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In this edition...
Swish, swish, swish goes the sound of the takeover rumour machine! What will come out of the wash surrounding the rumours that a bidder is on the prowl for Pharmaxis? We list six reasons why it might be given the once-over, including the relatively near term decision date in the US for Bronchitol for CF. On the other side of the ledger, ASX-listed life science companies have been making acquisitions of their own, ranging from Somnomed's very modest purchase of a French dental appliance company to Mayne Pharma's ambitious (up-to) US$120 million purchase of US private generics business Metrics Inc.
As ever with M&A, value and price are topical but the capacity to sustain and fund assets acquired will be issues for investors to consider.
Companies Covered: BNO, BLT, MYX, PXS, SOM

	Bioshares Portfolio
Year 1 (May '01 - May '02)	21.2%
Year 2 (May '02 - May '03)	-9.4%
Year 3 (May '03 - May '04)	70.6%
Year 4 (May '04 - May '05)	-16.3%
Year 5 (May '05 - May '06)	77.8%
Year 6 (May '06 - May '07)	17.4%
Year 7 (May '07 - May '08)	-36%
Year 8 (May '08 - May '09)	-7.4%
Year 9 (May '09 - May '10)	50.2%
Year 10 (May '10 - May'11)	45.4%
Year 11 (May '11 - May '12)	-18.0%
Year 12 (May '12 - current)	-12.6%
Cumulative Gain	**202%**
Av. annual gain (11 yrs)	**17.8%**

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

Rumours of Takeover Circle Pharmaxis

The Pharmaxis (PXS: $1.34) share price is being drawn into two directions at the moment. There are rumours that a takeover of the company may be in the planning, which has driven the share price up 25%. And the company just released the first quarter sale of Bronchitol, which shows a slow penetration rate into the Australian and European markets.

For a larger pharmaceutical company eyeing off Pharmaxis, it would be a opportune time to strike and launch a takeover bid. The initial sales of any new medical product is generally slow as the marketing campaign to clinicians begins. Marketing of a new drug can not start until product/marketing approval is received.

Pharmaxis released a response to an ASX query about its share price movement at the market close on Monday, stating that it was not aware of any reasons as to why the price had risen on high volume on Monday. In response to further questions at a conference call this week about the heightened recent interest in the stock, CEO Alan Robertson stated that the company had nothing further to add than what had been released to the market on Monday.

One interesting item to note is the last point the company made in its response to the ASX on Monday, saying that the company "…continues to explore all available options to capture the full value of its US new drug application for Bronchitol", which the company had discussed in previous quarterly reports.

In our view, there is a reasonable chance that there may be some grounds to market rumours of a potential takeover of the company.

Quarterly Update

In the UK market, Pharmaxis has started selling Bronchitol. At the moment patients need to seek reimbursement independently and wider adoption is not expected until the company gets the backing of NICE (the National Centre of Clinical Excellence).

Pharmaxis met with NICE at the start of September. An updated recommendation from NICE is expected in mid October. In June this year NICE viewed Bronchitol as not being cost effective. Pharmaxis has presented more health economic data around Bronchitol for the treatment of cystic fibrosis. While the company will not be dropping its price, one possible outcome is that if patients do not respond to Bronchitol after six weeks of treatment, then reimbursement may not be recommended. The company has found a correlation between non responders at six weeks at the same people not responding positively to therapy at six months.

Pharmaxis has trained 17 of the 27 specialist CF clinics in the UK, with all of the centres having been visited. Three hospitals are currently preparing formulary applications to

Cont'd over

allow it to access the drug for their patients. The company said there has been positive feedback from almost all centres visited.

Time to Penetrate Market
We expect the market take-up of Bronchitol will be gradual. The CF centres first need to be trained. The centres will need to identify which patients it thinks should be targeted first. Patients will need to be screened to ensure the Bronchitol powder does not cause agitation of the airways (which occurs in a small percentage of patients)

Robertson said the roll out of the drug in Australia and in Europe has been consistent with expectations.

Initial Sales
In the first quarter of this financial year, Bronchitol generated sales of $237,000.

Germany
In Germany there are 134 CF clinics. All centres have now been visited, with 83% trained and 40% having completed the initiation test on at least one patient. To date 6% of all people with CF in Germany have completed an initiation test. Robertson said the conversion from initiation to full access is excellent.

The price to the patient is 35 Euros per day, although this is not the ex-factory price for Pharmaxis, which is lower.

To date, 202 pharmacies in various regions have ordered Bronchitol, however it is unclear how many people with CF are now using the drug.

Australia
In Australia there are 3,000 people living with CF, and they are assisted at 22 CF clinics. The retail price in Australia is $31 per day. The drug is on all of the formularies and each state has already put in orders for the drug. At the moment around 100 patients are transitioning from special access scheme to paying through the PBS system.

Other countries
Bronchitol is also being sold into Austria, where there are 1,000 people living with CF, and Denmark, where only two centres look after the 500 people with CF. Robertson said there were no funding issues in Denmark for patients to get the drug. In France, the reimbursement process is currently underway and is expected to be completed in Q1 2013.

USA
In the USA, the FDA has specified 18 March 2013 as the target date for an assessment of Bronchitol for CF. It is like that an advisory panel will convene to review the drug application in January next year. Pharmaxis' first Phase III trial delivered a statistically significant positive outcome. The second Phase III trial narrowly missed achieving statistical significance.

Robertson was buoyed by last month's FDA panel decision to vote in favour of Novartis' new version of the tobramycin drug for CF, which similarly delivered a positive result in the first Phase III and then missed the endpoint in the second trial.

IP Protection
In response to a question about whether there will eventually be generics to Bronchitol, Robertson cited the multibillion dollar asthma drug Seratide. Seratide, also an inhaled drug, has been off patent for many years, still with no generic competitors, because drug blood levels are not a meaningful measure of equal comparison, so generics drug sponsors need to conduct their own clinical studies.

Synergies with Kalydeco
Vertex Pharmaceuticals' drug Kalydeco was approved by the FDA in January this year. It sells for a whopping US$294,000 a year, and is suitable for only a small subset of people with CF (4%). Robertson believes Bronchitol has natural synergies with Kalydeco, as patients on Kalydeco still require assistance to clear mucous, including physiotherapy and lung drainage.

Summary

Investors should not expect any massive surges in Bronchitol sales for the short to medium term. Bronchitol is a very effective drug in clearing mucous and in improving and maintaining healthy lung function in people living with cystic fibrosis. Bronchitol will very likely find its place as a chronic therapy for people with CF. However, there is likely to be an initial phase, where CF clinics and people with CF will need to be educated about the drug's benefits and those patients for whom it will be most suitable.

In the mean time, Pharmaxis is exposed to a potential takeover from a pharmaceutical company that is more patient than many share market investors.

Pharmaxis is capitalised at $413 million with $71 million in cash at the end of September.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

6 Reasons Why Pharmaxis Might be a Takeover Target

- Bronchitol approved for treatment of CF in Europe and Australia
- US approval for Bronchitol (CF) potentially in March 2013
- Opportunity to expand to a bigger market, bronchiectasis, which is six times larger than CF
- Slow initial sales penetration of Bronchitol in CF will place downward pressure on share price
- An estimated $360 million has been invested into Pharmaxis over the last 10 years
- Manufacturing has been set up in house, and sales and distribution networks are in place in Australia and Europe

Four Off-Shore Acquisitions

Company	Target	Headline Terms	Assets	Notes/Contingent Events
Bionomics (BNO)	**Eclipse Therapeutics**	**A$10 M**	ET101 antibody drug candidate, anticpated to enter clinic in 2014	Biogen Idec and others to hold 6.5% of BNO
Date Announced	Domicile	Cash Component	Prelinical data suggest anti-tumour activity as single agent and in combo	Shares escrowed for 6-12 mo
17/09/2012	USA (San Diego)	Unstated potential cash earnouts	US$2 M in seed funding; US$15 M spent earlier by Biogen Idec	Bionomics to invest $4 in San Deigo assets
Current SP	Description	Shares Issued (M)	Manufacturing agreement with Lonza	
$0.32	Cancer stem cell company spun out of Biogen Idec	23.9	Second compound ET102, a bi-specific antibody	
Current Capn.	Headcount	Shares Issued as %	Cancer stem cell assay technology	
$118	~3	**6.5%**		
Mayne Pharma (MYX)	**Metric**	**US$105 M**	Contract services business; product business, inc. distribution	Earn-out #1 of US$10 M is calculated at 6 X EBITDA to 30/6/13
Date Announced	Domicile	Cash Component	Revenues US$51.6M at 30/6/2012	
4/10/2012	USA (Greenville, NC)	US$15 M earnout	Gross margin 61.6%	
Current SP	Description	Shares Issued (M)	300 staff (150 chemists)	
$0.22	Manufacturer and distributor of generic medicines	325	9 current products plus 11 in development	Earn-out #2 of US$5 M is calculated on 2 X EBITDA >S$19.8 million to 30/6/13
Current Capn.	Headcount	Shares Issued as %		Break fee to Metrics of US$1.3 M
$105	300	**68%**		
Benitec Biopharma (BLT)	**Tacere Therapeutics**	**US$1.5 M**	Phase I/II-ready HCV program	Potential cash royalty on future licensing events
Date Announced	Domicile	Cash Component	Advanced pre-clinical program in macular degeneration	75% shares escrowed for 12 mo
11/10/2012	USA	$0.00		
Current SP	Description	Shares Issued (M)	Data and materials	
$0.016	RNAi therapeutics company	102.321345		
Current Capn.	Headcount	Shares Issued as %		
$17	1	**9.5%**		
Somnomed (SOM)	**Orthosom**	**€300 K**	Est. sales force, infrastructure	Acquired from Aliseo S.A.
Date Announced	Domicile	Cash Component	Orthosom oral products	Direct competitor or Narval, acq by Resmed in 2009
9/10/2012	France	€300 K		
Current SP	Description	Shares Issued (acquired)		Aliseo issued 35% stake in SOM French subsidiary with Aliseo acquiring €300K of SOM shares
$0.85	Manufacturer and distributor of oral appliances	35% stake in French subsidiary plus $460K shares		
Current Capn.	Headcount	Shares Issued (acquired) as %*		* Shares not issued directly, rather acquired
$36	10	**1.1%**		

Four Off-Shore Acquisitions

Over the last four or so weeks, four ASX-listed science companies have announced acquisitions of off-shore companies. Three businesses were located in the US and in Europe. If anything its proves that ASX companies are as active in M&A from a bidders point of view and see it as a normal aspect of doing business. Below we describe the four acquisitions and point out the key challenges facing the companies after they complete and bed down the acquisitions.

Bionomics/Eclipse Therapeutics

Bionomics (BNO: $0.33) acquired Eclipse Therapeutics in mid-September, paying $10 million in an all scrip deal. Eclipse is a San Diego company focused on developing drugs that target cancer stem cells. Eclipse was spun out of Biogen Idec, and the deal has resulted in Biogen Idec (with others) holding a 6.5% stake in Bionomics.

Eclipse's lead compound is a monoclonal antibody that binds to an unnamed cancer stem cell target. The antibody is expected to move into the clinic in 2014.

Bionomics' rationale for the acquisition was to expand its oncology pipeline beyond its lead cancer compound BNC105. Biomonics CEO Deborah Rathjen said the acquisition would "provide Bionomics with an important strategic base in the US, the world's largest pharmaceutical market."

Comment

The issue with Bionomics' acquisition of Eclipse is not to do with the focus of the technology on drugs that target the cancer stem cells, but on its decision to move into the cancer biologics area, an area which is entirely new for the company.

Antibody dug development is not the same as synthetic chemistry drug development because the manufacturing process is completely different, requiring cell culture systems to be developed and optimised for the best possible yields. It is generally more expensive and the process is heavily loaded at the front end (prior to entry in to clinical studies) in terms of time and cost.

Bionomics will make an investment of $4 million in its newly acquired San Diego assets this financial year. At June 30, 2012, Bionomics retained cash of $17 million. Bionomics anticipates receiving $10 in milestone payments from Ironwood Pharmaceuticals for progress made with IW-2143 over the next 18 months. Bionomics may not be factoring in such payments into its budget, but if it is it would be unwise. However, it should be also noted that Bionomics is very likely to receive more than $3 million in refunds from the R&D Tax Incentive Scheme.

One reading between the lines of Bionomic's acquisition of Eclipse Therapeutics is that the company is hedging its bets on the outcome of its trials of its small molecule cancer drug BNC105. This compound is being evaluated in a Phase II trial in renal cancer (152 patients) and a Phase I/II trial in ovarian cancer (134 patients). Results of the renal cancer trials are expected in mid-2013 and the ovarian cancer trial in mid-2014. If the results of the renal cancer trial are not strong enough to support the out-licensing of the compound then Bionomics will by that time be much closer to advancing ET101 (from Eclipse) into clinical studies in 2014.

A Phase II study of BNC105 that had been designed to enroll 60 patients with mesothelioma was discontinued after 30 patients had been treated.

Bioshares recommendation: **Speculative Hold Class B**

Benitec Biopharma/Tacere Therapeutics

Benitec Biopharma (BLT: 1.6 cents) will acquire Tacere Therapeutics, a California-based, privately held biotech company. Tacere has been commercialising ddRNAi technology which was licensed in October 2006 from Benitec but in the therapeutic areas of Hepatitis C and eye diseases. Tacere was founded by former staff members of Benitec, who had joined Benitec when it acquired Avocel Inc (Sunnyvale, California) in May 2004. Benitec acquired Avocel for 7.6 million shares or approximately 9% of issued capital, a consideration of $7.3 million.

Benitec will issue 102.3 million shares, representing 9.5% of issued capital, to acquire Tacere for a consideration of US$1.5 million. Additionally, a cash royalty on future licensing revenue may be payable.

Tacere's lead program is TT-034, a Hepatitis C therapeutic which had been partnered to Pfizer in 2008 but was returned to Tacere in 2012 following Pfizer's closure of certain operations in the UK. TT-034 is Phase I/II ready, with pre-clinical safety and toxicology studies completed.

Hepatitis C is an attractive opportunity for Benitec's gene silencing technology because it is a disease in which a permanent negation of the virus is desirable and because the market opportunity is very large and poorly served, with drug resistance a problem that eventuates with almost all chemical therapies. TT-034 targets three separate, highly conserved regions of the HCV genome, which means that resistance issues are likely to be less of an issue.

Benitec's challenge is to fund the Phase II trial of TT-034. However, the drug candidate has been de-risked sufficiently through its development program at Pfizer to warrant investment, with drug effectiveness being measurable potentially in a short time frame.

Although a pre-IND meeting with the FDA has been held, a further challenge is to submit an IND and to have it accepted by the FDA.

The Tacere acquisition represents a major step forward in value creation (or value re-capture) for Benitec.

Bioshares recommendation: **Speculative Buy Class A**

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Mayne Pharma/Metrics

Mayne Pharma (MYX: 22.5 cents) is acquiring privately held Metrics Inc, a contract pharmaceutical development company for US$105 million in cash with another US$15 million due on an earn out basis. The first earn-out payment of US$10 million is calculated at 6 times EBITDA to June 30, 2013, and the second earn-out payment of US$5 million is calculated on 2 times EBITDA in excess of US$19.8 million to June 30, 2013.

The full acquisition price of US$120 million occurs (i.e. the earn-out is triggered) if Metrics achieves an EBITDA for FY2013 of US$22.3 million, which would represent an acquisition multiple of 5.4 times. [Metrics' EBITDA for FY2012 was $US16.1 million.]

Mayne is funding the acquisition through a combination of debt and equity. It will raise $65 million though a mix of placements and a non-renounceable rights offer. It will further raise $US48.5 million in debt.

The equity raisings include an institutional placement, an institutional entitlement offer, a retail entitlement offer and a conditional placement to several directors of Mayne and certain Metric shareholders. The equity raisings are being done at 20 cents a share or a 20.3% discount to the 'theoretical ex-raising price' which is the 'theoretical price at which Mayne Pharma shares should trade immediately after the ex-date for the equity raising'. Otherwise the raising is being conducted at a 33% discount to the 20 day average share price prior to the announcement.

The acquisition is expected to close on November 15, 2012. The total cost of the transaction but excluding earn-outs, in Australian currency, is $109.6 million, comprising $102.6 million in payments to vendors and transaction fees of $7 million.

Acquisition Rationale

The arguments stated by Mayne in favour of the acquisition are that it provides direct access to the world's largest pharmaceutical market in the US, strengthens and diversifies Mayne's revenue streams across contract services, generic and proprietary products, and expands and diversifies Mayne's pipeline of new products. The acquisition also will facilitate the cross-selling of Mayne products through the Metrics network in the US, and in vice-versa through the Mayne network in Australia.

Comments

Mayne investors should be asking three questions about the Metrics acquisition: Is it a good business? Is Mayne paying a fair price for the target company? Will Mayne's board and management be able to manage the combined operations of the enlarged entity?

Metrics generated revenues of US$24.1 million from its contract services business in the 12 months ending June 30, 2012 and US$27.5 million in revenues from its generic drug manufacturing and distribution business for the same period.

Gross margins for these two business segments were 62% and 61% respectively (or 61.6% for the business overall). By way of comparison, Mayne Pharma's gross margin for the same period, but across its entire business, was 46%.

These margins indicate that Metrics is a superior business to Mayne Pharma with its scale of operations, its integrated structure and its sales focus on the US generics market contributing to these margins.

Mayne is paying a sales multiple of 2.3 times (assuming performance hurdles for FY2013 are met), implying that Metrics has and will continue to grow revenues at a healthy rate and is therefore willing to pay a premium of sorts for that growth. Businesses with low residual growth typically sell on a multiple of 1 times sales or less.

The two businesses are similar in many respects and synergies can be expected to be exploited going forward. This may result in some activities being wound down in Australia or even conversely expanded, depending on the analysis of combined operations future opportunities. One synergy already identified is that Mayne will be able to access Metrics' expertise in the pain drug area. Another will be to funnel work for Metric's contract manufacturing customers into Mayne's under-utilised facility in Salisbury, South Australia.

An attraction for Mayne is that Metrics offers a mature sales and distribution platform in the US. This, for example, may change Mayne's approach to its commercialisation strategy for SUBACAP, its improved formulation of the anti-fungal drug itraconazole.

The challenge for the enlarged company is to develop generic products which compete with only one or two other drugs (including generics and the original branded product).

While the acquisition appears to be made on reasonable terms, the question of integration at the board and management level is the more difficult one to answer. The addition of the President of Metrics, Phil Hodges, to the Mayne board is a positive move. However, the success of the acquisition will be improved if the Mayne Pharma board makes room for, and is in fact dominated by members with deep experience in the pharmaceutical industry, especially generic drug development and marketing. It is also crucial that the board doesn't initiate changes to Metrics operations which could cause the loss of skilled and experienced staff.

One consideration for investors is to ask what are the implications for Mayne Pharma if its revenues from Doryx sales fell again. Doryx revenues accounted for 40% of Mayne's revenues in FY2012. Although Doryx revenues fell by 46% in FY2011 and have held up somewhat, the threat to the revenue line and the issue of revenue dependency on Doryx is the point to note. Another major fall in Doryx revenues, if nothing else changed in the Mayne business, would in all likelihood result in a major decline in Mayne's share price.

Bioshares recommendation: **Speculative Hold Class A**

Cont'd over

Bioshares Model Portfolio (12 October 2012)

Company	Price (current)	Price added to portfolio	Date added
Nanosonics	$0.500	$0.495	June 2012
Osprey Medical	$0.31	$0.40	April 2012
QRxPharma	$0.75	$1.66	October 2011
Somnomed	$0.85	$0.94	January 2011
Phylogica	$0.025	$0.053	September 2010
Biota Holdings	$0.69	$1.09	May 2010
Tissue Therapies	$0.42	$0.21	January 2010
Bionomics	$0.33	$0.42	December 2007
Cogstate	$0.350	$0.13	November 2007
Sirtex Medical	$9.99	$3.90	October 2007
Clinuvel Pharmaceuticals	$1.60	$6.60	September 2007
Pharmaxis	$1.34	$3.15	August 2007
Universal Biosensors	$0.90	$1.23	June 2007
Alchemia	$0.590	$0.67	May 2004

Portfolio Changes – 12 October 2012

IN:
No changes

OUT:
No changes

Somnomed /Orthosom

Sleep apnea dental appliance company Somnomed (SOM: $0.85) has acquired a French dental appliance company, Orthosom, the second largest in the French sleep apnea dental appliance market after Resmed's Laboratoires Narval. Resmed acquired Laboratoires Narval SA in October 2009 for €8 million and contingent payments of €2 million. Resmed introduced the Narval CC product into the US in June 2012.

Somnomed paid €300,000 for Orthosom in addition to a 35% share of Somnomed's French (Somonomed France) subsidiary to the French vendor Aliseo SA. In turn, Aliseo SA is to purchase €300,000 worth of Somnomed scrip (~460,000 shares).

The deal supplies Somnomed with an established distribution and sales infrastructure into which it can slot its Somnodent products. Somnomed received regulatory and reimbursement approval for its Somnodent product in France in July 2012.

Somnomed Executive Chairman Dr Peter Neustadt said that acquisition was a step that would save time and money. For a small cash outlay that has been re-invested in Somnomed, Somnomed is in a stronger position to sell its products into Europe's second largest healthcare market.

Somnomed's Somnodent product sells for €300-€350 in France, with reimbursements to dentists around €200 under that countries public health insurance program.

Somnmed had worked on achieving its French regulatory and reimbursement goals for more than year. Prior to the acquisition, the company's view was that it would be a good achievement to breakeven in that market in 2013/14 but accepts that it takes three years to break even in new markets. With the acquisition in place, the likelihood of getting to break-even has increased.

Europe accounted for 27% of Somnodent's unit sales in FY2012 (of ~15,000 units). These sales largely occurred in the Scandinavian and Benelux countries. Sales into Germany still remain low with the German public health insurers, which represent 90% of the insured population, still not reimbursing the device.

The point for investors to take note of is that France and Germany represent a very large growth opportunity for Somnomed, and more so if reimbursement becomes more widely available in Germany.

Somnomed's acquisition of Orthosom is both attractive price wise and logical, boosting the company's market access in France in terms of time to market as well as in terms of a physical footprint.

Bioshares recommendation: **Speculative Buy Class A**

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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