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In this edition...
Starpharma's BV development program for Vivagel could be another case study in how get it right as an Australian drug developer. The strategy is to develop a drug as effective as rivals but offer superior features on the safety, convenience or compliance front. Vivagel doesn't indiscriminatly kill bacteria – a good thing – but has a treatment rate on par with antibiotics.
QRxPharma, which is in the home straights towards a licensing deal, has developed a combination pain drug which reduces the side effects associated with equi-analgesic doses of morphine and oxycodone. Other drugs developed, or being developed, according to this strategy, include Acrux's Axiron and Mayne Pharma's SUBACAP.
The Editors
Companies Covered: HCG, GTG, PRR, QRX, SOM, SPL

	Bioshares Portfolio
Year 1 (May '01 - May '02)	21.2%
Year 2 (May '02 - May '03)	-9.4%
Year 3 (May '03 - May '04)	70.0%
Year 4 (May '04 - May '05)	-16.3%
Year 5 (May '05 - May '06)	77.8%
Year 6 (May '06 - May '07)	17.3%
Year 7 (May '07 - May '08)	-36%
Year 8 (May '08 - May '09)	-7.3%
Year 9 (May '09 - May '10)	49.2%
Year 10 (May '10 - May'11)	45.4%
Year 11 now commenced	-26.9%
Cumulative Gain	**208%**
Av. annual gain (10 yrs)	**21.2%**

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Blake Industry & Market Analysis Pty Ltd
ACN 085 334 292
PO Box 193
Richmond Vic 3121
AFS Licence
No. 258032

Enquiries for *Bioshares*
Ph: (03) 9326 5382
Fax: (03) 9329 3350
Email: info@bioshares.com.au

David Blake
Ph: (03) 9326 5382
Email: blake@bioshares.com.au
Mark Pachacz
Ph:03 9348 9317
Email: pachacz@bioshares.com.au

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Bioshares

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

Clear Path to Market for Starpharma's BV Product

Starpharma (SPL: $1.165) recently swapped its marketing partner for its Vivagel coated condoms from **Reckitt Benckiser** to Australian based **Ansell**. It delays the launch of the product by around 12 months and Starpharma's new partner has a smaller market share. Although the change is disappointing for shareholders, Starpharma's bacterial vaginosis (BV) program has become the main focus for the business.

Earlier this month Starpharma received the green light from the FDA for its planned Phase III studies in BV. Starpharma was very pleased with the agreed structure of these trials, including the agreed endpoints. The trials will be similar in design to its successful Phase IIb trial. This paves a clear path forward for commercialisation of Vivagel for the treatment of BV.

This is potentially a very lucrative asset for Starpharma. If the company can repeat its results from its Phase IIb studies in the two pivotal studies involving around 220 women each, then it will access a US$350 million a year market, of which around US$250 million is in the US. And that is for treatment alone. The market for the prevention of BV is even larger, estimated by the company at over US$1 billion a year.

Starpharma's Vivagel will compete against a range of oral and topical antibiotic products which all have their shortfalls. For instance, metronidazole has been shown to be carcinogenic in mice, can not be taken with alcohol and does not have antiviral activity. Also beneficial to Starpharma is that the metronidazole gel and the clindamycin cream are still branded products, costing between $90-$120, so its main competition is not against budget generic products. The other problem with antibiotics is that they indiscriminately destroy all bacteria, which can result in secondary fungal infections.

Phase IIb Trial Results

In the Phase IIb trial in BV, the 1% Vivagel solution was shown to achieve a 74% clinical cure in the days after treatment, and a sustained cure (two to three weeks after treatment) of 46%. These were statistically significant results. They were also in line with treatment results from antibiotics of between 35%-65%. Vivagel was applied once a day for seven days.

Phase III Trials

Starpharma will start the Phase III trials later this year or in early 2012. The trials will not be long, taking around six months to recruit, with only one week to treat and two weeks follow-up. It is expected results will be available by the end of 2012. The company is seeking to get the product on the market in 2014.

Starpharma will license the product to a partner. It has interest from potential partners already. There is the possibility the company could have an agreement in place before the completion of the trial, pending positive trial results.

Cont'd over

Patent

Starpharma has found that the 1% dose delivered a better result than the higher and lower dose. It seems that giving too high a dose can upset the balance in normal vaginal flora and restrict efficacy. Starpharma has filed a patent on the 1% strength for treating BV, potentially extending out protection to 2032.

Prevention of BV

Starpharma will also likely look to run pivotal studies in the prevention of BV. A Phase IIb study commenced in August this year. The company will likely need to raise further funding to conduct a prevention study.

Condom Microbicide Product

Starpharma has two partners for its condom microbicide products. In Japan, it has partnered with Okamoto Industries, which has around 60% of that market. Ansell has around a 20% rest of the world market share. Ansell has a fast growing condom business, around 20% a year, and that it is based in Australia significantly simplifies the collaborative arrangement.

Starpharma was not its former partner's only issue, following the acquisition of its condom business SSL last year. It has since had major manufacturing and legal issues with its Indian condom manufacturer. Starpharma has been quick to exit a poorly functioning licensing arrangement with Reckitt Benckiser, that can largely be attributed to a company integration fallout.

It is expected that microbicide condom sales should start in the second half of 2012.

Other Programs

Starpharma has a raft of early stage R&D collaborations to apply its dendrimer chemistry technology to the improvement of compounds in multiple industries. These include the improvement of pharmaceutical products, agricultural products and even animal health products.

It is working with a range of agrichemical and pharmaceutical companies around improved product properties. Some of these have not been announced because they are at an early stage. Its collaboration with Eli Lilly has been expanded several times, according to CEO Jackie Fairley.

Starpharma may also take its own drug reformulation program into the clinic, that being a form of docetaxel with a substantially improved absorption profile. It does not use detergents and therefore the side effect profile should also be better.

Summary

To its credit, Starpharma has been able to progress the commercialisation of Vivagel for the treatment of BV rapidly. After serendipitously observing the effect Vivagel had in treatment of BV in Vivagel in a safety trial in 2009, in just three years it may be in a position to have a product that could be ready to be filed for approval (end of 2012).

While its condom microbicide product has been delayed, revenues are expected to start later next year. Other collaborative and in-house programs should also progress into the clinic in the next one to three years.

At the end of September Starpharma had $17 million in cash. Starpharma is capitalised at $289 million.

Bioshares recommendation: **Speculative Accumulate Class A**

Bioshares

Prima Biomed's European Manufacturing Facility Gets Green Light

Prima Biomed (PRR: 19 cents) this week received clearance for its manufacturing facility in Germany which will process material for the company's forthcoming Phase III trial with CVac. Prima is looking to start its pivotal Phase III study by year end of its cancer vaccine in women with ovarian cancer. The study will enrol up to 1,000 patients in 22 countries. Recruitment is expected to be completed in early 2013, with the primary aim to assess a benefit in progression free survival versus the placebo arm.

The study will be conducted in Australia and the US, and with the majority of patients (around 70%) expected to be recruited to the trial in Europe. The trial will involve around 150 centres.

Phase III Trial Design

The trial will recruit women with ovarian cancer who have completed debulking surgery to remove the majority of the tumour load. Prior to chemotherapy, trial participants will undergo leukapheresis to allow an autologous (patient specific) vaccine to be prepared for the course of the treatment.

Patients will then undergo chemotherapy. If the patients achieve complete clinical and radiological remission, they will start treatment with their specific CVac vaccine. The trial participants will be equally divided into a placebo and a CVac treatment group.

The aim is to ensure 800 women initiate treatment in either group. Patients will receive six doses of CVac, once a month for the first three months, then every quarter for the next nine months.

Experienced Drug Commercialisation Team

Over the last three years, Prima has put together a very experienced drug development and commercialisation team. Its CEO, Martin Rogers, has been able to articulate the Prima story well and raise substantial funds from local and international investors. The company has installed Lucy Turnball as Chairman. Ian Frazer is on Prima's Advisory Board Chairman. His brother Neil Frazer is the Chief Medical Officer with 25 years drug development experience. Matthew Lehman is based in Europe and has had experience in over 100 clinical trials. Dr Sharron Gargosky, based in the US, is running the CVac program. She has been involved with three successful orphan drug approvals.

Dubai Sales to Commence this Year

Earlier this year Prima received approval to sell its vaccine in Dubai. The company expects to treat its first patient in Dubai by year end. Rogers sayid Dubai has the best medical infrastructure in the Middle East. The aim is to develop a first class 'on-shore' medical treatment in Dubai, rather than having to travel overseas, and CVac fits in with that larger strategy for Dubai.

For Prima, Dubai will be a pilot commercial program. The revenues will not be the key output. Prima will have the potential to expand the use of this vaccine into treatment of other cancers that over-express the mucin-1 protein. These include breast cancer, renal cancer, lung cancer and pancreatic cancer. The cancer vaccine will be made in Melbourne for Dubai at the Peter MacCallum Cancer Institute.

Prima recently announced the completion of enrolment in its Phase II ovarian cancer study. Interim results from this study are expected to be presented at ASCO next year. Progression-free survival data is expected to be reported in late 2012 or early 2013.

Summary

Prima is now well funded, having raised $41 million earlier this year, with a bank balance of $51 million at the end of September. Those funds are sufficient to take the company out to 2014. Prima is capitalised at $192 million. Its current cash burn rate is $1.4 million per month.

Milestones

- Phase III 1,000 patient ovarian cancer trial to start - Q4 2011
- Sales of CVac in Dubai to start - Q4 2011
- Interim results from Phase IIb study to be presented - May 2012
- Final results from Phase IIb study -Late 2012
- Recruitment completed in Phase III CVac trial - Q1/Q2 2013

Bioshares recommendation: **Speculative Buy Class B**

Bioshares

QRxPharma – Gaining Momentum

Shares in QRxPharma (QRX: $1.61) posted an 11% gain this week on the back of a 9% gain in the previous week. The momentum in the stock is likely to continue in the lead up to the company executing a partnering deal for its immediate release version of MoxDuo for the treatment of moderate-to-severe pain before the end of the year. The company has flagged that has an interest in structuring a co-promotion deal in North America.

QRxPharma submitted a New Drug Application to the FDA in August 2011. The FDA's response is expected to be received in mid 2012.

MoxDuo combines two opioids, morphine and oxycodone, in 3:2 ratios e.g. 18mg morphine:12 mg oxycodone. The drug has been shown to decrease side effects associated with equivalent doses of morphine and oxycodone by between 50%-75%.

What makes a deal potentially attractive to a pharmaceutical marketing partner is the fallout in the pain medication market which will see at least an annual 100 million scripts for immediate release pain drugs disappear from the market. This is a consequence of the FDA's decision in January 2011 to limit any combination drug to a maximum of 325mg of acetaminophen (known as paracetamol in Australia) per dosage unit because of the potential for severe liver damage, with a three year phase out for higher dose forms. For 2010, there were 131.2 million prescriptions written for hydrocodone/acetaminophen combination drugs and 31.9 million scripts for oxycodone/acetaminophen combination drugs. An estimated 100 million prescriptions of hydrocodone/acetaminophen combination products contain more than 325mg acetaminophen per dosage unit.

QRxPharma has argued that efforts by pharmacists or others to copy its now successfully demonstrated ratios will be difficult to achieve, given that the standard dose forms of morphine and oxycodone do not lend themselves to combination (presumably requiring inconvenient manipulation). However, a major barrier for would-be copiers is that the use of separate drugs demands twice the re-imbursement paperwork, and aslo exposes potential legal liability issues.

In our view, QRxPharma is well-placed to secure a partnering deal in the US for MoxDuo IR. However, what remains to be seen is if the company elects to trade off a higher up-front payment for lower royalties at the back end of the deal.

QRxPharma is capitalised at $240 million and retained cash of $32 million at September 30, 2011.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

Stock Briefs

Genetic Technologies (GTG: $0.14) – Chasing PPOs for Brevagen

Genetic Technologies launched the Brevagen predictive risk test for breast cancer in women in June 2011. The test combines genetic information with non-genetic information (such as age at live-first-birth, age at menarche) to support doctors as they manage the health of their female patients. The market opportunity is one million 'at risk' biopsy patients per annum.

Initial marketing activities since launch include contacting 800 physicians and placing 600 test kits. On the payment front, which is the most important element of the commercialisation process for any pharmaceutical or medical device or diagnostic company, the company has begun a credentialing process with *preferred provider organisations* (PPOs).

In the US healthcare system insurance schemes are associated with healthcare management schemes. Within the *health maintenance organisation* system there is less choice, with most care emanating from a network provider. Under the PPO framework, there is more choice for insured parties to select from a range of preferred providers. However, (according to GTG) the top ten PPOs represent more than 60% of covered lives, which is why Genetic Technologies has begun a credentialing process with those groups.

On the IP assertion side of the business, covering its rights over aspects of non-coding DNA for genetic analysis, Genetic Technologies expects to defend its property until 2022, and also claiming six years prior infringement where applicable. The company generated $14 million in revenues from this estate in FY2011 and can expect to garner $5.5 million in settled contracted annuities to 2015.

The company continues to look for distressed assets to purchase.

Genetic Technologies recorded receipts of $2.4 million for the September quarter and a net operational cash flow of -$1.3 million. Genetic Technologies is capitalised at $65 million and held cash of $14.8 million at September 31, 2011.

Bioshares recommendation: **Speculative Buy Class A**

Somnomed (SOM: $1.16) – A Seasonal Easing in Quarterly Sales Volumes

Somnomed released sales figures for the September quarter. Unit sales of its SomnoDent dental appliance product slipped in the quarter by 8%, to 6,732 units, influenced by the northern hemisphere holiday season. However, on a moving annual total basis, unit sales increased by 28% to 26,585 units. SomnoDent is used to treat mild-moderate sleep apnea.

Growth was stronger in Europe, up 45% in the September quarter from the same quarter in 2010, compared to the US where unit sales increased by 24%. Compared to the September quarter 2010, gross margins increased from 64% to 66%.

During the quarter, Somnomed received official registration and assignment of a PDAC reimbursement code, which allows US Medicare registered dentists to receive re-imbursement from patients covered by Medicare. This gives the company access to 46 million people aged 65 and over who are covered by the US Government's Medicare insurance program, or approximately 15% of the total US population. The official registration completes the initial coverage determination by Medicare made in January 2011. Coverage by other insurance providers often follows the lead taken by Medicare.

The primary driver for sales of dental appliance sleep apnea units is poor compliance with continuous positive air pressure devices. However, insurance coverage in the US is essential in also driving acceptance of Somnomed's products.

Somnomed is capitalised at $47 million and retained cash of $3.75 million at September 30, 2011.

Bioshares recommendation: Speculative Buy Class A

Helicon Group (HCG: $0.019) – One for The Watch List

Helicon Group will shortly be changing its name to Consegna Group, once shareholder approval is received at its AGM. The name change will formalise the process of turning the Helicon Group shell into a very active medical assets development vehicle.

The progress made at Helicon Group has been marked and rapid, with the company now commercialising four different assets. Helicon Group in effect became a shell company in May 2010. The first assets, the Vibrovein needle vibration and the BreatheAssist nasal dilation technoloies, were acquired in November 2010, the Linguet buccal drug delivery technology in August 2011 and the Aspen Medisys thermo-nano particle acquisition was formalised in October 2011.

The Aspen Medisys deal was varied from its original intent so that only a nominal up-front payment was made, to be followed by a first milestone payment of $1.4 million in HCG scrip, due by July, 2012 (previously $1.5 million in scrip due by December 31, 2012). However, the acquisition is subject to shareholder approval and other conditions.

More recently, Helicon announced the completion of tests that quantify certain physical features of the Vibrovein vibrating needle technology. The tests, conducted by Invetech, showed that the Vibrovein vibrating needle required 60% less force than a standard hypodermic needle to penetrate a membrane similar to human skin.

Helicon Group is capitalised at $10.8 million and held $0.9 million in cash at September 30, 2011.

Bioshares recommendation: **Speculative Buy Class B**

Bioshares Model Portfolio (28 October 2011)

Company	Price (current)	Price added to portfolio	Date added
QRxPharma	$1.66	$1.66	October 2011
Mayne Pharma Group	$0.385	$0.435	September 2011
Genetic Technologies	$0.14	$0.18	August 2011
Acrux	$3.45	$3.37	June 2011
Psivida	$4.05	$3.95	May 2011
Bioniche	$0.70	$1.35	March 2011
Somnomed	$1.16	$0.94	January 2011
Phylogica	$0.060	$0.053	September 2010
Biota Holdings	$0.79	$1.09	May 2010
Tissue Therapies	$0.59	$0.21	January 2010
Atcor Medical	$0.08	$0.10	October 2008
Impedimed	$0.55	$0.70	August 2008
Bionomics	$0.41	$0.42	December 2007
Cogstate	$0.19	$0.13	November 2007
Sirtex Medical	$4.75	$3.90	October 2007
Clinuvel Pharmaceuticals	$1.55	$6.60	September 2007
Pharmaxis	$1.31	$3.15	August 2007
Universal Biosensors	$0.85	$1.23	June 2007
Alchemia	$0.28	$0.67	May 2004

Portfolio Changes – 28 October 2011

IN:
QRxPharma has been added to the portfolio as momentum builds in the lead-up to the company signing a partnering deal.

OUT:
No changes

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, Circadian Technologies, Biota Holdings, Impedimed, QRxPharma, Patrys, LBT Innovations, Hexima, Mesoblast, Atcor Medical, Tissue Therapies, Viralytics, Phosphagenics, Immuron, Phylogica, Bluechiip, pSivida, Antisense Therapeutics, Benitec, Allied Healthcare Group

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