ISSN 1443-850X

In this edition...
Biota has struck an agreement to merge with Nasdaq-listed Nabi Biopharmaceuticals, to secure a Nasdaq listing and access more than $50 million in cash, delivering a total cash pool of $100 million. The goal is to access the deeper biotech capital market in the US. Biota also plans to de-list from the ASX.
Cogstate now holds $5.6 million in cash, following strong sales in the December quarter, and growth is expected to continue.
Clinuvel is a stock to watch despite falling cash levels, with its Scenesse drug for EPP being prepared for wider sales in Europe, assuming approval is obtained at the end of this year.
pSivida's eye drug Iluvien, partnered with Alimera, has been approved in Europe, in the wake of a rejection by the FDA in 2011.
The Editors
Companies Covered: BTA, CGS, CUV, PVA

	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	-17.7%
Cumulative Gain	**246%**
Av. annual gain (10 yrs)	**21.4%**

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

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Individual Subscriptions (48 issues/year)
$375 (Inc.GST)
Edition Number 452 (27 April 2012)

Bioshares

27 April 2012
Edition 452

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

Biota Plans Merger with Nasdaq-listed Nabi Biopharmaceuticals and ASX De-listing

Biota (BTA: $0.825) has revealed plans to effect a back-door listing on the Nasdaq through a reverse merger with Nabi Biopharmaceuticals. The merged entity would be renamed Biota Pharmaceuticals and Biota Holdings would be de-listed from the ASX. The proposal is unanimously supported by the directors of Biota. The new entity would see existing Biota shareholders with 74% of the company and Nabi shareholders with the balance of 26%. The combined entity would hold approximately US$100 million in cash.

A break-fee of $2 million applies to both parties in the event of the merger not proceeding.

Biota is paying a 19% premium to obtain the $US54 million in cash to held by Nabi at the close of the transaction, which is the equivalent to Biota issuing new shares at a 16% discount (based on the 10 day volume weighted average share price to April 20, 2012).

Biota's Arguments for the Merger

One of Biota's arguments for merging with Nabi is to 'attract and enhance' the number of US institutional shareholders on its share register. A listing on the Nasdaq would, it is argued, increase the trading liquidity of Biota stock.

Biota's desire is to secure value recognition in a stock market that is broader and deeper than the ASX. Biota's share price has ranged from a low of $0.69 and a high of $1.25 cents in the last 12 months. Its capitalisation just prior to the announcement of the merger was $172 million.

Biota held cash of $56.5 million at December 31, 2011. It is managing a US$231 million contract with the US public health agency BARDA to develop the long-acting influenza drug laninamivir for the US market (up to the point of filing a New Drug Application). Other programs include BTA798 for treating rhinovirus infection in patients with asthma, COPD and cystic fibrosis patients. This compound recently successfully completed a Phase II trial. It also has a suite of other pre-clinical anti-infective compounds.

Biota also sees the merger as a means to access capital to fund prophylaxis (prevention) trials for laninamivir. The BARDA contract only provides funding for the trials for the treatment of influenza.

Cont'd over

Biota is also concerned about the loss of royalty revenues that will occur when Relenza comes off patent, starting in the US in 2014.

Nabi Biopharmaceuticals – A Cashbox

Nabi Biopharmaceuticals is essentially a cashbox, following the failure of its NicVax smoking cessation vaccine in a Phase III trial. Its current assets include US$96 million in cash, an ongoing combination study of NicVax in Europe and an out-licensed product Phoslyra. However, only US$54 million would be contributed to the merged entity with the balance, less satisfaction of outstanding liabilities, to be distributed to Nabi shareholders. This is expected to be between US$25 million and US$30 million.

Scheme of Arrangement

For Biota, the merger process will be conducted through a Scheme of Arrangement, a legal process now familiar to investors in biotech in Australia, with the most recent example being that of Cellestis which was acquired by Qiagen. A Scheme of Arrangement is one in which the merger must be approved by an Australian Court, which in the case of Biota and Nabi would be the Supreme Court of Victoria. Unlike takeovers which require a more than 90% of shareholder votes to agree to the takeover, a Scheme of Arrangement requires only 75% of shareholder votes to agree to the merger.

Change of Management

The positions of CEO and CFO will move to the US after the merger is completed and with a new management expected to be installed.

Comments

We are not convinced by Biota's argument that a Nasdaq listing effected through a reverse merger with a US Nasdaq listed biotech company will necessarily generate the uplift in liquidity and increase in the number and proportion of US institutional investors on its register. We are also not convinced that a Nasdaq listing will improve the company's capital supply options, both in terms of cost and availability, that Biota has put on the table as reason for re-domiciling in the US and de-listing from the ASX.

The supply of capital to ASX life science firms from 1999 onwards suggests that the ASX-listed life science sector is capable of attracting domestic and international capital. In every calendar year since 2003, with the exception of the GFC year of 2008, a minimum of $500 million has been raised by ASX listed firms. The average annual capital inflow for the period 2003-2011 was $585 million. The bulk of these funds have been raised to support the mid-to-late stages of commercialisation of assets as well as the initial stages of market entry.

There is reasonable evidence to suggest that the ASX has proven to be an exchange that has been able to generate liquidity for a subset of stocks and facilitate capital supply for most later stage biotechs.

The Australia-US Biotech Capital Pathway

Several North American biotehcs have listed on the ASX, including Heartware in 2005 and more recently Bioniche, Reva Medical and GI Dynamics, with Osprey Medical and Ventus Medical expected to list on the ASX in the near future. There are a number of ASX-listed, US-incorporated companies which are for the most part developers of Australian or New Zealand originated technologies – these include Universal Biosensors and Sunshine Heart. Osprey Medical's technology also emanates from Australia.

And a handful of Australian companies are or were dual ASX and Nasdaq listed, most notably Progen Pharmaceuticals, Novogen, Unilife, Genetic Technologies and most recently Prima Biomed.

Pharmaxis and Chemgenex Pharmaceuticals (acquired by Cephalon in 2011), initiated Nasdaq listings but went on to voluntarily cancel their listings and terminate their registrations with the US SEC in 2009. Pharmaxis said that following a review of its Nasdaq listing that the "benefits of the Nasdaq listing could no longer justify the ongoing costs." Chemgenex said that the decision was taken "following a detailed review of the limited benefits generated by the listing as compared to the significant, and growing compliance costs of maintaining it."

What is apparent about the Australia-US biotech capital pathway is that the ASX has proven to be an attractive stock exchange for some US companies and that the Nasdaq largely has not been an exchange that has proven to be beneficial for Australian life science firms.

Laninamivir Rights

An important issue for the proposed merger is the lack of clarity that exists with respect to the rights to laninamivir outside of Japan. Biota and Daiichi Sankyo cross licensed their long acting flu drug programs to each other in October 2003. (The laninamivir compound in fact was originally developed by Daiichi Sankyo, being effectively a pro-drug of the Relenza active). However, Daiichi Sankyo retained an option to manufacture and market laninamivir, or CS-8958 as it was then known, in Japan if it funded trials in Japan. It exercised this option in 2009, with the statement made at the time that "Biota and Daiichi Sankyo will share commercial returns from licensing outside of Japan."

Laninamivir received marketing approval in Japan in September 2010. Biota receives a royalty on sales of laninamivir in Japan of 4%.

Biota currently describes its relationship with Daiichi Sankyo regarding the ex-Japan rights for laninamivir as follows: "Biota and Daiichi Sankyo are exploring options for development and commercialisation of laninamivir ex-Japan." (See Biota website)

At an analysts' briefing last year, Biota CEO Peter Cook said the company would fine tune the rights to laninamivir outside of Japan with Daiichi Sankyo once Phase III trials had been completed. Any marketing approval received by Biota in the US would be 100% owned by Biota. However, how net income from any sales of laninamivir outside of Japan is distributed remains unclear.

In a briefing held this week Biota Chairman Jim Fox said "Biota has the rights to deliver (laninamivir) into the stockpile. That's our primary mission as far as selling internationally goes. The only rights that are agreed on are that (Daiichi Sankyo) can sell into

Cont'd over

– Biota cont'd

Japan and we cannot. Otherwise we will be the company with rights to manufacture and produce an FDA approved product, not Daiichi, and that's where it lies."

A key issue that needs be addressed is commercial entitlements to laninamivir. As a co-owner of laninamivir, will Daiichi Sankyo be entitled to 50% of profits from these markets or will the agreement between Biota and Daiichi Sankyo bring forth an arrangement in which Daiichi Sankyo receives a royalty from sales in those markets? And how will development costs and manufacturing be taken into account? These are issues the Independent Experts Report may find challenging in order to deliver a "fair and reasonable" assessment of the merger proposal.

Capital Budgeting

Biota has argued that a reason to shift to the US is to access a superior biotech capital market for the purpose of expanding the company's programs and capabilities. However, what does not appear to have been considered by the company and placed in front of shareholders as an option is the narrowing of the company's activities to concentrate on fulfilment of the BARDA contract. This would give Biota a very tight focus, a feature often welcomed by investors, but it could also mean that funding required to support cash-flow related commitments for the BARDA contract could have a greater likelihood of receiving investor support. Acrux's development of Axiron is a recent example of a focused development program that resulted in a $22.5 million investment round that has already delivered a $100 million dividend.

Summary

The proposed merger between Biota with Nabi Biopharmaceuticals lacks incentives for Biota shareholders. There is no immediate guarantee of value creation or appreciation through the link-up. And the argument that an Australian biotech needs to move to the US to access deeper capital markets is not supported by capital inflow into the local market in this sector over the last decade. That the proposed merger also does not offer a dual listing for shareholders is also disappointing. While Australian investors can invest in US stocks reasonably easily, it's unlikely there will be many analysts covering the stock locally.

We recommend that shareholders vote against the merger proposal.

Bioshares recommendation: **Hold**

Bioshares

pSivida's Iluvien Gains Approval

pSivida's (PVA: $2.40) partner, **Alimera Sciences**, has gained approval for Iluvien for the treatment of chromic diabetic macular edema in Austria. Alimera has gone down the decentralised approval process. Six other countries – the UK, France, Germany, Italy, Spain and Portugal – have voted in favour of the drug and approvals in those countries are also expected in coming months. These seven countries account for 320 million people.

Alimera expects to have the product available for sale in Europe by the end of this year. In Austria there are around 40,000 people suffering from DME. Iluvien is a depot injection that lasts for three years. It will compete against **Roche**'s Lucentis, which needs to be injected into the eye every six weeks and is very costly, at around $1,000 per treatment. Iluvien is expected to sell for between $5,000-$10,000 for a three year treatment.

Alimera had its application for marketing approval knocked back by the FDA last year. In Europe, the regulators have accepted a more narrow use of the drug in patients with chronic DME, where the improvement was considerably higher.

The FDA would not accept a re-assessment of the results based on effects on sub-populations in the trial. European regulators had encouraged a 'sub-cut' analysis after it had submitted its application, according to pSivida CEO Paul Ashton. It is unlikely Alimera will repeat trials in the US in the chronic DME population and an appeal of the FDA decision is also very unlikely as appeals are rarely successful.

Although the efficacy of Iluvien was good, it wasn't good enough taking into account its side effect profile according to the FDA. Breaking it down into chronic and acute patients, the risk/benefit was deemed acceptable in Europe in patients will chronic stage DME. In the chronic patient group, 18.4% experienced an increase in intraocular pressure and 3.6% of these required an incisional surgical procedure.

Alimera is now capitalised at only $100 million. Its current cash balance is US$33 million. It is still owned 50% by venture capital investors, which have invested US$140 million into the company. Whilst the company is planning to launch the drug into Europe, its relatively low cash balance and its low market value would suggest that a trade sale of the technology may be more likely.

If Alimera were acquired by a larger partner, that partner may possibly undertake further trials in the US. pSivida stands to receive around a 15% profit share from sales of Iluvien.

pSivida is focusing on applying its eye drug delivery technology to other areas of need. There is also the option of using the same Iluvien product and developing the product for a more serious eye disease but smaller indication, called uveitis.

pSivida is capitalised at US$50 million. The company had US$18.7 million in cash at the end of last year. It will be worth monitoring Alimera Sciences' commercialisation plans for Europe.

Bioshares recommendation: **Speculative Hold Class B**

Clinuvel Pharmaceuticals Continues Preparations for Scenesse Market Launch

Clinuvel Pharmaceuticals (CUV: $1.80) is continuing much of the preparatory work required to get its product approved by major regulators around the world. In recently completed a very positive end of Phase II meeting with the FDA and this week announced that two major insurers in Switzerland would reimburse the treatment for EPP.

Clinuvel is commercialising Scenesse, which is a depot injection of a peptide that increases the melanin density of the skin for the treatment of a variety of conditions. These include EPP, which is characterised by a severe intolerance to sunlight (a small orphan disease), and vitiligo, a discoloration of the skin, which is much more common.

Potential sales estimates for the product for EPP are between $50-$100 million a year, and for vitiligo around $400 million a year.

Clinuvel is making sure that once its drug does reach the market that uptake is a fast as possible. Awareness amongst clinicians, patients and now even regulators is very high. When Clinuvel announced it would be conducting a 100 patient Phase III trial in EPP in the US recently, it had 135 patients express an interest in the trial, which the company passed on to the seven clinical trial centers that will be involved in the trial.

Clinuvel's CEO, Philippe Wolgen, believes that in a contracting economy, it's important to make sure insurers accept a drug on their list and that it's better to find out earlier whether insurers will reimburse the drug. While most pharmaceutical groups work on reimbursement after approval, Clinuvel is progressing reimbursement and the regulatory approval process in parallel. Clinuvel first starting looking into reimbursement for Scenesse in Europe in 2009 and has been working on reimbursement in Switzerland for the last two years.

On Clinuvel's side is that EPP is a very small indication and it won't make a big dent in the budgets of payors. The Swiss insurers that have come on board are two of the elite insurers who Wolgen believes will set the tone for wider reimbursement. The reimbursement price is the same as the current selling price in Europe, which is 32,250 Euros per patient per year. Wolgen believes it is essential to get uniform pricing on Scenesse worldwide.

Earlier this year Clinuvel submitted Scenesse for approval in Europe. A decision is expected towards the end of this year. Switzerland is not part of the European Union. Clinuvel will likely submit Scenesse for approval in Switzerland before a decision is received from the European regulator (EMA).

Health Economic Assessments

Clinuvel has completed health economic assessments on Scenesse. It is now working on reimbursement for Scenesse in other regions of Europe. In Italy, where the drug is currently available under a special law for novel pharmaceutical products, Clinuvel generated sales of $1 million last year. We expect that will double if Clinuvel receives wider European approval and it can actively promote the drug to doctors. Having the product available in Italy ahead of wider approval has been very useful for Clinuvel from a number of aspects, including logistics.

US FDA Path

In March this year Clinuvel had a meeting with the FDA to discuss Clinuvel's forthcoming Phase III trial in EPP. The outcome and what transpired during the meeting was particularly pleasing and reassuring for Clinuvel. In 2005, under different management, Clinuvel had submitted the same compound for clinical trials in the US as a tanning drug. It was promptly knocked back, and this has made regulatory progression in the US substantially more difficult.

In the March meeting with the FDA, four of the key reviewers from 2005 who knocked back the clinical trial application are now supporting its clinical development in EPP. And importantly, there were no adjustments to the trial protocol submitted. Wolgen said this meeting delivered a maximum outcome.

Clinuvel will now start its Phase III trial in May, which will run over the US summer. Patients will be treated for six months (three injections), with the trial expected to be completed by year's end.

Vitiligo Indication

Clinuvel is conducting two trials in the US in patients with non-segmental vitiligo, which is uneven discoloration of the skin and is particularly prominent in people with dark skin. Preliminary results from one arm of one of the open label studies in the US was presented at a scientific meeting last month.

Early observations are that Scenesse accelerates repigmentation. Current treatment is particularly onerous, requiring treatments three times a week for 18 months with narrow band ultra violet light (NB-UVB). Data from 15 patients showed that repigmentation started earlier when Scenesse was combined with NB-UVB, one week earlier and requiring 30% less NB-UVB treatment sessions. The combination therapy was shown to be highly effective in the African American population, with repigmentation close to 100% in some of this patient group.

The US trials are now in a completion phase and results should be released in coming weeks. The company is planning a Phase IIb trial in Europe and the US in around 100 patients. It's likely this trial will involve more implants of Scenesse (six compared to four in the current trials) with less frequent NB-UVB treatment (twice per week compared to three times per week in the current trials). The trials will take 10 months to complete after recruitment.

One of the aims of the trial is to have a less onerous and shorter therapy period with lower radiation exposure to the patients.

Summary

Clinuvel is building its case for the approval of Scenesse in Europe. That the drug is now in commercial use in Italy and that two

Cont'd over

Bioshares Model Portfolio (27 April 2012)

Company	Price (current)	Price added to portfolio	Date added
Osprey Medical	$0.40	$0.40	April 2012
QRxPharma	$1.77	$1.66	October 2011
Mayne Pharma Group	$0.310	$0.435	September 2011
Acrux	$3.99	$3.37	June 2011
Somnomed	$0.90	$0.94	January 2011
Phylogica	$0.050	$0.053	September 2010
Biota Holdings	$0.83	$1.09	May 2010
Tissue Therapies	$0.46	$0.21	January 2010
Atcor Medical	$0.08	$0.10	October 2008
Bionomics	$0.41	$0.42	December 2007
Cogstate	$0.305	$0.13	November 2007
Sirtex Medical	$6.40	$3.90	October 2007
Clinuvel Pharmaceuticals	$1.80	$6.60	September 2007
Pharmaxis	$1.30	$3.15	August 2007
Universal Biosensors	$0.79	$1.23	June 2007
Alchemia	$0.520	$0.67	May 2004

Portfolio Changes – 27 April 2012

IN:
We have added Osprey Medical at its IPO Offer Price ahead of its listing next week.

OUT:
No changes

Cogstate Builds Cash Reserves

After a decade or so of hard work, the pieces are all starting to come together for Cogstate (CGS: 30.5 cents).

A very strong December sales quarter translated into a correspondingly strong cash flow quarter in March. The company received $4.4 million from its customers, a net cash inflow of $2.1 million and it finished the quarter with $5.6 million in cash reserves.

The company's sales for the first nine months of this financial year were $9.3 million, a 66% improvement over the previous corresponding period.

CEO Brad O'Connor is confident its clinical trials will continue to expand. He said the company's technology continues to gain more acceptance from its customers with the company building its expertise in the clinical trials space.

Milestones to look out for include a licensing deal for the company's cognitive testing technology as a broad population-based dementia test. O'Connor remains confident that a licensing deal in this area with a major partner can be secured. The big picture goal for Cogstate is for its test to become available to every GP, worldwide, to aid in early diagnosis for illnesses such as Alzheimer's disease.

Cogstate's cash reserves place the company in a comfortable position to play its role in achieving this goal.

Cogstate is capitalised at $23 million.

Bioshares recommendation: **Buy**

Bioshares

– Clinuvel cont'd

major Swiss insurers have got behind the product does not mean the EMA will approve the drug. However this building support from patients, clinicians and payors will make it harder not to approve the drug.

Clinuvel is capitalised at $56 million. At the end of March it had $9.3 million in funds.

Bioshares recommendation: **Speculative Buy Class B**

Bioshares

How Bioshares Rates Stocks

For the purpose of valuation, Bioshares divides biotech stocks into two categories. The first group are stocks with existing positive cash flows or close to producing positive cash flows. The second group are stocks without near term positive cash flows, history of losses, or at early stages of commercialisation. In this second group, which are essentially speculative propositions, Bioshares grades them according to relative risk within that group, to better reflect the very large spread of risk within those stocks. For both groups, the rating "Take Profits" means that investors may re-weight their holding by selling between 25%-75% of a stock.

Group A

Stocks with existing positive cash flows or close to producing positive cash flows.

Buy	CMP is 20% < Fair Value
Accumulate	CMP is 10% < Fair Value
Hold	Value = CMP
Lighten	CMP is 10% > Fair Value
Sell	CMP is 20% > Fair Value

(CMP–Current Market Price)

Group B

Stocks without near term positive cash flows, history of losses, or at early stages commercialisation.

Speculative Buy – Class A

These stocks will have more than one technology, product or investment in development, with perhaps those same technologies offering multiple opportunities. These features, coupled to the presence of alliances, partnerships and scientific advisory boards, indicate the stock is relative less risky than other biotech stocks.

Speculative Buy – Class B

These stocks may have more than one product or opportunity, and may even be close to market. However, they are likely to be lacking in several key areas. For example, their cash position is weak, or management or board may need strengthening.

Speculative Buy – Class C

These stocks generally have one product in development and lack many external validation features.

Speculative Hold – Class A or B or C

Sell

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