ISSN 1443-850X

Companies covered: AVH, DXB, FTT, OSP

	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 - May '15)	23.0%
Year 15 (May '15 - May '16)	33.0%
Year 16 (May '16 - current)	21.8%
Cumulative Gain	**798%**
Av. Annual gain (14 yrs)	**18.9%**

Bioshares is published by Blake Industry & Market Analysis Pty Ltd.

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Individual Subscriptions (48 issues/year)
$440 (Inc.GST)
Edition Number 677 (9 December 2016)

Bioshares

9 December 2016
Edition 677

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

Factor Therapeutics Set to Commence 168 patient Phase II Study

Factor Therapeutics (FTT: $0.075) is set to start a major Phase II study in the US of its wound healing drug candidate, VF-001, in patients with chronic venous leg ulcers. That trial will seek to enroll 168 patients over the next six months across 26 sites. Prompt recruitment into this study and a potential readout from the trial are two major drivers for this stock price over the next nine to 12 months.

This week Factor Therapeutics held a three day meeting in Florida with is clinical investigators involved in the trial and its CRO, Parexel, that will be coordinating the trial. Executive Director of Factor Therapeutics Christian Behrenbruch said that around 85% of the investigators involved with the trial were present at the meeting, which coincided with a major wound healing conference in Florida.

Patient Backlog At Several Sites

Behrenbruch expects the first patient to be recruited into the trial any day now, with patients ready to go. At two sites there is a backlog of between 30-40 potential trial candidates who could be recruited into the study. An update on recruitment into the study is likely to be provided to the market in February, with a six month recruitment timeframe to be "a brilliant outcome", said Behrenbruch. At this point Factor Therapeutics is expecting recruitment to be completed by around mid 2017 with results to be released at the end of Q3 or early Q4 next year.

Recruitment will be concentrated in three regions in the US, thus improving management of the trials. The regions take in Texas and Florida, Southern California and Nevada, and New York, Pennsylvania and Washington DC. At this point, one site is recruiting patients, at the Miami Dade Medical Research Center.

One aspect that will support timely recruitment into the study is that there are no major Phase II or Phase III trial underway in the US for venous leg ulcers therapeutic candidates. Factor Therapeutics has an additional six sites that have been qualified for the study that it can access.

Completing recruitment into this study on time is essential for the company for a number of reasons.

First, it will signal success of the company's corporate turnaround in the last 12 months following a successful $15 million capital raising this year and a change in direction from Europe to the US regulatory pathway and therapeutic markets.

Second, rapid recruitment means the company can get to a major inflexion point (readout of the Phase II trial) without raising additional funds.

Cont'd over

Third, it will also demonstrate clinical need and build interest in a new wound healing technology for the treatment of venous leg ulcers.

Conference Presentation

This week Behrenbruch presented at the 2016 Innovations in Wound Healing conference held in Key Largo, Florida. Behrenbruch said it is an invitation only event. The meeting covers the latest in clinical research and presents novel paradigms in wound healing. In a session titled "Update in Clinical Trials", Factor Therapeutics was one of only three companies to present. Behrenbruch's talk was titled "Targeted Growth Factors for Advanced Wound Care". That session was chaired by Bill Marston, who is the Lead Investigator in Factor Therapeutics' Phase II study. Marston is the Chief of the Division of Vascular Surgery at the University of North Carolina.

Trial Design

The 168 patients to be recruited into the Phase II trial will be randomised into three arms, with one being the standard treatment dose of 14 mcg of VF-001 (with standard-of-care treatment), one arm investigating a dose 10 times larger of VF-001, and the control being standard-of-care. Patients will be treated for 12 weeks and followed up for a further 12 weeks. The primary endpoint will be the percentage of wound closure. One of the secondary endpoints will be the number of patients with complete wound closure.

Factor Therapeutics will be using Aranz Medical's imaging technology, developed in New Zealand, to image and monitor patients' wounds. Behrenbruch said this has become the gold standard for clinical trials in wound care.

The patients recruited into the study will be those with what are termed Margolis 1 level wounds. They make up about 25% of venous leg ulcers and is the unmet clinical need and the open market for Factor Therapeutics. Margolis 0 wounds are viewed as moderate disease and Margolis 2 as severe disease. The former is well served by existing treatments and the latter, which makes up 6% of venous leg ulcers, is a very difficult to treat subset. (Of interest, Dr David Margolis, whose work this grading system based on, is part of the Factor Therapeutics' Medical Advisory Board).

New Technology from Monash University

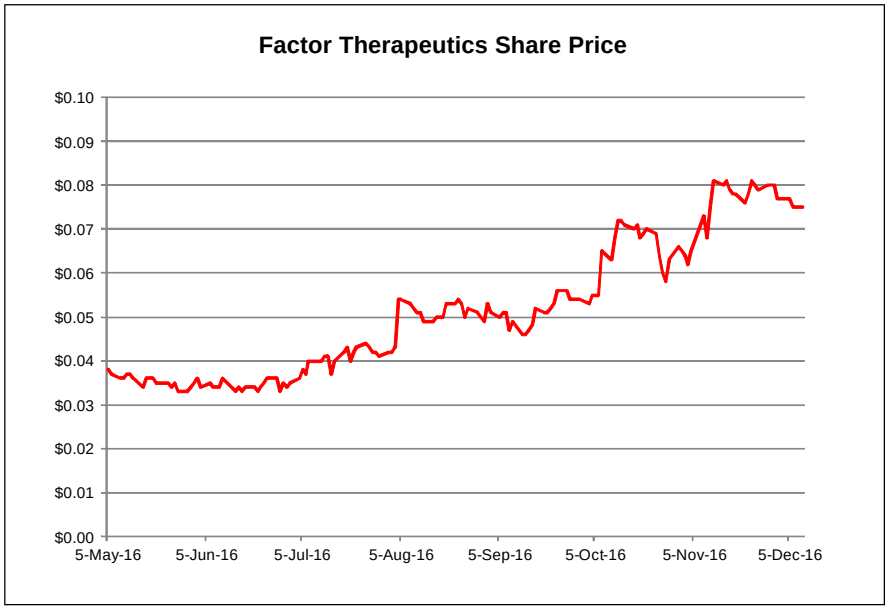
Although the Phase II study is the primary focus for Factor Therapeutics, the company last month formed a collaboration with Monash University, with an option to commercialise a novel wound healing technology using an anti-inflammatory approach.

The aim is to broaden the company's pipeline by developing a new program to treat orphan diseases in skin care. A Monash team has conducted a screening program for novel wound care compounds and found an existing drug that is in use as an oral anti-inflammatory, for the treatment of conditions such as ulcerative colitis. It was found that this anti-inflammatory may have positive wound healing properties for the skin.

Factor Therapeutics will seek to develop a formulation of this compound for the treatment of an orphan indication such as Harlequin Ichthyosis, which is a genetic disorder that results in chronic wounds that need to be continuously treated. However, there is also the potential for the company to combine some of its existing technologies to develop an improved therapy to using the existing anti-inflammatory drug alone.

The benefit of working with an existing drug compound is that regulatory development can be accelerated through a 505(b)(2) pathway in the US. Working on orphan diseases can also command higher prices with a more streamlined path to market which often require smaller clinical studies.

One of the likely drivers behind Factor Therapeutics' orphan skin disease, drug development program is the addition to its board in September of Dr Robert Ryan. Ryan was co-founder, President and CEO of Scioderm. Scioderm developed an orphan skin-cancer treatment for the rare, gene-based disease epidermolysis bullosa. Ryan sold the company to Amicus Therapeutics in September last year for a total deal value worth US$847 million (US$229 million upfront), with only US$25 million invested to take that program from pre-IND to Phase III in just two years.



Summary

Factor Therapeutics is capitalised at $55 million. The company held cash of $12.5 million at the end of September. The company has made excellent progress in the last 12 months re-engineering its commercial strategy, recapitalising the company, transferring manufacturing to the US, strengthening its board, gaining regulatory clearance and readying the company for a large Phase II study in the US.

Bioshares recommendation: **Speculative Buy Class B**

Bioshares

Avita Medical – ReCell US Trial Conclusion Ahead in Q1 2017

Avita Medical (AVH:$0.125) is on track to complete several milestones in 2017 for ReCell, its novel burns treatment technology. ReCell is a device which enables a process that begins with the harvesting of healthy skin cells from a patient, which are then expanded and sprayed on a burn. The product is also suitable for cosmetic and reconstructive procedures and is also being evaluated as a treatment for diabetic foot ulcers.

The company expects to complete its US burns trial in Q1 2017 (as early as January). The trial will conclude when the last of the 30 patients in the trial will have completed 52 weeks of follow-up. It will file a Premarket Approval Application (PMA) submission with the FDA in Q2 2017, with an expectation to receive a clearance from the FDA in late 2017 or early 2018.

The PMA process requires applicants to submit evidence of safety and efficacy, which generally means that applicants must sponsor clinical trials. The process is more rigorous and expensive than the 510(k) process which allows applicants to base their submissions on other devices (what are called predicate devices) that have already been cleared.

Under a Compassionate Use program, the FDA approved an expansion of the trial for an additional 48 patients, typically for patients with large body surface area burns.

The FDA has made ReCell available on a Continued Access basis to the seven burns centres that have participated in the trial, allowing up to 60 patients to be treated on this basis.

Avita's US burns US trial is the company's beachhead for entering the US market. What makes its especially noteworthy is that it is being supported by the US Government's Biomedical Advanced Research & Development Authority, a defence preparedness organisation which supports the development of a new technologies, and when validated, may buy and stockpile the products that have emerged from the process.

BARDA is paying Avita Medical $27.9 million to complete its US trial and FDA PMA process. The total potential value of the BARDA contract is US$53.9 million plus a US$7.96 million extension awarded in June 2016.

The company is anticipating a stockpiling order for 5,000 devices in latter part of 2017, which may coincide or precede the acceptance of the ReCell PMA.

The US Burns Trial

The endpoint of Avita Medical's 30 patient burns trial is confirmed treatment area closure at eight weeks or sooner. For each patient, a ReCell treated area will be compared to an area treated with skin graft, with ReCell being measured on a non-inferior basis.

The trial will also compare expansion ratios, comparing the donor sites used to the treatment sites, including donor skin required for secondary treatment. In this case, the hypothesis being explored in the trial is that less donor skin will be required for ReCell treated areas.

For small burns, Avita cites a 1:80 ratio e.g. a 1cm^2 donor area can be used to treat an area 80cm^2.

Funding

The company raised $9 million in September, leaving it with $10.6 million at the close of the quarter. While the company is in a position to support activities through 2017, it recognises it must find capital to support the launch of ReCell in 2018. It has appointed Westwicke Partners to help form a capital markets strategy.

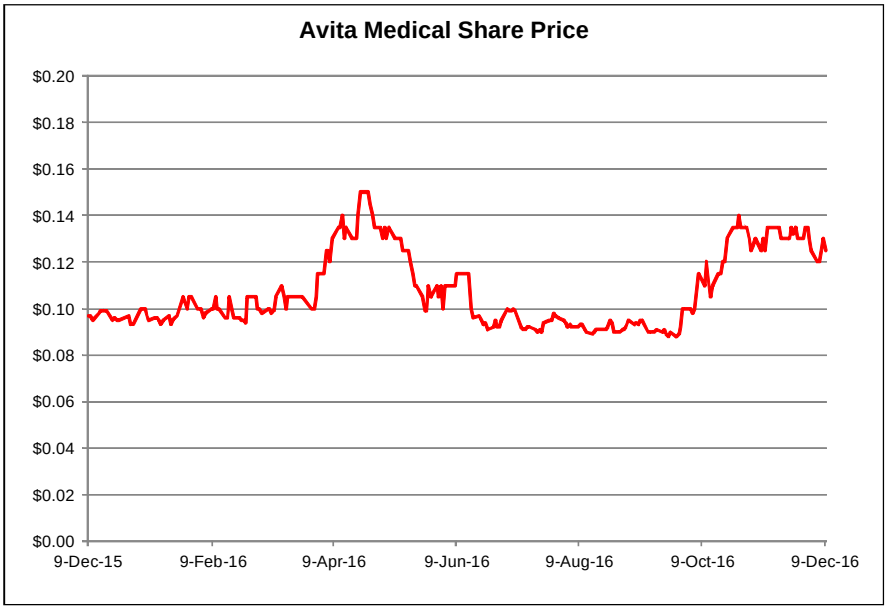
Summary

The positive developments which have taken place since September, including the FDA's Continued Access and Compassionate Use authorisations, have helped lift the stock by 40%. We expect further gains in the stock in 2017 once its submits its PMA submission and has the PMA accepted by the FDA.

Avita Medical is capitalised at $80 million.

Bioshares recommendation: **Speculative Buy Class B**

Bioshares



Dimerix Completes Enrolment for Phase II Trial (Part A)

Dimerix (DXB: $0.008) has completed enrolment for the first part of its Phase II trial of DMX-200 in chronic kidney disease. A total of 27 patients have been enrolled with final results due in mid 2017.

Some interim results were released in October from the first 11 patients who had reached what should be an effective dose of the drug treatment (90mg per day of propagermanium) in this escalating dose study.

Those early results showed that a clinically meaningful result (greater than 50% reduction in proteinurea levels) was achieved in 27% (three from 11 patients). In the announcement this week, the company said that the positive trend reported in the interim results was continuing.

Dimerix CEO Kathy Harrison said that achieving such a reduction in CKD would be a commercially meaningful product. Upon completion of Part A of this study next year, Dimerix is aiming to gain a better understanding of the optimum dosing level for patients as well as a better understanding of which patients are likely to respond better to this treatment. This should help broaden the number of patients who can benefit from this treatment.

Dimerix's DMX-200 combines two existing drugs, irbesartan, which is an anti-hypertensive that is prescribed to patients with CKD, and propagermanium. Through its proprietary screening technology, Dimerix has found that two receptors in the kidney (angiotensin II type I and CCR2) have a joint interaction. Irbesartan blocks the angiotensin II type I receptor and propagermanium blocks the CCR2 receptor. Preclinical studies have shown that blocking both receptors has more than a simple additive effect.

Dimerix is currently reformulating the propagermanium compound, which currently needs to be taken three times a day, into an extended release version that would only be taken once daily. That reformulation is being done in Melbourne, with two versions currently being assessed.

Dimerix will then conduct a pharmacokinetic study with that formulation under an IND, prior to commencing the second part of the Phase II study in Australia with the new formulation. Part B of the Phase II study is expected to start in 2H 2017. That study will recruit around 30 additional patients again based on an optimum dosing regime elicited from the current study.

Harrison said that Part B of the study should deliver a better result as the patients will remain on the one (optimum) dose.

Preliminary discussions with potential partners have started, however more data will be needed before any licensing deals are conducted.

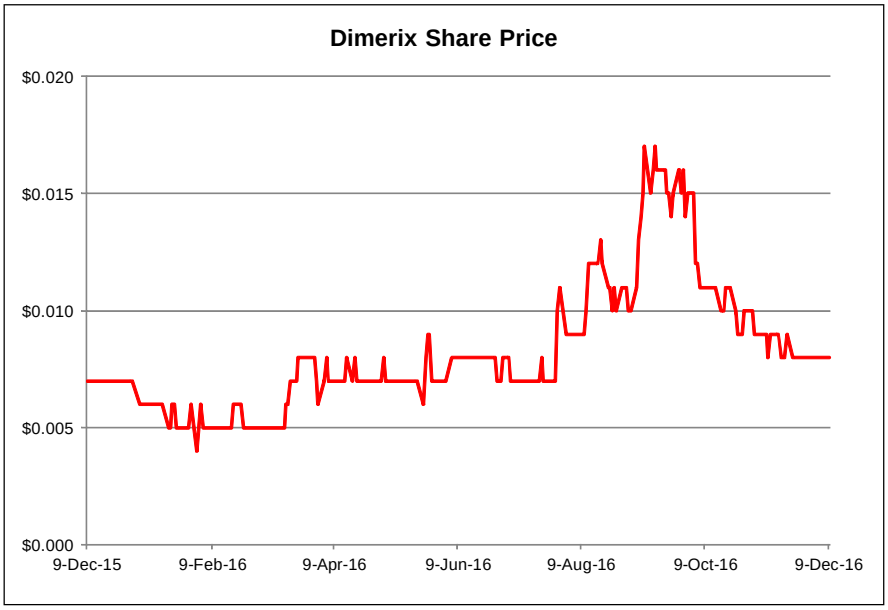
One of the benefits of DMX-200 is that it does not replace existing treatments but includes an existing medicine (irbesartan) with an additional treatment, (propagermanium) that has a benign safety profile.

The development of a proprietary formulation of propagermanium will help the company secure a stronger commercial position around the technology.

Dimerix is capitalised at $12 million and held cash of $1.5 million at September 30, 2016.

Bioshares recommendation: **Speculative Buy Class B**

Bioshares



Bioshares Model Portfolio (9 December 2016)

Company	Price (current)	Price added to portfolio	Recommend-ation	Cap'n ($M)	Date added
Factor Therapeutics	$0.075	$0.054	Spec Buy B	$55	September 2016
GI Dynamics	$0.025	$0.024	Spec Buy C	$12	May 2016
Adherium	$0.350	$0.495	Spec Buy A	$60	March 2015
Bionomics	$0.350	$0.295	Spec Buy A	$169	March 2016
Reproductive Health Science	$0.061	$0.150	Spec Buy B	$5	December 2015
Rhinomed	$0.018	$0.032	Spec Hold B	$15	December 2015
AirXpanders	$1.120	$0.745	Spec Hold A	$264	September 2015
Osprey Medical	$0.465	$0.695	Spec Buy B	$120	September 2015
Clinuvel Pharmaceuticals	$7.65	$4.15	Spec Hold A	$365	December 2014
Innate Immunotherapeutics	$0.800	$0.190	Spec Buy A	$178	November 2014
Opthea	$0.680	$0.160	Spec Buy A	$102	November 2014
Impedimed	$1.050	$0.245	Spec Buy A	$393	December 2013
IDT Australia	$0.175	$0.260	Spec Buy B	$43	August 2013
Viralytics	$1.150	$0.300	Spec Buy B	$276	August 2013
Somnomed	$3.61	$0.94	Buy	$207	January 2011
Cogstate	$1.100	$0.13	Spec Hold A	$125	November 2007

Portfolio Changes – 9 December 2016

IN:
No changes

OUT:
No changes

Strong Unit Sales Growth Expected for Osprey Medical in CY17

Osprey Medical (OSP: $0.47) raised $29 million in an eagerly sought after capital raise, which was completed in September. The company is now funded to expand its efforts to sell DyeVert into a total of 20 targeted US sales regions by the end of 2017.

DyeVert is a medical device which reduces the amount of contrast media (dye) that is injected into patients undergoing stenting or angiography. Contrast media has toxic properties and has the potential to cause kidney damage or exacerbate the injury in patients with damaged or poorly functioning kidneys.

The company is using two years of sales experience gained in the San Antonio area, where it has 16 out of 23 hospitals on its books. Osprey Medical CEO Mike McCormick described this as "an astronomical penetration rate."

What has been driving the take-up of DyeVert has been its ability to lower a hospital's acute kidney injury (AKI) score for catheterisation laboratory (cath lab) procedures from say 12%, being well above the accepted benchmark for performance, to say 5%, which is below the national median figure of 6.4%, from using DyeVert.

The company now has now employed 15 sales representatives and will add five more in 2017.

As the sales force powers up, McCormick is confident the company can add at least 10 new accounts each quarter, as well as post greater than 20% growth, quarter on quarter, for unit sales. The company's most recently recorded unit sales in the San Antonio area was 196 devices in the September quarter, compared to 180 in June quarter and 128 in the March quarter.

DyeVert is a single use product. The company is intends to maintain its average selling price in the range of US$350-US$360 per device.

Sales and Adoption Process

The sales strategy adopted by the company is based on cardiologists first sampling DyeVert, who in most cases respond positively. The next step is for the device to pass through each hospital's technology review committee, which examines the potential for a product to displace an existing product or to deliver cost savings or both. In the case of DyeVert, it is not replacing a product; rather it delivers cost savings by preventing kidney injury for at-risk patients, saving on hospital re-admission costs and penalties from funding sources such as Medicare.

The review process takes between three and four months to complete. The next stage of the process is for Osprey Medical to work with cardiologists and their nursing staff to integrate DyeVert with recommended standard-of-care. To succeed in integration, nursing staff need to screen patients at risk of acute kidney injury, by checking serum creatinine levels, deliver appropriate hydration to the screened patients and then ensure a DyeVert device is available for use with the patient. Adoption is recognised when a hospital includes DyeVert and the screening and hydration tasks on a cath lab's schedule of tasks.

Looking ahead again into 2017, investors should look out for publication of performance data for DyeVert, either formal or informal, based on the broader use of the device. The data will be of importance for helping hospitals set baselines, at the individual, system and region level. This data should prove to extremely valuable to Osprey Medical's marketing efforts.

If Osprey Medical exceeds its unit sales targets in 2017, the stock can be expected to benefit as a consequence. Osprey Medical is capitalised at $120 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. 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

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