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In this edition...
Sirtex Medical is a front page story for investors not because it revenues for FY2013 exceeded $100 million nor because its sales came close to $100 million. It's an investment story with lessons galore, the first being that it has been managed as a business not a project, the second being that changing medical behaviour takes time. We first wrote about SRX in 2001 when the company had a cumulative 600 treated patients under its belt. In 2013, Sir-Spheres were used to treat 7,300 people. Yet the company has ambitions to go beyond that...but all in good, steady, patient time. Mimetica is seeking a backdoor listing through Telesso Technologies. Although Phase II results won't appear until 2015, its acne drug MTC896 Gel is worth a look.
Companies covered: NAN, SRX, UBI, Mimetica (Backdoor listing - TEO)

	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)	40.2%
Cumulative Gain	**399%**
Av. annual gain (12 yrs)	**16.6%**

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Bioshares

16 August 2013
Edition 516

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

Sirtex Medical Nudges $100 Million in Sales; Retains Cash of $52 Million

Sirtex Medical (SRX: $12.56) delivered a very solid result for FY2013. Total revenue was up 16% to $100.3 million. Sales of Sir-Spheres were $96.7 million for the full year and unit sales increased by 19% to just under 7,300 for the year. The company's net profit after tax was $18.2 million, up 7% over the previous year.

Sirtex continues to work towards its '2020' vision, a time when the company is anticipating there will be a step change in use of its Sir-Spheres liver cancer treatment. At this week's conference call, CEO Gilman Wong said the company continues to invest heavily in preparation for that step change, which is expected to occur if positive results emerge from post market studies with its liver cancer therapy.

At the moment there are five major studies underway with Sir-Spheres. There are two goals for conducting these studies. The first is to get the therapy more widely used for not only secondary cancers that have spread from the colon to the liver, but also for the treatment of primary liver cancer (HCC). In the US, the therapy is only approved for secondary liver cancer, however it is used off-label for primary liver cancer as well.

The second aim is to have the therapy moved from a salvage therapy, when all other treatment options have been exhausted, to a first line treatment option.

In France, the company is conducting a study comparing Sir-Spheres against an approved liver cancer drug Nexavar (Sorafinib) used in the treatment of HCC in 400 patients. There has been a surge in recruitment in this trial, with 150 patients having been recruited. Recruitment is expected to be complete at the end of 2014 and is currently 44% recruited. France is about the only market where these therapies are not reimbursed, which allows the company to complete the trial without patients switching to the other therapy once their disease starts to progress.

In 2013, 567 patients were recruited into Sir-Spheres clinical studies. A first key study to look out for will be the SIRFLOX study, which is looking at Sir-Spheres used as a first line therapy. This data is due to be released at the end of 2014. In FY2013 Sirtex invested $15.8 million in clinical trials. In other trials underway, SIRveNIB is 53% complete and FOXFIREGlobal is 46% recruited. These trials will deliver data on around 2,000 people with primary and secondary liver cancer.

Sirtex also invested $6.6 million in R&D. One of the most important products to come out of the R&D pipeline is a new delivery system for the Sir-Spheres. Delivery is a crucial step in this treatment. Incorrect delivery of the radioisotopes, which occurs in a small number of cases, can cause some severe side effects. Any improvements in the ease of use and the reduction in side effects will be very beneficial to this therapy and the company.

Cont'd over

– Sirtex Medical cont'd

Regional Sales

The Americas, which includes North and Latin America, delivered a solid 21% growth in unit sales, with sales for that region accounting for 70% of overall sales. Manufacturing capacity in the US is due to triple.

In Europe, the Middle East and Africa, dose sales only increased by 9% however 30 treatment centres have been opened to deliver the treatment and Europe remains the backbone of its clinical programs according to the company. This year will see the rollout of a European data collection program to monitor patient outcomes, which will also deliver valuable information.

In the Asia Pacific region, unit sales were strong, up 29% (and a 26% growth in sales). However, that region only accounts for 5% of total sales.

The biggest increase in costs was in sales and marketing expenses, which increased by $6.3 million for the year. The company delivered a 10 cent per share dividend in October last year. Sirtex finished the year with $52 million in cash.

Sirtex Medical is capitalised at $704 million.

Bioshares recommendation: **Take Profits**

Bioshares

Nanosonics – Meets Expectations

Nanosonics' (NAN: $0.835) results for FY2013 were in line with expectations. Sales were $14.9 million ($14.7 million forecast) and the net loss slightly higher than expected at $5.8 million ($4.0 million expected) from higher staff costs.

The good news for investors is that sales from here on should start to accelerate. We had previously forecast sales for FY2014 to be $24.6 million. However with a very strong June quarter with $6.3 million in sales, we now expect full year sales for this financial year to be closer to $30 million.

The other good news for investors is that this should move the company into profitability in this financial year.

This week it was announced that GE Healthcare would be forming a dedicated Trophon sales organisation. This is very positive news and should see sales accelerate even faster in the US. GE Ventures will also be investing in the Trophon product, by funding an integrated marketing program for North America. Nanosonics is seeking to have its Trophon system become the new standard of care for ultrasound probe reprocessing in the US according to CEO Ron Weinberger. With a global installed base of around 2,500 units, and 500 customers in the US in the first year of sales, we have upgraded our overall peak market penetration to 40% in North America. As a result, our revised valuation for Nanosonics has increased to 95 cents per share.

Nanosonics is capitalised at $219 million.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

Universal Biosensors – Small Blip in Strip Sales from Recall with Next Product on Track for 2013 Launch

The key line item for investors in Universal Biosensors (UBI: $0.70) to monitor is the quarter service fees that UBI receives from its partner Lifescan. UBI receives about US$1 cent for each glucose strip sold, regardless of who manufactures the product.

Impact of Product Recall

In March there was a product recall linked to the glucose meter which UBI does not make. This affected volumes in April and May, but June strip volumes returned to the Q1 strip sales levels. At a conference call this week, CEO Paul Wright said the company expected to see some impact on strip sales. However that impact has been relatively short lived.

Although strip service revenues were lower in the June quarter than the March quarter as a result, the service fee for the half was still up 56% over the previous corresponding period at $1.6 million.

UBI reported its half year results to the end of June. Overall sales fell by 35% to $9.6 million and a net loss of $7.7 million (3.4 million in 2012). The main reason for the fall in sales was the 82% drop in service revenue, to only $0.8 million. This is revenue that UBI gets from its partners for development work conducted.

This year UBI is doing no product development work with Lifescan, after a major product development in 2012. It has also not received any milestone payments from Siemens this year. The $500,000 that it did receive in the June quarter was from Siemens for cost reimbursements. Wright said that the company was now moving from R&D contract revenue to generating revenue from strip sales.

In the June half, R&D costs jumped by 47% to $7.9 million, which was due to the launch preparation for the three coagulation testing products it is developing in partnership with Siemens. Unlike the Lifescan deal, UBI is sharing in more of the upside but also contributes to more of the development costs. Development of the coagulation products made up 80% of R&D costs, but 40% of those costs will not be ongoing.

Decline in Manufacturing Revenue

Manufacturing revenue, which is termed product revenue by the company, was also down, 24% for the half over the previous corresponding period. There were two reasons for this fall. The first was due to the product recall. The second was because Lifescan now has its own manufacturing facility operating. That Lifescan is now making its own strips comes as no surprise, with UBI having assisted with the technology transfer to Lifescan.

CEO Wright expects that Lifescan is planning its own second manufacturing line. This is why Wright stressed the key line item to monitor is strip service fee revenue (which is effectively a royalty stream), which UBI receives regardless of who makes the strips.

On the questions of predicting manufacturing volumes going forward, Wright said this is very challenging.

Xprecia Stride Analyzer to be Launched CY2013

Wright confirmed that the company is expecting its second product to be launched this year. That product, to be sold by Siemens, will be called the Xprecia Stride Analyser. It will be used to set correct warfarin dosage by measuring PT/INR. Currently there are over seven million people in the world using warfarin. This product will be used at point-of-care to get immediate blood coagulation levels. UBI will be the exclusive manufacturer of the strips.

We expect UBI will receive milestone payments from Siemens (of US$1.5 million) from each product launched, with the first likely in the second half of this year. Wright said the launch is not that far away. UBI will is waiting to receive an advanced order to start manufacturing strips for commercial launch.

Payment to Lifescan

Upon the launch of this first product outside of the Lifescan partnership, UBI will be required to pay Lifescan between US$1.3-US$1.6 million, which is effectively a reimbursement of 50% of patent costs around the technology.

UBI will also use the same strips to sell a home test to be used by patients and carers, in a meter developed independently. Meter development is continuing and the company is in discussions with potential distributors.

Summary

UBI had $18.1 million in cash at June 30. The company is capitalised at $122 million.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

NOTICE

The 4th Australian Microcap Investment Conference

The 4th Australian Microcap Investment Conference is being held in Melbourne at the Sofitel on Collins on Tuesday the **22nd** and Wednesday the **23rd** of **October**.
Biotech companies presenting include Biotron and Invion.

www.microcapconferences.com

IPO Profile – Mimetica

Dermatology company Mimetica is seeking a backdoor listing through Telesso Technologies (TEO). Telesso was previously known as Eiffel Technologies, from 2001 until 2008.

Mimetica, founded in June 2001, is developing MTC896 Gel as a topical treatment for acne vulgaris. The active ingredient of MTC896 Gel is a small molecule compound which blocks the Melanocortin-5 receptor (MCR5) and stops the production of sebum, (the substance that clogs hair follicles).

Mimetic's funding history includes investments of $14.5 million and a Commercial Ready grant of $1.7 million.

The Capital Raising

Telesso and Mimetica are seeking to raise a minimum of $6.5 million (26 million shares at 25 cents) and a maximum of $8 million to progress the development of MTC896 Gel. Mimetica is to be acquired by Telesso Technologies for $15.75 million. This figure includes $1.5 million of Convertible Notes which will be converted into 6 million Telesso shares.

Major shareholder QIC has committed $1.5 million towards the capital raising.

The proforma cash position for the merged entity, assuming the minimum capital raise, will be $7.5 million, and the shares on issue at completion, 98 million.

The Acne Drug Market

The acne drug market is large in terms of value of sales. The Mimetica Offer Document quotes the global acne market as being worth US$2.8 billion in 2010. The market is divided into topical treatments and oral treatments. Topical treatments contain active drug ingredients such as benzoyl peroxide, sulfur, resorcinol and salicylic or azelaic and various Vitamin A derivatives (retinoids). Oral treatments include antibiotics, contraceptives and isotretinoin.

Each of these class or group of drugs has one or more limitations which therefore create an opportunity for new approaches. Benzoyl peroxide is suitable only for mild acne but it causes irritation. Topical and oral antibiotics can also become subject to resistance, and in some cases (e.g. Doryx - doxycycline hyclate) are limited to dosing through the winter months. Contraceptives can't be used by males, and even with females, benefit takes months to occur. Oral isotretenoin (brand names Accutane and Roaccutane) gives rise to severe side effects, including birth defects. Its use is highly regulated.

The acne drug market is dominated by generics, which has driven down the value of sales over time. The dominance of generics has implications for the entrance of new branded, patent protected, drugs which must combat price sensitivity created by generic drugs for lower priced treatments.

Clinical Programs Completed and Planned

MTC896 Gel has been evaluated in four clinical studies to date, including a 30 subject irritation study, a 30 subject phototoxicity study and a 203 subject skin sensitisation study. These studies confirmed, respectively, that MTC896 was not irritating, phototoxic or allergenic. These studies have indicated that an appropriate concentration for MTC896 Gel was 0.75% w/w.

However, a Phase II study in 135 patients did not meet its primary endpoint of a statistically significant reduction in sebum secretion in all subjects at four weeks.

Mimetica deemed that the emergence of a downwards trend in squalene secretion (a biomarker of sebum) is sufficient evidence to progress with further clinical studies.

Hence the plan for Telesso/Mimetica is to conduct a larger and longer Phase II trial, which would enrol 240 subjects. The active arm would see MTC896 Gel applied twice daily for 12 weeks, with the control arm applying vehicle control gel twice daily for the same period.

The primary endpoint of the study would relate to the reduction in the number and severity of inflammatory and non-inflammatory lesions (an endpoint consistent with contemporary studies).

Prior to the commencement of the Phase II study, Telesso/Mimetica will conduct a 12 week toxicology study of MTC896 Gel in two animal species. These studies are designated as critical path milestones, because negative results could have the potential to bring about the termination of the entire program.

The clinical development of MTC896 Gel is covered by a US Investigational New Drug application which was cleared in 2009.

The current capital raising would support the merged entity through to the completion of end of Phase II (in mid-2015).

Major Shareholders

Assuming the completion of the minimum offer, Start-up Australia will have a 21% interest in the merged entity, Starfish Ventures 20%, AustralianSuper PE 12%, MTAA 11% and QIC will hold 11%.

Proposed Board and Management

The board post acquisition of the entity will comprise Dr Cherrell Hirst as Chair, Nick Peace (Starfish Ventures), Dr Ross MacDonald and Dr Rob Crombie, who will become the company's part-time CEO. Current CEO Dr Michael Thurn will take on the COO role.

Strengths

An attractive feature of MTC896 Gel is that it is a new approach for the treatment of acne treatment. New approaches, coupled to long patent lives, can increase the attractiveness of a technology to a licencing partner or acquirer.

Mimetica has refreshed the patents covering its technology so that its patent protection now extends out to 2029.

The total cost of development for MTC896 going forward relative to market opportunity is likely to be reasonable in terms of market opportunity. Two Phase III trials (each recruiting 500 subjects), for example (we estimate), might cost in the order of $15 million.

Bioshares Model Portfolio (16 August 2013)

Company	Price (current)	Price added to portfolio	Date added
Invion	$0.067	$0.060	August 13
IDT Australia	$0.370	$0.260	August 13
Viralytics	$0.320	$0.300	August 13
Circadian Technologies	$0.230	$0.270	March 2013
Tissue Therapies	$0.270	$0.255	March 2013
Benitec Biopharma	$0.290	$0.40	November 2012
Nanosonics	$0.835	$0.495	June 2012
Somnomed	$1.14	$0.94	January 2011
Cogstate	$0.390	$0.13	November 2007
Universal Biosensors	$0.70	$1.23	June 2007

Portfolio Changes – 16 August 2013

IN:
No changes.

OUT:
No changes.

The clinical development formats and protocols for acne drugs are well understood and are short in duration of the treatment period. The table below lists five Phase III trials underway. Generally speaking, an acne drug is tested over a 12 week period with the primary endpoints relating to reduction in lesions.

Weaknesses

The principle weakness for MTC896 Gel, in a strategic sense, is that it is being developed for a market dominated by generics. This means that the pricing of MTC896 Gel is dependent on achieving oustanding success in the clinic so that it can comfortably compete on a range of points of difference including acne reduction, lack of irritation and inflammation, absence of toxicity and year round administration.

Another characteristic of the acne drug market is that acne occurs across a spectrum, ranging from mild to very severe. What is yet to be determined is where MTC896 Gel is likely to be placed on the spectrum, and where the optimum financial returns can be found.

Another potential weakness for MTC896 Gel is that it being developed as a twice a day treatment, in contrast to the development of once-a-day treatments, as evidenced by GlaxoSmithKline's Duac Once Daily.

Summary

Although the key inflection point for MTC896 Gel will not be met until 2015 when the Phase II proof-of-concept trial is completed, interest in the offer stems from simple clinical endpoints, and relatively low risk and cost associated with the development of the product.

Offer Closes: 27 September, 2013

Bioshares

Selected Active Phase III Trials - Acne Vulgaris

Company	Drug Product	Comparator/s	Num. Pts	Duration	Expected Completion	Primary Endpoint
Taro Pharmaceuticals	Adapalene and Benzoyl Peroxide Gel 0.1%/2.5%	**Epiduo** (Adapalene and Benzoyl Peroxide Gel 0.1%/2.5% [manuf. by **Galderma**]; placebo	965	12 weeks	Oct-13	Inflammatory and non-inflammatory lesion counts
Taro Pharmaceuticals	Clindamycin 1%/Benzoyl Peroxide 5% Topical Gel	**Duac** Topical Gel (Clindamycin 1%/Benzoyl Peroxide 5%) [manuf. by **Stiefel**]; placebo	650	11 weeks - for bioequivalence	Oct-13	Bioequivalence of test gel to reference gel [mean percent change from baseline to week 11 in the number of inflammatory lesions]
Taro Pharmaceuticals	Clindamycin Phosphate and Benzoyl Peroxide Gel, 1.2%/2.5%	**Acanya** (Clindamycin Phosphate and Benzoyl Peroxide)Gel, 1.2%/2.5% [manuf. by **Valeant**]; placebo	1210	12 weeks	Sep-13	Mean percent change in inflammatory lesion counts; % change from baseline to week 12 in the inflammatory lesion counts
GlaxoSmithKline	Duac **Once Daily** Gel (1% Clindamycin as Clindamycin Phosphate and 5% Benzoyl Peroxide)	1% clindamycin phosphate gel (twice daily)	1020	12 weeks	Apr-14	Lesion count
Galderma R&D	CD0271 0.3% /CD1579 2.5% Gel	CD0271 0.3% /CD1579 2.5% Gel [SEVERE SUBJECTS]; placebo	493	12 weeks	Aug-14	Composite success rate defined as the percentage of subjects with an IGA of clear or almost clear

Source: www.clinicaltrials.gov

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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