

Fitgenes is a Private Company Corporate subscriber to Bioshares

Will Precision Recruitment be the Product that Leverages the Cogstate Technology?

After having a difficult year in FY14 with sales largely flat at $12.3 million ($12.5 million for FY2013), Cogstate (CGS:$0.31) recently announced the signing of its largest contract to date, valued at $7.3 million. Cogstate now has contracted future revenue of $19.7 million, with $9.1 million of that expected to be recognised in the current financial year. That means sales this year will be at least $9.1 million and could reach $15-$20 million this year by our estimates.

This large contract signed was for the provision of what is called rater training services in a large Phase III Alzheimer's disease trial.

Cogstate will train 525 staff (raters) to conduct what includes the traditional pencil and paper tests used in Alzheimer's disease drug trials. Rater training is required to ensure consistency across staff in the capture of subjective data.

The trial will enroll 1,551 patients. Cogstate will also provide central administration of data. The trial will *not* use Cogstate's proprietary electronic cognitive test.

This is lower margin work for Cogstate, with the contract relating to generic services. Around two years ago Cogstate decided to enter the rater training sector to be in a position to offer a fuller spectrum of services in the clinical trials market.

Precision Recruitment: A New Product for all Alzheimer's Trials

The spectrum of work in the Alzheimer's disease drug trials market has now expanded further, with Cogstate introducing what it calls Precision Recruitment.

If rater training is the generic end of the market, and its cognitive testing platform (which makes up most of company's sales) being a proprietary product with competition from other electronic cognitive testing platforms, Precision Recruitment is a unique product offering at the moment which could deliver the company its highest margins.

Precision Recruitment is being offered to pharmaceutical and biotech companies to screen patients for primarily Alzheimer's disease trials. The reason there is a need for this service now is twofold.

Firstly, with the advent of tests now to image plaque build up in brain while patients are alive (this has only become possible in the last few years), drug companies are wanting to image patients for trials to make sure they do actually have signs of early stage Alzheimer's disease.

In a Phase III trial for the drug candidate bapineuzumab, it was found after the trial that 25% of patients recruited into the trial did not have Alzheimer's. That drug trial failed, as have most Phase III Alzheimer's trials.

The problem is that to recruit 1,500 patients into a Phase III Alzheimer's trial with confirmed amyloid build up in the brain (amyloidosis), it is necessary to screen around 15,000 patients. That would cost around $100 million and would add an extraordinarily high cost to the trial making it commercially unviable.

If an electronic test such as Cogstate's Precision Recruitment test can reduce the number of patients to say 5,000 that need to be imaged in order to recruit 1,500 patients with confirmed amyloid build up in the brain, then that offers a major cost saving, as well as a very important reduction in recruitment time.

The second reason for demand for a sensitive screening tool into Alzheimer's disease drug trials is the outcome of a failed large Phase III Alzheimer's disease trial. Although Eli Lilly's Phase III trial failed, the drug candidate solanezumab was shown to have some effect in early stage patients.

This has shifted most of the Alzheimer's disease drug development to finding a treatment for patients with early stage disease. But once again, diagnosing patients with early stage disease to go into these drug trials is much more difficult than finding patients with moderate to severe Alzheimer's disease who have very clear symptoms of disease.

Through its involvement in the ABIL study (Australian Imaging, Biomarker and Lifestyle Flagship Study of Ageing) which started in 2006, Cogstate's test showed a strong correlation of cognitive decline with amyloid plaque deposits in the brain. The people screened into this study were those with Alzheimer's disease, those with cognitive impairment and healthy volunteers.

What is not known is how effective Cogstate's test will be in screening a general population for inclusion into an Alzheimer's disease study.

Although Cogstate can not lay claims as to how effective its test will be in this setting, its involvement in the ABIL study and the successful outcomes from that study gives Cogstate a very strong argument that its test should be considered as a screening tool, particularly in the absence of any other proven screening tools for detecting early stage Alzheimer's disease without brain imaging.

Success Fee Model for Cogstate

The Precision Recruitment test will be sold under a new business model for Cogstate. Rather than charging for each trial candidate who uses the test, Cogstate will be paid a set fee for each patient successfully recruited into the trial i.e. those patients who have plaque build up in the brain as confirmed by a brain imaging test.

So if Cogstate screens 15,000 patients, it will only be paid for the 1,500 patients enrolled into the study who have confirmed early stage plaque build up.

It is potentially a high margin product for the company and if it becomes a successful product, could become Cogstate's most important and valuable product application in our view.

Cont'd over

Patient Registry – A Potentially Valuable Asset

Cogstate is seeking to leverage the Precision Recruitment offering further. For the 70% or so of requested trial participants who do not make it into the imaging stage, their progress will be monitored by Cogstate, with patient consent, and those details will not be passed on to the drug developer.

In this way, Cogstate will be able to build a very large database of potential patients for subsequent trials as those patients progress. Access to this patient registry will be offered to sponsors for new trials.

Cogstate has indicated it expects to sign Precision Recruitment contracts valued between $3-$6 million this financial year. In June this year Cogstate signed its first Precision Recruitment contract, valued at $1.8 million over two years.

CEO of Cogstate Brad O'Connor said the company was approached by this customer to provide this service. This first contract is along the standard set fee model for Cogstate, and is not based on successful recruitment and diagnosis, as future contracts are expected to be.

O'Connor said that recruitment into Alzheimer's disease trials, both planned and those underway, is a very big issue. The problem is that these companies are trying to recruit patients with amyloidosis, said O'Connor, but these people are often asymptomatic.

Only a spinal tap or brain imaging can confirm amyloid build-up. O'Connor stated that only Cogstate is offering this type of precision recruitment tool at the moment. All of the companies talking to Cogstate now have amyloidosis as an entry criteria into their Alzheimer's disease trials.

The final commercial version of the Precision Recruitment product is expected to be ready next month. It's a process that has taken 12 months. This will include sponsor (client) dashboards, that will allow the sponsor to receive data in real time. The test has also been modified to allow patient testing to be conducted by themselves at home.

Using the Cogstate Precision Recruitment tool is essentially a license said O'Connor. For Cogstate, there are no throughput costs; the sponsors can screen as many patients as they like, only paying for this who are successfully recruited into the trial.

The sponsor's interest is aligned with Cogstate's interest under this model, which O'Connor stated is a structure that the partners are receptive to.

Enters Alzheimer's Phase III Drug Trial Market

The primary endpoint for all Phase III drug trials to date has been changes in cognition as measured by the ADOS-Cog test. Cogstate has not been able to enter this market with its own test previously because its test has not been validated by the FDA as an acceptable endpoint.

However recruiting patients into Phase III clinical studies for Alzheimer's disease is a different matter and the test does not need to have FDA validation. Through its Precision Recruitment product, Cogstate can now access part of this market.

Cogstate has also entered the rater training market (see above), training staff to provide the ADOS-Cog test, with a large $7.3 million contract signed this month.

Providing this service potentially has another benefit, and that is that it may help secure Precision Recruitment contracts from the same customer. Cogstate is currently bidding its Precision Recruitment product for the same customer with which it recently signed the $7.3 million rater training contract. Cogstate's Precision Recruitment test can also be used in screening for other clinical trials where cognitive impairment is a key measure.

Risks

There is a chance that Cogstate's Precision Recruitment technology will not be effective in detecting a high enough percentage of patients with early amyloid plaque build up. It is likely that some of the first contracts for this product may be smaller pilot studies to better gauge how effective the test is. Cogstate will be able to release data from its first trial where Precision Recruitment is used as a screening tool.

Summary

Summary has built a successful clinical trials business around providing cognitive testing of patients with novel clinical drug candidates, primarily, but not only in cognitive impairment diseases. It has built a product that is useful in detecting subtle changes in cognition in an objective measurement tool.

However it has been unable to successfully leverage that technology for larger market applications such as management of concussion in sport or in dementia screening (in Canada) yet. The Precision Recruitment product may be the successful leveraging of the company's core technology that it has been seeking.

Changes to the way Alzheimer's disease drug candidates are being developed has changed the demands from drug developers who now seek a tool that can measure subtle changes in cognition and detect early stage disease to lower the expensive imaging costs associated with confirming Alzheimer's disease status. This change provides a significant commercial opportunity for Cogstate.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

Bioshares Model Portfolio (15 August 2014)

Company	Price (current)	Price added to portfolio	Date added
LBT Innovations	$0.125	$0.130	July 14
pSivida	$4.970	$3.800	May 14
Invion	$0.075	$0.089	February 14
Impedimed	$0.310	$0.245	December 13
Analytica	$0.033	$0.025	December 13
Imugene	$0.016	$0.022	November 13
Oncosil Medical	$0.120	$0.155	September 13
IDT Australia	$0.260	$0.260	August 13
Viralytics	$0.265	$0.300	August 13
Tissue Therapies	$0.320	$0.255	March 2013
Somnomed	$1.78	$0.94	January 2011
Cogstate	$0.310	$0.13	November 2007

Portfolio Changes – 15 August 2014

IN:
No changes

OUT:

No changes

Antisense Therapeutics' Phase II Acromegaly Results This Month

Antisense Therapeutics (ANP: $0.145) expects to announce the results from its Phase II study in acromegaly by the end of this month. The company announced positive interim results in December last year.

The current study treated 26 patients with its antisense compound, ATL1103. Those patients were tested with two different doses of the compound. One group received a 200mg dose, and the second received a 400 mg dose. Patients were treated three times in the first week, receiving a subcutaneous injection, and then once weekly treatment for a further 12 weeks, with a two month follow up period. There was no placebo arm, with patients being compared to baseline.

In the interim results reported in December last year from the first eight patients in the trial, the 200mg dose was not shown to be effective across the patient group. However, the higher dose did achieve a 30% mean reduction in serum IGF-1 levels, which is the main parameter to measure for efficacy. That result also showed a direct correlation with patient weight, with a greater reduction in the smaller patients. If the largest patient in the study was excluded, who weighed over 120kg and achieved only a 4% reduction in IGF-1 levels, then the mean IGF-1 reduction was 38%.

CEO of Antisense Therapeutics, Mark Diamond, said the drug was well tolerated with no patient withdrawals and that the company could explore higher doses.

If the current Phase II trial is successful, Diamond says the program may move straight into a Phase III study, after some additional toxicology work is completed. That trial could involve 100-150 patients, with possibly two trials, and could also explore first line therapy. Those trials could run for six to 12 months, starting in the second half of 2015.

Acromegaly Market Opportunity

The main drug treatment for acromegaly is a drug called Octreotide. This drug is a one month depot injection that works in about 60% of patients. For the other 40% of patients, the drug Somavert is an option. However, Somavert has several shortfalls, thereby opening up some commercial opportunities for Antisense's ATL1103.

Somavert is an expensive drug, costing around $60,000 a year. In Australia, that drug is not reimbursed through the PBS system. The drug needs to be injected daily or twice daily, it needs to be reconstituted from a powder, it has been shown to cause elevated liver enzymes as well as increasing growth hormone levels. Not surprisingly the drug has a poor compliance level.

By comparison, ATL1103 involves a once weekly subcutaneous injection, and so far has shown no issues with elevated liver enzyme levels or growth hormone levels. ATL1103 blocks the same target as Somavert.

A greater than 30% reduction in IGF-1 levels should deliver a commercially viable product, however this depends on the starting levels in the patients of IGF-1. It is expected that longer treatment will continue to achieve further reductions in IGF-1 levels.

Somavert was shown to normalize 97% of patients in its registration (longer) trials. However, in clinical practice, this was reduced to around 70% due to poor compliance. Longer term trials with ATL1103 looking at higher doses and the percentage of patients returned to normal IGF-1 levels will be of future interest.

Trial Delay

Antisense's Phase II trial result has been delayed because of the request from clinicians involved in the trial to add an additional two patients into the study, which could be a positive sign. Interim results from the 400mg dosed group suggests there should be good chance of positive results in this group once again, particularly where the dose per kg is higher, as seen in the lighter patients in the interim study.

Diamond expects there will be partnering interest after the Phase II trial results (if positive). Patent protection around this program goes out to at least 2025.

Antisense Therapeutics is capitalised at $21 million. A **Hold** rating is placed on the stock given that the company had only $1.3 million in cash at the end of June, although it has access to a further $0.95 million from a non-equity funding facility.

Bioshares recommendation: **Speculative Hold Class B**

How Bioshares Rates Stocks

For the purpose of valuation, Bioshares divides biotech stocks into two categories. The first group are stocks with existing positive cash flows or close to producing positive cash flows. The second group are stocks without near term positive cash flows, history of losses, or at early stages of commercialisation. In this second group, which are essentially speculative propositions, Bioshares grades them according to relative risk within that group, to better reflect the very large spread of risk within those stocks. For both groups, the rating "Take Profits" means that investors may re-weight their holding by selling between 25%-75% of a stock.

Group A

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

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

(CMP–Current Market Price)

Group B

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

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

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

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

Speculative Hold – Class A or B or C

Sell

Corporate Subscribers: Cogstate, Bionomics, Impedimed, QRxPharma, LBT Innovations, Tissue Therapies, Viralytics, Phylogica, pSivida, Antisense Therapeutics, Benitec BioPharma, Admedus, Calzada, Invion, Circadian Technologies, Imugene, Analytica

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