

In this edition...

Wound healing company Tissue Therapies has edged closer to a key moment in its commercial history with the anticipated approval and launch of VitroGro in Europe in the next two months. The company has 120 pallets of its product ready to distribute.

The fifth North American biotech company in 18 months is set to list on the ASX shortly. Ventus Medical has a novel therapy for the treatment of sleep apnea and snoring with the first product selling into the US, Australia and NZ.

And Osprey Medical made a successful listing on the ASX this week, listing at a slight premium to its 40 cents listing price. It is a quality company and should be closely monitored.

The Editors

Companies Covered: OSP, TIS, Ventus Medical IPO Profile, Quarterly Cash Analysis

	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%
Cumulative Gain	245%
Av. annual gain (11 yrs)	17.8%

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Bioshares

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

Tissue Therapies – Approval & Product Launch Approaching

A pivotal time in Tissue Therapies' commercial development is approaching. The company is awaiting European CE Mark approval, with a decision expected by the end of May. If approved, the company will launch the product in Europe at the end of June, in the UK and Germany.

Not only are the launch countries in Europe the same as for **Pharmaxis** with its cystic fibrosis treatment Bronchitol, but the two companies are also using contracted sales and distribution parties to sell their products into continental Europe, rather than going through distributors or licensing to a major partner.

Tissue Therapies' VitroGro wound healing product is made by two manufacturers in Belgium. It currently has 120 pallets of the product stored in a warehouse in Europe.

It's likely the product will sell for around €100 for one treatment. This equates to about half the price of existing animal based products.

Tissue Therapies will start selling its products into the specialist wound clinics. In the UK these are Primary Care Trusts, with 70 major PCTs being the initial target in the UK.

The VitroGro product is very easy to apply, being a small clear liquid that is placed on the wound. The results have been very consistent, according to CEO Steven Mercer, even in end-stage patients.

In the company's major clinical trial which will support the company's regulatory approval application in Europe, 44 patients with chronic wounds were enrolled. These patients had not responded to current standard of care therapy for three years. After treatment with VitroGro for 10 weeks (one treatment per week mostly), a remarkable 82% of patients showed partial or complete healing.

Tissue Therapies believes it has a complete commercial package. At a recent wound care conference there was very strong interest in the product from key opinion leaders according to Mercer. That the product is approaching commercial reality appears to be driving this interest, together with the excellent clinical data. Mercer said the company has strong clinical data, strong scientific data to support the product and strong health

Cont'd over

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Ventus Medical – IPO Preview

US medical device group Ventus Medical is seeking to list on the ASX at the end of this month. Ventus was formed in 2005 and is based in California. The company is commercialising an adhesive nose strip for the treatment of sleep apnea and to prevent snoring.

In 2000, **Axon Instruments** was the first US company to list on the ASX following the SEC issuing a 'no action' letter which now makes it possible for US private companies to list on the ASX. Since December 2010, four North American biotechs have listed on the ASX, the most recent being **Osprey Medical**, which listed last week at a 5% premium to its 40 cents a share listing price.

Technology Concept

The concept of the Ventus technology is that the strip is placed over the nostrils. It allows air in but restricts air out through a simple one-way valve mechanism. This retention of air in the lungs creates a back pressure and thereby maintaining the airways open during sleep. The company has two main products. The first is called Provent Sleep Apnoea Therapy, and the second is called Provent Snoring Therapy. Both devices work on the same concept.

The devices work on the basis that the user breathes through the nose and the mouth is closed during sleep. If the user breathes through the mouth rather than the nose during sleep, then a chin strap is recommended to keep the mouth closed during sleep.

To date Ventus has raised US\$62 million in equity funding and US\$7 million through a convertible note. Ventus first started selling its products into the US in 2009 on a limited basis. It expanded its commercial rollout in the US substantially last year. In 2011, the company generated revenue of just under US\$1.2 million, up from US\$181,000 in the previous year.

Ventus is seeking to raise \$40 million in its initial public offering. The offer is not underwritten. These funds are expected to bring the company to a breakeven level in 2014. The funds are primarily to be used to expand the company's sales and marketing efforts. The company has 36 staff, all based in the US.

– *Tissue Therapies cont'd*

economic data, which has not been previously required for existing wound care products.

The company will maintain an on-line patient registry on its new multi-lingual website and this data will contribute to its health economic data package, important for negotiating reimbursement. Once the company receives CE Mark Approval it will start the reimbursement process.

At the end of March Tissue Therapies had \$8 million in funds. The company expects this will be sufficient to commercialise its product. These funds may be used to start a trial in the US on venous ulcers, although this will likely start once European approval is received. That trial is expected to take 18 months to complete.

Distribution Model

The company's model is to sell largely through distributors, although it supports its US distributors with its own sales force as well of 15 sales representatives who market the product to sleep specialists. The company may in the future consider increasing its direct to consumer sales approach. The company currently has two distributor contracts in the US, one in Australia, India and Hong Kong, and one distributor for Singapore and Malaysia.

The company's target market initially for its sleep apnea treatment product is for those people who have stopped using the CPAP machines, which is the gold standard in the treatment of sleep apnea. The company estimates that each year in the US, 700,000 people become non-compliant with CPAP therapy.

Regulatory Approval

The Provent sleep apnea product is on the market in the US, New Zealand, Hong Kong and Australia (through BMedical Pty Ltd, at a cost of around \$100 for a box of 30 strips). The product is approved for sale in Canada, with sales expected in that country in the second half of this year. Sales in Malaysia and Singapore are also expected to start in the second half of this year, and in India, Europe, China and Japan in 2013 and beyond.

In most parts of the US, the sleep condition needs to be diagnosed before patients can access the Provent device, which allows for reimbursement. In Australia no diagnosis is required.

The Provent snoring treatment product is expected to be launched in the second half of this year. This will be a less expensive product, at around \$25 per 30 strips.

Intellectual Property

The company looks to have a very tight patent position, with 12 US patents granted, a further 26 pending, and 35 patent applications pending outside of the US with nine issued patents outside of the US.

Cont'd over

The company will start a second trial in the US in patients with diabetic ulcers, however this trial, and any other subsequent trials or commercial launches will be funded from European VitroGro revenue.

Tissue Therapies listed on the ASX in 2004. Like many biotechs, it's been a long road to commercialisation endpoints, with delays along the way. However, as with an increasing number of biotechs in Australia, Tissue Therapies is on the cusp of commercial success.

Tissue Therapies is capitalized at \$95 million.

Bioshares recommendation: Speculative Buy Class A

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– *Ventus cont'd*

Clinical Trials

The company has completed 10 clinical trials with the products. Results from seven of these trials have been published. The data looks very good. In a 250 patient trial, the therapy reduced the apnoea-hypopnoea index (AHI), a measure of the severity of sleep apnea, by 60% in patients with severe obstructive sleep apnea.

In another study, snoring was reduced by 50%. In a study conducted by one sleep specialist outside of the clinical in 131 patients, some stunning results were achieved. Of the 75% of patients who completed the study (25% were not able to adjust to the therapy), 90% were able to successfully treat their sleep apnea.

There was an 88% reduction in the AHI sleep apnea index in people with severe sleep apnea. What helped deliver such an extreme result was that the clinical investigator used a positioning therapy (so patients would not sleep on their backs) and/or a chin strap in 50% of the study group.

Capitalisation

On a pre-money basis, the company is valued at \$110 million on an undiluted basis at the company's issue price of 50 cents per CDI, or \$130 million on a fully diluted basis.

Board and Management

The company has a very experienced board and management team. It has recently installed an Australian Chairman, Jonathon Pinshaw, who was formerly Managing Director of OPSM, Freedom Furniture and CEO of Brierly Investments. Another Australian, Christine Bennett, also joined the board this year as a non-executive director. Dr Bennett is Dean of the School of Medicine at the University of Notre Dame in Sydney and was formerly a director of Heartware.

Another non-executive director, Holger Liepmann, joined the board in February this year. Mr Liepmann was formerly executive VP of Abbott Laboratories' Nutrition unit. The company's CEO, Peter Wyles, joined in June 2010, and has worked with Bayer Healthcare for 15 years.

Lead Manager

The lead manager and corporate advisor to Ventus is Inteq, which assisted Reva Medical and GI Dynamics list on the ASX. Inteq helped raise \$100 million for Heartware, \$85 million for Reva Medical, and \$80 million for GI Dynamics.

Comments

There are few treatment options for sleep apnea and snoring. Effective treatments are CPAP which was pioneered by Resmed with research from Australian scientist Colin Sullivan. Oral splints, which work by bringing the jaw forward during sleep also appear to be quite effective, with Australia's Somnomed the leader in this field. Nasal strips placed across the nose provide some assistance. There is surgery, which is a very painful procedure with questionable results, and throat lubricating sprays which have little effect.

Very successful businesses can be built in this market because it is a massive market. **CNS Inc** which developed Breath Right Nasal Strips was sold to **GlaxoSmithKline** for £280 million. These

strips are sprung and attach on to the outside of the nose, helping to open up the nasal airway. Sales of these strips reached GBP 92 million in 2009 for GSK.

Australia is the home of sleep medicine, and this is one of reasons Ventus is listing in Australia. The sleep apnea and snoring therapy markets remain under-served and an increase in the options for patients will always be welcomed. Although there a number of therapies available, compliance is the major issue. Patients will want to select the most appropriate therapy to that is suitable for them. All devices are intrusive and require adjustment. The major benefit for Ventus is that its devices are one of the least intrusive. However they will not be suitable for all.

Not Underwritten; Repayment of Convertible Note

The offer is not underwritten. If it does not raise its full \$40 million, it may require an additional capital raising before it reaches a breakeven point.

The company has a fairly high burn rate, generating a loss from operations of US\$14.6 million last year. If the full amount is raised the company will repay US\$7 million of a convertible note facility it has with two US venture capital shareholders.

The Ventus prospectus is extremely well detailed. Investors are required to the prospectus prior to subscribing to the offer which can be downloaded at <http://www.ventuspublicoffer.com.au>.

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Osprey Medical Makes Successful Listing

Osprey Medical (OSP: 41.5 cents) made a successful listing on the ASX this week, finishing the week at a 3% premium to its listing price. Osprey is commercialising the CINCOR system that removes potentially harmful contrasting agents used in coronary stent implant procedures. The technology was first developed by the IDI Baker Institute in Melbourne.

About 25% of this patient population is at high risk of kidney damage. The company raised \$20 million and now has the funds to commence a global 600 patient trial in the third quarter this year. The potential market for this product is estimated at US\$600-US\$800 million a year. There are no exact competitors to the CINCOR system at this stage, although work-flow adoption will be a natural hurdle for the company to overcome. That means the company has the market to itself although will need to build that market.

The device is approved in Europe. The company is ready to start selling the system in Germany and the Netherlands first, focusing on key opinion leaders initially.

Osprey is capitalised at \$42 million. It's an excellent time to enter this stock.

Bioshares recommendation: Speculative Buy Class B

Bioshares

4.7B Reporting Companies – Cash Balances March 31, 2012

Sorted by Survival Index

Code	Company	Cash Receipts (\$M)	Nett Op. Cash Fl. (\$M)	Cash End 3/03/12 (\$M)	Survival Index	Comments/Events post reporting date	
1	HCT	Holista Colltech	\$3.7	\$0.0	\$1.4	A	Not App
2	LBT	LBT Innovations	\$0.0	-\$0.1	\$3.2	A	Not App
3	UBI	Universal Biosensors	\$6.6	\$0.1	\$15.7	CY	Not App
4	BNO	Bionomics	\$5.6	-\$1.4	\$18.8	A	10.2 Received \$6M from sale of property
5	SOM	Somnomed	\$10.2	-\$0.3	\$3.1	A	6.8
6	BXN	Bioyne	\$0.6	-\$0.3	\$2.5	A	6.7 Formerly Probiomics - recommenced trading on April 4
7	SPL	Starpharma	\$1.4	-\$6.1	\$46.6	A	5.7
8	NDL	NeuroDiscovery	\$0.0	-\$0.4	\$2.4	A	4.9
9	AVX	Avexa	\$0.0	-\$2.0	\$12.9	A	4.9
10	BIT	Biotron	\$0.0	-\$1.5	\$8.7	A	4.4
11	NEU	Neuren Pharmaceuticals	\$0.0	-\$0.4	\$7.2	CY	4.3
12	MSB	Mesoblast	\$0.0	-\$42.9	\$226.4	A	4.0
13	ADO	Anteo Diagnostics	\$1.1	-\$1.2	\$5.6	A	3.4
14	RHT	Resonance Health	\$1.3	-\$0.3	\$1.2	A	3.4
15	RVA	Reva Medical	\$0.005	-\$4.380	\$52.551	CY	3.0
16	QRX	QRxPharma	\$0.0	-\$6.9	\$27.3	A	3.0
17	GID	GI Dynamics	\$0.1	-\$5.2	\$60.2	CY	2.9
18	BRC	Brain Resource Corp	\$0.7	-\$3.1	\$11.3	A	2.7
19	OBJ	OBJ	\$0.0	-\$1.1	\$3.7	A	2.6
20	PXS	Pharmaxis	\$1.2	-\$28.2	\$91.6	A	2.4
21	AVH	Avita Medical	\$2.2	-\$3.1	\$9.4	A	2.2
22	PRR	Prima Biomed	\$0.0	-\$14.4	\$42.8	A	2.2
23	VLA	Viralytics	\$0.0	-\$2.4	\$7.0	A	2.2
24	SIE	Scigen	\$4.6	-\$0.5	\$3.4	CY	1.7
25	ACU	Acuvax	\$0.0	-\$0.4	\$0.8	A	1.7
26	MGZ	Medigard	\$0.0	-\$0.2	\$0.4	A	1.6
27	GTG	Genetic Technologies	\$4.9	-\$5.5	\$11.4	A	1.6
28	ACL	Alchemia	\$0.0	-\$8.4	\$17.3	A	1.5
29	ANP	Antisense Therap.	\$0.0	-\$1.8	\$3.5	A	1.5
30	ALT	Analytica	\$0.0	-\$0.9	\$1.6	A	1.4
31	IMU	Imugene	\$0.0	-\$0.7	\$1.2	A	1.3 Acquiring Linguet drug delivery technology from CGP
32	BLT	Benitec	\$0.2	-\$2.3	\$4.0	A	1.3
33	NAN	Nanosonics	\$7.9	-\$4.4	\$7.4	A	1.3 Raised \$15.5 M in placement; SPP to follow
34	ACG	Atcor Medical	\$5.9	-\$0.6	\$0.9	A	1.2
35	MLA	Medical Australia	\$7.2	-\$0.6	\$0.8	A	1.1
36	PAB	Patrys	\$0.1	-\$3.7	\$5.3	A	1.1
37	LCT	Living Cell Technologies	\$3.1	-\$2.0	\$2.7	A	1.0
38	EMS	Eastland Medical Systems	\$2.9	-\$1.5	\$1.8	A	0.9
39	PYC	Phylogica	\$1.3	-\$3.2	\$3.9	A	0.9 Expecting contract revenue of US\$0.5M
40	CUV	Clinuvel Pharmaceuticals	\$0.9	-\$8.1	\$9.3	A	0.9
41	PBT	Prana Biotechnology	\$0.0	-\$5.9	\$6.6	A	0.8 Raised \$2.28 M through placement
42	LER	Leaf Energy	\$0.1	-\$0.6	\$0.7	A	0.8
43	TIS	Tissue Therapies	\$0.1	-\$7.4	\$8.0	A	0.8 9 months of expenditures include \$3 M of inventory build
44	BDM	Biodiem	\$0.6	-\$1.3	\$1.3	A	0.8
45	IPD	Impedimed	\$2.2	-\$8.8	\$9.3	A	0.8 Conducting Rights Issue to raise up to \$13.7 M
46	GBI	Genera Biosystems	\$0.0	-\$1.2	\$1.1	A	0.7 Announced SPP
47	UNS	Unilife	\$1.8	-\$30.0	\$26.3	A	0.7
48	BCT	Bluechiip	\$0.0	-\$1.5	\$1.1	A	0.6
49	CBB	Cordlife	\$5.1	-\$3.5	\$2.4	A	0.5
50	CBZ	CBio	\$0.1	-\$9.0	\$5.7	A	0.5 Adopted revised scientific plan following strategic review
51	ISN	Isonoa	\$0.0	-\$3.9	\$2.5	A	0.5
52	AHZ	Allied Healthcare Group	\$4.8	-\$2.7	\$1.6	A	0.4
53	UCM	USCOM	\$0.7	-\$1.3	\$0.8	A	0.4
54	CDY	Cellmid	\$0.1	-\$1.4	\$0.7	A	0.4 Completed \$1.5 M placement
55	CGP	Consegna Group	\$0.0	-\$2.9	\$1.5	A	0.4
56	OMI	Occup. & Medical Innov.	\$0.0	-\$0.3	\$0.1	A	0.4 Terminated mining acq.
57	IMI	IM Medical	\$0.0	-\$2.2	\$0.7	A	0.3 Sold radiology business
58	ACW	Actinogen	\$0.0	-\$0.6	\$0.2	A	0.3 Conducting rights issue
59	CXD	CathRx	\$0.0	-\$5.4	\$1.6	A	0.2
60	AGX	Agenix	\$0.0	-\$1.5	\$0.3	A	0.1 Entered \$1.2 M funding agreement with Fortrend Securities
61	AYX	Austofix	\$0.9	-\$0.5	\$0.1	A	0.1 Has access to \$700K bank facility
62	HTX	Healthlinx	\$0.0	-\$1.6	\$0.2	A	0.1 Has access to \$3M funding agreement with US investor
63	BNE	Bone Medical	\$0.0	-\$0.8	\$0.0	A	0.0 US\$6 M Convertible note facility with La Jolla Cove Invest. Part.
64	SLA	Solagran				A	DNR Suspended from trading
65	SHC	Sunshine Heart				A	DNR

Bioshares Model Portfolio (4 May 2012)

Company	Price (current)	Price added to portfolio	Date added
Osprey Medical	\$0.42	\$0.40	April 2012
QRxPharma	\$1.78	\$1.66	October 2011
Mayne Pharma Group	\$0.330	\$0.435	September 2011
Acrux	\$4.12	\$3.37	June 2011
Somnomed	\$0.87	\$0.94	January 2011
Phylogica	\$0.050	\$0.053	September 2010
Biota Holdings	\$0.85	\$1.09	May 2010
Tissue Therapies	\$0.57	\$0.21	January 2010
Atcor Medical	\$0.07	\$0.10	October 2008
Bionomics	\$0.39	\$0.42	December 2007
Cogstate	\$0.305	\$0.13	November 2007
Sirtex Medical	\$6.48	\$3.90	October 2007
Clinuvel Pharmaceuticals	\$1.79	\$6.60	September 2007
Pharmaxis	\$1.30	\$3.15	August 2007
Universal Biosensors	\$0.70	\$1.23	June 2007
Alchemia	\$0.465	\$0.67	May 2004

Portfolio Changes – 4 May 2012**IN:**

No changes

OUT:

No changes

4.7B Reporting Companies – Cash Balances March 31, 2012 (Cont'd)**Legend:**

Not App. : The SI calculation for these companies is not calculated due to the companies reporting positive operational cash flows, or in some cases marginally negative operational cash flows.

A: The SI calculation for these companies is based on the average of the last three quarters of NOCF.

CY: The SI calculation for these companies is calculated on the last quarter of NOCF, annualised.

Commentary

For the March quarter 2012, we calculated that 26 biotech companies reporting under the ASX's 4.7B rule had cash sufficient to support less than one year's worth of operations, based on net operational cash flows. Two companies, Sunshine Heart and Solagran, which is currently suspended from trading, did not report.

Of note, post-March 31, was that Imugene, which has failed on successive occasions to commercialise (through various partnerships) its animal vaccine technology struck an agreement with Consegna Group to acquire its Linguet drug delivery technology, thereby accessing Imugene's cash of \$1.3 million. Impedimed is conducting a rights issue to raise \$13.7 million and Nanosonics completed a placement to raise \$15.5 million. Allan Gray (formerly Orbis Investment Management) committed \$10.6 million in the placement.

Small cap life science companies that are not required to comply with the 4.7B Rule include: Acrux, Advanced Medical Design and Manufact., Immuron, Biota Holdings, Bioniche, Cogstate, Circadian Technologies, Clovercorp, Compumedics, Cryosite, Cyclopharm, Telesso Technologies, Ellex Medical Lasers, IDT Australia, ITL Corp, Calzada, Medical Developments Int., Novogen, Optiscan Imaging, Progen Pharm., Phosphagenics, Sirtex Medical and Virax Holdings.

Re-domiciled companies, pSivida and Heartware International no longer comply with the 4B Rule.

Each quarter, the majority of ASX listed biotech companies are required to report their cash positions. In turn, a key analytical measure we present each quarter is the 'Survival Index' (SI). The index measures how many years those cash reserves will last, based on a company's recent spending patterns. It is limited because it does not account for companies that may increase spending in the next period of activity.

The index is derived for this quarter by dividing the average of net operational cash flows (NOCF) for the last three quarters ending March 31, 2012, into each company's cash assets as recorded at March 31, 2012. For companies that report on December 31 full year basis, the index is based on the first quarter of net operational cash flows (NOCF), annualised. The NOCF is the net of receipts and outgoings incurred in support of operational activities.

As a rule of thumb, companies that present with an SI of less than one are likely to be raising funds to support their activities, or are in the process of doing so. A healthy SI is either two or more. Companies with SIs of less than 0.5 may be in positions of funding stress and investors should investigate such stocks with a greater degree of concern.

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: Pharmaxis, Starpharma Holdings, Cogstate, Bionomics, Circadian Technologies, Biota Holdings, Impedimed, QRxPharma, LBT Innovations, Mesoblast, Atcor Medical, Tissue Therapies, Viralytics, Phosphagenics, Immuron, Phylogica, Bluechiip, pSivida, Antisense Therapeutics, Benitec BioPharma, Allied Healthcare Group, Genetic Technologies, Calzada, Bioniche

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