

In this edition...

The late Stephen Covey penned a very useful guide to living, 'The Seven Habits of Highly Effective People'. He could well have written a book titled 'The Seven Habits of Highly Innovative Companies', with a key chapter headed, "Begin with the Business Process in Mind", mimicking the original chapter, "Begin with the End in Mind." The business process in the microbiology departments of pathology labs is what LBT Innovations targeted 3 years ago, to yield an automated plate assessment system. It has finalised a joint venture with Hettich AG of Switzerland to advance commercialisation of the system and this week it became the beneficiary of an ARC Linkage Grant to develop a suite of follow-on products.

Companies Covered: GID, LBT, POH, 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 - May '13)	3.1%
Year 13 (May '13 - Current)	5.7%
Cumulative Gain	276%
Av. annual gain (12 yrs)	16.6%

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Bioshares

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

LBT Innovations – Adds Another Productivity Tool to the Microbiology Lab

LBT Innovations (\$0.08) has received an ARC Linkage Grant to develop follow-on products for its Automated Plate Assessment System (APAS). This follows its recently announced tie-up with **Hettich AG Switzerland** to establish a 50:50 joint venture (JV) vehicle to develop the APAS.

LBT Innovations with its partner, the **Australian Centre for Visual Technologies (ACVT)**, has received a grant of \$510,000 from the Australian Research Council's Linkage Grants Program. LBT Innovations will contribute an equal sum of \$510,000 to the project. However, LBT Innovations will receive a world-wide exclusive perpetual license from the ACVT parent body, the **University of Adelaide**.

The Automated Plate Assessment System arose from a collaborative program between the ACVT and LBT Innovations, which commenced in 2010.

The APAS is an optical recognition system which uses mathematical processes to categorize agar plates which are used to culture samples for identification of bacterial pathogens. Agar plate technology was first developed in 1887 and its use has remained largely unchanged since then.

The APAS technology automates a procedure that is currently a manual and time consuming task in pathology labs. APAS can decide if a plate has significant growth, how much growth there is and assign an identification category. Approximately 60% of plates routinely do not require attention. By way of example, a 3,000 plate a day facility employs 12 lab technologists to process plates. APAS could theoretically be deployed to reduce that staff commitment by at least 50%. The APAS system could in time be improved to identify some bacterial infections with greater certainty.

Features of the JV

LBT Innovations has received an upfront payment of \$2 million from Hettich AG. Hettich will inject \$4 million into the JV in different stages to develop products for commercial launch. Separately, Hettich will invest in various hardware and the robotic elements necessary for full product development.

Cont'd over

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The JV will operate under the name 'Clever Culture'. LBT Innovations' Vice President of Global Business Development, Peter Bradley, will take on responsibility for the JV and the relationship with Hettich. He will also be tasked with identifying routes to market for the system. Several options at this stage include partnering with the Hettich parent company in Germany, aligning with a single whole of world distributor or developing a marketing alliance with an agar plate supplier.

Hettich AG Switzerland

Hettich AG Switzerland is a privately owned Swiss company. It is an affiliate of the family owned German company Andreas Hettich AG GmbH. Hettich manufactures equipment used in medical scientific laboratories including centrifuges, incubators, freezers, ovens and evaporators under their own label as well as on an OEM basis. However, Hettich's main offering in the microbiology market is an automated incubator. The Hettich group employs 600 people with 400 people in manufacturing roles.

APAS – LBT's Second Technology

The APAS is the second technology that LBT Innovations has developed. The first, a plate streaking technology, now sold as Previ Isolea by **bioMerieux**, has been a source of some frustration for LBT Innovations, given that this larger partner has substantial marketing and market development control over the product.

The JV arrangement with Hettich, in contrast, is much more satisfying for LBT Innovations, giving the company 'a bit more say in the destiny of the technology', according CEO Lusia Guthrie. The JV links a highly capable engineering firm to a smaller company with strong connections to the microbiology lab. The JV also means that LBT is exposed to more risk (and potentially capital demands) in the development of the APAS.

Development and Approval Pathway

LBT Innovations estimates that it will take between 12 and 18 months to finalise development of the APAS product. The process will require trials demonstrating the specificity and sensitivity of the finished product, to support either a PMA or 510 (k) *de novo* approval from the FDA. CE Mark and TGA approval will also be sought.

Market Opportunity

The market opportunity for the APAS is a function of the number of laboratories which process tests for bacterial infections on a volume basis. These labs are typically independently run or hospital-based facilities.

LBT Innovations estimates there are 28,000 facilities which represent the broadest market for the APAS. If low volume labs are excluded (<400 plates a day), the figure decreases to 15,000. Of these an estimated 1,200 facilities process in excess of 10,000 plates a day. This is the core market that the joint venture must target and dominate.

However, the potential addressable market is expanded where these facilities operate more than one agar plate incubation unit. It is expected that the JV could sell 2-3 APAS units for every one installed Previ Isolea system. It also expected Hettich will be con-

tributing its incubator to the APAS sales package.

There is a distinct upper limit constraint to unit or volume potential of the addressable market. However, it would make sense for product pricing to be based on a savings/value created model in which annual labour costs are displaced by automated systems. A value based pricing model could yield valuable returns to the joint venture. The price of an APAS unit may be in the order of \$150,000-\$200,000, with final pricing still to be established.

Workforce Demographics

A second driver for adding productivity tools into the pathology business is that most workers are older. The task of replacing them is complicated by younger workers being more selective (not necessarily rationally) about employment and career options in laboratory-based workplaces.

One interesting aspect of the pathology sector is that unlike some industry sectors in high-cost first-world economies which have exported jobs to lower cost off-shore destinations, the vast bulk of pathology services have been fixed to specific geographies and localities. An implication of geographic rigidity is that the demand for technology to provide productivity solutions is high.

Status of Royalties from Previ Isolea

bioMerieux now has 400 Previ Isolea instruments installed on world-wide basis. The uptake of this product, which was launched in 2009, was greatly slowed by the impact of the GFC. Royalty revenues from bioMerieux were \$0.58 million in FY2012 compared to \$0.43 million for the previous corresponding period, with the total to December 31, 2012 being \$1.8 million. LBT Innovations has yet to exceed its minimum royalties agreement with bioMerieux.

Funding and Finance

LBT Innovations held cash of \$1.6 million at March 31, 2013. Its cash position has been boosted by the receipt of the upfront payment from Hettich of \$2 million. Allowing for the ARC Linkage Grant commitment, LBT's cash position we estimate to be closer to \$2.5 million.

LBT Innovations is a modestly run organisation. Its expertise is in designing productivity solutions for the microbiology lab. To speed up its goal of developing new products it may seek fresh capital. However, LBT Innovations now has a track record for innovation and has greatly expanded its partnering know how. This means that its ability to attract new investors, if desired, should be much improved.

Summary

LBT Innovations suits the patient investor with an appreciation for value creation from the application of innovative thinking in the microbiology lab. Investment gains over the long term are the appeal with this stock.

LBT Innovations is capitalised at \$8 million.

Bioshares recommendation: Speculative Buy Class B

Bioshares

Somnomed Confirms US Turnaround With Record Quarter Sales

Somnomed (SOM: \$1.045) had flagged in April that it had issues it needed to resolve in its US operations. This week the company had confirmed that a turnaround in that region was occurring. The company achieved record sales of its oral appliances used in the treatment of sleep disorders with over 10,000 devices sold globally in the June quarter. And there is more 'turnaround' on the way according to the company.

US Sales

Sales in the US increased by 10% in the June quarter over the previous corresponding period, which was a stark improvement on the March quarter, which by our calculations was less than the December quarter unit sales. For FY2013 the company sold 35,841 devices (which sell for around \$500 each), which was up 16% on the previous year.

The problem in the US was that some of its sales and supply processes were not performing which meant the company had lost customers. However, it is now getting those customers back with a new and expanded management team in place. Somnomed has a medical marketing initiative directed to sleep physicians in place and it expects to start to see results from this second half of 2013.

European Sales

Sales in Europe remained very strong, up 36% over the previous corresponding quarter. Sales growth in Japan increased 31% from a low base in the June quarter and Asia Pacific sales were up 9%.

Acquires German Company

Somnomed also announced this week it had acquired its licensee in Germany, called **Orthosleep19 GmbH**. The acquisition comes with around nine staff. The licensee sells less than 200 devices a

month, primarily the Somnomed devices. Orthosleep19 operates as a licensee rather than a distributor. Somnomed also has licensees in Canada and the US. The licensees manufacture Somnomed devices under license. Orthosleep19 had reached a point where it could not keep up with orders and had Somnomed manufacture some of its devices as well.

Somnomed has a long and established relationship with the owner of Orthosleep19, Mr Konrad Hofmann, who was the inventor of the proprietary flex polymer material that is now incorporated in the company's Somnodent products to make the fitting more comfortable for users. Mr Hofmann also owns 50% of the company that manufactures the flex material (**SMH Biomaterials**, which stands for Soft Materials Hofmann).

There are a number of benefits from the acquisition. The first is that the company will now have direct access to the customers in Germany (dentists). It will also be able to manufacture the devices at a lower cost base at its facility in Manilla. And it will be better positioned to seek reimbursement in Germany, which is very poor, working with its dental network customer base. At present there is no government reimbursement for CPAP devices or oral appliances such as the Somnodent products.

Another positive for Somnomed in the year ahead is the strengthening US dollar, with the company generating an estimated 60% of its revenue from North America.

Somnomed is capitalised at \$45 million.

Bioshares recommendation: **Buy**

Bioshares

GI Dynamics Raises \$57.5 Million

GI Dynamics (GID: \$0.59) announced this week that it has received investment commitments to raise \$57.5 million. Those funds will give the company around \$74 million, which should be sufficient for the company to complete its 500 patient pivotal US study which is now underway, and for working capital requirements.

The capital raising, which is part dependent on shareholder approval, places the company in a solid financial position as it continues with the global rollout of its EndoBarrier treatment for people with Type 2 diabetes and obesity.

The company is also offering a share purchase plan which could raise up to \$2.5 million.

GI Dynamics is capitalised at \$233 million (assuming the completion of the placement).

GID will be covered in more depth in the next edition of *Bioshares*.

Bioshares recommendation: **Speculative Hold Class B**

Bioshares

Bioshares Model Portfolio (5 July 2013)

Company	Price (current)	Price added to portfolio	Date added
Atcor Medical	\$0.072	\$0.082	May 2013
Circadian Technologies	\$0.240	\$0.270	March 2013
Tissue Therapies	\$0.125	\$0.255	March 2013
Benitec Biopharma	\$0.014	\$0.016	November 2012
Nanosonics	\$0.720	\$0.495	June 2012
Somnomed	\$1.05	\$0.94	January 2011
Cogstate	\$0.345	\$0.13	November 2007
Universal Biosensors	\$0.76	\$1.23	June 2007

Portfolio Changes – 5 July 2013

IN:
No changes

OUT:
No changes

Phosphagenics CEO Suspended

The board of Phosphagenics (POH:10.5 cents) has suspended Dr Esra Ogru from her position of Co-CEO following the discovery of what appears to be irregular transactions in relation to its invoicing and accounting records.

POH is capitalised at \$107 million and has funds on hands of \$14.1 million.

We are placing the stock under review pending the outcome of the board’s finalisation of its investigation.

Bioshares recommendation: **Under Review**

Bioshares

Corrections - Bioshares 509

Capital Raisings

Prima Biomed raised a total of \$6.17 million from its SPP; Progen Pharmaceuticals raised a total of \$5.19 million from its rights issue; Consegna advised that it received a total of \$0.381 for its options rights issue; The total funds received during the quarter was \$67.1 million.

Index Table

The year on year per cent change for Viralytics was -8%, not -91%.

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, Impedimed, QRxPharma, LBT Innovations, Mesoblast, Tissue Therapies, Viralytics, Phosphagenics, Phylogica, Bluechiip, pSivida, Antisense Therapeutics, Benitec BioPharma, Allied Healthcare Group, Calzada, Bioniche, Atcor Medical, Invion, Circadian Technologies

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