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In this edition...
Pharmaxis received a unanimous rebuttal by an advisory panel formed by the FDA to examine its new drug application for Bronchitol for cystic fibrosis.
An issue was the purported efficacy of Bronchitol from the first Phase III trial (CF301), with the FDA's analysis based on an Intent to Treat (ITT) population, which showed that Bronchitol was no better than the control arm. In contrast, Pharmaxis used a modified ITT population, ignoring many subjects that dropped out of the trial, to prove efficacy. The FDA did not agree with Pharmaxis' approach and was critical of its methodology.
Quarterly sales reports have revealed the positive impact of a destocking effect at Nanosonics and the beneifits of three acquisistions in Europe for Somnomed.
Companies Covered: NAN, PXS, SOM, Cash Flow Analysis

	Bioshares Portfolio
Year 1 (May '01 - May '02)	21.2%
Year 2 (May '02 - May '03)	-9.4%
Year 3 (May '03 - May '04)	70.6%
Year 4 (May '04 - May '05)	-16.3%
Year 5 (May '05 - May '06)	77.8%
Year 6 (May '06 - May '07)	17.4%
Year 7 (May '07 - May '08)	-36%
Year 8 (May '08 - May '09)	-7.4%
Year 9 (May '09 - May '10)	50.2%
Year 10 (May '10 - May'11)	45.4%
Year 11 (May '11 - May '12)	-18.0%
Year 12 (May '12 - current)	-3.3%
Cumulative Gain	**234%**
Av. annual gain (11 yrs)	**17.8%**

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Bioshares

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

Pharmaxis – FDA Panel Rebuff Means Further CF Trial Likely for Bronchitol in US

Pharmaxis (PXS: $0.715) had its drug application for Bronchitol for the treatment of cystic fibrosis (CF) reviewed by an FDA drug advisory committee. All 14 members of the committee voted against recommending the drug for approval. Some panel members indicated if they were voting for approval in adults only then their decision may have been different.

FDA Issues with the Bronchitol New Drug Application

Prior to the advisory committee meeting the FDA released a Statistical Review document for the advisory panel. That document detailed some major concerns about the new drug application, with a negative panel decision a more than likely outcome.

There were two core issues the FDA has with Pharmaxis drug submission. The first was the exclusion of patients in the efficacy calculations who discontinued treatment within the first six weeks. The second was the rate of hemoptysis (coughing up of blood), in particular the higher rate in children than the control arm.

Treatment of Early Drop Outs

In the first Phase III study, the drop out rate in patients was very high, with 34% not making it through to the six month point. In the second Phase III study, 15% did not complete six months of treatment.

The issue for the FDA was that in the first trial, 12% of patients did not make it to week six, compared to 5% in the control arm. Pharmaxis wanted to exclude these patients from the efficacy calculations. At a pre-NDA meeting the company was told that "post-hoc analyses are often considered hypothesis generating, and conclusions of such analyses usually require confirmation in a subsequent study." So it's unlikely the FDA will accept this approach in its final decision and this is certainly the tone in the FDA briefing document and that reflected in the decision from the advisory panel.

Excluding the early drop outs, statistical significance was achieved in the first study in the primary measure of lung function, but not if the early drops were counted as failed treatments. In the second Phase III study, statistical significance was achieved when including the early drop outs. The drop out rate was much lower in the second Phase III study.

High Hemoptysis Rate

Hemoptysis is physiological event that occurs in people with cystic fibrosis. In these Phase III trials, people with a recent history of a major hemoptysis episode were excluded from the trial. People who could not tolerate Bronchitol were also screened out of the trials. A safety concern around hemoptysis was raised by the FDA and the advisory committee.

Cont'd over

There was little difference in the number of episodes of hemoptysis in adults in the safety study, with 10.6% reporting hemoptysis in the Bronchitol treatment arm, and 8.2% in the control arm (where patients received a low dose of Bronchitol).

However, the concern was in children, where 4% in the six to 11 years age group reported hemoptysis compared to none in the control group. And in those aged 12-17, 9.1% reported hemoptysis versus 3.1% in the control group.

The FDA had previously noted that normally new drugs are tested in an adult population first before moving into children. The FDA also made the point in 2007 that justification of the same dose in adults and children would need to be provided.

Comments/Analysis

The approach taken by Pharmaxis, in excluding those patients who discontinue treatment early (in the first six weeks), is understandable on one level. Bronchitol is being commercialised as a chronic therapy, not an acute therapy. Of the 30,000 people in the US with CF, physicians would be likely to quickly work out whether a CF patient could sustain therapy or not. So in working out whether this therapy is efficacious as a chronic therapy, not acute, those who can not tolerate the drug in the first six weeks arguably could be excluded.

However, the FDA made it clear that changing the goal posts once the results are in is not viewed favourably, and most drug developers would be aware of this stance. As a result, the view taken by the FDA, as detailed in the briefing document, should not have been unexpected. The requirement for an additional trial is now probable.

If Pharmaxis is required to conduct an additional trial in the US, our view is that the first additional trial will be in adults, given both the FDA and the EMA (European regulator) have taken the approach of analysing these two treatment groups (adults and children) separately.

Pharmaxis has learnt a lot from conducting two Phase III trials. The second Phase III trial had a much lower drop out rate than the first trial. It also has a better grasp about recruitment, and when baseline values should be taken for trial participants.

The issue of hemoptysis, where patients cough up blood, became important for the FDA panellists. Pharmaxis needs to provide a deeper understanding of this issue, including how common hemoptysis is in general in people with CF, how serious an issue is the bleeding, how 'temporary' it is, and if it in fact is a sign of efficacy in that the lungs are being cleared through the use the Bronchitol.

Given the concern about hemoptysis in children, another issue potentially for the company to explore is the dose and whether the same dose in adults is optimal for younger patients.

Pharmaxis Accesses $40 Million in Funding

After the advisory panel decision was given, Pharmaxis announced it had accessed funding of $40 million. The funding will come from NovaQuest Pharma Opportunities Fund III.

This is an unusual funding agreement for an Australian biotech company. NovaQuest will invest US$20 million in Pharmaxis in the next 30 days, and a further $20 million may be invested at Pharmaxis' option by the end of January 2014, based on the company achieving set regulatory and commercial milestones.

Rather than receiving equity in Pharmaxis as consideration, NovaQuest will receive a royalty from sales in Europe for eight years and for seven years from launch in the US. The royalty rate will be low single to low double digit royalty rates, depending on the funds invested and on Bronchitol sales

The funding achieves two things for Pharmaxis. Firstly it provides funding for a likely additional CF trial or trials in the US. The funding also serves as protection from an unsolicited takeover of the business with commercial returns from the Bronchitol asset now to be shared with NovaQuest.

Summary

In the event of a rejection from by the FDA on March 18, 2013, for Pharmaxis' new drug application for Bronchitol, which we consider to be highly likely, there will be a number of issues for Pharmaxis to address before it will be able to bring its drug onto the market in the US.

It will likely need to conduct an additional trial, starting probably in adults, and then exploring use of the drug in a second trial in people less than 18 years of age. The dosage in children may also need to be reviewed, in light of the higher rate of hemoptysis over the control arm. If additional trials are required, we expect this will defer market approval in the US by at least two and a half years.

The ability of patients to tolerate this drug has also shown to be an issue, which will impact on compliance and market adoption of the drug. The company will also need to provide a deeper understanding on the degree of hemoptysis in patients taking the drug.

Funding is not an issue for the medium term, with Pharmaxis maintaining access to around $100 million (the company had $65 million in funds at the end of December).

Bonchitol has now emerged as a drug (or drug candidate) with limitations and the commercial prospects for Bronchitol in the CF indication have been diminished as well as in all probability considerably delayed in the US. Convincing arguments in favour of holding the stock at current price levels have evaporated with uncertainy prevailing over the timing of future re-entry.

Pharmaxis is capitalised at $221 million.

Bioshares recommendation: **Sell**

Somnomed Posts Solid Topline Growth in December Quarter

Somnomed (SOM: $0.43) has delivered a solid headline result for the quarter ending December 31, 2012. Unit sales of the company's sleep treatment devices increased by 16% over the previous corresponding period (pcp), to 8,950. Revenue growth was higher, at 34% over the pcp, with the latest quarter sales of $4.85 million.

The reason why sales growth exceeded MAS (mandibular advancement splint) device sales was because of the acquisition of its distributor in Holland in January 2012, where sales from the distributor were included in the most recent quarter, but device sales to Holland were included both to the distributor in 2011 and direct in 2012.

Mixed Volume Growth Rates

Growth in unit sales in Europe was very good, increasing 26% over the pcp. In Asia, unit sales were reasonable, at 15%. North America, which contributes to around 60% of sales, was a little disappointing, growing at just under 12% by our calculations – disappointing because it is not in the 25%-35% target range that the company is aiming for.

Acquisition of Three European Distributors

The acquisition of three distributors in Europe in 2012 will help drive European sales and help the company secure its dominant position in that fractionated market. The company indicated that in January it started selling Somnomed devices through its recently acquired French distributor. The acquisition of the Dutch distributor a year ago has already had a meaningful contribution to sales. And the Swedish distributor acquisition will also contribute to sustained European growth. The company has more acquisitions it is considering.

The approach the company is taking in Europe is a tried and tested model, where it builds critical mass and local presence through acquisitions of smaller operators.

US Growth Challenges

In the US, the company has some challenges to sustain high growth which it is addressing. The company is in the process of reorganizing its sales and marketing team, which is moving from a dental only sales team to a dental and medical sales team.

The company currently has around eight internal sales staff in the US. Last year it appointed a new head of its North American Operations, Kien Nguyen, who has the task of moving the North American business from moderate growth back to high growth. The company expects recent changes to impact on North American sales from the second half of this financial year.

In the first half of FY2013, the company sold 17,180 devices. It generated a positive cash flow of $128,000 for the period. The company expects a stronger period in the second half, which generally contributes to around 55% of total sales.

Somnomed is capitalised at $43 million.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

Nanosonics Delivers a Quality Result as Destocking Effect Takes Hold

Nanosonics (NAN: $0.51) has reported a quality quarterly result. Sales increased by just 16% over the pcp to $3.2 million. Net cash outflow for the quarter was $1.85 million, up from a cash spend of $729,000 in the pcp. So what makes this a good result?

Sales in FY2012 increased to around $3 million a quarter. However this was assisted by inventory stocking orders from Nanosonics' partner GE Healthcare. In the first quarter of this financial year sales fell to only $1.2 million with GE making its way through its inventory built up in the previous four quarters. The latest December quarter result is the first indication of accelerated market demand in the US outside of initial stocking orders from GE.

Comparison with Somnomed

Comparing Nanosonics with Somnomed is worthwhile. Both companies increased sales by the same amount in the December quarter, although Somnomed's sales ($4.85 million) exceed those from Nanosonics. Nanosonics has a market value two times higher that Somnomed at $133 million. But the reason for that is Nanosonics' higher quality of sales.

By quality of sale, we refer to the threat from competition, both current and future, the requirements for customers to use products, and the repeat and compounding sales.

Nanosonics is seeking to make the Trophon system the gold standard globally for disinfection of ultrasound probes. It replaces unsafe chemical methods and has already become the gold standard of disinfection of probes in some regions including Australia. In Australia and New Zealand there are around 700 installed systems, representing around 30% market penetration. There is currently little threat to new competition (for Trophon) and flaws with existing alternatives.

Driver – Mandated Use

One of the major drivers to this technology is mandating use of the product by healthcare authorities. In Australia in some areas this is already the case, where healthcare practitioners are required to use the company's Trophon device to disinfect intra-cavity probes between use in patients.

The third reason for high quality of earnings is the business model for Nanosonics. The company sells the Trophon system, sells for around $5,000 to distributors. But it also sells consumables, including the hydrogen peroxide canisters, that can only be bought from Nanosonics. Consumable sales are currently around 50% of total sales. This model will see a compounding effect, where the more Trophon units it sells, the higher the total consumable sales will be.

Cont'd on page 5

4.7B Reporting Companies – Cash Balances December 31, 2012

Sorted by Survival Index

Code	Company	Cash Receipts ($M)	Nett Op. Cash Fl. ($M)	Cash End 31/12/12 ($M)		Survival Index	Comments/Events post reporting date
ACG	Atcor Medical	$4.25	$1.10	$2.14	A	**Not App**	
ACW	Actinogen	$0.00	$0.05	$0.30	A	**Not App**	Received tax refund during quarter of $290K
HCT	Holista Colltech	$3.08	$0.38	$1.26	A	**Not App**	
SOM	Somnomed	$8.90	$0.13	$3.54	A	**Not App**	
SIE	Scigen	$17.61	$0.48	$1.73	CY	**Not App**	
UBI	Universal Biosensors	$30.25	-$3.30	$23.65	CY	7.2	
AVX	Avexa	$0.00	-$0.88	$11.88	A	6.8	
NDL	NeuroDiscovery	$0.00	-$0.18	$2.26	A	6.3	
NEU	Neuren Pharmaceuticals	$0.00	-$1.50	$8.64	CY	5.8	
CDY	Cellmid	$0.29	-$0.21	$1.78	A	4.2	
RHT	Resonance Health	$0.80	-$0.14	$1.03	A	3.8	
NAN	Nanosonics	$5.36	-$3.53	$25.77	A	3.6	
MSB	Mesoblast	$0.00	-$25.37	$178.65	A	3.5	
VLA	Viralytics	$0.00	-$1.24	$8.15	A	3.3	
ADO	Anteo Diagnostics	$1.23	-$0.71	$4.20	A	2.9	
OSP	Osprey Medical	$0.00	-$5.38	$14.57	CY	2.7	
GID	GI Dynamics	$0.37	-$18.65	$49.43	CY	2.6	
PYC	Phylogica	$0.15	-$0.74	$3.63	A	2.4	
LBT	LBT Innovations	$0.00	-$0.50	$2.42	A	2.4	
IVX	Invion	$0.02	-$0.75	$3.43	A	2.3	(Formerly CBio)
RVA	Reva Medical	$0.00	-$17.84	$37.36	CY	2.1	
PXS	Pharmaxis	$1.54	-$15.95	$64.86	A	2.0	Signed $40 funding agreement with Novaquest Pharma Opp. Fund
BIT	Biotron	$0.00	-$1.59	$6.30	A	2.0	
AVH	Avita Medical	$1.62	-$3.65	$14.39	A	2.0	
PAB	Patrys	$0.00	-$1.62	$6.09	A	1.9	
CUV	Clinuvel Pharmaceuticals	$0.86	-$2.96	$10.11	A	1.7	
SPL	Starpharma	$0.32	-$10.24	$33.18	A	1.6	
BRC	Brain Resource Corp	$0.47	-$1.64	$5.11	A	1.6	
ANP	Antisense Therap.	$0.00	-$1.70	$5.10	A	1.5	
LCT	Living Cell Technologies	$3.43	-$0.82	$2.35	A	1.4	
OBJ	OBJ	$0.04	-$0.94	$2.70	A	1.4	
PRR	Prima Biomed	$0.00	-$9.90	$28.07	A	1.4	
QRX	QRxPharma	$0.00	-$6.04	$16.60	A	1.4	
BXN	Bioxyne	$0.27	-$0.21	$0.51	A	1.2	
BDM	Biodiem	$0.00	-$0.95	$2.33	A	1.2	
ACU	Acuvax	$0.01	-$0.22	$0.48	A	1.1	
IPD	Impedimed	$1.57	-$4.72	$9.65	A	1.0	
PBT	Prana Biotechnology	$0.00	-$4.55	$8.84	A	1.0	
GTG	Genetic Technologies	$5.26	-$3.13	$5.94	A	0.9	
ISN	Isonea	$0.02	-$2.13	$3.80	A	0.9	
GBI	Genera Biosystems	$0.03	-$0.67	$1.13	A	0.8	
BCT	Bluechiip	$0.04	-$1.03	$1.61	A	0.8	
SUD	SUDA	$2.33	-$0.81	$1.27	A	0.8	(Formerly Eastland Medical)
MGZ	Medigard	$0.00	-$0.13	$0.19	A	0.7	
AHZ	Allied Healthcare Group	$3.65	-$1.41	$1.99	A	0.7	Completed $2.9M Share Purchase Plan
BNO	Bionomics	$1.89	-$6.87	$9.25	A	0.7	Anticipates $4.2M tax refund and US$2M milestone pmt
UCM	USCOM	$0.42	-$0.70	$0.90	A	0.6	
IMI	IM Medical	$0.00	-$0.29	$0.33	A	0.6	
ALT	Analytica	$0.00	-$0.60	$0.61	A	0.5	Access to $400K Line of Credit
ACL	Alchemia	$1.57	-$7.71	$6.25	A	0.4	CEO resigned 25/1/13
BLT	Benitec	$0.28	-$1.77	$1.22	A	0.3	
CBB	Cordlife	$4.15	-$1.60	$1.09	A	0.3	Sold interest in Shandong Cord Blood Bank for US$8.65M
IMU	Imugene	$0.00	-$1.23	$0.74	A	0.3	
MLA	Medical Australia	$4.76	-$0.66	$0.31	A	0.2	
TIS	Tissue Therapies	$0.00	-$4.24	$1.97	A	0.2	
UNS	Unilife	$1.01	-$19.93	$8.06	A	0.2	Activated ATM facility to raise US$3.85M
CGP	Consegna Group	$0.00	-$1.26	$0.21	A	0.1	Tranche 2 of placement raised $192K; conducting SPP
AGX	Agenix	$0.00	-$0.58	$0.05	A	0.0	Accessing $5M funding (Fortrend Securities); $3M (Baycrest Capital)
BNE	Bone Medical	$0.00	-$0.54	$0.04	A	0.0	US$6M Convertible note facility with La Jolla Cove Invest. Part.
HTX	Healthlinx	$0.03	-$0.63	$0.04	A	0.0	US$9M Convertible note facility with La Jolla Cove Invest. Part.

Bioshares Model Portfolio (1 February 2013)

Company	Price (current)	Price added to portfolio	Date added
Psivida	$1.40	$1.550	November 2012
Benitec	$0.014	$0.016	November 2012
Nanosonics	$0.510	$0.495	June 2012
Osprey Medical	$0.64	$0.40	April 2012
QRxPharma	$1.00	$1.66	October 2011
Somnomed	$1.00	$0.94	January 2011
Cogstate	$0.350	$0.13	November 2007
Clinuvel Pharmaceuticals	$2.41	$6.60	September 2007
Universal Biosensors	$0.88	$1.23	June 2007
Alchemia	$0.320	$0.67	May 2004

Portfolio Changes – 1 February 2013

IN:
No changes

OUT:
No changes

4.7B Reporting Companies – Cash Balances Dec. 31, 2012 (Cont'd)

Legend:

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

A: The SI calculation for these companies is based on theaverage of the last half-year of NOCF, annualised.

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

Commentary

There were 60 ASX listed life science companies for which we tabulated cash flow receipts, net operational cash and for which we calculated Survival Index figures for the December quarter.

There were 22 companies which retained cash resources at December 31, 2012, sufficient to fund less than one year's worth of operational activities (based on previous spending patterns). There were 12 companies with less than six month's cash at hand.

Agenix, Bone Medical and Healthlinx, on the face of it, had the weakest cash positions at December 31, 2012. However, their access to lines of funding that can be accessed periodically, has and will continue to maintain the viability of these companies at a base level.

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

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

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

Small cap life science companies that are not required to comply with the 4.7B Rule include: Acrux, Advanced Medical Design and Manufact., Immuron, Bioniche, Cogstate, Circadian Technologies, Clovercorp, Compumedics, Cryosite, Cyclopharm, Ellex Medical Lasers, IDT, ITL Corp, Calzada, Medical Developments Int., Novogen, Optiscan Imaging, Progen Pharm. and Phosphagenics
Re-domiciled companies,pSivida and Heartware International no longer comply with the 4B Rule, as does Sunshine Heart

– Nanosonics cont'd from page 3

UK Disinfection Processes Under Review

Following the death in 2011 of a patient from an infection contracted from an ultrasound probe, the procedures for disinfection of ultrasound probes in Scotland and Wales are now being reviewed with England also to review ultrasound probe disinfection practices. Every NHS Hospital Trust is currently reviewing its probe disinfection processes according to Nanosonics. These reviews have the potential to have the Trophon product selected as the gold standard for probe disinfection in that region.

Another important feature of the Trophon system that other processes do not have is that it facilitates tracking of cleaning processes, which further reduces the risk of cross-contamination between patients.

Nanosonics is capitalised at $133 million.

Bioshares recommendation: **Speculative Buy Class A**

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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