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Bioshares

1 November 2013
Edition 527

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

Unexpected Bonus for Universal Biosensors

The Commonwealth Government's 45% R&D tax rebate is proving to be a very valuable and helpful feature for many Australian biotech companies. To be eligible, however, the catch is that companies must be generating less than \$20 million in annual revenue. For Universal Biosensors (UBI: \$0.60), while investors are disappointed that revenues for this year are unlikely to match the \$30 million achieved in 2012, the good news is that UBI now expects to receive a \$5-\$6 million rebate in 2014 for this calendar year (UBI's financial year ends December 31).

The drop in revenue for UBI is good on another level for the company. UBI manufactures glucose test strips for its partner Lifescan. For the first nine months of this year, revenue fell by 73% over the previous corresponding period, from \$14.6 million to \$8.6 million. However, this is a very low margin revenue stream, delivering a 7% gross margin last year and only a 1% gross margin this year.

Lifescan Facility in Scotland

In October this year, Lifescan announced that it was installing a second manufacturing line in Scotland, which brings its capacity up to 1.5 billion strips a year. It was always understood that Lifescan would conduct the lion's share of the manufacturing according to the CEO of UBI, Paul Wright. In fact, UBI assisted Lifescan, for a fee, to replicate UBI's own facility, in Scotland.

The key metric to measure for UBI is its service fee, which equates to around US 1 cent for each strip that Lifescan sells. There are about 17 billion electronic glucose strips sold each year and Lifescan sells about 4.5 billion of those. If Lifescan was to convert all of its customers to the UBI designed strips, which are used in the OneTouch Verio meters, then it would equate to an annual service fee to UBI of US\$45 million a year.

At the current capacity of Lifescan's plant, that equates to an annual service fee of US\$7.5 million for each of the two manufacturing lines. Lifescan had a recall issue in mid 2013 because its meters would not send an alarm for extremely high glucose levels but that has now been corrected. This caused strip sales to fall from a UBI service fee of \$840,000 (or around 88 million strips assuming exchange rate at the end of the quarter) for the March quarter, to \$760,000 (70 million strips) in the June quarter and rebounding to \$883,000 (an estimated 82 million strips sold) in the September quarter.

Factors at Play in the BGM Market

There are a number of factors in play at the moment in the blood glucose monitoring market. There is pressure on pricing in the US market, with Medicare (servicing those over the age of 65 years) reducing reimbursement by more than 60%, low price generic players have entered the market although are not expected to make a significant impact, and there is some shift occurring to other distribution channels such as mail orders.

Cont'd over

	Bioshares Portfolio
Year 1 (May '01 - May '02)	21.2%
Year 2 (May '02 - May '03)	-9.4%
Year 3 (May '03 - May '04)	70.6%
Year 4 (May '04 - May '05)	-16.3%
Year 5 (May '05 - May '06)	77.8%
Year 6 (May '06 - May '07)	17.4%
Year 7 (May '07 - May '08)	-36%
Year 8 (May '08 - May '09)	-7.4%
Year 9 (May '09 - May '10)	50.2%
Year 10 (May '10 - May '11)	45.4%
Year 11 (May '11 - May '12)	-18.0%
Year 12 (May '12 - May '13)	3.1%
Year 13 (May '13 - Current)	66.6%
Cumulative Gain	493%
Av. annual gain (13 yrs)	20.4%

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– UBI cont'd

However, the regulators are tightening standards, requiring better accuracy and improved performance. This should benefit the larger, established players, and for UBI it may be beneficial as it may see Lifescan focusing more on its newer OneTouch Verio products (Verio) that UBI designed rather than the older OneTouch Ultra (Ultra) product range from Lifescan.

The Verio strips designed by UBI offer significant cost advantages to the existing Ultra products from Lifescan. Presumably this only applies when Verio strip production reaches a more economical level. For that to occur, diabetic customers need to convert over to the Verio meters, which will take time for an estimated four million people to do (this figure assumes each customer uses three strips a day). Based on current strip sales, about 7% of Lifescan's customers have been converted to Verio meters so far.

As mentioned above, the most important metric for investors to monitor with UBI at the moment is the quarterly service fee, which equates to strip sales. Any acceleration of Verio strip sales that generates over \$1 million a quarter (\$883,000 last quarter) in service fees for UBI should be matched with an acceleration in UBI's share price.

Continuous Glucose Measurement Competition

Abbott, Medtronic and DexCom have had continuous glucose measuring systems approved by the FDA. These systems involve the insertion of a small sensor under the skin, with the readout displayed on a meter worn on the belt. This approach is more expensive than using glucose strips but is obviously more convenient to users. However these monitors are not as reliable nor as accurate as glucose strips, and as such, it is recommended that patients confirm blood glucose levels using a glucose meter (and strips) according to the NIH. It is expected that continuous glucose measurement may address around 10% of the market.

The rate at which diabetes is diagnosed in the US continues to grow at alarming rates. According to the CDC, in 1995, only three states in the US had greater than 6% of the population diagnosed with diabetes. In 2010, all 50 states in the US had more than 6% of their populations diagnosed with diabetes.

This trend suggests the demand for glucose testing will continue to increase.

Siemens Collaboration - Launch Delay

UBI is developing four new blood coagulation testing products with its partner Siemens. Recently UBI announced that the launch of the first product, a PT/INR used in warfarin titration, would not occur this year. That launch has now been extended by six months and is now expected by the end of June 2014.

The reason for the delay is the difficulty in recruiting patients with large INR levels (the high-end bleeders) into the clinical trial to validate the accuracy of the test. According to Wright, Siemens has a large team working on the launch of these products. In Europe, Siemens will self-certify through a CE Mark process, and in the US the product will be filed for approval under a 510k. We expect the product to be launched in Europe first.

Although warfarin has been under competition from oral Factor Xa anticoagulants such as Xarelto, at the Ausbiotech's Biotech Invest 2013 conference this week, the point was made by one panelist that there was pushback from some doctors in prescribing this new class drugs because of their high cost, which suggests the very large warfarin market will exist for some time to come.

UBI spent \$12.8 million on R&D in the last nine months. The reason for the high spend is because the company wants to capture more value from the coagulation products. UBI will sell the strips to Siemens, which we expect will be very profitable for UBI, and it will also be entitled to a profit share if the products are very successful. Wright said the company's R&D spend will fall when each of the coagulation products are released.

UBI is due to receive four more milestone payments which we estimate is worth \$6 million in total. Wright estimated that the coagulation testing products may be worth as much as the glucose testing business to UBI in the future.

At Home Testing Product

The collaboration with Siemens is for use of the diagnostics in the hospital setting. UBI is independently commercialising a product for use outside of the hospital, including at home by patients. The company has developed a prototype meter and is signing up distributors. We expect a European launch for this product in the second half of 2014.

Summary

We expect UBI's quarterly service fees from Lifescan to increase steadily each quarter, reaching \$1 million a quarter we estimate either the December 2013 or March 2014 quarters. These fees are essentially an ongoing royalty stream for UBI. The company will benefit from up to \$6 million in an R&D rebate next year. There are up to an estimated \$6 million in milestone fees due from the Siemens collaboration, and we expect at least two product launches next year, these being the PT/INR tests by Siemens and the other by UBI.

UBI has been sold down to very attractive levels due to the six month delay in the launch of the Siemens PT/INR product. The fall in revenue from manufacturing glucose strips for Lifescan should be viewed as positive in light of the very small margins and that UBI is now eligible for the R&D tax rebate.

Whilst there is some pressure on pricing in the US in the glucose strip market and some competition emerging from continuous glucose testing products, the 17 billion glucose test strip business is unlikely to contract with the growing numbers of diabetics diagnosed. Lifescan's decision to install a second glucose test strip manufacturing line confirms its interest in the Verio products.

UBI is capitalised at \$105 million and retained \$14.7 million in cash at the end of September.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

US Biotech Trends and Implications for Australian Biotechs and Investors

More than 250 investors attended the **2013 Ausbiotech Biotech Invest** conference which was held in Melbourne this week. The keynote address was given by Eric Shiozaki from the UK funds management group **Aposite Capital**. Some of the key points made in that presentation should be of interest to readers and are summarised below.

Shiozaki offered a US perspective of the biotech industry and trends. The biotech sector was in a troublesome time in 2009, with financial markets in disarray, skyrocketing US unemployment, a looming patent cliff for pharmaceutical companies and a declining US venture capital industry.

However, four years later, the Nasdaq Biotech Index (NBI) is now trading at all-time highs. Biotech IPOs are performing said Shiozaki, with the 45 companies that have listed since 2012 now up 80% on average, and the NBI is up 101% since 2012. The pricing of biotech IPOs has also improved. In 2010 and 2011, biotechs needed to offer a 45% discount to their valuation to list, but in 2012 and 2013, the discount has only been 14%, with improved pre-money valuations as well. Shiozaki noted that the recent IPOs had been particularly strong in the US. Shiozaki said there is strong demand for high quality IPOs in the US and there is relatively low short (selling) interest in the US at the moment.

One of the drivers of this positive environment in the US has been the flow out of bonds and into equity markets. Another important factor has been the plethora of new, game changing drugs that have reached the market. "Highly innovative drugs are making it to market", said Shiozaki. Shiozaki listed the following drugs that through 'real innovation' have generated 'real excitement':

- o Yervoy (melanoma)
- o Eylea (wet AMD)
- o Kalydeco (cystic fibrosis)
- o Kynamro (an antisense drug for the treatment of high cholesterol)
- o Incivek (triple therapy for hepatitis C)
- o Brilinta (prevention of stroke and heart attack)
- o Eliquis (anticoagulant)
- o Zytiga (metastatic prostate cancer)
- o Xtandi (metastatic prostate cancer)
- o Xalkori (kinase inhibitor cancer drug for lung cancer (NSCLC))
- o Tafenlar (kinase inhibitor for melanoma)
- o Perjeta (metastatic breast cancer)
- o Kyprolis (Multiple myeloma, developed by Onyx Pharmaceuticals and since acquired by Amgen for US\$10.4 billion)
- o Erivedge (basal cell carcinoma)
- o Mekinist (metastatic melanoma)
- o Kadcyla (HER2-positive metastatic breast cancer)
- o Belviq (obesity)
- o Xeljanz (a kinase inhibitor for rheumatoid arthritis)
- o Tecfidera (relapsing multiple sclerosis)
- o Breo Ellipta (COPD)
- o Invokana (type 2 diabetes)

Of the above list, 10 of the drugs are for the treatment of cancer, which shows a high level of interest in cancer drug companies and also arguably a push by the FDA to give patients with cancer more therapeutic options.

Shiozaki said there is more to come with all-oral Hepatitis C regimens approaching, PCSK inhibitors (for cardiovascular indications), and PD-1 inhibitors in cancer immunotherapy as programs to monitor.

36 NCEs Approved in 2012

In a panel session that followed Shiozaki's address, Josh Funder from GBS Venture Partners noted that there were 36 new chemical entities approved in 2012 (which is a high number) and that three of those came from GBS investee companies. Funder said that innovation is driving payment and that they (payors) are very disinterested in me-too drugs. GBS has had two of its investee companies list in the US, with one due to list (Celladon), with a gene therapy approach to heart failure. (This week Celladon announced it would increase its IPO raise to US\$92 million).

Funder said 2013 is the strongest year since 2000 but the hot money is yet to be moving into venture capital. Shiozaki agreed with fewer VCs and less capital available. Shiozaki said venture capital is out of favour with LP (limited partner) investors. By way of example, CALPERS, which has an alternate investment portfolio of US\$49 billion, had a VC target allocation of 7% in 2010 and that target allocation has dropped to only 1%. However, some LPs are increasing their target allocations. An example Shiozaki cited was the Oregon Public Employees Retirement Fund, with US\$62 billion under management, increasing its VC allocation target from 16% to 20% in July this year. In a positive development in the VC industry, on Friday this week Orbimed announced the closing of a US\$735 million medical device fund.

Shiozaki said that with no (major) innovation, there are no pharmaceutical type premiums, with pricing more similar to generics. Me-too type products are not as easy to develop with more competition in the US market according to Shiozaki.

Breakthrough Therapy Designation

Shiozaki said that the FDA is evolving. In July last year the FDA released a new 'breakthrough therapy' designation for drugs seeking to meet important unmet clinical needs. Shiozaki said this is a move by the FDA to bring 'superior drugs to market sooner'. Under this designation, there is the potential to get drugs to market with only Phase I/II data only.

To date, 27 breakthrough therapy designations have been awarded with 41 applications being rejected. Shiozaki said we are likely to see the first drug approved under this category. That in fact occurred on Friday this week with Genentech's drug Gazyva approved for the treatment of untreated chronic lymphocytic leukemia. Genentech generated positive results in a 356 patient trial.

Shiozaki believes the FDA is positioning itself to work more closely and collaboratively with the industry.

Cont'd on page 4

4.7B Reporting Companies – Cash Balances September 30, 2013

Sorted by Survival Index

Code	Company	Cash Receipts (\$M)	Nett Op. Cash Fl. (\$M)	Cash End 30/09/13 (\$M)	Survival Index	Comments/Events post reporting date	
1	ACG Atcor Medical	\$2.29	\$0.18	\$3.23	A	Not App	
2	LCT Living Cell Technologies	\$2.69	\$0.16	\$4.76	A	Not App	
3	NDL Oncosil Medical	\$0.00	-\$0.35	\$10.78	A	15.0	
4	SOM Somnomed	\$0.00	-\$1.07	\$3.29	A	9.8	
5	PAA Pharmaust	\$0.00	-\$0.39	\$3.51	A	6.3	
6	RHT Resonance Health	\$0.00	-\$0.16	\$0.93	A	5.2	
7	MSB Mesoblast	\$0.00	-\$22.69	\$292.15	A	4.6	
8	NAN Nanosonics	\$0.00	-\$1.77	\$22.15	A	4.4	
9	AVX Avexa	\$0.00	-\$0.96	\$10.63	A	3.6	
10	OBJ OBJ	\$0.00	-\$0.54	\$5.26	A	3.6	
11	SPL Starpharma	\$0.00	-\$2.45	\$31.48	A	3.2	
12	ADO Anteo Diagnostics	\$1.82	\$0.74	\$3.27	A	2.6	
13	RGS Regeneus	\$0.00	-\$0.38	\$10.26	A	2.6	
14	LFC Life Corporation	\$0.00	-\$0.34	\$7.33	A	2.4	
15	ISN Isona	\$0.01	-\$2.09	\$12.65	A	2.3	
16	PBT Prana Biotechnology	\$0.00	-\$3.08	\$20.02	A	2.2	
17	HCT Holista Colltech	\$1.43	-\$0.46	\$1.15	A	2.0	
18	BRC Brain Resource Corp	\$0.27	-\$0.60	\$4.26	A	2.0	
19	PRR Prima Biomed	\$0.00	-\$4.81	\$31.37	A	1.9	Suspended Phase III CANVAS trial following -ve Phase II trial results
20	LBT LBT Innovations	\$0.00	\$0.91	\$1.78	A	1.9	
21	GID GI Dynamics	\$1.28	-\$28.19	\$70.89	CY	1.9	
22	CUV Clinuvel Pharmaceuticals	\$0.19	-\$1.46	\$11.14	A	1.7	
23	PXS Pharmaxis	\$0.00	-\$10.13	\$53.41	A	1.5	
24	BNO Bionomics	\$0.67	-\$5.86	\$16.83	A	1.4	
25	OSP Osprey Medical	\$0.00	-\$5.96	\$10.20	CY	1.3	Completed \$14 M placement
26	RVA Reva Medical	\$0.00	-\$16.88	\$27.88	CY	1.2	
27	PAB Patrys	\$0.00	-\$1.30	\$3.80	A	1.2	
28	AVH Avita Medical	\$1.04	-\$1.89	\$8.69	A	1.2	
29	CDY Cellmid	\$0.57	-\$0.43	\$1.65	A	1.2	
30	UCM USCOM	\$0.00	-\$0.36	\$1.22	A	1.1	
31	UBI Universal Biosensors	\$12.88	-\$10.18	\$14.67	CY	1.1	Expects to receive \$5-6 M tax rebate for CY13 (in CY14)
32	ANP Antisense Therap.	\$0.00	-\$0.91	\$3.11	A	1.0	
33	BIT Biotron	\$0.00	-\$1.27	\$3.52	A	1.0	
34	BCT Bluechiip	\$0.00	\$0.08	\$2.27	A	1.0	Completed \$1.02 Tranche 2 of capital raising
35	BLT Benitec	\$0.12	-\$5.03	\$6.18	A	1.0	
36	PYC Phylogica	\$0.00	\$0.00	\$1.78	A	0.9	
37	SUD SUDA	\$1.98	-\$0.49	\$1.55	A	0.9	
38	SIE Scigen	\$16.50	-\$2.15	\$2.52	CY	0.9	
39	CGP Consegna Group	\$0.00	-\$0.09	\$1.54	A	0.8	
40	ACL Alchemia	\$3.44	-\$2.57	\$10.16	A	0.8	Received \$8.8 M R&D Tax Refund
41	IPD Impedimed	\$0.68	-\$1.59	\$5.62	A	0.8	
42	VLA Viralytics	\$0.00	-\$1.75	\$3.32	A	0.7	Received \$1.9 M R&D Tax Refund
43	QRX QRxPharma	\$0.00	-\$3.42	\$8.51	A	0.7	
44	NEU Neuren Pharmaceuticals	\$3.59	-\$3.83	\$2.76	CY	0.5	Completed \$21.5 M placement
45	AHZ Allied Healthcare Group	\$2.20	-\$1.12	\$1.72	A	0.4	Closed a \$10.4 M capital raising
46	MLA Medical Australia	\$2.15	\$0.01	\$0.26	A	0.4	To acquire stem cell vet company Medivet for \$11 M
47	IVX Invion	\$0.01	-\$1.41	\$1.75	A	0.4	In-licensed zafirlukast from AstraZeneca; to pay \$0.5 M license fee
48	BDM Biodiem	\$0.00	-\$0.55	\$0.62	A	0.3	To delist from the ASX
49	AGX Agenix	\$0.02	-\$0.27	\$0.39	A	0.3	Divested AGX-1009, US\$2M to be paid in 3 tranches
50	TIS Tissue Therapies	\$0.00	-\$2.25	\$2.63	A	0.3	Undertaking capital raising
51	IMU Imugene	\$0.00	-\$0.19	\$0.38	A	0.3	Raised \$2.5 M; Acquired Biolife Sciences Qld
52	MGZ Medigard	\$0.00	-\$0.04	\$0.05	A	0.2	
53	GTG Genetic Technologies	\$1.03	-\$2.47	\$1.80	A	0.2	Has received a commitment from u/w for \$0.5 M
54	UNS Unilife	\$1.00	-\$10.11	\$10.15	A	0.2	Access to US\$22.5 M loan facility
55	BXN Bioxyn	\$0.36	-\$0.16	\$0.10	A	0.1	Received \$0.4 M R&D Tax Refund
56	ACW Actinogen	\$0.00	-\$0.13	\$0.02	A	0.1	To be recapitalised
57	ACU Acuvax	\$0.00	-\$0.01	\$0.03	A	0.1	
58	GBI Genera Biosystems	\$0.01	-\$0.43	\$0.11	A	0.1	Issued \$0.129 M Convertible Notes
59	BNE Bone Medical	\$0.00	-\$0.04	\$0.00	A	0.0	Monthly payments from funding partner delayed
60	ALT Analytica	\$0.00	-\$0.58	-\$0.02	A	0.0	Received \$0.5 M R&D Tax Refund

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 the average of the last five quarters of NOCF, annualised.

CY: The SI calculation for these companies is calculated on the average of the last three quarters of NOCF, annualised.

Bioshares Model Portfolio (1 November 2013)

Company	Price (current)	Price added to portfolio	Date added
Imugene	\$0.022	\$0.022	November 13
Oncosil Medical	\$0.125	\$0.155	September 13
Calzada	\$0.075	\$0.073	September 13
Invion	\$0.115	\$0.060	August 13
IDT Australia	\$0.430	\$0.260	August 13
Viralytics	\$0.340	\$0.300	August 13
Circadian Technologies	\$0.245	\$0.270	March 2013
Tissue Therapies	\$0.250	\$0.255	March 2013
Benitec Biopharma	\$0.580	\$0.40	November 2012
Somnomed	\$1.24	\$0.94	January 2011
Cogstate	\$0.445	\$0.13	November 2007
Universal Biosensors	\$0.60	\$1.23	June 2007

Portfolio Changes – 1 November 2013**IN:**

Imugene has been added to the portfolio, following its acquisition of Biolife Sciences Qld. See last week's edition of Bioshares for discussion.

OUT:

No changes.

4.7B Reporting Companies – Cash Balances September 30, 2013 (Cont'd)**Commentary**

There were 60 ASX listed life science companies (a year ago, 61) for which we tabulated cash flow receipts, net operational cash and for which we calculated Survival Index figures for the September quarter.

There were 24 companies which retained cash resources at September 30, 2013, sufficient to fund less than one year's worth of operational activities (based on previous spending patterns). There were 17 companies with less than six month's cash at hand.

The positive impact of Commonwealth Government's R&D Tax Incentive scheme with more companies recognising refunds in their cash flow statements. At least five companies recorded refunds in the September quarter and another four have received refunds post September 30, 2013. Universal Biosensors (see story on page 1) expects to receive a \$5-6 million refund next year.

It also also worth noting three capital raising completed after the end of the quarter, with Neuren Pharmaceuticals taking advantage of an exuberant share price to raise \$21.5 million, Allied Healthcare raising \$10.4 million on the back of very solid progress and Osprey Medical raising \$14 million for current and future product development.

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. pSivida, a re-domiciled company, does not comply with the 4B Rule.

– Shiozaki cont'd

Tips for the Australian Biotech Sector

Shiozaki said Australian biotechs should focus on building great companies with innovative biology and strong management teams. Local companies should seek to establish leadership in novel biology classes and diseases, such as in stem cell therapies, companies should understand their value proposition, leverage their proximity to Asia, and to do some 'home cooking', with Australia a place where Phase I studies can be conducted swiftly and cost effectively relatively to other western countries. And pharmaceutical companies are increasingly outsourcing R&D so biotechs should use this trend to their advantage.

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 last five quarters ending September 30, 2013, into each company's cash assets as recorded at September 30, 2013. For companies that report on December 31 full year basis, the index is based on the last three quarters 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 than 0.5 may be in positions of funding stress and investors should investigate such stocks with a greater degree of concern.

Phosphagenics TPM-Oxymorphone Phase I Trial

Phosphagenics (POH: \$0.135) recently completed a second Phase I trial of its TPM-Oxymorphone patch. The trial was designed to study the safety and pharmacokinetics (pk) profile of multiple applications of the patch. Oxymorphone is an opioid-class pain drug.

According to the company's filing of trial information on the Australian New Zealand Clinical Trials Registry (ID ACTRN12613000932763), the trial enrolled 12 healthy subjects. Each subject received four 3-day transdermal patches. Each patch contained 56.8 mg of oxymorphone.

The reference drug, and potential competitor, for TPM-Oxycodone is Opana ER, which is marketed by Endo Pharmaceuticals. Opana ER is an oral formulation which comes with black box warnings concerning abuse potential and life threatening respiratory depression. Opana ER is indicated for the relief of moderate to severe pain in patients requiring continuous around-the-clock opioid treatment for an extended period of time. Opana ER comes in seven different strengths, ranging from 5 mg to 40 mg, with dosing recommended every 12 hours. Hence, the maximum daily dose is 80 mg, or 240 mg over three days. This could be contrasted to Phosphagenics' patch delivering 56.8 mg over three days.

Phosphagenics said that its Phase I repeat dosing trial showed it could deliver oxymorphone to achieve a maximum plasma concentration in subjects, as 'high as that produced by a single oral dose of the highest strength Opana ER tablet (40 mg)'.

What the company did not include in its announcement of the Phase I trial results were the actual figures for plasma concentration, specifically the peak value (the C_{max} value), as well as the AUC figure, which is a measure of bioavailability. The company should have been able to present time series data, given that each subject in the trial had 59 blood samples collected over the 12 day trial.

The communication of such data would have enabled investors to make a meaningful comparison with data included on the Opana ER drug label.

Phosphagenics' lack of transparency concerning its most recent clinical trial announcement is very disappointing, especially given that it described the trial results as surpassing expectations. We iterate our opinion expressed in earlier editions that the board should be fully replenished so that the company be overseen by a board unencumbered with supervisory links to the fraud discovered at the company this year.

Phosphagenics is capitalised at \$138 million.

Bioshares recommendation: **Sell**

Bioshares

Pharmaxis Takes Second Tranche of NovoQuest Funding

Pharmaxis (PXS: \$0.13) has elected to take up an additional US\$20 million in funding from the NovoQuest Pharma Opportunities Fund III, following the receipt of US\$20 million in January 2013. The funding will not actually be received until the first patient is randomised into its Phase III cystic fibrosis trial for Bronchitol, sometime in 2014, but before 17 October 2014.

Novoquest will ultimately receive compensation that equates to low double digit royalties, given that the full US\$40 million has been sought.

The decision to take up the additional NovoQuest funding sends a signal that Pharmaxis is possibly is not completely confident of licensing the North American rights for Bronchitol for CF on the terms that it would prefer.

This decision by Pharmaxis, in our view, greatly reduces the chance that a prospective licensing partner might make a bid for Pharmaxis, as suggested in *Bioshares* 525, and in which we assumed a licensee or acquirer would take on the clinical trial and registration costs needed to get Bronchitol to market.

While a partner may have tolerated a revenue entitlement to NovoQuest from sales of Bronchitol in European territories, even paying it out, the combined European and US obligations to NovoQuest make the Bronchitol for CF asset far less appealing.

We reverse our recommendation made in *Bioshares* 525 and place a Sell on the stock.

Pharmaxis is capitalised at \$40 million

Bioshares recommendation: **Sell**

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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