

**In this edition...**

Somnomed is a small company with a big future. This device company markets an oral device which is used to manage sleep apnea. What will drive sales is the low compliance rate with CPAP devices. Somnomed has been reinforcing its sales capacity in Europe by buying local distributors. While modest, these acquisitions can be expected to put the company on an even firmer footing. Somnomed is also one of our Top 6 Stock picks for 2013. The Bioshares Top 6 Stock picks for 2012 came in with an average gain of 20%. Another company consolidating its business is Mayne Pharma, which has acquired the Australian rights to Kapanol from GSK.

Bionomics has confirmed BNC375 as its Alzheimer's disease candidate.

**Companies Covered: BLT, BNO, MYX, NAN, PVA, SOM, TIS, UBI**

	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 - current)	-12.3%
<b>Cumulative Gain</b>	<b>203%</b>
<b>Av. annual gain (11 yrs)</b>	<b>17.8%</b>

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Blake Industry & Market Analysis Pty Ltd  
ACN 085 334 292  
PO Box 193  
Richmond Vic 3121  
AFS Licence  
No. 258032

Enquiries for *Bioshares*  
Ph: (03) 9326 5382  
Fax: (03) 9329 3350  
Email: info@bioshares.com.au

**David Blake - Editor**

Ph: (03) 9326 5382  
Email: blake@bioshares.com.au

**Mark Pachacz - Research Principal**

Ph: (03) 9348 9317  
Email: pachacz@bioshares.com.au

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# Bioshares

14 December 2012  
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*Delivering independent investment research to investors on Australian biotech, pharma and healthcare companies.*

## **Somnomed Reinforces Global Distribution Networks through EU Acquisitions**

Somnomed (SOM: \$0.83) manufactures and sells the Somnodent products used to stop snoring and reduce the occurrence of sleep apnea. Its products consist of two mouth guards which extend and prevent the bottom jaw from moving backwards during sleep and cutting off airways.

Over the last 12 months, Somnomed has announced the acquisition of three sleep product distribution businesses in Europe. In January it acquired its distributor in the Netherlands. In October it announced the acquisition of the second largest oral appliance company in France. And this week the company acquired its distributor in Sweden. Buying the distributors allows the company to have more control of the end market user and of how it markets its products.

Somnomed has paid approximately \$430,000 for the Swedish business in shares and cash, with up to \$86,000 more in shares based on the achievement of milestones. The business employs four people. As with each of its acquisitions, Somnomed will install one to two of its finance people into the local operation.

What the acquisition brings for Somnomed is not only an ability to drive sales in Sweden, but also to drive sales into other Scandinavian countries including Norway, Denmark and Sweden. Somnomed's CFO Neil Verdal-Austin said reimbursement in Sweden, Norway and Denmark was very strong.

Although the acquisition will add to unit sales in the first year, it is expected to take a year until sales become meaningful and the businesses becomes earnings accretive. Both the Dutch business and the Swedish distributor were previously selling the Somnomed device, where the French business has now only started selling the Somnomed products.

At an oral appliance conference at the end of last month in France, Somnomed's new French subsidiary generated strong interest, even from dentists using the Narval products (acquired by ResMed). Dentists showed interest in switching to the Somnomed products because the competing product was too flexible, according to Verdal-Austin.

The acquisition of the Dutch subsidiary earlier this year has been different to the purchases of the French and Swedish acquisitions, in that the acquisition was immediately EBITDA positive and it has had a meaningful impact on unit sales. The Dutch business was bought for €1 million in cash and shares for a 50% stake, with an earn out for the remaining 50% over five years. The Dutch business had six employees at the time of acquisition.

*Cont'd over*

### **Christmas – New Year Publication Schedule**

The next of edition of Bioshares (486), dated December 31, 2012 will be emailed to subscribers on January 1, 2013. The subsequent edition of Bioshares (487), dated January 18, will be emailed to subscribers on January 21, 2013. (Note, *Bioshares* is published 48 times a year)

## Mayne Pharma Acquires Kapanol from GlaxoSmithKline

Mayne Pharma (MYX: \$0.32) has bought back the Australian rights to Kapanol from **GlaxoSmithKline** for an upfront payment of \$10.6 million, payable by February 1, 2013 with a further \$3.4 million payable by February 1, 2014. Another \$0.5 million will be paid for inventory.

Kapanol is a modified release morphine formulation that is delivered orally. The drug comes in 10mg, 20mg, 50mg and 100mg dose forms. Kapanol is used to provide treatment where breakthrough pain is problem such as with cancer patients.

The acquisition includes the trademarks, marketing authorizations, technical material and inventory. Trailing 12 months sales of Kapanol to October 31, 2012 were \$5.5 million, putting the value of the transaction at 2.5 times sales.

GlaxoSmithKline will continue to sell Kapanol in the other territories where it retains rights and will also continue to supply API from its Port Fairy, Victorian plant.

### History

Kapanol was first developed by Mayne Pharma's antecedent, F.H. Faulding, and has been manufactured by Mayne Pharma for GlaxoSmithKline since GSK licensed the drug from Faulding in 1990. Faulding regained the US, Canada, the UK and Ireland rights in 1993.

Kapanol is also known as Kadian in the US where it is sold by Watson Actavis. Actavis acquired the drug through its acquisition of Alpharma in 2005, which had earlier acquired Mayne's (formerly Faulding's) US orals business, Purepac, in December 2001.

In 1996, Kadian became the first Australian developed drug and sponsored by an Australian company to obtain FDA approval.

### Australian Market

Annual sales in Australia of modified release opioid analgesics currently are running at ~\$90 million with Kapanol commanding a 6% market share. Kapanol's local competitors are MS Contin and

OxyContin. Mayne expects to take market share from MS Contin which is dosed 2-3 times a day compared to 1-2 times for Kapanol.

### Funding of the Acquisition

Mayne Pharma is funding the acquisition through a placement of \$18 million to institutional investors. The placement is fully underwritten by Credit Suisse and UBS, at a price of 29.5 cents per share and representing a 8.5% discount to the 5 day VWAP. An SPP will be made available to shareholders on the same terms, which the company intends to leave open through the coming Australian holiday period.

Mayne Pharma CEO Scott Richards said the acquisition would be earnings accretive in FY2014.

### SUBACAP Update

Mayne expects SUBACAP (itraconazole, an antifungal) to receive marketing authorisation in four European countries in early 2013, with the completion of decentralised procedure imminent.

Mayne also expects to file an NDA with the FDA in 2013 and now anticipates that a Phase III trial will not be required.

### Comment

CEO Scott Richards has made yet another move in his strategy to build a larger, profitable generics business whose competitive advantage in part is based on developing generics that are more complex to manufacture and formulate.

One outcome of the Kapanol acquisition is that it will allow Mayne to build a small sales force (less than 20) to market not only Kapanol, but other drugs currently in Mayne's portfolio, or that could be in-licensed and introduced into the Australian market.

Post-placement and at the placement price, Mayne Pharma is capitalised at \$160 million.

*Bioshares* recommendation: **Hold**

**Bioshares**

– *Somnomed cont'd*

### Distribution Agreement for Compliance Measurement

Earlier this week, Somnomed also announced that it had signed a distribution agreement with the maker of a compliance measurement device for sleep disorder treatment products. Somnomed will have the rights to include this device for use in oral appliances, including its own.

In Europe and the Asia Pacific region, Somnomed has exclusive rights to sell the technology for use in all oral appliances, and in the US, it has rights to include the device in its own Somnodent oral appliances.

Including the compliance measurement feature in the Somnomed products gives it an added marketing feature, where insurers, truck driving associations and sleep physicians can monitor compliance of the product, as well as other input measurements such as movements during the night and head position. Groups such as

the US Trucker's Association, which has over 11 million members, requires its drivers diagnosed with sleep apnea to be treated and have proof of compliance. Somnomed can now market to these groups.

The compliance device can simply be opted-in to the Somnodent product range. It is a small sensor that sends a signal wirelessly to a base station and data is transmitted to a cloud information service operated by the manufacturer, Braebon Medical Corporation.

### Summary

Somnomed is following the tried and tested model adopted by Cochlear and ResMed, where distributors were acquired in Europe whilst sustaining a direct marketing effort in the US. There are more acquisitions in the pipeline according to the company.

*Bioshares* recommendation: **Buy**

**Bioshares**

## **Bionomics Nominates BNC375 as Alzheimer's Drug Candidate**

Bionomics (BNC: \$0.35) has concluded validation studies of its lead compound for treating Alzheimer's disease and other cognitive deficit diseases. BNC375 modulates the alpha-7 nicotinic acetylcholine receptor.

Bionomics intends to 'dual track' the drug candidate, in that it will seek to license the compound but also prepare for clinical studies, work to file an Investigational New Drug Application (IND) and commence GMP manufacturing scale and toxicology studies.

BNC375 is a *positive allosteric modulator* (PAM) of the alpha-7 nicotinic acetylcholine receptor. This receptor is involved in a range of cognitive functions including memory and attention. The drug candidate's therapeutic potential extends beyond Alzheimer's disease to schizophrenia, for which it is hypothesised that it is a loss of cognition that causes hallucinations and delusion.

Positive allosteric modulators work by 'potentiating' or 'amplifying' the signal that occurs when a ligand binds to its receptor. BNC375 amplifies the effect of acetylcholine when it binds to its receptor. BNC375 also only works when acetylcholine is 'actively' binding to its receptor. The advantage of a PAM such as BNC375 is that a drug toxicity state, termed cholinergic excess, is avoided which means, in practical terms, that the side effects of nausea and vomiting are avoided.

Bionomics' BNC375 is a highly attractive program because the drug candidate has potential to treat symptoms of Alzheimer's disease, which is an extremely large and growing market opportunity that is poorly served.

### **Competitor Programs**

There are at least two competitor programs to Bionomics' BNC375 program. Whereas BNC375 is a positive allosteric modulator, **Targacept's** TC-5619 and **EnVivo Pharmaceuticals** EVP-6124 are alpha-7 agonists. EnVivo Pharmaceuticals describes EVP-6124 as a co-agonist that sensitizes the alpha-7 receptor.

Targacept's TC-5619 recently failed a Phase IIb trial in patients with ADHD. EnVivo Pharmaceuticals EVP-6124 has completed a Phase IIb in patients with Alzheimer's disease and has provided important validation of the alpha-7 target by showing a statistically significant effect on cognition and clinical function from a six month dosing regime in 409 patients with subjects that received the 2 mg dose. EnVivo Pharmaceuticals is now planning to initiate Phase III studies.

### **Next Steps**

The challenge for Bionomics is now to turn BNC375 into a quality licensing asset which is a task which will take a reasonable amount of time. However there is the chance that pharmaceutical companies take an early licensing interest in the program.

The alpha-7 program was first conceived in 2009 and also approved by the Bionomics board in the same year, with the program having commenced in 2010. Bionomics' relatively rapid progress has occurred because the company has in-house drug design and neuro-biology resources.

### **IWL-2143 (BNC210) IND Cleared**

Bionomics anti-anxiety drug candidate IWL-2143 (BNC210), partnered with **Ironwood Pharmaceuticals**, passed a key milestone recently when the IND submission for IWL-2143 to the FDA was cleared when the 30 day comment period expired without further comment or questioning from the FDA. Ironwood is now in a position to commence clinical studies which could potentially commence before the end of the calendar year.

### **Deal Flow 2013**

Bionomics has flagged that in addition to BNC375, BNC105 (a cancer treatment drug candidate) and the Kv1.3 ion channel program (previously licensed to Merck Serono) are also candidates for partnering in 2013.

The company has also articulated the potential for the pre-clinical partnering opportunities to originate from the cancer stem cell program it gained through the acquisition of Eclipse Therapeutics this year.

### **Summary**

Bionomics is a stock that contains a mix of positives and negatives. The company's drug development expertise in the CNS diseases area is a strength. Deal flow prospects for 2013 are also a positive, however, investors should not be overly optimistic regarding deal terms. Bionomics' cash position is on the low side, and coupled with the need to fund its new US operations means the likelihood of a capital raising during 2013 has now increased.

Bionomics is capitalised at \$127 million and retained cash of \$13 million at September 30, 2012.

*Bioshares* recommendation: **Speculative Hold Class B**

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**Advance Notice – The 2013 Bioshares Biotech Summit – Queenstown, NZ, July 19-20**

**Bioshares Model Portfolio (14 December 2012)**

Company	Price (current)	Price added to portfolio	Date added
Psivida	\$1.25	\$1.550	November 2012
Benitec	\$0.015	\$0.016	November 2012
Nanosonics	\$0.490	\$0.495	June 2012
Osprey Medical	\$0.40	\$0.40	April 2012
QRxPharma	\$0.80	\$1.66	October 2011
Somnomed	\$0.83	\$0.94	January 2011
Cogstate	\$0.330	\$0.13	November 2007
Clinuvel Pharmaceuticals	\$1.86	\$6.60	September 2007
Pharmaxis	\$1.21	\$3.15	August 2007
Universal Biosensors	\$0.90	\$1.23	June 2007
Alchemia	\$0.550	\$0.67	May 2004

**Portfolio Changes – 14 December 2012****IN:**

No changes

**OUT:**

Following a very strong run in recent months, Sirtex Medical has been removed from the portfolio, with a **Take Profits** recommendation guiding the decision. **Switching** to Somnomed is an additional recommendation for investors looking for a stock with similar attributes to Sirtex, but without substantial appreciation built into its share price.

**Top Six Stock Picks – Performance for 2012**

The six stocks selected in late 2011 as our best picks for 2012 performed very well over the year. (Note that due to pause in publishing over the forthcoming Christmas period we are closing the 'year' slightly under the full twelve month period.)

The average performance of the Top Six was 20%, more than double the gain in the All Ordinaries Index. Five stocks posted positive gains, led by Alchemia with a 77% increase. The worst performer was QRxPharma, which fell 48% over the year, although at its worst point following the FDA delivery of a Complete Response letter it reflected a decrease of 67%.

Our Top Six Stock Picks for 2013 can be found on the next page.

**Bioshares 2012 Stock Picks Performance**

Company	Code	Price 23-12-2011	Price 14-12-2012	Change
Alchemia	ACL	\$0.31	\$0.55	77%
Cogstate	CGS	\$0.24	\$0.33	38%
Clinuvel Pharmaceuticals	CUV	\$1.55	\$1.86	20%
Pharmaxis	PXS	\$1.04	\$1.21	16%
Universal Biosensors	UBI	\$0.770	\$0.900	17%
QRxPharma	QRX	\$1.530	\$0.795	-48%

**Average Gain Bioshares Top 6 Stock Picks****20.0%**

ASX All Ordinaries Index	4192	4595	9.6%
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**Short Positions – CORRECTION**

Please note that there was error in last week's Short Positions table. At 3 December 2012, Cochlear had 5.0 million shares in the short position, representing 8.73% of the company's stock.

**Short Positions in ASX Life Science Stocks****10 December 2012**

Company	Shares being shorted (M)	Percentage of total shares on issue
Cochlear	4.90	8.60%
Acrux	10.80	6.49%
Mesoblast	10.40	3.60%
Pharmaxis	7.50	2.44%
Starpharma	5.70	2.00%
Prima Biomed	6.30	0.59%
Sigma	6.60	0.56%
Psivida	0.05	0.56%
CSL	2.66	0.53%
ResMed	3.30	0.21%
Genetic Technologies	0.57	0.18%
QRxPharma	0.13	0.09%
Sirtex Medical	0.03	0.06%
Prana Biotechnology	0.10	0.03%
Allied Healthcare Group	0.10	0.01%



## Top Six Stock Picks – 2013

### Nanosonics (NAN: \$0.49) (Cap. \$128 million)

Nanosonics generated sales in FY2012 of \$12.3 million, up from \$2.2 million in the previous year. The company has added six additional sales staff in the US (a total of eight staff) to support GE Healthcare with its marketing efforts. The company looks to have breached the tipping point for getting its device accepted in the medical sector.

In Australia and New Zealand, there are approximately 700 units installed, representing roughly 30% market penetration. Whilst there was a sales dip in the first quarter of this financial year, at just under \$1.2 million, due to stocking orders already in place, the company expects current quarter sales to exceed those in the previous corresponding period (\$2.8 million). The company also expects sales in this financial year to "build on the growth achieved last year". We'll take that to assume the company expects to exceed last year's sales, suggesting a strong second half to the year.

### Somnomed (SOM: \$0.83) (Cap. \$36 million)

In FY2012, Somnomed generated sales of \$15.2 million, up 23% on the previous year. It is currently trading at 2.4 times sales (market capitalisation / sales). We expect sales growth to be maintained in excess of 25% per annum for the next few years.

Somnomed is currently selling around 32,000 of its oral appliances each year for the treatment of snoring and sleep apnea. It generated a net profit of \$0.7 million last financial year and at the end of September had \$3.7 million in cash. The company is determined to fund its global expansion from existing cash flow and from cash holdings.

Somnomed has built a global network to sell its sleep treatment products into. The network is improving, with the acquisition of three distributors in Europe this year, whilst maintaining a direct sales force in the US. At some point, Somnomed will become a very appealing acquisition target.

### Universal Biosensors (UBI: \$0.90) (Cap. \$155 million)

UBI is another stock displaying strong growth in revenue. In the six months to 30 June this year, the company increased revenue to \$14.7 million, from \$6.3 million in the previous corresponding period.

Revenue is accelerating from the electronic glucose test strips the company makes for Lifescan. The company is also expected to see its second product hit the market in 2013 through its partner Siemens Healthcare Diagnostics. The first product to be sold by Siemens is the PT/INR test, which is a point-of-care test for helping titrate correct warfarin levels.

UBI recently raised additional funds, \$12 million, that will allow it to accelerate the development of its tests, including a PT/INR test that can be used in the home setting (outside of the Siemens partnership), its immunoassays, and its molecular diagnostics.

### Tissue Therapies (TIS: \$0.32) (Cap. \$55 million)

Tissue Therapies is awaiting regulatory approval in Europe to allow it to start selling its wound treatment product, VitroGro ECM. There is a very large market potential for Tissue Therapies and results from its study in patients with venous ulcers that had not healed for three years look very good.

Tissue Therapies has manufacturing and sales and distribution teams in place. Awareness among wound treatment specialists is high according to the company. However, it appears the company will not get approval until the second half of 2013.

The delay for the company brings with it a problem of funding; the company was down to \$3.7 million in cash at the end of September.

Although the stock was removed recently from the Bioshares Model Portfolio due to funding concerns, Bioshares is confident the company will raise additional funds and will get product approval in Europe in 2013. Given these are our stock picks for the whole of 2013, we have included Tissue Therapies in this selection of stocks at this point.

### pSivida (PVA: \$1.25)(Cap. \$29 million)

What might galvanise pSivida's share price in 2013 is if Iluvien, a depot product for Diabetic Macular Edema (DME), is approved by the FDA. The drug has been partnered to Alimera Sciences. The drug has been knocked back twice by the FDA but the companies now know the product is approvable for the sub-indication of *chronic* DME in Europe. If approved in the US, pSivida stands to gain a US\$25 million milestone payment from Alimera.

European sales of Iluvien are set to kick-off in 2013 Q1. However a second potential stock price driver for pSivida is if Iluvien sales perform very strongly in their first six months, mimicking the growth rate of Regeneron's Eylea. Eylea was launched November 2011 and in the nine months to September 2012 had generated sales of US\$562 million. Iluvien offers equivalent benefits to Lucentis and Eylea but is only injected once. Its downside is that around 20% of patients experience intra-ocular pressure, with 5% needing a small surgical procedure to relieve that pressure. pSivida has cash reserves of US\$18 million.

### Benitec Biopharma (BLT: \$0.015) (Cap. \$16 million)

Benitec Biopharma would not be considered as a 2013 stock pick if not for the fact of its Tacere acquisition this year. The acquisition brought back in-house two of the very best commercial opportunities for Benitec's gene silencing technology, being HCV and Age-related Macular Degeneration.

A trial is planned for HCV patients. However, the trial has to be cleared by the FDA's Recombinant DNA Advisory committee and an IND filing must also be cleared. Success with the IND filing would provide the grounds for a significant re-rating of the stock. The company will require funding to support its acquired programs, however, the attractiveness of the stock has improved markedly in 2012. Benitec is a high risk investment play.

**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, Biota Holdings, Impedimed, QRxPharma, LBT Innovations, Mesoblast, Tissue Therapies, Viralytics, Phosphagenics, Immuron, Phylogica, Bluechiip, pSivida, Antisense Therapeutics, Benitec BioPharma, Allied Healthcare Group, Calzada, Bioniche, Atcor Medical, Invion

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