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Companies covered: BNO, OSP, SVA, 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 - May '13)	3.1%
Year 13 (May '13 - Current)	59.7%
Cumulative Gain	**469%**
Av. annual gain (13 yrs)	**19.9%**

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Bioshares

21 March 2014
Edition 544

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

Bionomics Misses Primary Endpoint In Phase II Renal Cancer Study

Bionomics (BNO: $0.61) has missed its primary endpoint in a 139 patient Phase II study in renal cancer of its vascular disrupting agent BNC105 in conjunction with Novartis' mTor inhibitor Afinitor (everolimus). The control arm saw Afinitor administered alone.

The progression free survival (PFS) periods for patients in both arms were similar at six months. However Bionomics has been able to generate some biomarker data that will be useful in structuring subsequent trials. The plan for the company is now to partner the drug candidate for further development.

The median progression free survival outcome for those patients receiving Afinitor was 4.1 months, and slightly longer in the active arm receiving BNC105 plus Afinitor, with a median survival of 4.7 months.

The safety profile of BNC105 was positive in a relative sense, with no differences in safety between the two groups.

Retrospective Analysis

Bionomics has conducted a retrospective analysis on patient subgroups in the trial. A retrospective analysis, which while helpful to a company in structuring subsequent trials, has little impact on regulators in highlighting clinical efficacy.

Improved median PFS was seen in the active arm in patients with more advanced disease, such as those patients where the cancer has spread to the liver. In that subgroup of patients, median PFS of 6.6 months was achieved in he active arm (BNC105 plus Afinitor) compared to 2.8 months in the control arm (Afinitor only).

There was also a better result in patients with Furhman Grade 2 disease, but this was presumably not the case in healthier patients with Furhman Grade 1 disease, or more advanced patients with Furhman Grade 3 and 4 disease.

There was also a better outcome in patients who had previously had a kidney removed.

Biomarker Data

The positive outcome from the trial was that there was good correlation between biomarkers and PFS, which was to be expected. The biomarkers measured increased when the tumours had been disrupted. When this was seen to occur, with increases in seven biomarkers, it correlated with an improvement in PFS. The changes in the biomarkers were seen in the 24 hours after dosing with biomarker levels then falling.

In subsequent studies, Bionomics anticipates using what is called randomized discontinuation treatment. Only patients where there is an immediate increase in biomarker

Cont'd over

levels (i.e. evidence of tumour disruption activity) will continue with BNC105 treatment. Those who do not will move into the control arm. This patient enrichment approach has been used successfully with other oncology drugs including Sorafenib.

Clinical Studies Conducted

The company has completed a Phase I/II study in patients with mesothelioma with modest results. The top line results from this renal cell cancer study were disappointing, however patient enrichment using biomarkers should deliver better outcomes with BNC105.

Bionomics is also conducting a Phase I/II study in patients with ovarian cancer using BNC105. To date 15 patients have been enrolled. Of those 10 patients have seen a positive result in their tumours. Twelve patients have completed the six cycles of combination therapy of BNC105 with existing therapies (carboplatin and gemcitabine) and have moved into the six cycles of BNC105 monotherapy. One patient has completed the six cycles of BNC105 monotherapy and is continuing to receive treatment with BNC105.

Summary

Bionomics is now in a partnering process for BNC105 and it expects that future studies with BNC105 will be funded by a partner. The clinical study results achieved to date are unlikely to be sufficient to deliver a large partnering deal, in Bioshares view, that includes a substantial (>$10 million) upfront payment.

At the end of last year, Bionomics had $20.5 million in funds. Bionomics is capitalised at $254 million.

We retain a **Sell** recommendation on Bionomics, anticipating further price weakness ahead.

Bioshares recommendation: **Sell**

Bioshares

Can Universal Biosensors Turn The Corner?

Universal Biosensors (UBI: $0.34) has continued to see its share price slide. *Bioshares* recently met with the company for an update on developments.

UBI is not a favourite stock for many investors at the moment. However, it will be a potential turnaround story over the next 6-18 months if it can hit all of its milestones. By the end of 2015, the company expects to have five products on the market.

The first product, an electronic glucose strip, is already on the market and is being sold by Lifescan (Johnson & Johnson). Our estimates are that around 90 million of these strips are being sold each quarter, for which UBI receives around one cent (US) per strip sold. While 360 million strips a year may sound like a lot, at the moment that represents only 2% of the global market. We expect that strip volume to continue to increase, and once it accelerates, so should the UBI share price. Currently UBI's annual 'service fee' from these strips is tracking at $3.9 million a year.

The second product, a PT/INR test, is a diagnostic product that will be sold by Siemens into the hospital and speciality clinic market. That test will be used to calibrate warfarin dosage in patients. UBI has indicated that it expects that test to be launched in the third quarter of this year. Ahead of that, we expect that Siemens will place advanced orders on the strips with UBI.

With this product, UBI is paid for each strip it supplies Siemens. Where UBI receives one cent for each glucose strip Lifescan sells, UBI is likely to receive somewhere between $0.50 - $1.50 for each PT/INR strip it supplies Siemens. Although the market is much smaller for the PT/INR strips than for glucose, the potential revenue from each product to UBI is similar.

In 2015, UBI expects its partner Siemens to launch a further two coagulation tests, where once again the market will be smaller but the individual strip price is expected to be even higher. Next year UBI also expects to launch its own PT/INR test for use by patients at home.

Costs & Funding

The net cost to UBI for bringing four new products to market will be relatively low. Our estimates are that the spending on these products will be in the order of $30 million. However UBI is now eligible for a 45% tax rebate for this spend, with the company expecting a $6 million rebate this year. It has also received $8.5 million to date under the Siemens collaboration with a further $4.5 million due by our estimates.

The net development costs of these products should be closer to $10 million. If the company did not make this investment, it would be solely reliant on the success of the glucose test products being sold by Lifescan.

Last year UBI spent $15 million on R&D. Spending is expected to taper off in 2015. The company currently has around 80 staff. Manufacturing is expected to ramp up with the launch of the four new products over the next 21 months.

UBI has negotiated a debt facility rather than raise equity, which CEO Paul Wright says was far more agreeable for its major shareholders. The company has drawn down $16 million. It has an option to draw down a further US$10 million by the end of January next year. The company expects these funds will be sufficient to fund the business to profitability.

Summary

Although UBI had a disappointing year on many fronts in 2013, the business has a strong outlook over 2014 and 2015. Hitting major milestones and an acceleration in glucose strip service fee revenue have the capacity to deliver strong gains in this stock in the medium term.

Despite a range of external factors that have weakened UBI's share price (e.g. strip reimbursement pressures in the USA), the company's status with investors could be improved if a process of substantial board renewal was initiated.

Bioshares recommendation: **Speculative Buy Class A**

Simavita's Incontinence Assessment System Now Entering the US Market

Simavita (SVA: $0.815) markets the SIM incontinence assessment system. This comprises of a sensor which is integrated with an incontinence pad. The Wi-Fi enabled sensor delivers information about fluid deposition in real time to a pod (transceiver), which serves as the data acquisition device.

Data from the pod is then transferred to a PC via a USB connection, where reports for a 72 hour observational period are compiled. Incontinence activity is then linked via Simavita's point of care application (SIM assist) with other metrics recorded on Android or Apple devices.

Point of Difference – Detects Multiple Events

A key point of difference to other, simpler devices that detect saturation is that Simavita's sensor detects multiple events. Hence, the data collected is more accurate and reliable than both simpler sensor devices and manual assessment.

The primary application of the device is in aged care facilities, where the product has the potential to greatly improve the well-being of residents who require high levels of toileting care. In turn, the benefits delivered to age-care facility operators include savings in labour cost and in consumables.

Appropriate Selection of Incontinence Pads

Improvements to toileting care are possible because the data generated by SIM can be used to help guide the appropriate selection of incontinence pads, and with a better understanding of an individual's toileting cycles, optimise toileting visits.

The SIM system allows for the collection of information relating to the toileting visit itself (e.g frequency, quantity, appearance), for signs of cognitive impairment to be recorded (e.g. wandering, or verbal signs), and for linking to fluid intake, so that fluid balance can also be assessed.

The iPad or tablet-computer SIM assist application is designed to be easily used by nursing home workers.

Sales & Distribution

Simavita's SIM system is currently being marketed directly in Australia, where a razor/razorblades model operates. Gross profit margins are generated from the sale of consumables.

Sales have commenced in the US, where Simavita has appointed Medline as its distributor. Medline is the USA's largest manufacturer and distributor of healthcare supplies. The privately held Medline had a turnover of US$5 billion from its global operations in 2012.

The product will be formally launched by Medline in the US in May. Currently 15 nursing home groups have been solicited to participate in roadtesting the SIM system.

A Key Technical Improvement

Simavita's SIM system is now in its fourth generation. The current system, which received FDA clearance in 2013, uses Wi-Fi as its radio transmission protocol, unlike the earlier systems which used the low power Zigbee transmission protocol. The older systems cost $150,000-$200,000 to install in an aged care facility, whereas the set-up costs with Wi-Fi are zero because of the ubiquitous presence of Wi-Fi networks.

This key yet crucial change for Simavita could only take place when low power consumption Wi-Fi devices began to emerge in 2011. It took Simavita 18 months and $6 million to switch to a low powered Wi-Fi system.

Up until its IPO, $28 million had been expended on the development of the SIM system.

US Market Opportunity

Simavita's description of the US market opportunity counts 2.7 million beds in long term care facilities, at 16,100 skilled nursing facilities and 31,100 residential care facilities. Analysis of the cost of urinary incontinence from 2004 placed a figure of US$7,300 per bed for labour costs alone. Overall costs would be higher in today's dollars, due to inflation. Simavita calculates that its SIM system can deliver close to $1,600 in savings per bed per annum.

US Revenue Model

Underscoring the revenue model is the number of incontinence assessments that are made for a nursing home resident each year.

In the US this number is on average four per year. Assessments would be more typically performed on a rolling basis. A 100 bed nursing facility could hypothetically be conducting four 72 hour assessments at any one time, which would require four pods in such a centre.

Simavita will charge a software licence per each building at a nursing facility, in a range typical for software licences of greater than $1,000 but less than $3,000, with provision to charge an annual cost of 20% of the initial sign-on fee.

Simavita's revenue model also includes the sale (via Medline) of the hardware (the pods) as well as the consumable (the sensors).

The company estimates that revenue per site could range from $15,000 to $75,000 per site. At the lower end and assuming a 10% market penetration yields an annual revenue estimate of $71 million for the USA alone.

Risks

Perhaps Simavita's foremost risk is its cash position, which stands at $6.4 million. This will, in all likelihood, require topping up in the not too distant future. The company's net cash from financing activities at December 31, 2013, was $11.8 million. Funds received included $13.8 million from shares issued by Simavita Ltd (the Canadian parent company) and $2 million in shares issued by Simavita Holdings (the Australian subsidiary). Investment outgoings included $1.7 million in equity transaction costs and a net movement in borrowings of $2.5 million. (Debt of $3.4 million was eliminated from funds raised through the IPO.)

– Cont'd over

Bioshares Model Portfolio (21 March 2014)

Company	Price (current)	Price added to portfolio	Date added
Invion	$0.075	$0.089	February 14
QRxPharma	$0.865	$0.620	December 13
Impedimed	$0.225	$0.245	December 13
Analytica	$0.026	$0.025	December 13
Imugene	$0.015	$0.022	November 13
Oncosil Medical	$0.140	$0.155	September 13
IDT Australia	$0.300	$0.260	August 13
Viralytics	$0.320	$0.300	August 13
Tissue Therapies	$0.370	$0.255	March 2013
Somnomed	$1.64	$0.94	January 2011
Cogstate	$0.340	$0.13	November 2007
Universal Biosensors	$0.34	$1.23	June 2007

Portfolio Changes – 21 March 2014

IN:
No changes

Recommendations:

OUT:

No changes

Recommendations:

– Simavita cont'd

A second risk with Simavita is with its US distribution partner, Medline. This is a standard, but not trivial risk for small companies that depend on the sales reach of large, often multi-national, companies. As observed with Nanosonics' sales and distribution arrangements with GE Healthcare, the initial sales distribution process encountered teething problems and had to be restructured and supported with additional funding.

Summary

The prospects for Simavita's SIM system as a value adding product designed for the high growth aged care market is very appealing. It is one of the strongest investment thematics for investors to follow now and into the future.

However, investors would be better placed to watch and wait with this stock while the roll-out of the SIM product in USA takes place over the course 2014.

Feedback from a group of six nursing homes representing 2,000 beds, which will the first to trial the product, will be useful for any investment decision ahead. Additional feedback from a trial site in Denmark will also be worth monitoring.

Simavita is capitalised at $48 million.

Bioshares recommendation: **Sell – Revisit when funding base is strengthened and when the US launch delivers sales feedback**

Bioshares

Osprey's AVERT Trial

Osprey Medical (OSP: $0.625) initiated a 700 patient trial of its AVERT system in January. The trial will be conducted across 45 sites in the US, Europe and Australia. The AVERT system received a 510k clearance by the FDA in August 2013.

The AVERT trial is expected to cost US$6-US$7 million.

The company expects to complete the trial in first half of 2015. The goal of the trial is to generate a label claim for a reduction in contrast induced nephropathy (CIN). CIN is defined as post-procedure serum creatinine increase greater than or equal to 25% or an absolute increase of 0.5 mg/dl.

Osprey has terminated its PRESERV trial, in which its CINCOR system was to have been evaluated in 600 patients. Clinicaltrial.gov records show 17 patients were enrolled in the trial. Osprey has discontinued development of the CINCOR system in favour of the non-invasive and much simpler AVERT system.

The AVERT system minimises the amount of injected dye (contrast media) by up to 40%, by limiting reflux. The clinical benefit of the system applies to patients with chronic kidney disease undergoing a stent or angioplasty procedure for whom exposure to the contrast media is a threat to their kidneys.

Comment

Osprey has made a fundamental change to its business in displacing a first product with a quite different product, but which aims to achieve the same goal by different means. The company's original goal was for the CINCOR system to have received marketing clearance in the US by 2014. Clear messaging and clinical trial execution risk are critical for Osprey if it wishes to retain the support of investors.

Osprey Medical is capitalised at $77 million and held cash of $13 million at December 31, 2013.

Bioshares recommendation: **Sell – Revisit when clinical recruitment rate is established**

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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