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In this edition...
Two surgical approaches have been developed to help very obese people lose weight – gastric surgery and laprascopic banding. While successfull, gastric surgery is not reversible and is expensive. Banding is reversible but is also costly. A new approach developed by US company GI Dynamics is reversible, cheaper and also has promise in treating Type 2 diabetes. GI Dynamics is seeking an ASX listing, raising $80 million.
pSivida continues to expand its programs ahead of an FDA decision. UBI is continuing partnering activities for it PT test, and Starpharma's condom coating deal with Reckitt Benckiser has been terminated, with Ansell stepping into the breach.
The Editors
Companies Covered: PVA, SPL, UBI, IPO Profile - GI Dynamics

	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	-19.6%
Cumulative Gain	**238%**
Av Annual Gain (10 yrs)	**21.2%**

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Bioshares

19 August 2011
Edition 421

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

IPO Profile – GI Dynamics

GI Dynamics is a US medical device business based in Lexington, Massachusetts, which was founded in 2003. The company employs 38 people. GI Dynamics has developed a sleeve, the Endobarrier, that can be placed into the gastro-intestinal track, in order to both generate weight loss and address or control diabetes. The product has received CE mark approval in Europe and TGA approval in Australia. The Endobarrier is now commercially available in the UK, the Netherlands, Germany and Chile.

The device is an adjunct or alternative to bariatric surgery, which are surgical procedures performed to bypass the small intestine, including gastric bypass and gastric banding.

Gastric Bypass Surgery
Gastric bypass, otherwise known as Roux-en-Y gastric bypass, involves surgically reducing the size of the stomach pouch, bypassing the distal end of the stomach and the first section of the small intestine known as the duodenum, and then reconnecting after about 75 cm of bypass. The result is to generate malabsorption of food and develop a sense of satiety because less food has passed into the reduced stomach.

Laprascopic Banding
Laprascopic banding refers to the placement of an adjustable band around the stomach, thereby reducing the stomach pouch. Subjects must chew their food particularly well to allow food to pass through the band. The band can be adjusted to control stomach size and hence the feelings of satiety. In contrast to gastric bypass surgery, banding is reversible.

Gastric bypass and laprascopic banding have both shown to deliver significant weight loss in obese patients.

GI Dynamics' sleeve is a 60 cm long impermeable, thin polymer liner which is implanted in the intestine from the point where the intestine connects to the stomach. The liner is held in place with an anchor made of a bio-compatible memory metal (Nitinol). The device is inserted through the mouth using a catheter in a procedure that takes about 30 minutes with patients requiring anaesthesia or heavy sedation.

The sleeve works to delay digestion and interferes with metabolic processes.

What sets the Endobarrier apart from bariatric surgery is that it does not require surgery and is easily removed, although the device is expected to remain in place for twelve months to provide effective treatment.

Pricing
The Endobarrier is currently priced at around US$4,000, on top of US$4,000 to place and remove the device. In comparison, gastric banding costs $15,000 and gastric bypass costs between US$20,000-US$25,000.

Cont'd over

Clinical Trials

The company has conducted 13 trials to date, implanting the device into more than 500 people. A twelve month diabetes trial treated 22 patients with a Body Mass Index (BMI) range of 35.8-59.4. However, only 13 completed the trial at 12 months. HbA1c (a diabetes marker) levels decreased by an average of 2.3% (from high to almost within a normal range) at 12 months and an average weight loss of 20.2 kg was reported.

A 12 month obesity trial enrolled 43 patients, 16 of whom did not complete treatment. Of the 27 subjects who retained the Endobarrier, an average weight loss of 22.6 kg was achieved (from approximately 112 kg to 90 kg). The BMI of the patients in this group ranged from 35.4 -58.4. A BMI of greater than 30 is classified as obese.

One of the interesting features of the diabetes trial was the glucose control (as indicated by HbA1c levels) remained stable up to week 76, 24 weeks after the removal of the Endobarrier. In contrast, the weight levels trended upwards in the obesity trial in the 24 weeks after the Endobarrier was removed.

US Pilot Trial

GI Dynamics is following a PMA regulatory pathway in the US for the Endobarrier. The FDA has granted GI Dynamics an IDE for a pilot trial, expected to commence in mid 2012. The trial will enrol 78 patients with diabetes and are obese, and who are currently taking two oral anti-diabetic drugs. The subjects would be randomised to receive the device or a sham (no device implanted but receive endoscopic examination). The implants would stay in place for six-months, followed by a uniform nutritional therapy for six months.

The primary endpoint of the trial includes the change in HBA1c levels at six and 12 months and the percentage of patients who achieve benchmark values of HbA1c .

A pivotal clinical trial will then be required, which may need to enrol 300-400 patients.

IPO

The company is seeking to raise a minimum $80 million (net $72 million) and a maximum of $95 million. However $20 million of this is expected to flow from a US private placement. The company is issuing 72.7 million CDI's at $1.10 per share. GI Dynamics' indicative capitalisation is $304 million, excluding 36 million options outstanding on completion of the capital raising.

The capital raising is described as a global capital raising with the company seeking investments from Singaporean, Hong Kong, European and Australian residents (apart from the placement to existing US investors).

The company has chosen an ASX listing because "Australia has a history of being receptive to new technologies and GI Dynamics has found a receptive audience here", according to Bob Crane, the company's CFO.

The company believes the capital raising will, in addition to gross profits from sales, meet its requirements for the next three years.

Application of funds

GI Dynamics expects to allocate $25 million of minimum funds raised to sales and marketing, alongside $2.4 million for the expansion of its manufacturing capability.

The company has budgeted $5.5 million for the US pilot trial and $16.4 million for other clinical trials, including commercialisation trials.

A further $14 million will go towards R&D and $6 million will be used to repay convertible notes. In June 2011, GI Dynamics obtained bridging finance for a total of US$15 million, of which it drew down US$6 million on June 27, 2011. A sum of $5 million will be applied to general corporate costs.

Current Investors

To date the company has received US$75 million in capital funding. Prominent venture capital firms including Polaris Venture Partners, Advanced Technology Ventures, Catalyst Health Ventures and Cutlass Capital have invested in GI Dynamics. Johnson & Johnson's venture capital arm is also an investor as is Medtronic.

Shareholdings - GI Dynamics

Existing Holders	Shares	% 'age	Subscription Shares	Shares Post-offer	Converted to CDIs	% 'age
ATV Associates	6,375,480	15.6%	797,387	7,172,867	35,864,335	13.0%
Domain	6,375,480	15.6%	797,387	7,172,867	35,864,335	13.0%
Polaris	6,335,480	15.5%	792,384	7,127,864	35,639,320	12.9%
Medtronic	6,000,000	14.7%	865,801	6,865,801	34,329,005	12.4%
Johnson & Johnson Development Corporation	5,740,011	14.1%	-	5,740,011	28,700,055	10.4%
Seedling LLC	2,950,000	7.2%	-	2,950,000	14,750,000	5.3%
Cutlass Capital	2,672,716	6.6%	334,279	3,006,995	15,034,975	5.4%
Catalyst Health & Technology Partners	2,151,827	5.3%	-	2,151,827	10,759,135	3.9%
Directors	1,348,949	3.3%	-	1,348,949	6,744,745	2.4%
Management (not. inc Directors)	413,987	1.0%	-	413,987	2,069,935	0.8%
Other	432,673	1.1%	-	432,673	2,163,365	0.8%
Total Existing Shareholders	40,796,603	100.0%		44,383,841	221,919,205	80.2%
New Shareholders		0.0%	10,958,217	10,958,217	54,791,085	19.8%
Total - Post Offer	40,796,603	100.0%	14,545,455	55,342,058	276,710,290	100.0%

Source: Prospectus

Observations/Issues

GI Dynamics is currently involved in a patent dispute with the company that manufactures sleeve material for the Endobarrier. GI Dynamics is contesting the claims of **Gore**, which believes it is co-owner of all the company's patents. Gore also claims its supply agreement with GI Dynamics is void. Reliance on a sole supplier is a cause for concern.

– Cont'd over

Universal Biosensors – In Partnering Discussions for PT Test

Universal Biosensors (UBI: $0.90) has released its mid year results for the six months to June. The company's sales were largely flat, up just $0.2 million to $6.3 million. It generated a net loss for the period of $8.0 million, up from $4.4 million in the previous year. The company finished with cash of $17.5 million.

Manufacturing/product revenue from the company's glucose strips ($5.6 million) almost doubled from the previous corresponding half year ($2.9 million). However there was a sharp drop off in R&D revenue. Included in this service revenue is around a 1 cent per strip service fee that UBI receives for every strip sold by LifeScan, regardless of who makes it.

The glucose strips are now being sold in 90% of the European market and in Australia. LifeScan expects to launch the strips in the US by year's end. We expect the product will be accepted more quickly in the US market. LifeScan also expects to file the next Version 3 OneTouch Verio for approval in next year, and looks committed to supporting this new system. The current test, called OneTouch Verio, is one of the most accurate and fastest tests on the market, requiring a low sample volume. Another major factor for LifeScan is the potential low cost of manufacture compared to its competitors when at comparable volumes.

Focus on Second Product – Prothrombin Time Test

For UBI the major focus now is on its second product, called the prothrombin time test (PT test). This test will help patients on warfarin blood thinning therapy to calibrate their correct dosage. UBI is in partnering discussions. It intends to file the test for regulatory approval by the end of March next year, and it is seeking to have a major partner (potentially more than one to cover different segments) by this time. The CEO Paul Wright appears confident that this product will be partnered in this timeframe, our view by year's end.

The platform has now been validated by the glucose product. Wright said the partners have acknowledged the strength of the test, being its low cost, accuracy and ease of use. The company is looking for a similar model as the LifeScan deal, where it shares the risk and the upside.

Although glucose strips sell for around 50 cents each, a PT test strip is reimbursed in the US for $5.53. UBI could then charge a high cost per strip to its partner, say between 50 cents to $1.50 a strip. This would leave considerable margin for the partner as well. The manufacturing costs and effort is substantially lower than with existing manufacturing systems. We understand that where competitors require around 500 staff per manufacturing facility, UBI can achieve with around 20, such are the structural manufacturing advantages of the new technology. The simplicity and high throughput, continuous manufacturing system also brings with it a more reliable, accurate and consistent product.

The PT market is valued at $400 million a year. **Roche**'s CoaguChek-XS product for PT time measurement has the lion's share of the market, with about 75% market share.

UBI is capitalized at $143 million. It employs around 100 people, mostly at its manufacturing and R&D facility in Rowville, just outside of Melbourne.

Bioshares recommendation: **Speculative Buy Class A**

– GI Dynamics cont'd

One issue with heavily VC-backed companies is that such investors look to exit or reduce their holdings once the company has listed. The escrow provisions for the current VC investors are not stated explicitly in the prospectus, but are referred to as having variable escrow periods. Investors should monitor these escrow periods as and when they become public, usually at the time of listing.

An issue concerning the Endobarrier is the degree of acceptability of the device by patients. We note that nine of 22 patients in the 12 month diabetes trial and 16 of 43 patients in the 12 month obesity trial did not complete the trials due to "patient request, device obstruction, movement of the device or gastro-intestinal pain". However, we also note that the device is easily removed and discomfort can be addressed reasonably easily. The company, through ongoing research, and with the benefit of data flow from increased usage, may seek to improve selection procedures in favour of patients more likely to successfully retain the sleeve over twelve months of implantation.

The company's US commercialisation plans are not expected to yield sales until 2017 at the earliest. The company's pivotal trial design and plans have yet to be agreed to with the FDA. The company expects the pivotal trial to cost in the order of $20 million.

Summary

Although some concerns exist with the company, including litigation with a supplier, the GI Dynamics investment proposition is appealing for two reasons. The company's Endobarrier device appears to deliver benefits over bariatric surgery, including cost, reversibility and dispensation of the need for surgery itself.

Furthermore, the potential to concurrently address obesity and Type II diabetes, something not done by leading diabetes medicines, may open up revenues from a very large addressable market. However, with the company still pre-sales, the proposed capitalisation is optimistic.

Offer Information

The offer is not under-written.

Key Dates for The Offer

Opening Date – August 11, 2011
Closing Date – August 26, 2011
Allotment of CDIs – Sept. 1, 2011
CDI's Commence Trading – Sept. 5, 2011

A copy of the prospectus can be downloaded from :

https://www.gidynamicspublicoffer.com/Validation/?ReturnUrl=%2fHome%2f

pSivida Expands Programs as FDA Review Approaches

pSivida (PVA: $4.20) is arguably one of the leading global companies in the area of miniaturised drug delivery systems for the eye. It has two products on the market, which are marketed by **Bausch & Lomb**, and its third product, Iluvien, partnered with **Alimera Sciences**, is due for final review from the FDA around November 12 this year.

Its first product, Vitrasert, for the treatment of CMV retinitis was approved in 1996. Retisert for the treatment of Uveitis was approved in 2005. And Iluvien for the treatment of diabetic macular edema has completed two Phase III trials and is under review by the FDA. There are currently no therapies for this condition, however close behind pSivida (and its partner Alimera Sciences) is **Roche** with Lucentis.

Pfizer Deal & Glaucoma Program

pSivida recently negotiated a new agreement with **Pfizer** to use a polymer-based bio-erodible implant filled with the eye drug lotanoprost. The glaucoma drug, sold under the trade name Xalatan, generated sales of $1.2 billion a year and went off patent in the US in March 2011 and European markets in July 2011.

Pfizer will pay pSivida $2.3 million and pSivida will run a 100 patient Phase II trial which will cost up to $3 million and will take about 12 months to complete. If the depot injection is successful in reducing intraocular pressure, Pfizer has the right to license the program with an upfront payment of $20 million, $145 million in further milestones and a double digit royalty.

Tethadur – Biosilicon Technology Finds a Potential Use

pSivida was founded on its biosilicon technology, which is a bio-erodible material that the company was seeking to develop however for which a commercial use could not be found.

pSivida is now working on using the technology to deliver long acting protein drugs into the body. This technology is similar to the very successful pegylation technology, in that both aim to lengthen the half life of protein drugs in the body. However, pSivida's technology would not change the original compound. The concept is that the drug could be mixed with granules (powder) of the biosilicon, which would take up the drug inside the silicon granules. As the granules dissolve, the drug would then be released. A different release rate could be achieved by use of a different pore size of the silicon, and the drug could be easily loaded into the delivery system by soaking and shaking the two ingredients.

This technology could be used for improved biologic drugs, developed by biosimilar companies looking to improve on the original biologic, or by the biologic drug originator looking to maintain exclusivity with an improved drug format.

Phase III Iluvien data

In the Phase III trials conducted by pSivida's partner Alimera Sciences, the three year data shows that in patients with DME, whilst there was a clear effect in all patients, the effect was more pronounced in patients with chronic DME (more than three years), which was about half of the patients on the trial. The percentage of patients with a 15 letter improvement from baseline at 30 months was 33,5% and 42.4% in the two trials, compared to 10.2% and 11.3% improvement respectively in the two control arms.

Alimera Deal Terms

pSivida stands to received US$25 million from Alimera upon US approval of Iluvien for DME. It also has a 20% ownership of the product, which should see it receive around a 15% royalty from sales. Sales of Iluvien have been forecast by other analysts at between US$250-$800 million.

pSivida is capitalised at US$90 million and had US$23 million in cash at the end of June.

Bioshares recommendation: **Speculative Buy Class B**

Bioshares

Bioshares Model Portfolio (19 August 2011)

Company	Price (current)	Price added to portfolio	Date added
Genetic Technologies	$0.16	$0.18	August 2011
Acrux	$3.77	$3.37	June 2011
Psivida	$4.20	$3.95	May 2011
Bioniche	$0.78	$1.35	March 2011
Somnomed	$1.28	$0.94	January 2011
Phylogica	$0.069	$0.053	September 2010
Sunshine Heart	$0.039	$0.036	June 2010
Biota Holdings	$0.87	$1.09	May 2010
Tissue Therapies	$0.45	$0.21	January 2010
Atcor Medical	$0.09	$0.10	October 2008
Impedimed	$0.60	$0.70	August 2008
Bionomics	$0.50	$0.42	December 2007
Cogstate	$0.17	$0.13	November 2007
Sirtex Medical	$5.15	$3.90	October 2007
Clinuvel Pharmaceuticals	$1.53	$6.60	September 2007
Pharmaxis	$1.01	$3.15	August 2007
Universal Biosensors	$0.90	$1.23	June 2007
Alchemia	$0.36	$0.67	May 2004

Portfolio Changes – 19 August 2011

IN:
No changes

OUT:
We have taken some profits with Starpharma and removed it from the portfolio. Following the change in licensing partners last week, there may be more of a fall in the share price to come which could present more favourable buying opportunities.

Starpharma Drops Reckitt Benckiser, Signs Ansell

Starpharma (SPL: $1.09) has terminated its condom coating deal with multi-national consumer goods company **Reckitt Benckiser** (RB) and signed a new condom coating deal with **Ansell**. Condoms were to be coated with Starpharma's microbicide Vivagel.

Starpharma CEO Jackie Fairly said more than one material breach of the agreement had occurred.

Starpharma originally signed a condom coating deal with **SSL International plc**. However, SSL was acquired by Reckitt Benckiser in November 2010. According to Fairley, a progressive reduction in capability of the former SSL element of RB to deliver was observed.

Comment

This is not the first time an Australian biotech company has suffered because a licensee has been acquired by another often larger firm.

Perhaps the most notable example is that of Biota, which argued that the merger of Glaxo with SmithKline Beecham in 2000 triggered a de-prioritisation of the development and marketing of the flu drug Relenza. Optiscan Imaging also appeared to experience unsatisfactory progress in the hands of Hoya, which acquired Pentax in January 2007. (See table below)

Revenues for Starpharma under SSL/Reckitt deal were expected to be considerable, as much $30 million per annum if a high percentage of condoms were coated with Vivagel. With Reckitt's share of the condom market of 40% twice that of Ansell's 20%, the base for discussing prospective revenues has changed (in our view) in favour of lower anticipated revenues.

Starpharma is capitalised at $270 million. Investors may be able to take advantage of price weakness that is likely to follow this recent setback which has seen market entry deferred to CY2012 for Vivagel coated condoms.

Starpharma held cash of $19 million at June 30, 2011.

Bioshares recommendation: **Lighten**

Deal Terminations or Handbacks Following Merger of Licensee with Other Company

ASX Company (Licensor)	Licensee	Acquiror	Date Merger	Comment
Starpharma Holdings	SSL	Reckitt Benckiser	Nov-10	Deal terminated by Starpharma. New agreement signed with Ansell
Optiscan Imaging	Pentax	Hoya	Jan-07	Ended 2nd-gen pdt development agreement with Hoya in March 2009
Biodiem	Schering Plough	Merck	Nov-09	Merck announced phasing out of Nobilon facilities in July 2010
Acrux	Akzo Nobel - Organon - Nobilon	Schering Plough	Mar-07	Two contraceptive programs were discontinued in Aug. 2008 following "re-prioritisation"
Biota	SmithKline Beecham	Glaxo	2000	Relenza was licensed to SKB in 1990. Biota sued GlaxoSmithKline in 2005 breach of contract, ultimately settling for $20 M in 2008.

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, Mayne Pharma Group, Impedimed, QRxPharma, Patrys, LBT Innovations, Hexima, Mesoblast, Atcor Medical, Tissue Therapies, Viralytics, Phosphagenics, Immuron, Phylogica, Bluechiip, pSivida, Antisense Therapeutics, Benitec

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