#### In this edition...

The 9th Bioshares Biotech Summit was held over July 19 and 20 in New Zealand. In this edition, a first round of coverage commences with a report on Nanosonic's CEO Ron Weinberger's presentation. Weinberger declared mistakes had been made but was also confident of the future for Nanosonics Trophon disinfection system. Weinberger said that best thing he had done was to place Nanosonics support staff along side GE (the company's North American distributor) sales staff, so that Nanosonics could stay close to customers. Weinberger's brief was to discuss the challenge of changing global healthcare practices, and staying close to the customer was one of several factors he believed would see their device adopted across global healthcare markets.

Companies Covered: CIR, GID, NAN, SOM, TIS, Photonz

	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)	14.4%
Cumulative Gain	276%
Av. annual gain (12 yrs)	16.6%

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

David Blake - Editor Ph: (03) 9326 5382

Email: blake@bioshares.com.au

Mark Pachacz - Research Principal
Ph:(03) 9348 9317

Email: pachacz@bioshares.com.au

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# Bioshares

22 July 2013 Edition 512

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

# The 9th Bioshares Biotech Summit Reports – Part 1

The 9th Bioshares Biotech Summit was held in Queenstown, New Zealand, from July 19 to 20. More than 140 attendees gathered to hear presentations from 27 speakers and listen to a panel of five biotech stock analysts and advisors comment on sector trends and issues.

Topics covered included 'Changing Global Health Practices', 'Platform Technologies - Moving Up the Value Chain', 'Tackling Europe', 'Lands of Opportunity', 'The Power in Manufacturing', 'New Kids on the Block', 'Social Media in Biotech' and 'Biotech Investment Rules from Three Professional Investors'.

Three Australian companies and one New Zealand company presented in the 'Private Company Preview' slot and the Mike Hirshorn Address was delivered by Dr Mitchell Glass, the CMO of Invion and who has, as a pharmaceutical industry veteran, presided over 50 Investigational New Drug applications to the FDA.

In this edition we commence our coverage of the event, leading off with a detailed report of Dr Ron Weinberger's talk in the 'Changing Global Health Practices' session.

Also included in this edition is coverage by Mike Nelson of the 'Tackling Europe' session and by Emma Senior of one speaker from the 'Lands of Opportunity' session and one from the 'The Power in Manufacturing' session. Mike and Emma are currently completing the Masters of Bioscience Enterprise degree at the **University of Auckland** and we invited them to assist with several management tasks and to sit in and hear first hand of some of challenges life science companies face as they take their products to market.

# 'Changing Global Health Practices' – Nanosonics

Nanosonics' CEO Ron Weinberger launched his presentation by describing the evolution of the company from being an IP based company to a product development technology applications company, through to being a fully-fledged manufacturing facility which is now selling product around the world

Nanosonics has developed and now markets the Trophon EPR, a closed, 15 kg 'microwave-sized', system for the disinfection of ultrasound probes. The system nebulises hydrogen peroxide, the disinfection agent, creating liquid droplets that are highly concentrated. This chemical is catalytically destroyed at the end of the process and is reduced to water and oxygen. Weinberger said that 'the entire ethos of our product is that it is entirely environmentally compatible, there are no toxic chemicals, there is no OH&S risk.'

The product is sold on Razor/Razor blades model in which consumables form the key plank for revenue generation for the business.

One of the drivers for the development of Nanosonics disinfection technology has been a revolution in the medical devices sector which has seen many more complex devices made of plastic and which contain sensitive electronics. This means that traditional disinfection from the application of heat at 140 degrees is not suitable.

Weinberger said another driver comes from shift by device users to demand disinfection at point of care rather that at central sterilization departments. Clinics or point of care locations within hospitals now hold significant medical equipment inventory. There is a reluctance to send equipment to a central sterilization or disinfection unit because the turnaround can be as long as 24 hours.

Weinberger said that when designers and inventors conceive of new products, they should not only look for unmet need but also look where there is 'clearly a challenge, a problem for medical practices. One where you can add dollar value and process value to generate revenue for the company but also for the customer.'

Weinberger was emphatic about the role of the customer in the commercialisation and sales process. 'We have to talk and think about the customer. It's how we to make the customer satisfied, and how we get repeat purchasers of a product that will generate revenues.'

# Awareness is the Key, as are Stakeholders

Weinberger said that awareness is a key to change people's behaviour. There are also many different stakeholders to work with including professional societies, regulatory authorities such as the FDA and the CDC, as well as authorities at the state level.

Professional societies can become indirect advocates of a product, which means they must 'buy in' to the product in the first place.

Weinberger commented on current disinfection processes (in the US) which uses toxic chemistry and are a source of OH&S problems for ultrasound transducer operators. The chemical solution approach is deficient because devices can't be fully immersed in solution – if they were the device would be fail.

This approach fails to meet the FDA's own guidelines (and the CDC's) but has been tolerated by the FDA because there has been no better alternative . 'If you ask the FDA, they say there is nothing better out there and we have to live with it,' said Weinberger.

In contrast to the disinfection by plunging a transducer into a chemical solution, the Trophon disinfection is executed in a self contained unit, which accepts the entire ultrasound probe. The disinfection process takes seven minutes. An important feature is that there is no toxic chemistry interface for the operator.

# **Relationship with Probe Manufacturers**

Nanosonics' Trophon is compatible with more than 500 ultrasound probes. Weinberger said that Nanosonics began developing relationships with probe manufactures five years before sales commenced. In effect this meant that marketing had to begin five years before sales commenced.

Weinberger noted that Nanosonics had to 'develop relationships with the OEM manufacturers to prove that our process was compatible with their products. If we had launched our product without those compatibilities we wouldn't had revenues for another five years.'

However, Weinberger now believes that relationship development was one of the best things they ever did, because the probe manufacturers are now 'an indirect advocate in the marketplace. That is huge boon for us because those are the reps that are going to the customers and are telling them that there is a better way to do this and will cut down the damage to their US probe.'

Initially, Nanosonics struggled to get ultrasound probes from manufacturers for compatibility testing. Now manufacturers come to Nanosonics because they are concerned about losing sales because of the potential lack of compatibility. The company allocates 80 machines at its site for probe compatability testing.

### **Role of Distributors**

Distributors have a role to play in the adoption challenge. They are 'strategically relevant' according to Weinberger. He commented that 'one important point we learnt is that there is no point in having distributors if they are not going to sell your product.' When Weinberger became CEO in 2011, the first thing he did was to remove all 23 European distributors and press the reset button.

Weinberger said 'you have to very hardnosed about which (distributors) will perform, and then set performance criteria mutually in return as to how that is going to happen.'

# Restructured Relationship with GE

Weinberger discussed his relationship with GE, Nanosonics exclusive distributor for North America. I have to travel around the world to make sure that people talk to each other, in order to make sure that there is alignment to sell your product into the customer base. When you do get that sense of motivation and the right sense of strategic alignment it can be a very powerful force, that power of these large companies to generate real sales and revenues. GE found that in six months they made \$10 million with a restructured process that we basically forced them into,' he said.

This restructured relationship involved Nanosonics staff being placed on the ground alongside GE staff, because of the principle that the people who have made the product and who have manufactured it are the ones with the passion, commitment and devotion to sales.

# Staying Close to the Customer

Staying close to the customer is then another factor in driving adoption. This is been accomplished by having (Nanosonics) people on the ground, working alongside GE and all other distributors. 'It has been the best thing I have ever done' said Weinberger. Nanosonics sales support staff 'teach, communicate, align, they

develop strategies in partnerships. They have completely changed the nature of how we do work,' he said.

# **Changing Disinfection Guidelines**

Weinberger attributed Nanosonics success in Australia, where there is an installed base of over 750 machines, to the fact that the Australian Society for Ultrasound Medicine, included Trophon EPR product into their guidelines. Now, every sonographer today in Australia receives the disinfection protocols and methodologies that must be followed. 'Sonographers don't care about the FDA, the TGA, CDC, they care about the professional societies and what the guidelines are telling them to do and the behaviours they need to undertake,' he said.

In addition to the influence by professional societies through their guidelines, another critical change factor are the accreditation and certification societies, such as Jayco (the Joint Commission on Accreditation of Healthcare Organizations) in the US. The accreditation and certification societies have the power to shut down noncompliant facilities. Given that the current manual process of disinfection is disliked by users, then it means that compliance is a major problem.

### **Indirect Advocates**

Weinberger said that the accreditation and certification societies 'are now indirect advocates for our product and the reason is that is that have actually had to sell to them, we have had to go to the CDC, to Jayco. We had to demonstrate to them the advantages that our product brings to compliance and so they are now also indirect advocates. We had no idea about this earlier!'

# The Benefits of Luminary Sites

Weinberger was adamant that having luminary sites adopt your product was necessary for adoption.

'You can't do it without them' he said. 'You can't not have Brigham and Women's, you can't not have the Mayo, you can't have Walter Reed and Johns Hopkins not be purchasers of your products.'

The reason behind the need for working with leading sites is that is where distributors take future purchasers to study the product. The luminary sites can in that sense become advocates for a company's products as well.

# **Product Trialling as a Sales Strategy**

Weinberger made the case for the trialling of products as a key step in the sales process. From his experience, over 85% of product trials convert to sales once customers have tried the Trophon product. The contrast is with the less effective catalogue and email approach. Customers 'need to see it, to touch it, they need to experience the value that it brings.' Even better than simply trialling as a sales method has been to set up trials to demonstrate workflow benefits. Nanosonics can now point to published data showing a 57% gain in workflow efficiency.

# **Tipping Point?**

Weinberger discussed the concept of a tipping point for Trophon sales. He said this was not something he could predict. However, he did indicate that there were some easier sales to be made from 6,000 hospitals in the US. One the other hand he said selling into private clinics (of which there are also about 6,000) was harder because they have higher cost constraints and higher operational budgets relative to their revenue streams.

# **Installed Base**

The current installed based of Trophon EPR systems is 2,500 units globally. Weinberger said that the company is committed to updating the market on its installed base figures as well as on blended margins data.

### In Conclusion...

Weinberger concluded by stating that Nanosonics is 'looking to be profitable in the very near future. We are cash flow positive. We are encouraged by the rate of sales. We are encouraged by the opportunity. It can only be done by failing along the way. There are a lot of things we have done very badly. There is a lot that we have learnt along the way. I think the future is very bright for this product and our technology platform moving forward.'

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Bioshares M	lodel F	Portfolio	(22	July	2013)
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Company	Price (current)	Price added to portfolio	Date added
Atcor Medical	\$0.105	\$0.082	May 2013
Circadian Technologies	\$0.250	\$0.270	March 2013
Tissue Therapies	\$0.140	\$0.255	March 2013
Benitec Biopharma	\$0.355	\$0.400	November 2012
Nanosonics	\$0.700	\$0.495	June 2012
Somnomed	\$1.20	\$0.94	January 2011
Cogstate	\$0.320	\$0.13	November 2007
Universal Biosensors	\$0.75	\$1.23	June 2007

# Portfolio Changes – 22 July 2013

IN

No changes

OUT:

No changes

# Tackling Europe

In this session, three companies, GI Dynamics, Tissues Therapies and Somnomed discussed the experiences they have had in gaining regulatory approval in Europe, or their country by country strategies to gain reimbursement and manage distributors.

# **GI Dynamics**

GI Dynamics (GID) (ASX:GID), based in Lexington, Massachusetts, sells the medical device EndoBarrier for the treatment of obesity and diabetes, an impermeable sleeve anchored at the stomach which extends a short distance into the intestine. It has been implanted into more than 1,000 patients to date and is being sold in eight countries, primarily in Europe.

Recently, GID secured an additional \$57.5 million in funding through an offering which closed on July 3. GID's cash position at June 30, including the recently raised funds of approximately was \$72 million. The funds will be used for their US-based pivotal trial, which began in the first quarter of 2013. In the quarter ending March 31, GID's cash burn was \$8.7 million, revenues were \$350,000 and deferred revenues were \$950,000. CFO Robert Crane praised the quality of GID's investors, which include the device heavyweight Medtronic and UK-based investment fund M&G, both of whom increased their position in the recent offering.

GID's initial target market is that of Type II diabetes sufferers who are obese. GID estimates a total of 63 million in this population worldwide, of which 19 million are in North America and 16 million are in Europe. They reason that focusing on this group will allow them to show a greater clinical impact.

Crane also explained that, despite a recent AMA ruling, obesity is seen as a lifestyle disease, while diabetes is unquestionably seen as a serious disease warranting significant expense. The focus on diabetes is thus a conscious choice to ease the process of reimbursement.

# **Allocation of Resources**

Crane raised the issue of how a company should allocate its resources when facing multiple markets and options. GID for instance has historically been focusing more on getting into Europe than on running a large pivotal trial, estimated to cost around \$50-60 million, reasoning that generating traction through early sales and beginning the path towards reimbursement would be more beneficial in the long run.

# **KOLS**

Crane emphasised the vital importance of winning over Key Opinion Leaders (KOLs) and key sites. In Germany, GID brought on-side the Society of Surgery, the Society of Diabetology and the Society of Gastroenterology, who came together for a consensus meeting in March, made statements about the benefit of EndoBarrier and are planning to jointly publish a consensus paper shortly.

With the support of those societies, GIS has secured Diagnosis Related Group (DRG) reimbursement and are making commercial sales, aiming next to secure national target reimbursement with stronger clinical data generated from the current deployment.

In the Netherlands, the European country in which GID has been present for longest, they entered the reimbursement pathway via the Innovation Rule Application, which facilitates contracts with hospitals to run pilot projects under a temporary DBC reimbursement code. They also received grants from Arnhem Hospital to treat 50 patients in Q1 2012 and 100-150 patients in Q1 2013. They expect permanent inclusion in the national payment system in 2015 following the pilot.

Crane concluded by emphasising the use of CE marking as a foundation for approval not just in Europe but also in many other jurisdictions worldwide, and re-emphasising the crucial role of KOLs in facilitating reimbursement and commercial viability. Europe, he said, is an investment which requires patience, but he is hopeful that it will pay off.

# Tissue Therapies

Tissue Therapies has developed the extracellular matrix scaffold product VitroGro primarily for the diabetic foot ulcer, venous leg ulcer and pressure ulcer markets, which CEO Stephen Mercer estimated at US\$30-40 billion, of which 42% is in the US and 22% is in Europe. While Tissue Therapies has warehouses stocked with the product in cold chain and a network of sales and logistics partners in place, problems with gaining CE mark approval in the Europe have held back sales for the past year.

Mercer explained that while the European Commission directive on medical devices is influential, it is a set of guidelines that is not legally binding. Tissue Therapies sought CE marking for similar reasons to those outlined by GID's Crane earlier: to build a foundation for approval in a wide range of jurisdictions.

Mercer emphasised the importance of selecting the right notified body for CE marking – in Tissue Therapies case, their criteria was expertise in their area, a proven track record and experience, a good reputation, links to consultants and KOLs and the capacity to perform QMS audits of their Australian operations.

VitroGro was classified as a Class III device by BSI (British Standards Institute), Tissue Therapies' notified body, and a CE mark was expected to be granted following completion of the conformance review in July 2013. However, the notified body decided that they were unsure whether Device Rule 8 or Rule 13 applied (the latter mandating a manufacturing data review by the EMA) and sought the advice of the MHRA. The MHRA confirmed the device classification and suggested that rule 13 applied. The notified body subsequently requested a manufacturing data review from the EMA.

The EMA however, following an 'informal survey', replied that the majority of their committee members disagreed with the classification of VitroGro as a medical device, insisted instead that it was a medicine and refused to proceed with the manufacturing review. Tissue Therapies, however, received in writing a state-

ment from the European Commission legal unit that the EMA is not a competent authority with regard to the classification of products.

Tissue Therapies is now applying pressure for the EMA to proceed with the manufacturing review, the final component necessary for obtaining a CE mark. Mercer reported that Tissue Therapies could begin sales a few business days following CE mark approval, and that there were 'payoffs to taking an aggressive legal stance" with these EU bodies. It is in the process of demonstrating that it has exhausted all channels available to it to proceed, whereupon it will take action against the EMA in the European Court if they continue to refuse to proceed with the manufacturing review.

Tissue Therapies will be submitting an application for a large, double-blind pivotal clinical trial next month for the FDA, who classify VitroGro as a biologic, a classification which does not exist in the EU. Planning for the trial is already complete, sites identified and CROs engaged. Mercer stated that the aim was for the trial to exceed expectations as demanded by regulators. In an earlier EU clinical trial for the venous leg ulcer indication, 34% of patients exhibited complete healing, and 42% at least 90% healing, within 12 weeks. Pain was also significantly reduced, with all patients in severe pain experiencing a reduction, 71% of patients in moderate pain and 67% of patients in mild pain. 13% of patients in mild pain experienced increased pain and all others remained stable.

Mercer reported that Tissue Therapies has also completed a healthcare economic modelling study in the UK demonstrating a 51% cost saving versus the standard of care and intends to conduct further studies in the UK and Germany. The company is also looking at burns and consumer applications.

# Somnomed

Somnomed (ASX:SOM) is a medical device company that manufactures, distributes and sells the SomnoDent Mandibular Advancement Splint for the treatment of obstructive sleep apnea, which sits in the mouth and functions by moving the lower jaw forward slightly. Somnomed is present in 22 countries, of which 13 are in Europe, and is profitable.

CFO Neil Verdal-Austin highlighted the complexity inherent in the business from the intersection between the dental, medical, reimbursement and patient components. He noted that the European market is unlike the US in that self-pay is extremely rare and reimbursement is almost exclusively via third party or government. He emphasised that in their experience, every single European country is fundamentally different and individual strategies are required to get the most out of each.

Somnomed's European business now makes up a third of their total business, with \$10 million in revenue in the last financial year. When they first entered Europe six years ago, they lacked the money to create direct sales channels. Their strategy has thus been to engage closely with local distributors and partners in order to acquire knowledge about each market, access networks

and seek vertical integration. They traded off profit margin for lower commercial risk and cost, with the aim of building critical mass as quickly as possible. Verdal-Austin also advised having a central office to avoid back-office duplication.

Verdal-Austin identified reimbursement as one of the most significant issues that the company has faced, with regulation also having a bigger presence than in the US, leading to a slower-moving and more bureaucratic market where payers have a lot of power. He stated that better methods of approach to reimbursers leads to better business, and that having a product that is both reimbursed and accepted by the medical community leads to a significant boost in customer awareness. In Holland, uptake went from 8% to 35% once reimbursement was secured. He also noted that compliance is becoming more and more of a fundamental issue for obtaining reimbursement, and that insurance companies respond well to offers to take on as much of the process as possible and remove their burdens.

Verdal-Austin outlined Somnomed's strategy as centring on the building of knowledge about and keeping hold of the whole cross-referral pathway between the company, the distributors, the dentists, the payers and the patients. He noted that the dental profession was not often used to dealing with reimbursement to the depth with which their medical partners do and thus that Somnomed acts as a facilitator with their dental base being their foundation.

The second phase of this strategy is for Somnomed to acquire these partner distributers with the revenue streams from the agreements in order to obtain more direct access to customers. Verdal-Austin stated that 'it is important that our partners of today don't become our competitors of tomorrow' and that distributer acquisition would generally occur once profits were stable and Somnomed has accumulated sufficient knowledge about the local market.

Verdal-Austin stated that these acquisitions could be challenging, particularly in terms of overcoming relationship challenges, coming to realistic valuations (an earnings multiple of three years is their standard metric) and communicating the need to focus on sales growth and the need for reporting, but that ultimately the integration that the strategy secures is much more significant. He cited the benefits of higher margins, the ability to drive strategic focus, implement 'methodical and measures sales and marketing plans' and track commercial activities in order to assess what is working and what isn't.

He closed by iterating that Somnomed sees Europe as an attractive and lucrative market made challenging by differences and significant diversity, with their keys to future growth and success being seen as partners, reimbursement and referral pathways.

Bioshares

- Mike Nelson

# Lands of Opportunity

In the 'Lands of Opportunity' session, Opthea CEO Megan Baldwin presented a full summary of the company's recent developments with their lead molecule VGX-300.

Opthea is a 100% owned subsidiary of Melbourne based Circadian Technologies, created to develop assets in Circadian's portfolio related to ophthalmologic drug development.

Opthea's lead molecule VGX-300 is a soluble receptor that specifically blocks the activity of VEGF-C and -D, two members of the endothelial vascular growth factor family involved with the progression of retinal and corneal diseases.

Opthea is focused on developing VGX-300 for the treatment of 'wet' (neovascular) Age-Related Macular Degeneration (AMD). This is a market Baldwin described as having significant potential, evidenced by competitor drug Eylea generating US\$838M in its first year of sales in 2012.

Opthea is currently working to build the pre-clinical data package and complete necessary studies required to submit an IND, following the receipt of encouraging animal model studies of VGX-300. It plans to commence phase I trials in H2 2014.

Opthea's intention is to initially develop VGX-300 as a combination therapy used to enhance the efficacy of existing competitor products available on the market (Eylea and Lucentis ) that selectively block VEGF-A but not VEGF-C or D. Baldwin noted there are other approaches in clinical development which are investigating this combinatory approach to treat wet AMD – such as Opthotech, a US-based company which is developing the PDGF inhibitor Fovista to be used in conjunction with Lucentis. Opthotech has recently completed Phase IIb trials for Fovista and is looking to commence Phase III trials in Q3 2013.

Opthea is also undertaking a de novo manufacturing programme for VGX-300 because it is unable to leverage much from Circadian's prior development of the mAb VGX-100. It is working towards cGMP manufacturing of clinical grade product.

Baldwin highlighted an advantage of VGX-300 in that it does not require systemic administration due to the dosing accessibility of the eye. This feature translates to significant cost savings for the company on the CMC side. However, the requirement for delivery of VGX-300 via intravitreal injection into the eye remains, with Opthea open to exploring possible delivery alternatives for VGX-300, although it is not planning to invest in a development programme in this area in the immediate future.

Baldwin said that Circadian has enough funds to see the manufacturing and development of VGX-300 progress for the next 12-18 months. However, Circadian will be looking to raise capital in order to hit further milestones for VGX-300 as well as for their other projects in oncology and diagnostics over the next 2 - 4 years.

– Emma Senior

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# The Power in Manufacturing

In the 'Power in Manufacturing' session James Campbell, the CEO of Photonz, (formally the CFO of ChemGenex Pharmaceuticals) outlined recent progress with the NZ-based manufacturing company. Photonz is a private company with a novel method for the production of the omega-3 fatty acid eicosapentaenoic acid (EPA) via algal fermentation. Campbell was recently appointed to the role of CEO, in a staged transition that saw Greg Collier (also ex-ChemGenex) assume the role of CEO at Invion.

Photonz is currently the only company of its kind producing EPA via algal fermentation (EPA is conventionally extracted from wild fish) and has an extensive patent estate and body of trade secrets to protect its proprietary fermentation technology. Photonz outsources all of its post-fermentation manufacturing processes to a variety of partners throughout Europe (UK, Belgium, France) as a strategy to reduce capital expenditure of the company.

During his talk, Campbell discussed a key product of the company EICONZ 80, an 80% concentrated EPA formulation for which Photonz is currently seeking GRAS-E approval with the FDA. This is a route to market that does not require no clinical trials. The move is a strategic one to flank the regulatory and IP position of an Irish competitor, Amarin Corporation, that has recently obtained approval of a 97% EPA drug for use in reducing the risk of a second cardiovascular event in cardiac patients.

Campbell stated it was unlikely that Photonz would produce the 80% tablets themselves, and that they were in talks with medical food manufacturers in this regard. The company is also pursuing talks with producers of pharmaceutical grade 97% EPA products (Amarin and Mochida) to explore further supply opportunities.

Transgenic plants pose a possible threat to the success of Photonz' algal production technology. Although when questioned, Campbell suggested that efforts by DuPont in this regard to date had been unsuccessful, and that there was uncertainty as to whether the EU and US markets would adopt EPA produced via a genetically modified source. Photonz is ready to commence commercial production and should have their 'GRAS-E approval done by the end of the year', with 'hundreds of kilograms of product ready at the end of the year, or early next year'.

– Emma Senior

**Bioshares** 

### Corrections - Bioshares 511

US IPO Window - Epizyme was incorrectly identified as being the top performing stock for the period under reference. Stemline Therapeutics was the top performing stock with a gain of 172%.

Bioshares Number 512 – 22 July 2013

# 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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