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Biosshares

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Edition 468

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

In this edition...

Biota shareholders will be asked to vote on that company's proposed merger with Nasdaq listed cash-box Nabi Biopharmaceuticals. There are several issues for Biota shareholders to consider, one of which is the proposal to delist Biota from the ASX. The move for the proposed merged entity to not maintain both a Nasdaq and an ASX listing is unusual and may work against the company's plan to rebadge itself as a US company.

Sunshine Heart has finally secured funds to support a pivotal trial of its C-Pulse heart assist device. The company must also conduct a 100 patient trial to generate data to support reimbursement in the EU. The biggest risk for the company is enrolling trial subjects in a speedy and timely manner.

We also report on John Cullity's overview of trends in global biotech M&A.

Companies Covered: BTA, SHC

	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)	-20.3%
Cumulative Gain	**175%**
Av. annual gain (11 yrs)	**17.8%**

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The Biota-Nabi Merger: Issues to Consider

Biota Holdings (BTA: $0.68) announced on April 23, 2012, that it would merge with US biotech, Nabi Biopharmaceuticals, to form Biota Pharmaceuticals, a US and Nasdaq-listed entity. However, the planned merger will not see an ASX listing retained, a move which will force current shareholders who wish maintain an interest in Biota's asset to do so via a shareholding in a US and Nasdaq listed firm.

Nabi Biopharmaceuticals is essentially a cash-box operation and would contribute U$54 million into the combined entity, although the potential exists for one of Nabi's assets, Phoslyra, to deliver an income stream.

The board of Biota has recommended the merger, unless a superior offer was to emerge. The merger is subject shareholder approval from both companies.

The preliminary consideration for the merger transaction has been calculated at US$46 million (the cash figure of US$54 million net of a discount on assets being acquired of US$7.7 million.)

The merger would result in Biota shareholders owning approximately 74% of the combined entity (and Nabi shareholders 26%).

Biota's board has sought the merger to "achieve better value recognition and liquidity through a stronger US shareholder base." The Biota board believes a "Nasdaq listing will increase options to deliver significantly higher value from future programs", and that the "merger will strengthen Biota's cash position on competitive terms".

Biota released its Scheme Booklet on August 10, 2012 (dated August 6, 2012). This document sets out the features of the merger as legally required under the process of a Scheme of Arrangement. The booklet also includes an Independent Experts Report (IER) prepared by Lonergan Edwards. Lonergan Edwards describes the merger as 'not fair when assessed based on the guidelines set out in RG111. Specifically we have calculated that the dilutionary effect of the Scheme reduces the portfolio value of Biota shares by some two to four cents per share.' However, the IER also says the offer is 'reasonable and in the best interests of Biota shareholders (in the absence of a superior offer).'

Biota's proposed merger with Nabi presents several issues for existing shareholders to contemplate and several of the claims made by Biota's board in favour of the merger warrant comment.

The Accessing Capital Argument

One the arguments put forward by the board of Biota in support of the merger with Nabi is that it is a means to access capital. The IER argues that the capital 'raised' through the merger will be achieved at a more attractive discount (10.6% – assuming a AUD:USD exchange rate of $1.02) compared to the median of 15% calculated from a sample set of 19

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companies which raised greater than $10 million from the March 2009 to November 2011.

In the IER, there are several errors in the table titled "Placement Discounts for ASX-listed biotechnology companies raising more than $10 million". One company listed, **Pharmaxis** (19.2% discount) conducted a rights issue, not a placement, and other companies, **Avita Medical** (33.3% discount) and (**Avexa** (31.7% discount) raised less than $10 million through placements. [The figures quoted in the report appear to have included funds obtained from SPPs.] Ignoring these three companies decreases the median discount calculated for the sample set to 13% (down from 15%).

The table excludes other ASX listed life science companies including **Impedimed**, **Unilife** and **Heartware**, which raised sums of $10 million or greater in the selected period and which could be included in the pool.

The methodology of comparing discounts (of the price of the capital raising price) to the last trading day price is not consistent with a widely accepted approach of pricing a capital raising on a Volume Weighted Average Price based on a number of trading days (e.g. five or ten) prior to the date of the announcement or of the initiation of a trading halt.

A Viable Biotech Equity Capital Market

However, the contention that Biota is able to raise capital through a merger with a US entity at a more favourable discount misses a key point about the history of life science equity capital markets in Australia.

The obvious lesson from the table in the IER itself is that a significant number of transactions (above $10 million) have taken place in the selected period. Many more have taken place outside that selected period and with many capital raisings being for sums less of than $10 million.

Since the 1999, the ASX has developed a viable biotech equity capital market. Since 1999, by our estimate just under $5 billion in funding has been raised by ASX listed biotech companies, predominantly in the form of equity capital.

The equity capital data ignores other sources of capital, including licensing income and other revenue received by ASX listed life science firms. The data also ignores capital returns received by shareholders of companies acquired by larger, generally off-shore firms. It is plausible that some of those dividends and capital returns have been re-circulated as fresh investment in ASX biotech stocks.

Ownership Composition

Some companies have been successful at changing their ownership composition from a retail to an institutional investor base, including international investors, without resorting to a listing on a foreign exchange.

For example, institutional shareholders own 45% of **Mesoblast** which in turn is split between domestic institutional investors (17%) and foreign institutional investors (28%). Employees and directors own 26% of the company, **Teva Pharmaceutical Industries** holds a 19.5% stake and retail shareholders 9.5%. **Acrux**'s share registry now includes about 55% institutional shareholders, up from an estimated 15% in 2005. **Pharmaxis**' records 65% of its shares as being held institutional investors.

Biota has a share register dominated by retail investors. Two institutional shareholders, **Hunter Hall Investment Management** (13.6%) and **East Hill Holding Company** (12.4%), appear to make up the largest known block of institutional interest in Biota, implying that much of the balance can be attributed to retail investors (~74%). The board of Biota's aggregate shareholding amounts to less than 1% of total shares.

Biota's merger argument ignores successful listings on the ASX of many life science companies that have drawn institutional support both locally and from overseas.

We suggest that Biota’s capital requirements could be addressed without recourse to a merger with a Nasdaq-listed cash box, following the pattern set by many other ASX listed life science firms, a number of which have raised capital to advance assets further down the value creation path.

The US Business Argument

An argument implied in the IER, that it is better for Biota to be redomiciled (and to be US listed) because it has a major contract with the US government, is not valid because a bevy of Australian life science companies have successfully sold medical products and services into the US without rebadging as a US company.

CSL, for example, has been contracted to supply influenza vaccines in the US and was never forced, nor saw the need, to redomicile it's vaccine operations. CSL also maintains a single listing on the one exchange, the ASX. Its single listing has never appeared to be an issue for investors in CSL, or an impediment to its capital requirements. It runs a global pharmaceutical business from headquarters in Australia.

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North American Biotechs Listed on the ASX

A number of foreign companies, including **Osprey Medical**, **Reva Medical** and **GI Dynamics**, have relatively recently made their sole and primary listings listed on the ASX, arguably attracted by the maturity of the ASX life sciences sector and lower compliance costs. And Canadian company, **Bioniche**, has made a secondary listing on the ASX.

Dual Listed Stocks

Dual ASX and Nasdaq listed life science companies currently include **Prima Biomed** and **Genetic Technologies**. Three companies, **Heartware**, **pSivida** and **Unilife** have redomiciled to the US and listed on the Nasdaq but they have also retained an ASX listing.

Alchemia is planning to demerge its oncology assets into a US entity (**Audeo Oncology**), which would be both ASX and Nasdaq listed.

One very successful ASX-listed medical product business is **Sirtex Medical**. This company operates a facility in the US and generates more than 60% of unit sales and almost 70% of sales by value in US. However, Sirtex does not appear to have felt the need to redomicile to the US or to list on the Nasdaq. A director of Biota, Richard Hill is also the on the board of Sirtex Medical.

Rest of The World Sales Opportunity

A second weakness in the Scheme Booklet is the paucity of discussion concerning the potential opportunity that exists for Biota to develop laninamivir for markets outside of the US . Commercialising laninamivir outside of the US (in Japan the marketing rights rest with **Daiichi Sankyo**), Biota may be able to rely on some of the clinical data and manufacturing resources established in support of a US FDA registration for laninamivir.

The rest of the world opportunity is also an attractive aspects in the Biota investment proposition. Assuming BARDA (the agency with which Biota has a *development* contract for laninamivir) awards Biota a contract for the *supply* of laninamivir following FDA approval, the company could be well placed to commercialise laninamivir for Rest-of-the-World markets (excluding Japan).

However, what continues as an unknown is how Biota and **Daiichi Sankyo** will manage the rights to laninamivir where it is marketed outside of Japan. It is a concern that Biota has entered into a merger transaction without clarifying those rights. At present, Biota and Daiichi Sankyo jointly own laninamivir, but Biota receives a royalty of 4% of net sales in Japan.

Both the Scheme document and the Nabi Pharmaceuticals' Proxy Statement state:

'*The collaboration and license agreement between Biota and Daiichi Sankyo does not fully address the respective rights and obligations of Biota and Daiichi Sankyo with respect to how laninamivir may be developed and marketed outside of Japan or how the proceeds from any direct sales by Biota or Daiichi Sankyo of laninamivir outside of Japan would be shared. Also, the agreement includes a provision which restricts either Biota or Daiichi Sankyo from developing, commercializing or otherwise handling or dealing with laninamivir in any country (or enter into any license, collaboration or agreement with a third party to do any of the foregoing).*

'*Unless Biota and Daiichi Sankyo come to an agreement with respect to the development and marketing of laninamivir outside of Japan, disputes between Biota and Daiichi Sankyo could result in litigation or arbitration, which can be expensive and time consuming. If any such dispute were to be resolved unfavourably to Biota, the amount of future revenue laninamivir generates could be reduced. This may have a material adverse effect on the business, results of operations or financial condition of the combined company.*'

The risk of litigation should not be taken lightly given Biota's less than successful litigation outcome with **GlaxoSmithKline** regarding the commercialisation of Relenza.

Trading of Shares in US and US-listed Companies.

The most dissatisfying feature of the proposed transaction from an Australian investor's point of view is that it proposes the delisting of Biota from the ASX. A dual listing could facilitate Biota's goal of restructuring its share register but in much more diplomatic manner that is more beneficial to many of the company's retail shareholders, some of whom would class themselves as loyal shareholders who may feel that a shareholding in Biota was a investment commitment to the commercialisation of Australian scientific discoveries.

There is relatively less appeal for Australian retail shareholders to directly own shares in US entities listed on US exchanges, and with no or little local analyst coverage also a factor to not invest in US only traded stocks. The Independent Experts Report notes that a disadvantage of the proposed merger is that 'transaction costs in terms of brokerage and foreign currency conversions are likely to be significantly higher for individual shareholders who wish to sell their shares on the NASDAQ.'

Bioshares recommendation: **Hold/Vote Against the Merger**

Key Dates for Biota Shareholders

Time and Date for Determining Eligibility to Vote at the Scheme Meeting - 7PM Sunday, 23 September, 2012

Scheme Meeting - Meeting Rooms 109 & 110, The Melbourne Convention Centre - 2PM Tuesday September 25, 2012

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Bioshares Model Portfolio (17 August 2012)

Company	Price (current)	Price added to portfolio	Date added
Nanosonics	$0.485	$0.495	June 2012
Osprey Medical	$0.37	$0.40	April 2012
QRxPharma	$0.70	$1.66	October 2011
Mayne Pharma Group	$0.350	$0.435	September 2011
Somnomed	$0.85	$0.94	January 2011
Phylogica	$0.024	$0.053	September 2010
Biota Holdings	$0.68	$1.09	May 2010
Tissue Therapies	$0.40	$0.21	January 2010
Bionomics	$0.28	$0.42	December 2007
Cogstate	$0.270	$0.13	November 2007
Sirtex Medical	$7.63	$3.90	October 2007
Clinuvel Pharmaceuticals	$1.57	$6.60	September 2007
Pharmaxis	$1.14	$3.15	August 2007
Universal Biosensors	$0.60	$1.23	June 2007
Alchemia	$0.535	$0.67	May 2004

Portfolio Changes – 17 August 2012

IN:
No changes

OUT:
No changes

International Drivers of Biotech M&A and Licensing

At this year's Bioshares Biotech Summit, John Cullity from biotech advisory firm **Torreya Partners,** examined the current drivers of licensing and acquisition activity between pharmaceutical companies and biotechs.

For Big Pharma, filling the near term revenue gap has become the second top reason for pharma-biotech M&A in 2011, up from number six reason in 2008. Strengthening late stage pipelines remains the top reason for M&A, and Venture Capital groups seeking an exit is reason number three (up from four in 2008).

A survey reported by Cullity showed that for pharmaceutical executives, 34% had increasing existing revenue earnings as their top priority, and 31% had filling their portfolio gaps as their main issue.

Cullity said the IPO market was opening up slightly, although that was not to be overemphasised.

M&A can be due to chasing revenue, chasing emerging projects and also can be about global expansion. Examples of companies looking for revenue consolidation are **Valeant Pharmaceuticals** in Canada, **Teva Pharmaceutical Industries** in Israel, and **Jazz Pharmaceuticals** and **Watson Pharmaceuticals** in the US. Examples of companies seeking global expansion through M&A include **Takeda** from Japan, with **Fosun** from China being one company to look out for which is looking to broaden its footprint. **Otsuka** from Japan is another, said Cullity.

The level of global M&A has been relatively constant, with 2012 expected to be similar to 2011 when US$181 billion in life sciences M&A deals were completed. However, it will be a slow year in Europe. According to Cullity, Australian biotech has now matured to a point where it is part of the international life sciences community.

For companies seeking exits, Cullity recommended they should really consider mid-sized life science companies as potential acquirers.

The US$11 billion purchase of Pharmasset by **Gilead Sciences** was arguably the deal of the year in 2011.

In 2011, M&A deals were driven largely by revenue consolidation, however in 2012 R&D has returned as a driver for M&A although they are smaller deal sizes. Cullity said one trend now is what are termed 'structured sales', which translates to lower upfront payments and allows big pharma to arbitrage risk. "Big pharma is increasingly looking to get risk of its books," said Cullity.

Cullity strongly encouraged biotech companies to undertake primary market research. For as little as $80,000-$100,000, biotechs can distil their product profile and also test and translate future sales forecasts into risk adjusted NPV calculations.

Market Appetite for Biotechs Strongest Since 2008

Moving onto the topic of investor appetite, Cullity believed there is a renewed appetite for high risk-higher return prospecting given the dismal yields from more conservative asset classes. Cullity said the demand for public healthcare investing is the strongest it has been since the market collapse in 2008. In the first quarter of 2012 investors put almost US$1.1 billion into follow-on deals.

Pharma Becoming More Conservative

The attitude of pharmaceutical companies is reflecting its changing investor base. In 2003, 35% of investors in these pharmaceutical companies were growth investors. That has dropped to only 6% now with index and value investors representing more of the register of these large pharmaceutical businesses. The message to managers from their shareholders is to play it safe said Cullity.

Cont'd over

Sunshine Heart Raises $20 Million – 'Strategic Investor' Enters Register

Sunshine Heart (SHC: 3.6 cents) is commercialising the C-Pulse heart assist medical device. The company has announced a $20 million underwritten capital raising which will see the company raise net of costs $18 million. The raising is being co-ordinated in the US with US investors. Existing venture capital investors, **GBS Venture Partners** and **CM Capital** will not be participating. Of particular interest is that a 'strategic investor' will be investing $3 million in this placement.

The underwriter also has a 30 day option to acquire additional shares in Sunshine Heart, which would deliver the company an additional $2.7 million in funds. The capital raising is being conducted at $7.00 a share, which equates to an ASX share price of 3.5 cents. One of the aims with this investment round was to bring in a new set of US investors onto the register.

The undisclosed strategic investor we speculate may be a potential licensee/acquiror of the technology. This investor will receive an observer seat on the board. There will be no other conditions on this investment. There are no warrants attached to any of the shares in this placement.

At the end of June, the company had $1.8 million in cash. It is spending around $1.1 million a month and that spend rate can be expected to increase once the clinical trial activity starts. However the company should be reimbursed from US devices used in its forthcoming US pivotal study. It's unclear how long the funds raised will last the company. Our expectation is that the company will have sufficient funds for 12-18 months.

Sunshine Heart is looking to initiate its US pivotal study by year's end, once it receives FDA approval to proceed. The company is in discussion with the FDA about its pivotal trial design, which could involve close to 400 patients. We expect the pivotal study will take approximately three years to complete, assuming a favourable rate of recruitment. That would place the release of results at the end of 2015.

CE Mark Certification

In July this year Sunshine Heart received CE Mark certification to sell its device into Europe. The company will conduct a post market clinical study in Europe in about 50 patients. The rationale is that the trial will confirm the efficacy of the device in leading European leading centres, generating data for reimbursement. However this trial will also mimic the US pivotal study. This open study will then give the company, investors and potential licensors or acquirors a gauge for the likely outcome of the US trial.

Assuming a favourable rate of recruitment, we would expect to see around 100 patients to have been implanted with the device in the US pivotal study and the European post market study in 2013. If the company can achieve that with some meaningful data emerging from Europe, then it should be reflected in a solid share price appreciation. The challenge for the company is to be able to achieve a high enrolment rate. In the company's 20 patient feasibility study, there were many delays in completing recruitment.

To make recruitment easier and increasing the appeal of is heart assist device, the company will be using a smaller driver and battery unit that have been combined into one. The new driver assembly is about half the size of the previous system. Another advantage is the minimally invasive procedure that will be used in some of the trial participants.

Canadian Study

Sunshine Heart is also conducting an investigational study in Canada. Four patients have already been approved and it is expected that 20 patients will be recruited into this trial. The company has also recently been granted approval by Canadian regulators to used the smaller driver unit.

Managing partner of GBS Venture Partners, Brigitte Smith, told attendees at this year's Bioshares Biotech Summit that it was an exciting time to get involved with Sunshine Heart. Whilst the company listed on the ASX too early, Smith said if the company went public now then it would be the right time. Smith said the company's US feasibility study had fantastic results, with some patients even able to disconnect from their heart assist devices because the device had improved the function of the heart.

Sunshine Heart is now capitalised at $66 million.

Bioshares recommendation: **Wait, Pending Evidence of Strong Recruitment Rates Emerges**

Bioshares

– Cullity cont'd

Cullity said that the outcome is that these companies now have a lower tolerance for early stage assets. Big Pharma is moving to more structured plays, where there is more exposure at the back end. Cullity also said there is increased pressure from shareholders to return capital through dividends and share buy-backs.

Summary

Cullity believes M&A is due to increase but there will be more structured back end deals. The maturity of the Australian biotech sector is now known and talked about in Europe and North America. And venture capital remains under pressure. This will see some VCs close their doors and others will prosper handsomely according to Cullity.

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

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

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