

Australian Life Sciences

SECTOR REPORT

Some good stories emerging

- **The Australian Life Sciences sector** came under pressure in the US sell-off which ran from 25 February to 14 April 2014 and saw the Nasdaq Biotechnology Index (NBI) lose 21% of its value. However a recovery is now underway. The NBI is up 15% since mid-April and the 13 ASX-listed Life Science stocks highlighted in this report have risen on average by 8.6% since 20 May in US dollar terms. We see strong value emerging from the clinical and pre-clinical programmes of the companies listed below, and commend them to investors with the appropriate risk tolerance.
- **Alchemia (ACL)** is completing Phase III with HA-Irinotecan, a new formulation of an old cancer drug. The Phase III data, in metastatic colorectal cancer, reads out shortly. BUY. Target price \$1.10.
- **Admedus (AHZ)** has gained CE Mark and FDA approval for its first product, a cardiovascular tissue patch called CardioCel. Admedus is also working on DNA vaccines. BUY. Target price \$0.25.
- **Bionomics (BNO)** reported important Phase II data earlier this year for its BNC105 drug. The drug worked at Phase II in metastatic renal cell carcinoma patients for key patient subgroups. BUY. Target price \$0.90.
- **Cellmid (CDY)** is being built around midkine, a multi-disease target. An anti-midkine antibody for cancer therapy goes to the clinic in 2015. BUY. Target price \$0.07.
- **Cynata (CYP)**, a regenerative medicine company, has technology that helps solve a key problem with adult stem cells, which is availability of cells at reasonable cost. BUY. Target price \$0.90.
- **Mesoblast (MSB)** is pioneering the exciting field of regenerative medicine. The company has numerous stem cell trials ongoing including several Phase IIIs, one with Teva. BUY. Target price \$8.50.
- **Nanosonics (NAN)** is now earning revenue from trophon EPR, which disinfects ultrasound probes. This product may become a healthcare industry standard, helped by GE as a distributor. BUY. Target price \$1.15.
- **Neuren (NEU)** is developing NNZ-2566, now in Phase II in Traumatic Brain Injury, Rett Syndrome and Fragile X Syndrome. Clinical success in any of these makes a potential blockbuster. BUY. Target price \$0.26.
- **Oncosil (OSL)** is developing a brachytherapy device similar to Sirtex's SIR-Spheres product. A registration trial in pancreatic cancer is getting underway aimed at FDA approval. BUY. Target price \$0.45.
- **Phosphagenics (POH)** has developed the world's first patches delivering the painkilling drugs oxycodone and oxymorphone. These products go to Phase II this year. BUY. Target price \$0.26.
- **Rhinomed (RNO)** is commercialising an internal nasal dilation platform called BreatheAssist. The initial BreatheAssist product launched into the sports performance market in January 2014. BUY. Target price \$0.12.
- **Sirtex Medical (SRX)** now has a \$100m-a-year business in its SIR-Spheres radioactive beads for the treatment of liver cancer. Data from some large clinical trials reads out from 2015. BUY. Target price \$21.00.
- **Tissue Therapies (TIS)** has in VitroGro ECM, a compelling wound healing product for the treatment of venous and diabetic foot ulcers. Granting of CE Mark could substantially re-rate the stock. BUY. Target price \$0.65.

STOCKS COVERED IN THIS REPORT

Company	Page No.
Admedus (AHZ)	6
Alchemia (ACL)	9
Bionomics (BNO)	12
Cellmid (CDY)	15
Cynata (CYP)	18
Mesoblast (MSB)	21
Nanosonics (NAN)	24
Neuren Pharmaceuticals (NEU)	27
Oncosil (OSL)	30
Phosphagenics (POH)	33
Rhinomed (RNO)	36
Sirtex Medical (SRX)	39
Tissue Therapies (TIS)	42

Disclosure

The author owns no shares in AHZ, ACL, BNO, CDY, CYP, MSB, NAN, NEU, OSL, POH, RNO, SRX and TIS.

Baillieu Holst Ltd has raised funds for Admedus Ltd and Rhinomed Ltd and earned fees in relation to those activities in the past 12 months.

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Recommendations

Buy: The stock's total return is expected to increase by at least 10-15% from the current share price over the next 12 months.

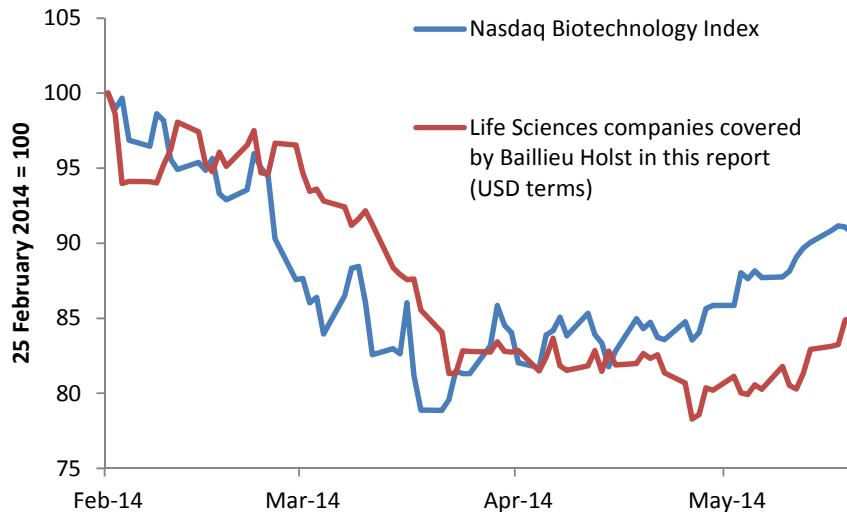
Hold: The stock's total return is expected to trade within a range of ±10-15% from the current share price over the next 12 months.

Sell: The stock's total return is expected to decrease by at least 10-15% from the current share price over the next 12 months.

Life Sciences – The recovery is underway

- **Tough times.** After a strong five year run, the Nasdaq Biotechnology Index sold off 21% between 25 February and 14 April, taking with it many Australian Life Science stocks.

FIG.1: THE NASDAQ BIOTECHNOLOGY INDEX DROPPED 21% IN LESS THAN TWO MONTHS, AND THEN STARTED RECOVERING. ASX-LISTED STOCKS FOLLOWED A MONTH LATER.



Source: Baillieu Holst

- **We see five main reasons for the recent sell-off:**
 - There was concern that as US monetary policy tightened, the environment for emerging companies would be less favourable;
 - There had been concerns that a bubble had been building up in the sector;
 - There had been concerns that drug pricing would come under pressure – the sell-off started when some market followers became worried that the \$84,000 price of Gilead's Sovaldi Hepatitis C drug was too high;
 - The area had been a strong performer in 2012 and 2013 so it was used as a 'funding area' for portfolio managers to realise cash in their portfolios; and
 - As in March 2000, biotech's downturn was part of a broader sell off of internet and software stocks.
- **The market has stabilised and is recovering.** Since about 14 April the market environment has been better, with the Nasdaq Biotechnology Index rising 15%:
 - Large-cap biotech stocks like Gilead, Celgene and Biogen Idec stabilised quickly because of positive cash flows and attractive valuations;
 - There was clinical success, such as InterMune's recent data with its IPF drug perfenidone¹;
 - There is a continued recognition that Big Pharma will need pipeline if it is to avoid the fate of AstraZeneca, which attracted a hostile takeover offer from Pfizer; and
 - The June 2014 agreement by Merck to buy Hepatitis C drug developer Idenix for US\$3.85bn suggests that Big Pharma remains eager to compete in new drug classes.

AstraZeneca could have avoided a takeover offer if its pipeline had been better

¹ See the InterMune press release dated 18 May 2014 and headlined 'Phase 3 ASCEND Study of Pirfenidone in Idiopathic Pulmonary Fibrosis Presented at American Thoracic Society (ATS) and Published in New England Journal of Medicine'.

Why biotechnology has enjoyed boom times in the US

- **The US biotech sector created significant value for investors for five years.** Since the start of the Global Financial Crisis in September 2008 the US biotech sector has generally trended upwards, with an occasional pause for breath. Even after the February-April 2014 sell-off, the benchmark Nasdaq Biotechnology Index is up 21.5% p.a. on September 2008. The boom, which took many people by surprise, was created by a number of significant factors:
 - **The high prices paid by pharma to acquire biotech companies.** The last five years has seen numerous transactions in which biotech companies were acquired by Big Pharma in order for those pharma companies to have new drugs in their pipelines. Probably the most notable deal was Gilead's. It paid US\$11.5bn in 2012 for Pharmasset, just as that company was entering Phase III with a suite of Hepatitis C drugs. Deals this year have included Lundbeck paying US\$685m for Chelsea Therapeutics.
 - **Clinical and regulatory success by many companies.** A lot of companies that went public during another boom in the late 1990s have now been able to go all the way and create new drugs more or less from scratch. Consider Exelixis (Nasdaq EXEL), a San Francisco-based drug developer. It went public on Nasdaq in April 2000. It gained FDA approval for its first product, a cancer drug called Cometriq, in November 2012. The FDA has recently been approving more drugs than usual. 2012 saw 39 new drugs, the biggest number in a decade, although that number fell to 27 in 2013.
 - **Passage of 'universal' health care in the US.** The Patient Protection and Affordable Care Act of 2010 (PPACA), which notionally brought universal healthcare to America (although the system will still, regrettably, leave many without coverage), was intended to enlarge the patient population for new drugs being created by biotech companies. Around 47 million people in America had no health insurance in 2012.
 - **Continued high prices for many drugs.** In an era of budget austerity there have been concerns that drug prices would gradually come down. While that happens for drugs that go off-patent, for many drugs on patent the prices are still quite economic for both the drug companies and the healthcare system (which gets value for money in terms of cost effectiveness). There has also been a big push in the biotech industry for Orphan Drugs (i.e. drugs for small patient and hitherto unserved patient populations) where high prices (e.g. US\$300,000 per year) are more acceptable.
 - **Increased understanding by investors of the value drivers in biotechnology.** Increasingly, generalist investors in America have been playing in biotech alongside the specialist funds. Basically fund managers have become aware of biotech and how the industry works.

America's Gilead paid US\$11.5bn for a drug development company called Pharmasset

FIG.2: THE NASDAQ BIOTECHNOLOGY INDEX HAS RISEN 21.5% PA SINCE SEP. 2008



Source: Baillieu Holst

Our approach to analysing Life Sciences companies

- **In order to get the most out of this note, the following factors need to be kept in mind:**
 - **We don't currently have HOLD or SELL recommendations.** We are generally bullish on the prospects of the Life Sciences sector in Australia and believe it is in the process of being re-rated over the medium term. In this note we have picked stocks that we regard as particularly good buying at current prices. There are Life Sciences companies on which we aren't so bullish for various reasons, and we have chosen not to publish on those companies.
 - **We value Life Science stocks using a probability-weighted DCF approach.** We create standard discounted-cash flow models for a company's programmes, and then adjusting for the probability of clinical or regulatory failure where the product is still in development. Our probability weights are fairly reliable because they are based on the long-term record of the biotech industry. For example, history suggests that a large molecule drug currently in Phase II development in the US has a 53% chance of successfully completing that Phase² and a 38% chance of gaining FDA approval. So for a model of a drug in Phase II we usually reduce our un-risked valuation by 62%. For a relevant discount rate, we use WACCs of between 12% and 16.4% depending on the risk. This is derived from a RFR of 3.7%; a MRP of 7.5%³ for 'medium risk' companies rising to 11.5% for 'speculative' companies, and an ungeared beta of ~1.1⁴. We calculate a base case and an optimistic case and use the low point of the two valuations in selecting our target price, unless the stock has surpassed the low point, when we use the midpoint instead.
 - **Our target prices may look aggressive, but that reflects current market inefficiencies.** In many instances our target price is way above the current market price. For example, our target price for Rhinomed is \$0.12 whereas the market is currently ~\$0.02. Australia, unlike the US with Nasdaq, hasn't traditionally been a market with high levels of analytical expertise in Life Sciences. This has led to pricing inefficiencies. However we argue that, with many companies now quite advanced in terms of their clinical or commercial development, the mispricing is set to become rarer.
 - **We use three kinds of risk – Medium, High and Speculative.** Frankly, 'Low risk' companies in the Life Sciences space don't exist given the potential for things to go wrong. We regard Life Science companies with existing businesses, or who have enough capital to reach the market with their products, as 'Medium' risk. Companies that have small revenue streams from marketed products but that are still potentially in need of capital are 'High' risk. Everything else is 'Speculative'.
 - **Life Sciences are best addressed with a portfolio approach.** Typically a small drug in Phase II has a ~20% chance of being successful⁵. This suggests that a carefully selected portfolio of around five companies at the Phase II stage of development has a good chance of paying off, if held over the five-or-so year time horizon it can take to move from Phase II to Phase III. In this note we present thirteen companies we think are worthy of inclusion in such a portfolio.

Traditionally Australia hasn't priced Life Science companies efficiently.

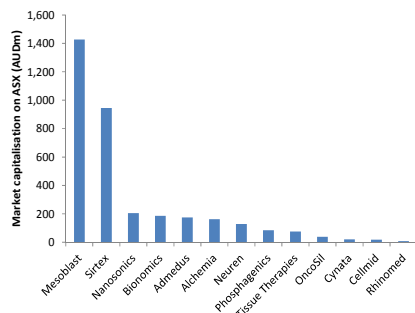
² See Di Masi et. al., Clinical Pharmacology & Therapeutics (2010) 87 3, 272–277.

³ We looked at MRP through time in choosing this figure. Specifically, we used the ten-year return for the All Ordinaries Accumulation Index for any period since 1979, less the Australian 10 year bond rate at the end of the relevant period. Using this approach MRP has been above 7.5% only 11.5% of the time since late 1989.

⁴ This is the standard for US biotech companies. That said, our analysis suggests that Life Sciences companies in Australia are counter-cyclical. Our Baillieu Holst Life Sciences Index has a beta of around 0.7 against the All Ordinaries Index.

⁵ Large molecules are closer to 40%.

FIG.3: BAILLIEU HOLST LIFE SCIENCES COVERAGE UNIVERSE



Source: Baillieu Holst

FIG.4: WE SEE CONSIDERABLE UPSIDE IN THE LIFE SCIENCES STOCKS THAT WE COVER

Code	Company	Current price (AUD c)	Target price (AUD c)	Upside to target
AHZ	Admedus	12.8	25	96.1%
ACL	Alchemia	49.5	110	122.2%
BNO	Bionomics	43.5	90	106.9%
CDY	Cellmid	2.5	7	180.0%
CYP	Cynata	46.0	90	95.7%
MSB	Mesoblast	439.0	850	93.6%
NAN	Nanosonics	80.0	115	43.8%
NEU	Neuren	8.3	26	213.3%
OSL	OncoSil	11.0	45	309.1%
POH	Phosphagenics	8.5	26	205.9%
RNO	Rhinomed	2.1	12	471.4%
SRX	Sirtex	1621.0	2100	29.5%
TIS	Tissue Therapies	29.5	65	120.3%
Average				160.6%

Source: Baillieu Holst

FIG.5 LIFE SCIENCE COMPANIES COVERED BY BAILLIEU HOLST

Code	Company	Headquarters	Cap (A\$)	Initiation price (AUD c)	Date of initiation	Price now (AUD c)	Change	Risk rating
AHZ	Admedus	Brisbane	174.2	15.5	27/11/2013	12.8	-17.7%	High
ACL	Alchemia	Melbourne	162.2	60.0	27/11/2013	49.5	-17.5%	High
BNO	Bionomics	Adelaide	185.7	81.0	27/11/2013	43.5	-46.3%	Speculative
CDY	Cellmid	Sydney	18.4	2.3	30/05/2014	2.5	8.7%	High
CYP	Cynata	Melbourne	20.7	36.0	30/05/2014	46.0	27.8%	Speculative
MSB	Mesoblast	Melbourne	1,428.0	615.0	27/11/2013	439.0	-28.6%	Medium
NAN	Nanosonics	Sydney	205.8	84.0	27/11/2013	80.0	-4.8%	Medium
NEU	Neuren	Melbourne	128.8	13.5	27/11/2013	8.3	-38.5%	Speculative
OSL	OncoSil	Sydney	39.1	13.0	17/03/2014	11.0	-15.4%	Speculative
POH	Phosphagenics	Melbourne	84.7	12.5	27/11/2013	8.5	-32.0%	High
RNO	Rhinomed	Melbourne	7.9	2.0	23/05/2014	2.1	5.0%	High
SRX	Sirtex Medical	Sydney	944.3	1200.0	27/11/2013	1621.0	35.1%	Medium
TIS	Tissue Therapies	Brisbane	76.3	23.0	27/11/2013	29.5	28.3%	Speculative
Average							-7.4%	

Source: Baillieu Holst and company data

Admedus (AHZ) – Growing with CardioCel

BUY. Target price \$0.25

- **Note:** Baillieu Holst Ltd has raised funds for Admedus Ltd and earned fees in relation to those activities in the past 12 months.
- **Company description.** Admedus has gained CE Mark and FDA approval for its first product, a cardiovascular tissue patch called CardioCel. First sales were made in Europe in November 2013 and in the US in May 2014. CardioCel is created using the company's ADAPT technology, which allows animal tissue to be prepared for use in humans without the usual calcification issues. Beyond tissue repair, Admedus is seeking to be a major player in the emerging field of DNA vaccines. It is the largest shareholder in Admedus Vaccines, which is developing DNA vaccine technology from the laboratory of Professor Ian Frazer at the University of Queensland.
- **Admedus has something new in soft tissue repair.** Traditionally animal tissue used for soft tissue repair in humans has quickly undergone calcium deposition, thereby limiting the usefulness of the tissue as it hardens and loses its flexibility. Admedus' ADAPT technology allows animal tissue to be prepared with about the same level of calcification as regular human tissue. The first product from this technology, CardioCel for the repair and reconstruction of heart defects, gained CE Mark approval in August 2013 and 510(k) approval from the FDA in February 2014. This followed on from favourable long-term (ie. multi-year) clinical data on the acceptability, functionality and durability of ADAPT patches. Admedus has launched the product in the paediatric congenital heart disease market and will widen it out to serve the adult market for coronary heart disease. The market approval in the US extends beyond cardio repairs into vascular and vessel tissue.
- **CardioCel brings many benefits.** Along with no calcification, CardioCel does not generate the cytotoxic issues seen with other products on the market and therefore facilitates an autologous regeneration around the implant. This means less repeat or re-do surgeries for patients. Also, CardioCel and ADAPT tissue is 'surgery ready' and off-the-shelf which has short term benefit in terms of time in surgery and therefore economic benefit.
- **There are many commercial opportunities coming for ADAPT.** Perhaps ~US\$1bn p.a. gets spent in the US on tissue repair solutions for hernia and pelvic floor repair alone, and ADAPT represents one of the few potential biological alternatives to existing products. Admedus will seek to target these markets as well as the orthopaedic market down the track. The company believes that ADAPT makes an ideal delivery system for therapeutic stem cells, an area of medicine expected to loom large over the next decade.
- **Admedus is a player in DNA vaccines.** Various companies and academic groups around the world have been working on DNA vaccines in both therapeutic and prophylactic indications for over two decades. There have been a number of technical hurdles that have prevented a DNA vaccine from proving successful in late stage clinical trials. However, many of these hurdles have been overcome, raising the prospect of approval for a DNA vaccine sometime in the next ten years. It is reasonable to expect the stock of Admedus, as a committed DNA vaccine player, to benefit from progress by the leading groups in the field, including the listed companies Inovio (NYSE MKT: INO, market capitalisation US\$530m) and Vical (Nasdaq: VICL, US\$102m)⁶. While its work in the field is still at an early stage, Admedus Vaccines has generated encouraging pre-clinical and early clinical data.
- **Admedus Vaccines has generated impressive pre-clinical and clinical results.** Admedus Vaccines has created a DNA vaccine for HSV-2 infection with both prophylactic and therapeutic potential in genital herpes. There is also a therapeutic vaccine in the works, to treat HPV infection. In October 2011, Admedus reported that the HSV-2 vaccine had generated a remarkable 90-100% survival rate for rabbits in a challenge study at 500 times the LD50 (the amount of virus that would kill half the rabbits). Importantly, this study showed that both arms of the murine immune system were being activated. The commercial value of the vaccine lies in the fact that there is currently no genital herpes vaccine, infection is life-long, and at least 25 million Americans aged 14-49 are infected⁷. Admedus Vaccines reported interim data from an HSV-2 Phase I clinical study in early 2014, which showed the vaccine's ability to generate a T cell response in healthy volunteers. Full data is expected later in 2014. Positive preclinical results for the HPV vaccine were reported in late 2012.

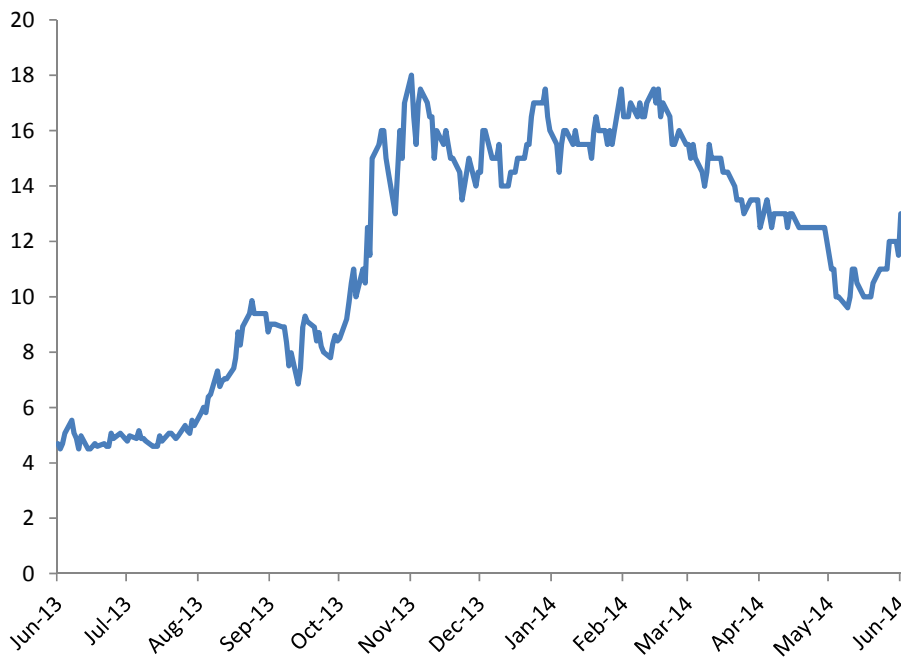
Admedus may have the first vaccine for genital herpes.

⁶ 12 June 2014 close on Nasdaq.

⁷ For the population as a whole the number may be closer to 50 million.

- **Admedus is undervalued on our numbers.** We value Admedus at \$0.27 per share base case and \$0.61 per share optimistic case. Our target price of \$0.25 sits at around the low point of our valuation range. We expect the market to re-rate Admedus as further clinical and pre-clinical data emerges and CardioCel gains commercial traction.
- **VALUATION METHODOLOGY.** Our probability-weighted DCF of Admedus⁸ was built as follows:
 - Our WACC was 14.2% (High risk);
 - We modelled payoffs from CardioCel (self-distributed) and the HSV-2 and HPV vaccine candidates (partnered, 21% probability of clinical and regulatory success⁹);
 - We assumed HSV-2 is licensed in FY16 (US\$100-200m in upfronts, US\$300-500m in milestones, 10-14% royalties) and HPV in FY18 (US\$100-200m in upfronts, US\$120-150m in milestones, 10-14% royalties), with the two products launching around 2-3 years after licensing.
 - We assumed peak sales of US\$600-900m for CardioCel, US\$2.5-3.2bn for HSV-2 and US\$1.2-2.2bn for HPV.
 - We assume no further equity capital needs to be raised.
- **MAJOR SHAREHOLDER:** Minderoo Group (Andrew Forrest, 12%).
- **KEY RISKS:** 1) Commercial risk for CardioCel; 2) Clinical risk for HSV-2 vaccine; 3) Clinical risk for HPV vaccine; and 4) Funding risk.

FIG.6 ADMEDUS SHARE PRICE



Source: Iress

⁸ Previous valuation range from 28 March 2014 was \$0.25 / \$0.56 – new valuation results from lower discount rate.

⁹ The probability of success for small molecules in Phase III. This is conservative because the HA component of the product would suggest a large molecule probability of 71%. See DiMasi et. al., Clinical Pharmacology & Therapeutics 87, 272-277 (March 2010).

Admedus - Financial Summary

Code AHZ
Analyst Stuart Roberts
Date 13 June, 2014
Share price \$0.130
Market capitalisation \$187m
Year end 30 June

Rating BUY
Price target \$0.25
Upside/downside 92.3%
Valuation \$0.273 / \$0.609
Valuation method Probability-weighted DCF
Risk High

PROFIT AND LOSS (A\$m)

Y/e June 30 (A\$m)	FY12A	FY13A	FY14E	FY15E	FY16E
Revenue	6	7	14	28	54
EBITDA	-10	-3	-2	1	12
D&A	0	0	-1	-1	-1
EBIT	-10	-3	-3	0	11
Net interest	0	0	0	2	2
Pre-tax profit	-10	-3	-3	2	13
Tax	0	1	0	0	0
NPAT	-10	-2	-3	2	13
Minority interests	0	0	0	0	0
Net profit after minorities	-10	-2	-3	2	13

BALANCE SHEET (A\$m)

Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
Cash	2	2	27	29	42
Current receivables	1	2	1	1	1
Inventories	2	2	2	2	2
Other current assets	0	0	0	0	0
Current assets	5	6	30	32	45
PPE	0	0	3	2	2
Intangible assets	3	10	9	9	9
Other non-current assets	3	1	1	2	2
Non-current assets	6	11	13	13	13
Total assets	11	17	43	45	58
Payables	0	1	0	0	0
Debt	0	0	0	0	0
Other liabilities	0	1	1	1	1
Total liabilities	1	1	2	2	2
Shareholders' equity	10	13	40	42	55
Minorities	0	2	1	1	1
Total shareholders funds	10	15	42	44	57
Total funds employed	11	17	43	45	58
W/A shares on issue	663	908	1,302	1,445	1,445

CASH FLOW (A\$m)

Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
NPAT plus discontinued ops.	-10	-2	-3	2	13
Non-cash items	7	-1	1	1	1
Working capital	-1	-1	-2	0	0
Other operating cash flow	0	0	0	0	0
Operating cashflow	-4	-4	-3	3	14
Capex	0	0	0	0	0
Investments	-2	-1	0	0	0
Other investing cash flow	0	0	0	0	0
Investing cashflow	-2	-1	-1	-1	-1
Change in borrowings	0	0	0	0	0
Equity raised	6	4	29	0	0
Dividends paid	0	0	0	0	0
Other financing cash flow	0	0	0	0	0
Financing cashflow	7	5	29	0	0
Net change in cash	1	0	25	2	13
Cash at end of period	2	2	27	29	42

EARNINGS (A\$m)

Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
Net profit (\$m)	-10.2	-2.4	-2.5	1.6	12.9
EPS (c)	-1.5	-0.3	-0.2	0.1	0.9
EPS growth (%)	N/A	N/A	N/A	N/A	711%
P/E ratio (x)	-8.4	-48.8	-66.7	117.8	14.5
CFPS (c)	-0.5	-0.4	-0.3	0.2	1.0
Price/CF (x)	-24.4	-31.9	-49.9	72.2	13.6
DPS (c)	0.0	0.0	0.0	0.0	0.0
Yield (%)	0.0%	0.0%	0.0%	0.0%	0.0%
Franking (%)	N/A	N/A	N/A	N/A	N/A
EV/EBITDA	-16.0	-58.6	-75.3	165.6	13.6
EV/EBIT	-15.6	-53.4	-55.3	3355.9	14.6

PROFITABILITY RATIOS

Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
EBITDA/revenue (%)	-157.1%	-37.3%	-15.8%	3.5%	21.9%
EBIT/revenue (%)	-161.3%	-41.0%	-21.5%	0.2%	20.5%
Return on assets (%)	-91.3%	-14.6%	-5.8%	3.5%	22.2%
Return on equity (%)	-98.0%	-16.0%	-6.1%	3.7%	22.8%
Return on funds empl'd (%)	-97.8%	-16.0%	-6.1%	3.7%	22.8%
Dividend cover (x)	N/A	N/A	N/A	0%	0%
Effective tax rate (%)	1.3%	20.0%	3.6%	0.0%	0.3%

LIQUIDITY AND LEVERAGE RATIOS

Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
Net debt/(cash) (\$m)	-2	-2	-27	-29	-42
Net debt/equity (%)	-19.6%	-16.2%	-65.6%	-67.4%	-74.9%
Net interest cover (x)	N/A	N/A	N/A	N/A	N/A
Current ratio (x)	7.8	6.7	58.4	59.8	80.9

INTERIMS

Y/e June 30 (\$m)	1H13A	2H13A	1H14A	2H14F	1H15F
Revenue	4	4	8	6	9
EBITDA	-2	-1	-1	-1	-4
D&A	0	0	0	-1	0
EBIT	-2	-1	-2	-1	-4
Net interest	0	0	0	0	1
Pre-tax profit	-2	-1	-2	-1	-3
Tax	0	1	0	0	0
NPAT	-2	0	-1	-1	-3
Minority interests	0	0	0	0	0
Net profit after minorities	-2	0	-1	-1	-3

VALUATION

	Base	Optim.
CardioCel (A\$m)	347.4	815.4
HSV-2 vaccine (A\$m)	28.0	56.1
HPV vaccine (A\$m)	16.4	42.5
Total value for technology (A\$m)	391.8	914.0
Value of tax losses	4.0	4.0
Underlying R&D cost	-9.6	-9.6
Cash now (A\$m)	25.4	25.4
Cash from options and cash to be raised	11.6	11.6
Total value (A\$m)	423.2	945.4
Total diluted shares (million)	1551.5	1551.5
Value per share	\$0.27	\$0.61
Valuation midpoint	\$0.44	
Share price now (A\$ per share)	\$0.130	
Upside to midpoint	239.3%	

Alchemia (ACL) – A big pay-day is coming

BUY. Target price \$1.10

- **COMPANY DESCRIPTION.** Alchemia has been built on technology for the discovery and synthesis of carbohydrate-based drugs. The company's first marketed product, a generic version of the blood thinning agent fondaparinux, gained FDA approval in July 2011 and Alchemia received A\$9.6m in profit share in FY13 from the product. Alchemia is in Phase III with HA-Irinotecan, a new targeted formulation of an off-patent cancer drug. The trial, in metastatic colorectal cancer patients, is expected to read out data in the third quarter of calendar 2014. Phase II data suggested a strong increase in Progression-Free Survival (PFS) for these patients.
- **Riding on Reddy's coat-tails.** Alchemia enjoys a 50% profit share from Dr Reddy's North American sales of fondaparinux, which we believe translates to a 25-30% revenue share. Dr Reddy's is a substantial player in the generic drug scene globally, with a current market capitalisation of US\$6.95bn¹⁰ and its US sales force has been growing in competitiveness in recent years. The Alchemia/Reddy's product was the first generic to GSK's Arixtra and it currently has a 33% generic market share by volume. We expect that its sales will grow over time due to concerns over deep vein thrombosis. We also expect that Reddy's will continue to lower manufacturing costs. We see potential for Alchemia to monetise its fondaparinux revenue stream through various strategic options.
- **Phase III data coming soon.** HA-Irinotecan is an off-patent cancer drug called Irinotecan (Pfizer's old Camptosar drug, peak sales US\$970m in 2007, before loss of exclusivity in 2008) but targeted using a hyaluronic acid (HA) formulation. Cancer cells overexpress receptors for HA on their surfaces, so formulating a cancer drug in HA better targets that drug. This allows more drug to get inside the tumour cells and thereby achieve higher efficacy with the same dose. In a 76-patient Phase II trial in metastatic colorectal cancer patients HA-Irinotecan more than doubled PFS, from 2.4 months in the control group to 5.2 months in the HA-Irinotecan group (p=0.017)¹¹. HA-Irinotecan's 415-patient Phase III trial in metastatic colorectal cancer, randomising 1/1 to FOLFIRI¹² or FOLF(HA)iri, completed enrolment in February 2013 and results are expected to be available in the third quarter of calendar 2014. The FDA and EMEA are only requiring a single trial of HA-Irinotecan, so Alchemia may be filing for approval in the first half of 2015. Alchemia has powered the study to show a >6 week improvement in PFS. The long wait for this trial to conclude – after the 350th progression event or death – suggests favourable outcomes for the treatment group. The company believes HA-Irinotecan's sales potential is > US\$0.5bn pa and it is currently looking at partnering options.
- **A valuable platform technology.** Alchemia calls its HA formulation technology 'HyACT'. There is strong upside for Alchemia from further HyACT products beyond HA-Irinotecan, given evidence that HA can increase the effectiveness of many other cancer drugs including doxorubicin, 5FU and methotrexate. There is also potential for Alchemia to build a strong pipeline from its carbohydrate drug discovery engine, called VAST. The company currently has collaborations ongoing with various companies including AstraZeneca.
- **A cancer stem cell play.** Alchemia is in Phase II with HA-Irinotecan in small cell lung cancer, potentially a US\$10bn market. This trial is important because it will investigate whether or not HyACT-formulated drugs can, by targeting CD44, kill cancer stem cells¹³. That Wall Street has been very interested in cancer stem cells is evidenced by Nasdaq-listed companies such as Verastem (VSTM, market cap US\$253m), Oncomed (OMED, US\$737m) and Stemline (STML, US\$212m)¹⁴.
- **Alchemia has good management.** CEO Thomas Liquard and his colleagues are taking a commercial approach to building value in Alchemia, seeking to conserve the company's cash ahead of the payday from fondaparinux and HA-Irinotecan.
- **Catalyst for a re-rating coming soon.** We value Alchemia on a probability-weighted DCF basis at \$1.15 base case and \$2.22 optimistic case. Our \$1.10 price target sits at around the low point of this range. We anticipate the stock being re-rated by the market as data read-out from the trial draws near.

HA-Irinotecan more than doubled Progression-Free Survival at Phase II in metastatic colorectal cancer

¹⁰ 12 June 2014 close of ADYs on NYSE, code RDY.

¹¹ See Cancer Chemother Pharmacol. 2011 Jan;67(1):153-63. Epub 2010 Mar 24.

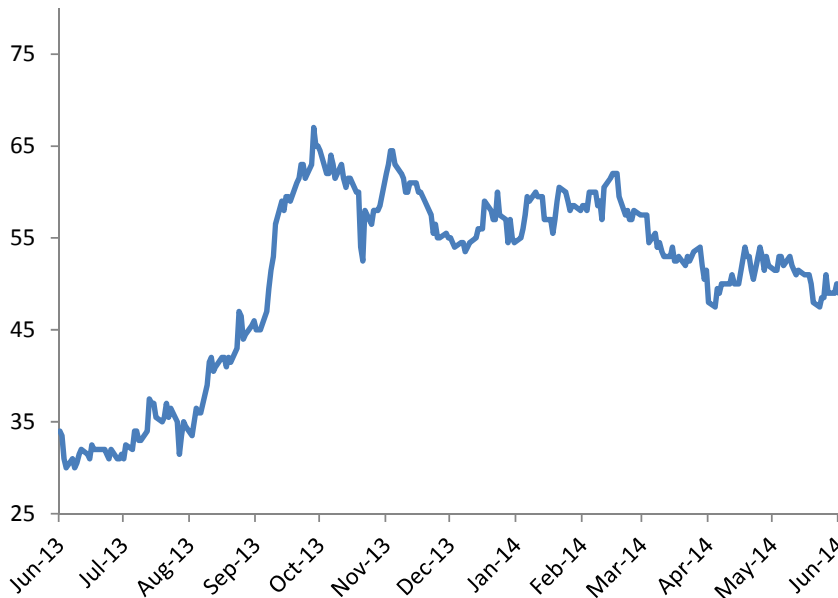
¹² FOLFIRI is folic acid (FOL) plus 5-fluorouracil (F) plus irinotecan (IRI).

¹³ CD44 is well known as a cancer stem cell marker. See Cancer Res. 2013 Jul 1;73(13):4112-22. Epub 2013 Apr 30.

¹⁴ 12 June 2014 close on Nasdaq.

- **VALUATION METHODOLOGY.** Our probability-weighted DCF of Alchemia¹⁵ was built as follows:
 - Our WACC was 14.2% (High risk);
 - HA-Irinotecan was modelled using 56% probability of clinical and regulatory success¹⁶, after which we assume the product licenses in FY15 for US\$40-70m upfront, US\$120-150m in regulatory/sales milestones, and 10-14% royalties. We modelled US\$800-1.2bn in year five sales for the licensee, peaking at US\$2.7bn-US\$3.9bn near the end of patent life.
 - The fondaparinux revenue stream was modelled on an assumption of Reddy's more or less maintaining current generic share, with generics approaching 90-100% of the market by the early 2020s. We assume that the overall market growth slows to around 3-5% by this stage as other classes of blood thinner step up in medical importance. For our base case we adjust pricing to account for another generic player but for our optimistic case we assume just three suppliers – Reddy's, Apotex and Aspen, which in September 2013 bought the rights to GSK's branded product.
 - We allowed a basic A\$20-40m valuation for VAST given that it would probably cost this much to develop a competing platform, while the platform is attracting collaboration interest and can allow a pipeline to be generated.
 - We assume no further equity capital needs to be raised.
- **MAJOR SHAREHOLDERS.** Allan Gray (18.2%), Hunter Hall (7.9%), Armada Trading (Tony Berg, 5.1%).
- **KEY RISKS.** 1) Failure of the Phase III for HA-Irinotecan; 2) Increased generic competition for fondaparinux; 3) Funding risk.

FIG.7: ALCHEMIA SHARE PRICE



Source: Iress

¹⁵ Previous valuation range from 28 November 2013 was \$1.06 / \$1.99 – new valuation results from lower discount rate.

¹⁶ The probability of success for small molecules in Phase III. This is conservative because the HA component of the product would suggest a large molecule probability of 71%. See DiMasi et. al., op. cit.

Alchemia - Financial Summary

Code ACL
Analyst Stuart Roberts
Date 13 June, 2014
Share price \$0.50
Market capitalisation \$161m
Year end 30 June

Rating BUY
Price target \$1.10
Upside/downside 122.2%
Valuation \$1.151 / \$2.217
Valuation method Probability-weighted DCF
Risk High

PROFIT AND LOSS (A\$m)					
Y/e June 30 (A\$m)	FY12A	FY13A	FY14E	FY15E	FY16E
Revenue	0	24	17	64	110
EBITDA	-14	-4	-2	44	89
D&A	-2	-2	-1	-1	-1
EBIT	-16	-5	-4	42	88
Net interest	0	0	1	2	5
Pre-tax profit	-15	-5	-3	44	93
Tax	0	0	0	0	-3
NPAT	-15	-5	-3	44	89
Minority interests	0	0	0	0	0
Net profit after minorities	-15	-5	-3	44	89

BALANCE SHEET (A\$m)					
Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
Cash	12	5	12	57	148
Current receivables	0	12	3	4	4
Inventories	0	0	0	0	0
Other current assets	3	9	9	9	9
Current assets	16	26	23	69	161
PPE	0	0	0	0	0
Intangible assets	16	15	13	12	11
Other non-current assets	0	0	0	0	0
Non-current assets	17	15	14	12	11
Total assets	32	41	37	81	172
Payables	3	5	3	3	3
Debt	0	0	0	0	0
Other liabilities	5	4	4	4	4
Total liabilities	8	9	6	7	7
Shareholders' equity	24	32	30	75	165
Minorities	0	0	0	0	0
Total shareholders funds	24	32	30	75	165
Total funds employed	32	41	37	81	172
W/A shares on issue	242	292	324	324	325

CASH FLOW (A\$m)					
Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
NPAT plus discontinued ops.	-15	-5	-3	44	89
Non-cash items	2	2	2	2	2
Working capital	1	-10	8	-1	0
Other operating cash flow	0	0	0	0	0
Operating cashflow	-12	-13	7	45	91
Capex	0	0	0	0	0
Investments	0	-6	0	0	0
Other investing cash flow	0	0	0	0	0
Investing cashflow	0	-6	0	0	0
Change in borrowings	0	0	0	0	0
Equity raised	20	12	0	0	0
Dividends paid	0	0	0	0	0
Other financing cash flow	0	0	0	0	0
Financing cashflow	20	12	0	0	0
Net change in cash	9	-7	7	45	91
Cash at end of period	12	5	12	57	148

EARNINGS (A\$m)					
Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
Net profit (\$m)	-15.1	-4.8	-2.8	43.9	89.5
EPS (c)	-6.2	-1.6	-0.9	13.5	27.6
EPS growth (%)	N/A	N/A	N/A	N/A	104%
P/E ratio (x)	-7.9	-30.3	-57.3	3.7	1.8
CFPS (c)	-4.9	-4.5	2.2	13.9	28.0
Price/CF (x)	-10.2	-10.9	22.5	3.6	1.8
DPS (c)	0.0	0.0	0.0	0.0	0.0
Yield (%)	0.0%	0.0%	0.0%	0.0%	0.0%
Franking (%)	N/A	N/A	N/A	N/A	N/A
EV/EBITDA	-10.4	-40.1	-70.4	3.4	1.6
EV/EBIT	-9.2	-27.9	-41.7	3.5	1.7

PROFITABILITY RATIOS					
Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
EBITDA/revenue (%)	-4195.8%	-15.2%	-11.9%	68.1%	81.0%
EBIT/revenue (%)	-4709.2%	-21.8%	-20.1%	65.9%	79.8%
Return on assets (%)	-46.6%	-11.5%	-7.6%	53.8%	52.1%
Return on equity (%)	-62.2%	-14.7%	-9.2%	58.7%	54.3%
Return on funds empl'd (%)	-62.2%	-14.7%	-9.2%	58.7%	54.3%
Dividend cover (x)	N/A	N/A	N/A	0%	0%
Effective tax rate (%)	2.6%	5.4%	0.0%	0.0%	3.5%

LIQUIDITY AND LEVERAGE RATIOS					
Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
Net debt/(cash) (\$m)	-12	-5	-12	-57	-148
Net debt/equity (%)	-50.9%	-15.6%	-39.1%	-76.2%	-90.0%
Net interest cover (x)	N/A	N/A	N/A	N/A	N/A
Current ratio (x)	3.3	4.4	6.9	17.8	40.5

INTERIMS					
Y/e June 30 (\$m)	1H13A	2H13A	1H14A	2H14F	1H15F
Revenue	9	15	5	13	28
EBITDA	-5	2	-5	3	17
D&A	-1	-1	-1	-1	-1
EBIT	-6	1	-6	2	16
Net interest	0	0	0	0	1
Pre-tax profit	-6	1	-5	3	17
Tax	0	0	0	0	0
NPAT	-6	1	-5	3	17
Minority interests	0	0	0	0	0
Net profit after minorities	-6	1	-5	3	17

VALUATION		
	Base	Optim.
HA-Irinotecan (A\$m)	274.7	594.5
Fondaparinux (A\$m)	49.9	63.5
VAST (A\$m)	20.0	40.0
Total value for technology (A\$m)	344.6	698.1
Value of tax losses	38.5	38.5
Underlying R&D cost	-19.2	-19.2
Cash now (A\$m)	14.0	14.0
Cash to be raised (A\$m)	3.6	3.6
Total value (A\$m)	381.5	735.0
Total diluted shares (million)	331.5	331.5
Value per share	\$1.15	\$2.22
Valuation midpoint	\$1.68	
Share price now (A\$ per share)	\$0.495	
Upside to midpoint	240.2%	

Bionomics (BNO) – Drug discovery powerhouse

BUY. Target price \$0.90

- **Company description.** Bionomics is a drug discovery company with two products in the clinic – BNC210, an anti-anxiety drug, and BNC105, a cancer drug which can disrupt the blood vessels feeding tumours. Both drugs have performed well in pre-clinical and clinical work. Bionomics licensed BNC210 to America's Ironwood Pharmaceuticals (Nasdaq IRWD) in January 2012 for a massive deal package worth US\$345m; the drug is now in Phase I. BNC105 has completed a Phase II trial in Renal Cell Carcinoma (RCC) and is in Phase II in ovarian cancer. The RCC trial read out data in March 2014 with favourable data for key subgroups. Behind BNC105 and BNC210 is an enviable pipeline of pre-clinical assets.
- **Bionomics' BNC210 may be the Next Big Thing in anxiety.** The clinical data indicates that BNC210 can relieve anxiety quickly, without causing sedation or being addictive. There is also evidence that the drug can function as an anti-depressant. The market for anti-anxiety drugs is US\$5-12bn globally, driven by the ~3% of the population that suffers from Generalised Anxiety Disorder. The global market for anti-depressants is worth ~US\$20bn. We expect a steady flow of milestone income for Bionomics between now and its 2019 launch. We estimate that Bionomics will receive a mid-double digit royalty on Ironwood's sales. Ironwood is a great partner to have for BNC210. It has already gained FDA approval for its first product, the constipation drug Linzess, and while it is now capitalised at US\$1.97bn¹⁷, Ironwood is not so big that BNC210 would fall between the R&D cracks.
- **BNC105 attacks cancer a number of ways.** BNC105 is a 'Pulsatile Activator of Tumour Hypoxia' (PATH) with three ways to attack solid tumours. The drug is demonstrated in various animal models to be able to bust up the vasculature of tumours but not touch healthy blood vessels. It is directly cytotoxic for cancer cells. And it induces cancer cell killing via apoptosis.
- **Bionomics has what we consider to be favourable Phase II data from its BNC105 cancer drug in metastatic renal cell carcinoma (mRCC).** In a 148 patient Phase II trial, where BNC105 was combined with Novartis' Afinitor, Progression-Free Survival was 4.7 months for BNC105+Afinitor, versus 4.1 months for Afinitor only. The market did not like this outcome because the comparison wasn't statistically significant, and roughly the same number of patients were Progression-Free at six months in each group. However, on a subgroup analysis, there was some very encouraging news to tell.
- **BNC105 worked well in several patient subgroups.** In Phase II, BNC-210+Afinitor treated mRCC patients with metastases to the liver enjoyed 6.6 months PFS versus only 2.8 months for Afinitor. For those patients that had a kidney removed, the comparable figures were 7.1 months and 4.1 months. And for patients with a particular kind of tumour pathology called 'Furhman Grade 2' PFS was 6.4 months vs 4.1 months. Future trials enriched for these patients can properly target BNC105 in mRCC.
- **The biomarker data is very encouraging.** Bionomics found in the mRCC Phase II that a bank of around seven biomarkers could predict with statistical significance, the level of PFS in the patients. This is important for future studies, because it can allow an 'adaptive design' clinical trial that recruits only patients with biomarkers predictive of efficacy. Adaptive design is set to become commonplace in late stage clinical trials as cancer drugs become more personalised.
- **Bionomics is a cancer stem cell play.** In 2012 Bionomics acquired Eclipse Therapeutics, which was pre-clinical with a couple of antibodies targeted at cancer stem cells. The earliest of these antibodies, BNC101, enters the clinic this year. There is potential for Bionomics to attract the same investors that have appreciated Verastem et al.
- **Bionomics is collaborating with Merck & Co. in the pain field.** In July 2013 Bionomics announced a collaboration with Merck looking for new pain drugs, with Bionomics in line to potentially get US\$172m in option exercise fees as well as development and regulatory milestone payments. Neuropathic pain alone is a US\$2-3bn market inadequately served by existing drugs, mostly opioid in nature (and therefore potentially addictive).
- **Bionomics has multiple drug discovery platforms.** Bionomics' proprietary Multicore, Angene and ionX drug and target discovery platforms have provided the company with an engine for future growth. These platforms have helped create valuable pre-clinical

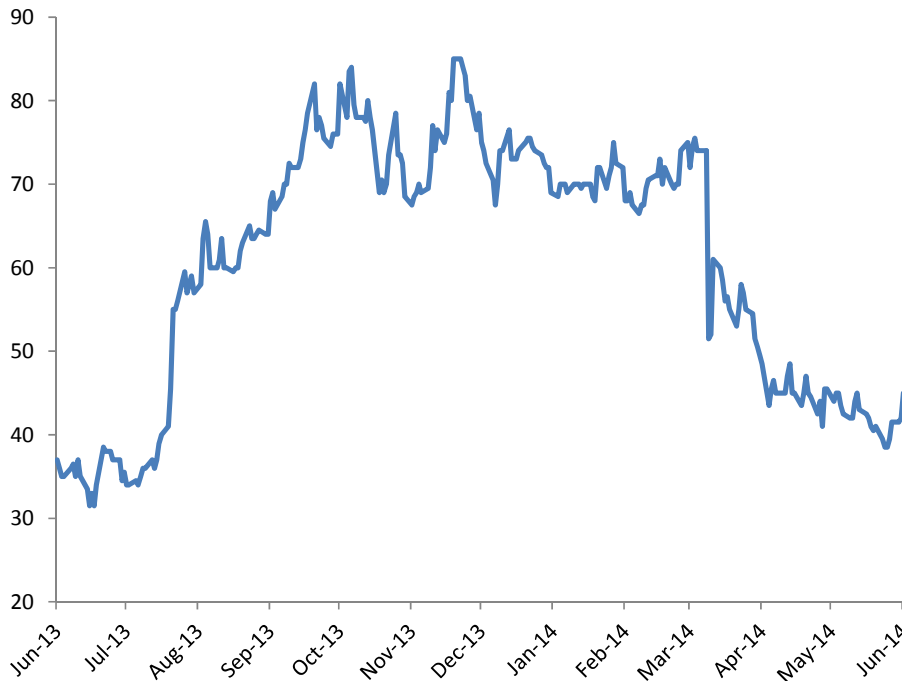
BNC105 is great for certain patient subgroups with renal cell carcinoma.

¹⁷ 12 June 2014 close on Nasdaq.

programmes including the Kv1.3 programme, with potential for anti-inflammatory drugs, and the BNC375 programme for Alzheimer's and other CNS disorders.

- **Bionomics has good management.** We like the commercial approach that CEO, Dr Deborah Rathjen has inculcated at Bionomics. Dr Rathjen and her colleagues have transformed Bionomics since 2005 and taken it way up the value curve.
- **Bionomics is undervalued on our numbers.** We value Bionomics on a probability-weighted DCF basis at \$0.95 base case and \$2.50 optimistic case. Our \$0.90 price target sits at around the low point of this range. We anticipate Bionomics being re-rated by the market on the basis of a partnering deal and further clinical data from BNC105.
- **VALUATION METHODOLOGY.** Our probability-weighted DCF of Bionomics¹⁸ was built as follows:
 - Our WACC was 16.4% (Speculative);
 - We modelled payoffs from BNC210 (anxiety, 32% probability of success), BNC105 (cancer, 32%), BNC101 (cancer, 21-38%), Nav1.7 (neuropathic pain, 21-38%), Kv1.3 (MS, 21-38%) and BNC375 (Alzheimer's, 11-19%);
 - We assume all products are licensed over the next six years for an average US\$40-70m upfront, US\$200-260m in milestones and 13-18% royalties; and
 - We assume average peak sales for a typical Bionomics licensed product of US\$2.1bn to US\$3bn.
 - We assume no further equity capital needs to be raised.
- **MAJOR SHAREHOLDERS.** Link Traders (Laurence Freedman, 9.6%), John Leaver (5.8%), Ausbil Dexia (5.8%) and Australian National University (5.2%).
- **KEY RISKS.** 1) Failure of the Phase II for BNC105 in RCC; 2) Ironwood's commitment to BNC210; and 3) Funding risk.

FIG.8: BIONOMICS SHARE PRICE



Source: Iress

¹⁸ Previous valuation range from 28 March 2014 was \$0.91 / \$2.31 – new valuation results from lower discount rate.

Bionomics - Financial Summary

Code BNO
Analyst Stuart Roberts
Date 13 June, 2014
Share price \$0.44
Market capitalisation \$182m
Year end 30 June

Rating BUY
Price target \$0.90
Upside/downside 106.9%
Valuation \$0.949 / \$2.499
Valuation method Probability-weighted DCF
Risk Speculative

PROFIT AND LOSS (A\$m)					
Y/e June 30 (A\$m)	FY12A	FY13A	FY14E	FY15E	FY16E
Revenue	9	11	28	100	104
EBITDA	-4	-9	6	75	78
D&A	-1	-1	-1	-1	-1
EBIT	-4	-11	5	73	77
Net interest	1	1	1	2	5
Pre-tax profit	-3	-10	6	75	81
Tax	0	0	0	-2	-24
NPAT	-3	-10	6	73	57
Minority interests	0	0	0	0	0
Net profit after minorities	-3	-10	6	73	57

BALANCE SHEET (A\$m)					
Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
Cash	17	22	20	60	76
Current receivables	0	1	1	1	1
Inventories	0	0	0	0	0
Other current assets	4	7	4	4	4
Current assets	22	31	25	65	81
PPE	1	1	1	1	1
Intangible assets	9	22	39	72	113
Other non-current assets	0	0	0	1	1
Non-current assets	9	23	40	74	115
Total assets	31	54	65	138	196
Payables	3	4	3	3	3
Debt	1	1	1	1	1
Other liabilities	1	7	12	12	12
Total liabilities	5	12	17	17	17

Shareholders' equity	26	41	48	122	179
Minorities	0	0	0	0	0
Total shareholders funds	26	41	48	122	179
Total funds employed	31	54	65	138	196
W/A shares on issue	345	374	417	418	420

CASH FLOW (A\$m)					
Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
NPAT plus discontinued ops.	-3	-10	6	73	57
Non-cash items	0	-5	1	1	1
Working capital	0	6	4	0	0
Other operating cash flow	0	0	0	0	0
Operating cashflow	-3	-9	11	74	58
Capex	6	0	0	0	0
Investments	0	-1	0	-1	0
Other investing cash flow	0	0	-13	-34	-42
Investing cashflow	6	-1	-13	-35	-43
Change in borrowings	-2	0	0	0	0
Equity raised	0	16	0	0	0
Dividends paid	0	0	0	0	0
Other financing cash flow	0	0	0	0	0
Financing cashflow	-2	16	0	0	0
Net change in cash	1	5	-2	40	16
Cash at end of period	17	22	20	60	76

EARNINGS (A\$m)					
Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
Net profit (\$m)	-3.1	-10.0	5.6	72.9	57.0
EPS (c)	-0.9	-2.7	1.3	17.4	13.6
EPS growth (%)	N/A	N/A	N/A	1194%	-22%
P/E ratio (x)	-47.8	-16.3	32.3	2.5	3.2
CFPS (c)	-0.8	-2.5	2.6	17.7	13.9
Price/CF (x)	-51.9	-17.3	16.8	2.5	3.1
DPS (c)	0.0	0.0	0.0	0.0	0.0
Yield (%)	0.0%	0.0%	0.0%	0.0%	0.0%
Franking (%)	N/A	N/A	N/A	N/A	N/A
EV/EBITDA	-46.0	-17.9	27.6	2.2	2.1
EV/EBIT	-38.6	-15.7	34.5	2.3	2.2

PROFITABILITY RATIOS					
Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
EBITDA/revenue (%)	-40.5%	-83.0%	21.6%	74.7%	75.2%
EBIT/revenue (%)	-48.3%	-94.2%	17.3%	73.5%	74.1%
Return on assets (%)	-10.1%	-18.7%	8.7%	52.7%	29.1%
Return on equity (%)	-12.1%	-24.2%	11.6%	59.9%	31.8%
Return on funds empl'd (%)	-11.6%	-23.5%	11.4%	59.4%	31.6%
Dividend cover (x)	N/A	N/A	0%	0%	0%
Effective tax rate (%)	5.8%	-0.4%	0.0%	3.2%	30.0%

LIQUIDITY AND LEVERAGE RATIOS					
Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
Net debt/(cash) (\$m)	-16	-21	-19	-59	-75
Net debt/equity (%)	-62.4%	-51.6%	-40.0%	-48.6%	-42.0%
Net interest cover (x)	N/A	N/A	N/A	N/A	N/A
Current ratio (x)	4.9	5.1	4.6	12.0	14.9

INTERIMS					
Y/e June 30 (\$m)	1H13A	2H13A	1H14A	2H14F	1H15F
Revenue	4	7	5	23	40
EBITDA	-3	-6	-6	12	26
D&A	-1	-1	-1	-1	-1
EBIT	-4	-7	-7	12	25
Net interest	0	0	0	1	1
Pre-tax profit	-3	-7	-7	12	26
Tax	0	0	0	0	0
NPAT	-3	-7	-7	12	26
Minority interests	0	0	0	0	0
Net profit after minorities	-3	-7	-7	12	26

VALUATION		
	Base	Optim.
BNC210 (A\$m)	128.5	238.3
BNC105 (A\$m)	117.4	276.3
Other products A(\$m)	125.3	518.1
Total value for technology (A\$m)	371.1	1032.8
Value of tax losses	23.9	23.9
Underlying R&D cost	-9.6	-9.6
Cash now (A\$m)	15.7	15.7
Cash from options and casg to be rai	3.9	3.9
Total value (A\$m)	405.0	1066.7
Total diluted shares (million)	426.8	426.8
Value per share	\$0.95	\$2.50
Valuation midpoint	\$1.72	
Share price now (A\$ per share)	\$0.435	
Upside to midpoint	296.3%	

Cellmid (CDY) – It's rare for one company to own a whole new target this big

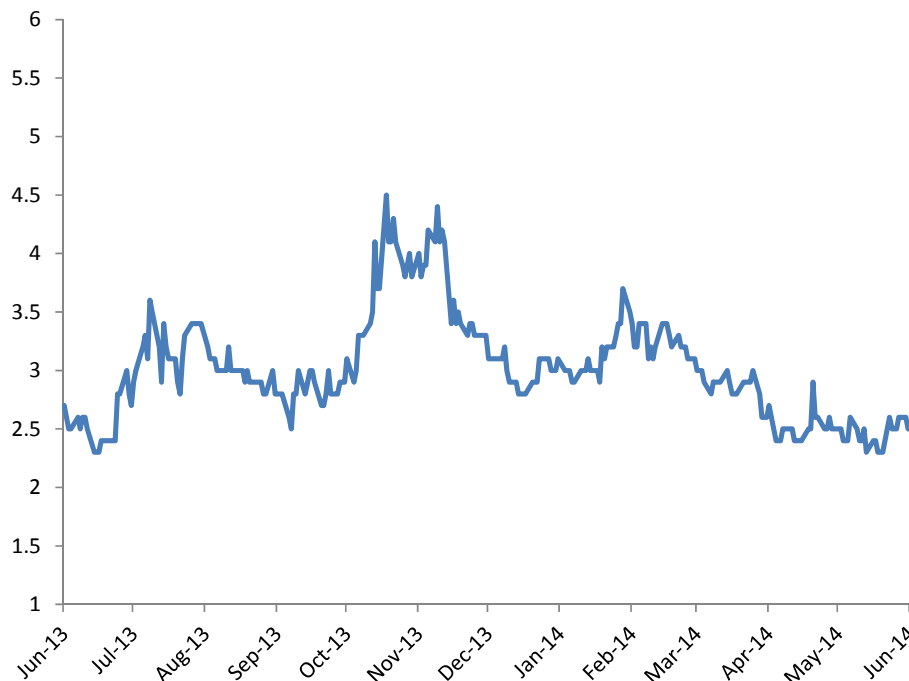
BUY. Target price \$0.07

- **Company description.** Cellmid is an early stage biotech company built around midkine, a protein known to contribute to various diseases including cancer, heart disease and inflammation. Cellmid intends to go to the clinic in the first half of 2015 with an anti-midkine antibody in cancer and has a number of licensing agreements with developers regarding the use of midkine as a cancer diagnostic. Cellmid also owns a small but growing business selling hair restoration products.
- **It's rare for one company to own a whole new target this big.** Midkine was discovered in 1988 at Nagoya University by Professors Takashi Muramatsu and Kenji Kadomatsu. Up until now midkine has not generally been referred to as a 'hot' new disease target, but the number of published papers in the field each year has grown steadily. Cellmid in effect positioned itself as the world leader in midkine research when it acquired privately-held, Cell Signals in 2008 for US\$1.5m plus 20 million shares. The acquisition gave Cellmid a library of around 120 anti-midkine antibodies and a comprehensive patent portfolio protecting midkine and midkine antagonists globally. Ordinarily, biotech companies differentiate themselves through the kind of drugs they have developed against targets that have been validated by others. By contrast, investors in Cellmid effectively control, through a comprehensive patent portfolio, a new target in midkine that is relevant across a wide range of diseases including heart disease and kidney disease, as well as cancer.
- **Cellmid intends to go to the clinic in the first half of 2015 with an anti-midkine antibody in cancer.** Given midkine's multiple roles in cancer progression across a range of tumours we see strong upside for this programme, especially since there is so much demand for new cancer antibodies from Big Pharma.
- **Cellmid is a player in personalised cancer medicine.** Cancer treatment is increasingly becoming 'personalised', meaning that drugs are being developed specific for subgroups within a patient population and administered depending on whether or not the patient expresses particular biomarkers. We expect midkine to be such a biomarker, which means that Cellmid already has the companion diagnostic for a future therapy. This ability to personalise its therapies will make it easier for the company to do business with Big Pharma.
- **Cellmid has developed a suite of midkine diagnostics.** On evidence that midkine can be used to diagnose cancer at an early stage, Cellmid has been able to secure three licensees for midkine diagnostics. The first of these, a bladder cancer diagnostic developed by the New Zealand biotech Pacific Edge under license from Cellmid, was launched in the US in mid-2013. Cellmid will earn near-term revenue from Pacific Edge as well as from America's Quest Diagnostics, which has developed a lung cancer diagnostic; and from Japan's Fujikara, which is developing a diagnostic for early stage cancer.
- **Cellmid sees potential for midkine antagonists in inflammation,** with the company particularly focused on acute kidney injury and chronic kidney disease, as well as the prevention of surgical adhesions.
- **Midkine may prove useful in heart disease,** with evidence that midkine can help to shrink the size of a myocardial infarct and also prevent cardiac remodelling following the infarct. Given the continuing high incidence of AMI and heart failure we see strong partnering interest emerging for midkine in these indications.
- **Cellmid also owns a hair regrowth business.** In 2013 Cellmid acquired the global rights to évolis, a clinically validated hair regrowth product that works through inhibition of FGF-5. Cellmid had previously licensed the rights to Australia for this product in 2010. With no major hair regrowth product having been launched globally since the 1980s, we see strong upside for the évolis range given the high level of hair loss in both sexes and the science that lies behind Cellmid's product. At the moment the business is small but Cellmid is building up its roster of global distribution partners.
- **Cellmid is undervalued on our numbers.** We value Cellmid at \$0.07 base case and \$0.26 optimistic case using a probability-weighted DCF approach. Our target price of \$0.07 sits at our base case.

Cellmid has three licensees for cancer diagnostics

- **VALUATION METHODOLOGY.** Our probability-weighted DCF of Cellmid was built as follows:
 - Our WACC was 14.2% (High risk);
 - We modelled payoffs from anti-cancer antibodies (19-38% probability of success), cancer diagnostics (no risk weighting) and hair care products (also no risk weighting).
 - We assume that the cancer antibody licenses in 2015-2016, for US\$10-20m upfront, US\$100-150m milestones and 10-14% royalties. We assume that the products launch by 2018-2019 and model peak sales of US\$1.7-\$2.2bn.
 - We assume that the diagnostics can gain a further US\$10-20m in upfronts and milestones by existing and future licensees. We model peak sales for all diagnostics of \$170-\$290m, with royalties ranging from 5% to 10%.
 - For the haircare products, we assume continued self-distribution with sales peaking at \$13m-36m. We assume gross margins of between 50% and 70% is achievable over time.
 - We assume that \$3m in equity capital needs to be raised at \$0.02 per share in order to complete the early clinical work on midkine in cancer.
- **MAJOR SHAREHOLDERS.** None.
- **KEY RISKS.** 1) Poor sales for hair care products and diagnostics; 2) Longer than expected development periods for various therapeutic programmes; 3) Clinical risk; and 4) Funding risk.

FIG.9: CELLMID SHARE PRICE



Source: Iress

Cellmid - Financial Summary

Code CDY
Analyst Stuart Roberts
Date 13 June, 2014
Share price \$0.03
Market capitalisation \$18m
Year end 30 June

Rating BUY
Price target \$0.07
Upside/downside 180.0%
Valuation \$0.07 / \$0.259
Valuation method Probability-weighted DCF
Risk High

PROFIT AND LOSS (A\$m)

Y/e June 30 (A\$m)	FY12A	FY13A	FY14E	FY15E	FY16E
Revenue	0	1	2	13	23
EBITDA	-3	-2	-2	1	10
D&A	0	0	0	0	0
EBIT	-3	-2	-2	1	10
Net interest	0	0	0	0	0
Pre-tax profit	-3	-2	-2	1	11
Tax	1	1	1	0	0
NPAT	-2	-2	-1	1	11
Minority interests	0	0	0	0	0
Net profit after minorities	-2	-2	-1	1	11

BALANCE SHEET (A\$m)

Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
Cash	1	2	3	7	17
Current receivables	0	0	0	1	1
Inventories	1	2	2	2	2
Other current assets	0	0	0	0	0
Current assets	2	4	5	9	20
PPE	0	0	0	0	0
Intangible assets	0	2	2	2	2
Other non-current assets	0	0	0	0	0
Non-current assets	0	2	2	2	2
Total assets	3	6	7	12	23
Payables	0	1	0	1	1
Debt	0	0	0	0	0
Other liabilities	0	0	0	0	0
Total liabilities	0	1	1	1	1
Shareholders' equity	2	5	6	11	22
Minorities	0	0	0	0	0
Total shareholders funds	2	5	6	11	22
Total funds employed	3	6	7	12	23
W/A shares on issue	427	564	735	835	835

CASH FLOW (A\$m)

Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
NPAT plus discontinued ops.	-2	-2	-1	1	11
Non-cash items	0	0	0	0	0
Working capital	0	0	-1	-1	0
Other operating cash flow	0	0	0	0	0
Operating cashflow	-2	-1	-2	1	11
Capex	0	0	0	0	0
Investments	0	0	0	0	0
Other investing cash flow	0	-1	1	0	0
Investing cashflow	0	-1	1	0	0
Change in borrowings	0	0	0	0	0
Equity raised	1	3	2	3	0
Dividends paid	0	0	0	0	0
Other financing cash flow	0	0	0	0	0
Financing cashflow	1	3	2	3	0
Net change in cash	-1	1	1	4	11
Cash at end of period	1	2	3	7	17

EARNINGS (A\$m)

Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
Net profit (\$m)	-2.0	-1.5	-1.4	1.2	10.5
EPS (c)	-0.5	-0.3	-0.2	0.1	1.3
EPS growth (%)	N/A	N/A	N/A	N/A	760%
P/E ratio (x)	-5.4	-9.1	-13.5	17.1	2.0
CFPS (c)	-0.4	-0.3	-0.3	0.1	1.3
Price/CF (x)	-6.1	-9.7	-9.2	23.1	2.0
DPS (c)	0.0	0.0	0.0	0.0	0.0
Yield (%)	0.0%	0.0%	0.0%	0.0%	0.0%
Franking (%)	N/A	N/A	N/A	N/A	N/A
EV/EBITDA	-5.6	-6.4	-7.3	13.0	1.4
EV/EBIT	-5.5	-6.4	-7.1	13.0	1.4

PROFITABILITY RATIOS

Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
EBITDA/revenue (%)	-2017.2%	-431.9%	-124.2%	8.6%	44.5%
EBIT/revenue (%)	-2025.4%	-435.1%	-128.1%	8.6%	44.4%
Return on assets (%)	-78.3%	-25.7%	-19.9%	10.6%	46.4%
Return on equity (%)	-94.4%	-29.0%	-21.9%	11.5%	48.9%
Return on funds empl'd (%)	-94.4%	-29.0%	-21.9%	11.5%	48.9%
Dividend cover (x)	N/A	N/A	N/A	0%	0%
Effective tax rate (%)	27.2%	33.8%	34.3%	0.0%	0.0%

LIQUIDITY AND LEVERAGE RATIOS

Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
Net debt/(cash) (\$m)	-1	-2	-3	-7	-17
Net debt/equity (%)	-50.3%	-33.1%	-44.7%	-61.4%	-79.2%
Net interest cover (x)	N/A	N/A	N/A	N/A	N/A
Current ratio (x)	6.2	5.9	7.7	10.0	18.2

INTERIMS

Y/e June 30 (\$m)	1H13A	2H13A	1H14A	2H14F	1H15F
Revenue	0	0	1	0	5
EBITDA	-1	-1	0	-2	-1
D&A	0	0	0	0	0
EBIT	-1	-1	-1	-2	-1
Net interest	0	0	0	0	0
Pre-tax profit	-1	-1	-1	-2	-1
Tax	1	0	1	0	0
NPAT	0	-1	0	-2	-1
Minority interests	0	0	0	0	0
Net profit after minorities	0	-1	0	-2	-1

VALUATION

	Base	Optim.
Cancer therapeutic (A\$m)	44.8	198.7
Cancer diagnostic (A\$m)	14.0	51.4
Consumer Health (A\$m)	10.1	46.2
Value of Cellmid technology	68.9	296.3
Value of tax losses	6.5	6.5
Underlying R&D cost	-9.6	-9.6
Cash now (A\$m)	3.4	3.4
Cash from options and cash to be raised	14.4	14.4
Total value (A\$m)	83.6	311.0
Total diluted shares (million)	1200.7	1200.7
Value per share	\$0.07	\$0.26
Valuation midpoint	\$0.16	
Share price now (A\$ per share)	\$0.025	
Upside to midpoint	557.3%	

Cynata (CYP) – Unlimited quantities of potent adult stem cells, no hassles

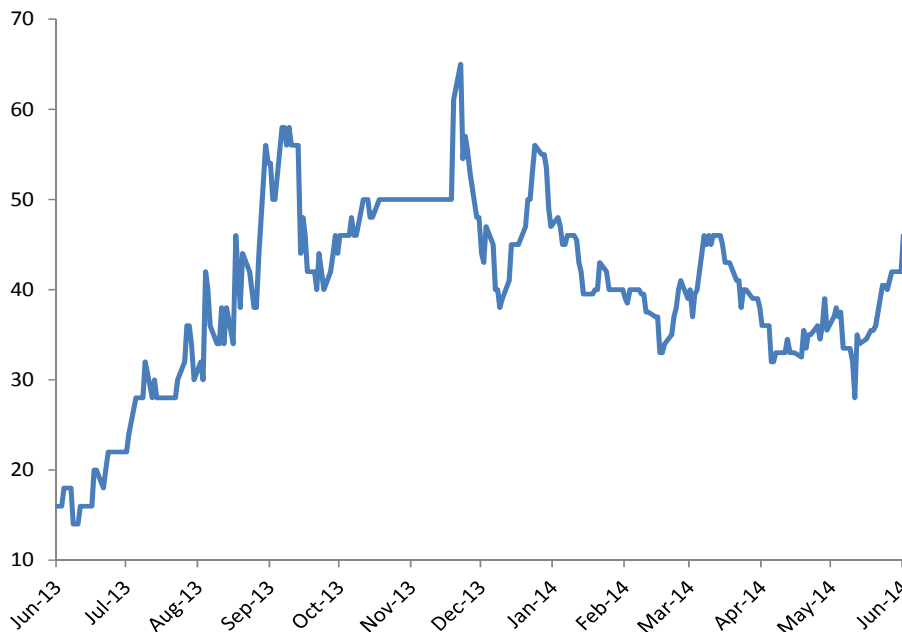
BUY. Target price \$0.90

- **Company description.** Cynata is a player in the emerging field of regenerative medicine. Its technology allows virtually unlimited quantities of Mesenchymal Stem Cells (MSCs) to be manufactured for therapeutic use from only a small number of initial donor cells. MSCs are adult stem cells known to be able to facilitate heart repair and rebuild bone and cartilage tissue as well as turn down inflammation. Cynata makes its MSCs from a precursor cell called the mesenchymoangioblast, which was discovered and patented at the University of Wisconsin-Madison in the US. The company is now working on manufacturing process development for its stem cells that involves the use of induced Pluripotent Stem cells (iPS cells). Next year it intends to dose its first patient, in a Graft-versus-Host Disease study.
- **The era of regenerative medicine and stem cells is here.** With science having learned a great deal about stem cells and regenerative medicine over the last 15 years, and the first regenerative medicine products now in late stage trials or gaining regulatory approval, the field is set to become increasingly important in modern medicine. We therefore see strong upside for stem cell companies as investors seek to gain exposure to this relatively new treatment paradigm.
- **Problem-solving stem cell therapy.** Cynata can solve a key problem in stem cell therapy, which is availability of stem cells. Cynata is based on a mesenchymal precursor called the 'mesenchymoangioblast'. The science suggests that a single colony of mesenchymoangioblasts can create up to 10^{22} mesenchymal stem cells. However Cynata starts with iPS cells that can differentiate into mesenchymoangioblasts. Since iPSCs can be expanded indefinitely, Cynata can, in effect, create unlimited number of MSCs. This abundance of stem cells points the way towards low-cost cellular therapy.
- **Ample therapeutic possibilities.** Mesenchymal stem cells have powerful therapeutic possibilities. They have the ability to facilitate the repair of damaged or diseased cardiac tissue. They can rebuild bone and cartilage. And they have well-characterised anti-inflammatory properties. Further, the relative lack of immunogenicity on the part of the stem cells also points to their potential to be used as off-the-shelf products.
- **Cynata is working with world leaders in regenerative medicine.** Professor Igor Slukvin of the University of Wisconsin-Madison, who invented the technology, is considered a thought leader in stem cells through his work on systems for making blood and angiogenic cells from human pluripotent cells. Wisconsin-Madison is a hotbed of stem cell development thanks largely to one of Slukvin's co-inventors, Professor James Thomson, who famously derived the first human embryonic stem cell line in 1998.
- **Cynata is a great 'concept stock' for the iPS Revolution.** Induced Pluripotent Stem Cells (iPS) are ordinary adult cells where pluripotency is induced using certain well understood cellular 'reprogramming' techniques. iPS technology is widely expected to make stem cells a medical reality without the ethical controversy that embryonic stem cells created a decade ago. Part of the 2012 Nobel Prize in Medicine went to Japan's Shinya Yamanaka for his invention of iPS cells. In 2013 Cynata became one of the first publicly traded companies in the world to make use of iPS technology. This makes Cynata a great concept stock for investors in the regenerative medicine field.
- **A Phase I trial in GvHD is planned soon.** Cynata is currently preparing for a small trial that will evaluate the ability of its stem cells to blunt GvHD. Given evidence from many studies that mesenchymal stem cells can be effective in this setting, we expect good things from Cynata's maiden clinical study.
- **There is potential for Cynata to collaborate on early stage science.** In June 2014 Cynata announced that small Australian company called Grey Innovation would be exploring whether Cynata's cells could treat lung disorders when delivered via new nebuliser technology. These kinds of collaborations have potential for building Cynata's pipeline without the company having to devote much of its own R&D resources.
- **Cynata has strong leadership.** CEO, Ross Macdonald brings years of drug development experience gained at companies such as F.H. Faulding and Stiefel. Executive Chairman, Stewart Washer has broad experience in developing early stage drug and medical device companies.

Professor Igor Slukvin is a thought leader in stem cells

- **Cynata remains undervalued, on our numbers.** Using a probability-weighted DCF approach, we value Cynata at A\$0.92 base case and A\$2.20 optimistic case. Our \$0.90 target price is derived from our base case. We see Cynata being re-rated to our target price as the company demonstrates the ability to make its stem cells at scale.
- **VALUATION METHODOLOGY.** Our probability-weighted DCF of Cynata was built as follows:
 - Our WACC was 16.4% (Speculative);
 - We assumed payoffs from three theoretical indications relevant to a mesenchymal precursor – osteogenesis imperfecta (as a model of an Orphan orthopaedic indication), Multiple Sclerosis (inflammatory) and Acute Coronary Syndrome (cardiovascular). Obviously there can be multiple licensing transactions but we think these three would indicate the potential at this early stage;
 - For each indication we used a 22% probability of success, this being the midpoint of success probabilities in the US between a small molecule in Phase I and a biological product in Phase I¹⁹.
 - We assume the following progression of licenses and payoffs for the three theoretical indications:
 - 1) osteogenesis imperfecta licenses in 2016-2017, for US\$20-40m upfront, US\$50-100m in milestones and 10-14% royalties. We model peak sales of ~US\$600-\$1,100m;
 - 2) Multiple Sclerosis licenses in 2017-2018, for US\$40-80m upfront, US\$80-120m in milestones and 12-16% royalties. We model peak sales of ~US\$1,600-\$2,900m;
 - 3) Acute Coronary Syndrome licenses in 2019-2019, for US\$50-120m upfront, US\$100-150m in milestones and 14-20% royalties. We model peak sales of ~US\$2600-\$3,400m;
 - We assume that \$20m in equity capital needs to be raised at \$0.30 per share in order for Cynata to move into mid-stage clinicals.
- **MAJOR SHAREHOLDERS.** None.
- **KEY RISKS.** 1) Scale-up risk; 2) Clinical risk; 3) Funding risk; Regulatory risk.

FIG.10: CYNATA SHARE PRICE



Source: Iress

¹⁹ See DiMasi et. al., op. cit.

Cynata - Financial Summary

Code CYP
Analyst Stuart Roberts
Date 13 June, 2014
Share price \$0.46
Market capitalisation \$25m
Year end 30 June

Rating BUY
Price target \$0.90
Upside/downside 95.7%
Valuation \$0.92 / \$2.204
Valuation method Probability-weighted DCF
Risk Speculative

PROFIT AND LOSS (A\$m)					
Y/e June 30 (A\$m)	FY12A	FY13A	FY14E	FY15E	FY16E
Revenue	0	0	0	1	9
EBITDA	-1	-1	-4	-9	0
D&A	0	0	0	0	0
EBIT	-2	-1	-4	-9	0
Net interest	0	0	0	0	0
Pre-tax profit	-2	-1	-4	-9	0
Tax	0	0	0	0	0
NPAT	-2	-1	-4	-9	0
Minority interests	0	0	0	0	0
Net profit after minorities	-2	-1	-4	-9	0

BALANCE SHEET (A\$m)					
Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
Cash	1	1	4	15	15
Current receivables	0	0	0	0	0
Inventories	0	0	0	0	0
Other current assets	0	0	0	0	0
Current assets	1	1	4	15	15
PPE	0	0	0	0	0
Intangible assets	0	0	5	5	5
Other non-current assets	0	1	0	0	0
Non-current assets	0	1	5	5	5
Total assets	1	2	9	20	20
Payables	0	0	0	0	0
Debt	0	0	0	0	0
Other liabilities	0	0	0	0	0
Total liabilities	0	0	0	0	0

Shareholders' equity	1	2	9	20	20
Minorities	0	0	0	0	0
Total shareholders funds	1	2	9	20	20
Total funds employed	1	2	9	20	20
W/A shares on issue	190	471	55	72	122

CASH FLOW (A\$m)					
Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
NPAT plus discontinued ops.	-2	-1	-4	-9	0
Non-cash items	0	0	1	0	0
Working capital	1	0	0	0	0
Other operating cash flow	0	0	0	0	0
Operating cashflow	-1	-1	-3	-8	0
Capex	0	0	0	0	0
Investments	0	-1	0	0	0
Other investing cash flow	0	0	0	0	0
Investing cashflow	0	-1	0	0	0
Change in borrowings	0	0	0	0	0
Equity raised	1	2	6	19	0
Dividends paid	0	0	0	0	0
Other financing cash flow	0	0	0	0	0
Financing cashflow	1	2	6	19	0
Net change in cash	1	0	3	11	0
Cash at end of period	1	1	4	15	15

EARNINGS (A\$m)					
Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
Net profit (\$m)	-1.5	-0.9	-4.0	-8.6	-0.2
EPS (c)	-0.8	-0.2	-7.2	-12.1	-0.1
EPS growth (%)	N/A	N/A	N/A	N/A	N/A
P/E ratio (x)	-56.8	-236.5	-6.4	-3.8	-313.7
CFPS (c)	-0.4	-0.2	-5.1	-11.5	-0.2
Price/CF (x)	-120.1	-282.8	-9.0	-4.0	-191.3
DPS (c)	0.0	0.0	0.0	0.0	0.0
Yield (%)	0.0%	0.0%	0.0%	0.0%	0.0%
Franking (%)	N/A	N/A	N/A	N/A	N/A
EV/EBITDA	-14.2	-20.5	-4.8	-2.3	-45.8
EV/EBIT	-12.6	-20.5	-4.8	-2.2	-44.7

PROFITABILITY RATIOS					
Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
EBITDA/revenue (%)	-434.7%	-2800.0%	-16196.0%	-868.8%	-4.5%
EBIT/revenue (%)	-488.6%	-2802.9%	-16196.0%	-869.3%	-4.6%
Return on assets (%)	-151.6%	-51.1%	-43.8%	-43.6%	-0.9%
Return on equity (%)	-180.6%	-55.8%	-45.0%	-44.1%	-0.9%
Return on funds empl'd (%)	-180.6%	-55.8%	-45.0%	-44.1%	-0.9%
Dividend cover (x)	N/A	N/A	N/A	N/A	N/A
Effective tax rate (%)	0.0%	0.0%	0.0%	0.0%	0.0%

LIQUIDITY AND LEVERAGE RATIOS					
Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
Net debt/(cash) (\$m)	-1	-1	-4	-15	-15
Net debt/equity (%)	-116.3%	-68.0%	-46.8%	-75.8%	-73.6%
Net interest cover (x)	N/A	N/A	N/A	N/A	N/A
Current ratio (x)	6.2	7.7	18.6	65.9	32.7

INTERIMS					
Y/e June 30 (\$m)	1H13A	2H13A	1H14A	2H14F	1H15F
Revenue	0	0	0	0	1
EBITDA	0	-1	-2	-2	-1
D&A	0	0	0	0	0
EBIT	0	-1	-2	-2	-1
Net interest	0	0	0	0	0
Pre-tax profit	0	-1	-2	-2	-1
Tax	0	0	0	0	0
NPAT	0	-1	-2	-2	-1
Minority interests	0	0	0	0	0
Net profit after minorities	0	-1	-2	-2	-1

VALUATION		
	Base	Optim.
Osteogenesis imperfecta (A\$m)	16.2	54.7
Multiple Sclerosis (A\$m)	35.9	108.8
Acute Coronary Syndrome (A\$m)	50.7	118.0
Value of Cynata technology	102.8	281.4
Value of tax losses	4.2	4.2
Underlying R&D cost	-9.6	-9.6
Cash now (A\$m)	5.7	5.7
Cash from options and cash to be raised	24.7	24.7
Total value (A\$m)	127.9	306.5
Total diluted shares (million)	139.0	139.0
Value per share	\$0.92	\$2.20
Valuation midpoint	\$1.56	
Share price now (A\$ per share)	\$0.460	
Upside to midpoint	239.6%	

Mesoblast (MSB) – Global leader in stem cells

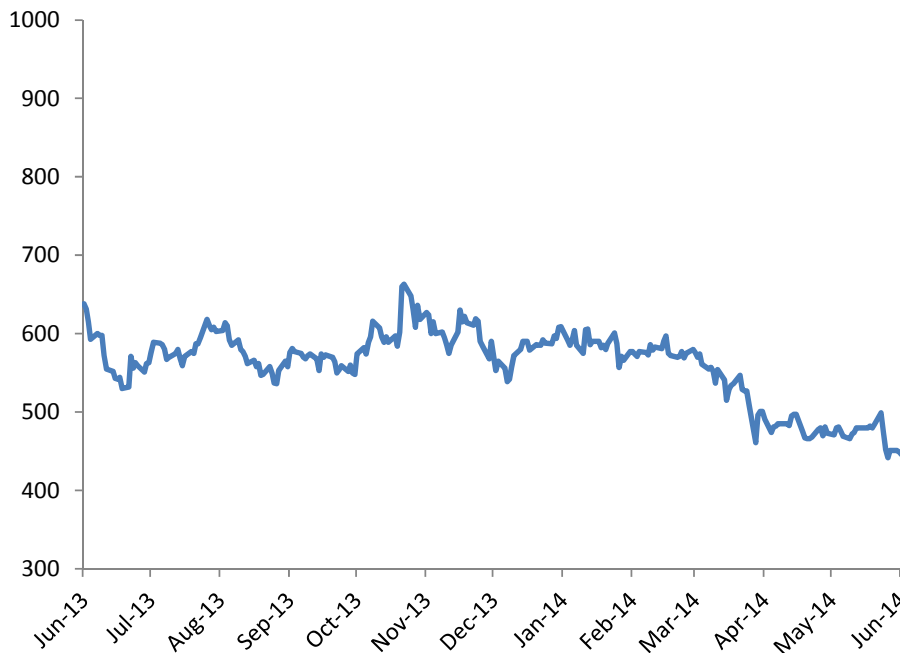
BUY. Target price \$8.50

- **COMPANY DESCRIPTION.** Mesoblast is creating clinical therapies from a class of adult stem cells called Mesenchymal Precursor Cells (MPCs). The company has been built on technology for obtaining and expanding MPCs from donors so that they can be stored and then used as an off-the-shelf therapy. Because MPCs have low immunogenicity, they can be given to patients unrelated to the donors. Mesoblast is at the regulatory stage with a therapy for acute Graft versus Host Disease (GvHD) and in Phase III in Crohn's disease, Bone Marrow Transplantation (BMT) and heart failure.
- **Mesoblast is the world's No. 1 stem cell company.** In recent years there has been a great deal of excitement about the therapeutic power of stem cells. A stem cell is any cell in the body with the capacity to develop into more specialised kinds of cells. Stem cells are also known for their ability to secrete various factors that promote tissue growth. The growing body of knowledge about stem cells has begun to realise the potential of regenerative medicine, in which doctors can repair or rebuild tissue that has been damaged by disease. Regenerative medicine is, in our view, going to be a creator of billion dollar products and Mesoblast leads the field globally in terms of having the most products in the clinic. Consequently we see potential for Mesoblast to evolve into a company considerably bigger than the one it is today.
- **Mesoblast has been a substantially 'de-risked' company for three years now.** A late 2010 partnering deal with a US pharma company called Cephalon transformed Mesoblast. At that time Cephalon put enough money into Mesoblast to take away its funding risk ahead of the first products being launched. While Cephalon was subsequently acquired by Teva, the world's 12th largest pharma company, the involvement of that company has proven to be positive because it has chosen to continue backing Mesoblast in the areas that Cephalon licensed.
- **Mesoblast has now moved to Phase III in heart failure, on the back of strong Phase II data.** In late October 2013 the FDA cleared the IND for a 1,700 Phase III trial of Mesoblast's MPCs in heart failure. This trial, which will be conducted by Teva, had been long-awaited by the market. In late 2011 Mesoblast unveiled the results of a Phase II 60 patient randomised, controlled trial in heart failure which saw a reduction in MACE (Material Adverse Coronary Events) of 78% for the treated patients versus the controls ($p=0.011$), a reduction in cardiac mortality of 89% ($p=0.02$), and a reduction in heart failure-related hospitalisation of 43%.
- **Mesoblast has bought its competitor's business.** In October 2013 Mesoblast acquired the cultured Mesenchymal Stem Cell therapeutic business of Osiris (Nasdaq OSIR). This transaction brought into Mesoblast's pipeline the late stage programmes in Crohn's and GvHD.
- **Mesoblast is well funded for multiple clinical programmes.** As at March 2014 Mesoblast held \$241m in cash with a burn rate for the previous year of ~A\$8m per month. Mesoblast is currently involved in clinical programmes in ten different applications, mostly cardiovascular and orthopaedic. In each case the company's technology has worked well at pre-clinical or clinical in indications of unmet medical need.
- **The path to market for Mesoblast is short.** With the FDA only requiring one Phase II and one pivotal trial before approving a stem cell therapy, we see Mesoblast as requiring a relatively short time before the MPC technology begins to yield commercial revenues. There is potential for Japanese approval after Phase II given recent changes to that country's pharmaceutical regulations to encourage regenerative medicine.
- **We have a high regard for Mesoblast's leadership team** led by Executive Director Professor Silviu Itescu, who owns around a fifth of the company and is its largest shareholder. Mesoblast has been highly commercial since its inception in the early 2000s.
- **We expect substantial news flow in 2014.** The next 12 months will feature, among other things, progress in four Phase III trials, potential GvHD approvals, some Phase II results in early Type 2 diabetes and diabetic nephropathy and, possibly, further partnering deals.
- **Upside from here.** Our \$8.50 target price for Mesoblast sits around the low point of our base case \$8.33 / optimistic case \$22.59 per share probability-weighted DCF valuation.

Mesoblast held A\$241m cash as at March 2014

- **VALUATION METHODOLOGY.** Our probability-weighted DCF of Mesoblast²⁰ was built as follows:
 - Our WACC was 12% (Medium risk, to reflect the fully-funded nature of the company);
 - We modelled payoffs from GvHD, Crohn's, BMT, heart failure, disc repair, spinal fusion, Type 2 diabetes and Rheumatoid Arthritis;
 - We assume all products not already licensed to Teva are licensed over the next four years with typical upfronts of US\$100-220m, milestones of US\$180-250m and 12-18% royalties;
 - We assume average peak sales for a typical Mesoblast licensed product of US\$1.6bn to US\$2.6bn;
 - We assume a steady roll-out of commercial products beginning with the GvHD and BMT applications in 2015-2016, with most major launches happening by 2019.
 - We assume no further equity capital needs to be raised.
- **MAJOR SHAREHOLDERS.** Silviu Itescu (21.2%), Teva Pharmaceuticals (17.3%), M&G (10%), Capital Group (6.7%) and Thorney (5.5%).
- **KEY RISKS.** 1) Failure of any of Mesoblast's clinical trials; 2) Delays on progress in trials; High burn rate; Key man risk in Silviu Itescu.

FIG.11: MESOBLAST SHARE PRICE



Source: Iress

²⁰ Previous valuation range from 30 January 2014 was \$8.28 / \$22.18 – new valuation results from lower discount rate.

Mesoblast - Financial Summary

Code MSB
Analyst Stuart Roberts
Date 13 June, 2014
Share price \$4.37
Market capitalisation \$1404m
Year end 30 June

Rating BUY
Price target \$8.50
Upside/downside 94.7%
Valuation \$8.329 / \$22.588
Valuation method Probability-weighted DCF
Risk Medium

PROFIT AND LOSS (A\$m)					
Y/e June 30 (A\$m)	FY12A	FY13A	FY14E	FY15E	FY16E
Revenue	28	24	45	366	555
EBITDA	-59	-70	-63	251	436
D&A	0	-1	-1	-2	-9
EBIT	-59	-71	-64	249	427
Net interest	10	11	13	16	31
Pre-tax profit	-49	-60	-50	265	458
Tax	-22	-2	0	-35	-137
NPAT	-71	-62	-51	230	321
Minority interests	0	0	0	0	0
Net profit after minorities	-71	-62	-51	230	321

BALANCE SHEET (A\$m)					
Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
Cash	206	315	228	432	745
Current receivables	11	12	17	17	17
Inventories	0	0	0	0	0
Other current assets	0	4	4	4	4
Current assets	217	332	250	454	767
PPE	2	3	4	27	56
Intangible assets	497	548	730	745	763
Other non-current assets	5	1	3	5	6
Non-current assets	504	552	738	777	825
Total assets	720	884	988	1,231	1,592
Payables	12	21	31	31	31
Debt	0	0	0	0	0
Other liabilities	230	232	332	332	332
Total liabilities	242	253	363	364	364
Shareholders' equity	479	630	624	868	1,228
Minorities	0	0	0	0	0
Total shareholders funds	479	630	624	868	1,228
Total funds employed	720	884	988	1,231	1,592
W/A shares on issue	283	293	322	323	326

CASH FLOW (A\$m)					
Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
NPAT plus discontinued ops.	-71	-62	-51	230	321
Non-cash items	10	15	13	14	21
Working capital	-1	-7	-24	0	0
Other operating cash flow	0	0	0	0	0
Operating cashflow	-63	-54	-61	244	341
Capex	-2	-1	-3	-25	-37
Investments	-2	-2	-1	-1	-1
Other investing cash flow	-1	-2	-26	-15	-18
Investing cashflow	-5	-5	-30	-42	-56
Change in borrowings	0	0	0	0	0
Equity raised	5	169	2	2	28
Dividends paid	0	0	0	0	0
Other financing cash flow	0	0	0	0	0
Financing cashflow	5	169	2	2	28
Net change in cash	-63	110	-89	204	313
Cash at end of period	206	315	228	432	745

EARNINGS (A\$m)					
Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
Net profit (\$m)	-71.1	-61.7	-50.5	229.8	320.7
EPS (c)	-25.2	-21.1	-15.7	71.2	98.5
EPS growth (%)	N/A	N/A	N/A	N/A	38%
P/E ratio (x)	-17.4	-20.7	-27.8	6.1	4.4
CFPS (c)	-22.2	-18.5	-19.1	75.6	104.8
Price/CF (x)	-19.7	-23.6	-22.8	5.8	4.2
DPS (c)	0.0	0.0	0.0	0.0	0.0
Yield (%)	0.0%	0.0%	0.0%	0.0%	0.0%
Franking (%)	N/A	N/A	N/A	N/A	N/A
EV/EBITDA	-19.8	-16.6	-18.5	4.6	2.7
EV/EBIT	-19.6	-16.5	-18.2	4.7	2.7

PROFITABILITY RATIOS					
Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
EBITDA/revenue (%)	-211.5%	-288.8%	-138.6%	68.5%	78.6%
EBIT/revenue (%)	-212.9%	-291.9%	-140.9%	67.9%	77.1%
Return on assets (%)	-9.9%	-7.0%	-5.1%	18.7%	20.1%
Return on equity (%)	-14.9%	-9.8%	-8.1%	26.5%	26.1%
Return on funds empl'd (%)	-14.9%	-9.8%	-8.1%	26.5%	26.1%
Dividend cover (x)	N/A	N/A	N/A	0%	0%
Effective tax rate (%)	-46.0%	-2.6%	0.0%	13.2%	30.0%

LIQUIDITY AND LEVERAGE RATIOS					
Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
Net debt/(cash) (\$m)	-206	-315	-228	-432	-745
Net debt/equity (%)	-42.9%	-50.0%	-36.6%	-49.8%	-60.6%
Net interest cover (x)	N/A	N/A	N/A	N/A	N/A
Current ratio (x)	4.9	6.6	4.2	7.6	12.8

INTERIMS					
Y/e June 30 (\$m)	1H13A	2H13A	1H14A	2H14F	1H15F
Revenue	10	14	15	30	132
EBITDA	-32	-38	-36	-27	76
D&A	0	0	-1	0	-1
EBIT	-33	-38	-37	-27	75
Net interest	5	6	6	8	7
Pre-tax profit	-28	-32	-31	-20	82
Tax	0	-2	0	0	0
NPAT	-28	-34	-31	-20	82
Minority interests	0	0	0	0	0
Net profit after minorities	-28	-34	-31	-20	82

VALUATION		
	Base	Optim.
GVHD (A\$m)	620.5	1692.1
Crohn's (A\$m)	216.5	690.8
Other programmes (A\$m)	1615.4	4836.7
Total value for technology (A\$m)	2452.5	7219.6
Value of tax losses	38.6	38.6
Underlying R&D cost	-9.6	-9.6
Cash now (A\$m)	241.4	241.4
Cash from options and to be raised (.	61.7	61.7
Total value (A\$m)	2784.7	7551.8
Total diluted shares (million)	334.3	334.3
Value per share	\$8.33	\$22.59
Valuation midpoint	\$15.46	
Share price now (A\$ per share)	\$4.365	
Upside to midpoint	254.1%	

Nanosonics (NAN) – Cleaning up

BUY. Target price \$1.15

- **COMPANY DESCRIPTION.** Nanosonics' lead product, called trophon EPR (yes, lower case 't' in trophon, to make the brand more distinctive), disinfects ultrasound probes at low temperatures using 'nanonebulant' technology. Nanosonics gained FDA approval for trophon EPR in February 2011 and in May 2011 the company named GE as its exclusive North American distributor. Nanosonics' FY13 revenue, driven by GE sales of trophon EPR, was \$14.9m. We see considerable upside for trophon EPR given the lack of adequate disinfection alternatives for hospitals and the high cost of treating hospital-acquired infections.
- **The Nanosonics product is ground-breaking.** trophon EPR disinfects ultrasound probes by generating a hydrogen peroxide nanoparticle mist. It works quickly (ie. in just seven minutes), does not damage the probes, is able to achieve high-level disinfection (ie. high levels of microbes killed) and avoids potential exposure to hazardous chemicals on the part of hospital workers. Comparisons with conventional disinfection systems are compelling. One Nanosonics-supported study, for example, found 79.5% of ultrasound probe handles manually disinfected with glutaraldehyde were still contaminated (see Nanosonics market release, 10/10/2013). trophon EPR's advantages have provided Nanosonics and its commercial partners with a ground breaking new product that has attracted a lot of attention in hospital administrator circles. Consider, for example, the March 2013 endorsement by America's Scripps Health network, which has described trophon EPR as 'ground breaking'.
- **Nanosonics helps to cut the cost of hospital acquired infections.** Hospital acquired infections (HAIs) are a serious issue globally. In the US it is estimated that there are around 2 million HAIs p.a., contributing to 100,000 deaths. Each HAI probably costs US\$5,000 on average to manage. With inadequate disinfection tools a key contributor to the rise of HAIs it's reasonable that a product as advanced as trophon EPR will gain a sizeable following on the economic benefits alone. There has already been favourable data generated in the cost effectiveness of its product (See J Ultrasound Med. 2013 Oct;32(10):1799-804).
- **trophon EPR is on its way to becoming the ultrasound industry standard for probe decontamination** with an increasing number of probe manufacturers now assessed by Nanosonics and certified for use with the trophon EPR technology. We expect that as governments look at managing their healthcare systems more efficiently, tools such as trophon EPR will become mandated as a preferred disinfection system. We look for such regulatory change in places that have serious issues with HAIs such as the UK.
- **The GE relationship bodes well for Nanosonics.** As at January 2014, 38 of the Top 50 hospitals in America have used trophon EPR, showing GE's market reach. In August 2013 GE announced that it would set up a dedicated trophon EPR sales organisation rather than just sell the product through its existing ultrasound sales team. We are particularly impressed by GE's commitment to trophon EPR. In addition to marketing the product, GE has also invested in the growth of Nanosonics as a company. GE's Healthymagination Fund, which invests in highly promising healthcare technology ventures, took a A\$7.5m four year 6% convertible note investment in June 2012. These notes convert at A\$0.75.
- **Toshiba is also a trophon EPR proponent.** In April 2013 Nanosonics secured Toshiba as a non-exclusive distributor for trophon EPR in the UK. We see this development as highly positive given Toshiba's established presence in the market for ultrasound machines and the potential for Toshiba to take on other markets later on.
- **Nanosonics continues to innovate,** with the company developing two significant new trophon EPR products in FY13 – a 'traceability package' that can record each disinfection cycle, and an 'in-field validation kit' that allows independent inspectors to certify that a trophon EPR system is working properly on a customer's premises.
- **Nanosonics has a solid balance sheet.** As at March 2014 the company had \$23.8m in cash reserves and no debt, having raised \$15.5m in a May 2012 placement at 53 cents per share.
- **Stock remains undervalued.** We value Nanosonics on a DCF basis at base case \$1.20 / optimistic case \$1.77. Our target price of \$1.15 sits at around the low point of our valuation range. We see Nanosonics being rerated to our target price as further commercial partners sign up and as GE's push for trophon EPR in the US gains traction.

Most top hospitals in America now use trophon EPR

- **VALUATION METHODOLOGY.** Our DCF of Nanosonics²¹ was built as follows:
 - Our WACC was 12% (Medium risk, to reflect the fact that trophon EPR now has a commercial following);
 - We modelled a declining growth rate for trophon EPR sales after our FY14-16 forecast window, from 30-35% in FY17 down to 4-10% in FY23;
 - We assumed COGS as a percentage of revenue stay the same (base case) or decline about 600 bp, from 33% to 27% (optimistic case);
 - We assume that growth in other operating costs gradually converges on the sales growth rate by 2023;
 - We use a 3% FY24 terminal growth assumption for a base case and 4% for an optimistic case, with EBITDA margins falling back to 35% for the terminal measure;
 - We assume no further equity capital needs to be raised.
- **MAJOR SHAREHOLDERS.** Maurice Stang (10.8%), Allan Gray Australia (10.8%), Bernard Stang (10.5%), Steve Kritzler (5.2%).
- **KEY RISKS.** 1) GE’s commitment to trophon EPR; 2) Cost saving efforts in hospitals; 3) Funding risk.

FIG.12: NANOSONICS SHARE PRICE



Source: Iress

²¹ Previous valuation range from 24 February 2014 was \$1.16 / \$1.71 – new valuation results from lower discount rate.

Nanosonics - Financial Summary

Code NAN
Analyst Stuart Roberts
Date 13 June, 2014
Share price \$0.80
Market capitalisation \$211m
Year end 30 June

Rating BUY
Price target \$1.15
Upside/downside 43.8%
Valuation \$1.202 / \$1.774
Valuation method DCF
Risk Medium

PROFIT AND LOSS (A\$m)					
Y/e June 30 (A\$m)	FY12A	FY13A	FY14E	FY15E	FY16E
Revenue	12	16	25	45	63
EBITDA	-5	-5	0	13	25
D&A	-1	-1	-1	-1	-1
EBIT	-6	-6	-1	12	24
Net interest	1	1	1	2	3
Pre-tax profit	-5	-6	0	14	27
Tax	1	0	0	0	0
NPAT	-5	-6	0	14	27
Minority interests	0	0	0	0	0
Net profit after minorities	-5	-6	0	14	27

BALANCE SHEET (A\$m)					
Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
Cash	29	24	25	47	75
Current receivables	3	4	3	4	5
Inventories	2	3	5	6	7
Other current assets	0	0	1	1	1
Current assets	35	32	34	57	87
PPE	1	2	2	2	2
Intangible assets	0	0	0	0	0
Other non-current assets	0	0	0	0	0
Non-current assets	2	2	2	2	2
Total assets	37	34	36	59	89
Payables	2	3	3	4	4
Debt	0	0	0	0	0
Other liabilities	8	9	10	10	10
Total liabilities	11	12	13	13	14
Shareholders' equity	26	22	23	46	76
Minorities	0	0	0	0	0
Total shareholders funds	26	22	23	46	76
Total funds employed	37	34	36	59	89
W/A shares on issue	235	261	263	263	265

CASH FLOW (A\$m)					
Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
NPAT plus discontinued ops.	-5	-6	0	14	27
Non-cash items	2	2	2	2	2
Working capital	-2	-1	0	-1	-1
Other operating cash flow	0	0	0	0	0
Operating cashflow	-5	-5	2	15	28
Capex	-1	-1	-1	-1	-1
Investments	0	0	0	0	0
Other investing cash flow	0	0	0	0	0
Investing cashflow	-1	-1	-1	-1	-1
Change in borrowings	0	0	0	0	0
Equity raised	15	1	0	8	2
Dividends paid	0	0	0	0	0
Other financing cash flow	7	0	0	0	0
Financing cashflow	23	1	0	8	2
Net change in cash	17	-5	1	22	29
Cash at end of period	29	24	25	47	75

EARNINGS (A\$m)					
Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
Net profit (\$m)	-4.7	-5.8	0.0	14.0	26.6
EPS (c)	-2.0	-2.2	0.0	5.3	10.0
EPS growth (%)	N/A	N/A	N/A	29749%	88%
P/E ratio (x)	-40.1	-36.2	4493.0	15.1	8.0
CFPS (c)	-2.1	-1.7	0.6	5.6	10.4
Price/CF (x)	-37.3	-46.4	124.1	14.2	7.7
DPS (c)	0.0	0.0	0.0	0.0	0.0
Yield (%)	0.0%	0.0%	0.0%	0.0%	0.0%
Franking (%)	N/A	N/A	N/A	N/A	N/A
EV/EBITDA	-37.6	-34.9	512.7	14.1	7.6
EV/EBIT	-31.8	-29.2	-267.5	15.2	8.0

PROFITABILITY RATIOS					
Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
EBITDA/revenue (%)	-40.0%	-32.7%	1.5%	29.4%	38.9%
EBIT/revenue (%)	-47.4%	-39.1%	-2.8%	27.3%	37.3%
Return on assets (%)	-12.8%	-17.1%	0.1%	23.6%	29.7%
Return on equity (%)	-18.0%	-26.6%	0.2%	30.4%	35.1%
Return on funds empl'd (%)	-18.0%	-26.5%	0.2%	30.3%	35.1%
Dividend cover (x)	N/A	N/A	0%	0%	0%
Effective tax rate (%)	11.9%	-0.6%	38.3%	0.0%	0.0%

LIQUIDITY AND LEVERAGE RATIOS					
Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
Net debt/(cash) (\$m)	-29	-24	-25	-47	-75
Net debt/equity (%)	-112.6%	-110.7%	-108.0%	-101.2%	-99.5%
Net interest cover (x)	N/A	N/A	N/A	N/A	N/A
Current ratio (x)	10.1	7.5	7.1	10.8	15.2

INTERIMS					
Y/e June 30 (\$m)	1H13A	2H13A	1H14A	2H14F	1H15F
Revenue	4	12	10	15	18
EBITDA	-6	1	-3	3	2
D&A	0	-1	-1	0	0
EBIT	-6	0	-4	3	1
Net interest	0	0	0	1	1
Pre-tax profit	-6	0	-3	4	2
Tax	0	0	0	0	0
NPAT	-6	0	-3	4	2
Minority interests	0	0	0	0	0
Net profit after minorities	-6	0	-3	4	2

VALUATION		
	Base	Optim.
Business (A\$m)	281.6	437.3
Value of tax losses	17.7	17.7
Cash as at Mar 2014 (A\$m)	23.8	23.8
Cash from options plus cash to be ra	1.6	1.6
Total value (A\$m)	324.7	480.3
Diluted shares on issue (million)	270.1	270.8
Value per share	\$1.20	\$1.77
Valuation midpoint	\$1.49	
Share price now	\$0.800	
Upside	86.0%	

Neuren Pharmaceuticals (NEU) – Undervalued Orphan Drug play

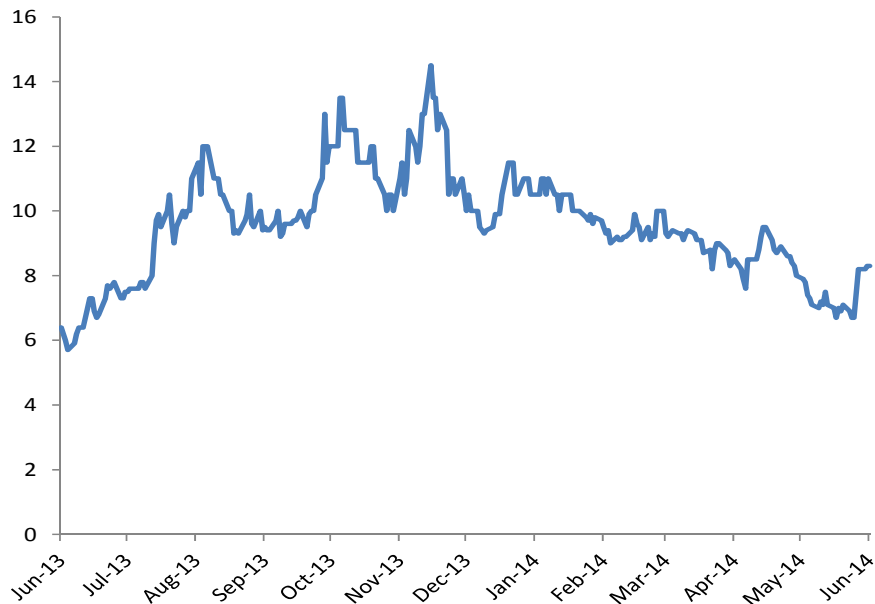
BUY. Target price \$0.26

- **COMPANY DESCRIPTION.** Neuren is developing NNZ-2566, a small molecule drug that in animal models has shown substantial efficacy in protecting brain cells from death after a Traumatic Brain Injury (TBI). The same drug, and another pipeline drug called NNZ-2591, has shown, also in animal models, that they treat the symptoms and underlying biological problems of two Autism Spectrum Disorders - Rett Syndrome and Fragile X Syndrome. Neuren's Phase II Rett clinical trial will report data this year with the Fragile X and TBI results coming in 2015. There are currently no drugs on the market that can treat any of these indications, suggesting the potential of NNZ-2566 to attract substantial licensing interest from Big Pharma and ultimately become a blockbuster.
- **Neuren's recently formed leadership team is impressive.** Executive Chairman Richard Treagus and CFO Jon Pilcher previously built Acrux through the development of the testosterone replacement product Axiron and a global partnering deal with Eli Lilly. Chief Scientific Officer Larry Glass has overseen Neuren's repositioning since 2009 in TBI and Autism and brings strong relationships with the US Army's Medical R&D command.
- **An estimated 1% of the population has an Autism Spectrum Disorder.** Consequently we believe that any clinical success for Neuren in Rett or Fragile X can unlock substantial licensing opportunities. Given the pharmaceutical industry's historic ability to charge very high prices for Orphan Drugs, we expect that NNZ-2566 could become a blockbuster with more than US\$1bn sales in Rett Syndrome and Fragile X alone.
- **Traumatic Brain Injury alone could create a blockbuster.** In the US alone there are around 1.7 million Traumatic Brain Injuries every year. However there are no approved drugs that can protect brain cells after such an injury. Success in Neuren's Phase II can therefore potentially unlock another billion dollar market.
- **Neuren is pursuing Fragile X Syndrome as a third indication for NNZ-2566.** In late 2012 Neuren unveiled pre-clinical evidence that NNZ-2566 worked to reduce the symptoms and biological abnormalities of Fragile X. This disorder, caused by mutations in the *fmr1* gene on the X chromosome, is characterised by intellectual disability, hyperactive behaviour, social withdrawal and seizures. The attraction of Fragile X for Neuren is that large pharma companies including Novartis and Roche already have drugs in the clinic for the indication, which could enhance Neuren's licensing prospects. A Phase II clinical trial in Fragile X is in progress and topline data from that trial will come in 2015. Fragile X, with an estimated US patient population of ~70,000, will be another Orphan indication for NNZ-2566.
- **Neuren is moving into concussion, another large unserved market.** A Phase II trial of NNZ-2566 in concussion will commence shortly at a US military training base, with results expected in 2015. There are no drugs currently available to treat concussion.
- **Neuren has a low burn rate since the current TBI trial is substantially funded by the US Army,** with ~US\$26m in non-dilutive funding have been made available to date.
- **Neuren could receive favourable regulatory treatment given the breakthrough nature of NNZ-2566.** The drug has received Fast Track designation and Orphan Drug status from the FDA and we believe that NNZ-2566 will be granted Breakthrough Status for both TBI and Rett Syndrome, as well as Fragile X, if the initial results from the Phase II trials are positive.
- **NNZ-2591 could prove to be another blockbuster after NNZ-2566.** This drug, a cyclic dipeptide, contains two of the peptides that comprise NNZ-2566 and is 100% orally bioavailable. NNZ-2591 has shown efficacy in animal models of Fragile X Syndrome as well as Parkinson's Disease, peripheral neuropathy and mild cognitive impairment.
- **Neuren may ultimately develop an Alzheimer's drug.** With NNZ-2566 and NNZ-2591 both demonstrated to lower neuroinflammation and promote neurite outgrowth, there is potential for these drugs to be trialled in Alzheimer's and dementia. The upside here is large, given that around one in eight people over the age of 65 has Alzheimer's or dementia and existing drug treatments are considered inadequate.

There are currently no approved drugs to treat TBI

- **On our estimates Neuren stock is undervalued.** Our target price of 26 cents per share is based on a risk-weighted DCF that values the stock at 26 cents base case and 66 cents optimistic case.
- **VALUATION METHODOLOGY.** Our probability-weighted DCF of Neuren²² was built as follows:
 - Our WACC was 16.4% (Speculative);
 - We modelled payoffs for NNZ-2566 and NNZ-2591, both with a 38% probability of success;
 - We assumed partnering deals for both compounds, NNZ-2566 in calendar 2015 (US\$100-200m in upfronts, US\$300-500m in milestones, 16-20% royalties) and NNZ-2591 in 2016 (US\$40-70m upfronts, US\$120-150m milestones, 10-14% royalties)²³;
 - We assume average peak sales for NNZ-2566 of US\$3.3bn-6.6bn, reflecting its use not just in autism and brain injury (where we assume both indications enter approved clinical use) but ultimately in other CNS disorders like Alzheimer's and stroke. For NNZ-2591 we modelled US\$2.9-3.7bn in peak sales.
 - We assumed NNZ-2566 product launch by 2017 and NNZ-2591 by 2020²⁴.
 - We assume Neuren is unable to take advantage of tax losses since they were incurred in New Zealand and Neuren is now an Australian company²⁵.
 - We assume no further equity capital needs to be raised.
- **MAJOR SHAREHOLDER.** Lang Walker (14.7%)
- **KEY RISKS.** 1) Delays in recruitment for the clinical trials; 2) Clinical failure; 3) Risk that the mechanism of action of NNZ-2566 isn't fully understood; 4) Funding risk.

FIG.13: NEUREN SHARE PRICE



Source: Iress

²² Previous valuation range from 28 November 2013 was \$0.26 / \$0.77 – new valuation results from lower discount rate and changed assumptions on licensing and product launches.

²³ Previously we had used 2015 and 2016 respectively.

²⁴ Previously we had used 2016 and 2019 respectively.

²⁵ We had previously assumed that tax losses were available.

Neuren Pharmaceuticals - Financial Summary

Code NEU
Analyst Stuart Roberts
Date 13 June, 2014
Share price \$0.08
Market capitalisation \$129m
Year end 31 December

Rating BUY
Price target \$0.26
Upside/downside 213.3%
Valuation \$0.26 / \$0.655
Valuation method Probability-weighted DCF
Risk Speculative

PROFIT AND LOSS (NZ\$m)					
Y/e June 30	FY11A	FY12A	FY13E	FY14E	FY15E
Revenue	4	5	4	6	98
EBITDA	-6	-6	-12	-6	85
D&A	0	0	0	0	0
EBIT	-6	-7	-13	-7	85
Net interest	0	0	0	2	3
Pre-tax profit	-6	-7	-12	-5	88
Tax	0	0	0	0	0
NPAT	-6	-7	-12	-5	88
Minority interests	0	0	0	0	0
Net profit after minorities	-6	-7	-12	-5	88

BALANCE SHEET (NZ\$m)					
Y/e June 30	FY11A	FY12A	FY13E	FY14E	FY15E
Cash	10	6	26	32	126
Current receivables	0	0	2	1	0
Inventories	0	0	0	-1	-2
Other current assets	0	0	0	0	0
Current assets	10	7	28	32	124
PPE	0	0	0	0	0
Intangible assets	5	4	0	0	0
Other non-current assets	0	0	0	0	0
Non-current assets	5	4	0	0	0
Total assets	15	11	29	32	124
Payables	2	3	2	2	1
Debt	0	0	0	0	0
Other liabilities	0	0	0	0	0
Total liabilities	2	3	2	2	1
Shareholders' equity	12	8	27	31	123
Minorities	0	0	0	0	0
Total shareholders funds	12	8	26	31	123
Total funds employed	15	11	29	32	124
W/A shares on issue	765	1,174	1,261	1,436	1,498

CASH FLOW (NZ\$m)					
Y/e June 30	FY11A	FY12A	FY13E	FY14E	FY15E
NPAT plus discontinued ops.	-6	-7	-12	-5	88
Non-cash items	2	2	2	2	2
Working capital	0	0	2	1	1
Other operating cash flow	0	0	0	0	0
Operating cashflow	-4	-4	-8	-2	91
Capex	0	0	0	0	0
Investments	0	0	0	0	0
Other investing cash flow	0	0	0	0	0
Investing cashflow	0	0	0	0	0
Change in borrowings	0	0	0	0	0
Equity raised	12	1	30	8	3
Dividends paid	0	0	0	0	0
Other financing cash flow	0	0	0	0	0
Financing cashflow	12	1	30	8	3
Net change in cash	8	-3	22	6	93
Cash at end of period	10	6	26	32	126

EARNINGS (NZ\$m)					
Y/e June 30	FY11A	FY12A	FY13E	FY14E	FY15E
Net profit (\$m)	-6.2	-6.5	-12.3	-4.9	88.0
EPS (c)	-0.8	-0.6	-1.0	-0.3	5.9
EPS growth (%)	N/A	N/A	N/A	N/A	N/A
P/E ratio (x)	-13.3	-19.0	-10.0	-26.0	1.5
CFPS (c)	-0.5	-0.3	-0.7	-0.2	6.1
Price/CF (x)	-20.2	-33.5	-14.7	-57.5	1.5
DPS (c)	0.0	0.0	0.0	0.0	0.0
Yield (%)	0.0%	0.0%	0.0%	0.0%	0.0%
Franking (%)	N/A	N/A	N/A	N/A	N/A
EV/EBITDA	-18.8	-17.2	-8.3	-14.9	1.1
EV/EBIT	-17.4	-16.1	-8.0	-13.9	1.1

PROFITABILITY RATIOS					
Y/e June 30	FY11A	FY12A	FY13E	FY14E	FY15E
EBITDA/revenue (%)	-133.4%	-123.0%	-297.2%	-95.6%	87.1%
EBIT/revenue (%)	-143.8%	-131.9%	-308.7%	-102.7%	86.7%
Return on assets (%)	-42.6%	-61.2%	-42.9%	-15.2%	71.1%
Return on equity (%)	-50.2%	-81.9%	-46.5%	-16.1%	71.7%
Return on funds empl'd (%)	-50.2%	-81.9%	-46.5%	-16.1%	71.7%
Dividend cover (x)	N/A	N/A	N/A	N/A	0%
Effective tax rate (%)	0.0%	0.0%	0.0%	0.0%	0.0%

LIQUIDITY AND LEVERAGE RATIOS					
Y/e June 30	FY11A	FY12A	FY13E	FY14E	FY15E
Net debt/(cash) (\$m)	-10	-6	-26	-32	-126
Net debt/equity (%)	-79.2%	-81.0%	-99.9%	-104.8%	-102.4%
Net interest cover (x)	N/A	N/A	N/A	N/A	N/A
Current ratio (x)	4.5	2.5	12.6	18.9	105.7

INTERIMS					
Y/e June 30 (NZ\$m)	2H12A	1H13A	2H13A	1H14F	2H14F
Revenue	3	3	1	3	4
EBITDA	-3	-4	-8	-3	-3
D&A	0	0	0	0	0
EBIT	-4	-4	-9	-4	-3
Net interest	0	0	0	1	1
Pre-tax profit	-3	-4	-9	-3	-2
Tax	0	0	0	0	0
NPAT	-3	-4	-9	-3	-2
Minority interests	0	0	0	0	0
Net profit after minorities	-3	-4	-9	-3	-2

VALUATION		
	Base	Optim.
NNZ2566 (A\$m)	311.5	858.5
NNZ2591 (A\$m)	99.1	234.4
Total value for technology (A\$m)	410.6	1092.8
Value of tax losses	0.0	0.0
Underlying R&D cost	-9.6	-9.6
Cash now (A\$m)	43.3	43.3
Cash from options and to be raised (A\$m)	3.7	3.7
Total value (A\$m)	448.0	1130.3
Total diluted shares (million)	1724.5	1724.5
Value per share	\$0.26	\$0.66
Valuation midpoint	\$0.46	
Share price now (A\$ per share)	\$0.083	
Upside to midpoint	451.3%	

OncoSil (OSL) – Another internal radiation success story

BUY. Target price \$0.45

- **Company summary:** Sydney-based OncoSil is developing a brachytherapy device that, implanted locally, can emit cancer-killing radiation into a tumour without damaging healthy surrounding tissues. The device, previously developed by the UK's Defence Evaluation and Research Agency, and then by a US biotech company called pSivida, was spun out into OncoSil in 2013. OncoSil's product is similar to Sirtex's SIR-Spheres product for the treatment of liver cancer. The OncoSil device has been trialled at Phase II in pancreatic cancer with favourable results. The company intends to file for CE Mark approval of the device this year as a pancreatic cancer treatment and is currently initiating a single pivotal study in pancreatic cancer for FDA approval, expected in 2016 or 2017.
- **The OncoSil brachytherapy works in pancreatic cancer.** Under pSivida the OncoSil technology was tried in four Phase I/II clinical trials, all with solid results. Phase IIa saw pancreatic cancer patients register a median overall survival of 10.2 months versus just 5.7 months with gemcitabine. The product also lowered abdominal pain in the patients. Phase IIb, which tested up to four times the dose of Phase IIa, had too few patients for survival data to be meaningful, but that study did show an improvement in the disease control rate from 82% to 100%, with all doses well tolerated.
- **There is demand for new pancreatic cancer therapies.** Around 46,000 Americans and 85,000 Europeans will be diagnosed with pancreatic cancer this year; and for these patients, the median overall survival after treatment with gemcitabine is only 8.5 months. There remains demand for new products that can extend this life expectancy further still, opening up the potential of a >US\$1.0bn market.
- **OncoSil will file for CE Mark of its brachytherapy this year.** This is because the Phase II data is considered sufficient. The nearness of first regulatory approval is likely to appeal to Life Science investors who prefer clinically de-risked technologies.
- **OncoSil initiating a single pivotal study ahead of US approval.** The company is currently preparing its IDE submission for a 150-patient randomised controlled study in pancreatic cancer patients, with interim analyses. This study is likely to conclude in 2016, seeing OncoSil on track for FDA approval in 2017. OncoSil understands that a two to three month improvement in Overall Survival and lowered pain scores are registrable endpoints.
- **OncoSil is funded to achieve a meaningful commercial outcome** after a \$10.3m placement and SPP in late 2013 at 12.5 cents per share. We believe this was more than enough to fund the pivotal study. As at March 2014 OncoSil held A\$10.3m cash. We estimate that the pivotal study, to be called ONC-301, will cost ~A\$8m to complete after R&D tax credits.
- **The development of OncoCal provides OncoSil with a good second generation technology.** OncoSil is currently developing a calcium-based delivery system to replace the current silicon-based system presently used for P³² delivery. Amongst other benefits, this technology brings outright ownership by the company, so that OncoSil's Next Generation brachytherapy product will be royalty-free.
- **Sirtex Medical has helped grow market acceptance for brachytherapy** with SIR-Spheres now a >US\$100m pa business at the revenue line, and growing rapidly thanks to excellent clinical outcomes in liver cancer. We think the success of Sirtex, and its current market capitalisation of >\$900m provides a good benchmark for OncoSil to aspire to.
- **OncoSil has good management.** We value OncoSil's leadership team highly. Chairman, Martin Rogers brought the cancer immunotherapy company, Prima Biomed (ASX:PRR) back from potential oblivion in 2007 and took it to Phase III in 2012. CEO, Dr Neil Frazer has a track record of clinical success gained at GSK and other companies, working mainly on cancer.
- **OncoSil is undervalued on our numbers.** We value OncoSil using a probability-weighted DCF approach at \$0.45 base case and \$1.14 optimistic case. Our \$0.45 target price sits at our base case. We see OncoSil being re-rated by the market as the ONC-301 study begins and CE Marking approaches.

OncoSil markedly boosted survival in pancreatic cancer at Phase II.

- **VALUATION METHODOLOGY.** Our probability-weighted DCF of OncoSil²⁶ was built as follows:
 - Our WACC was 16.4% (Speculative);
 - We assume a 50% probability of clinical success in the upcoming ONC-301 study;
 - We assume global launch of OncoSil in mid-2017;
 - We modelled revenue out to FY30 and then used FY31 as a terminal year. This is conservative since the OncoCal intellectual property provides coverage for the business out to ~2033;
 - We used a population model for pancreatic cancer using 27 First World jurisdictions in which the OncoSil brachytherapy is likely to be used in the future and assume a gradual increase in OncoSil's total patient pool, to around ~17-18% of all new cases by 2030;
 - Our assumptions on pricing and patient numbers suggest peak sales of US\$670m (base case) to US\$1.16bn (optimistic case);
 - We assume that OncoSil initially sells at US\$12,000 per dose (base case) to US\$15,000 (optimistic case), with prices increasing 2-4% pa;
 - We assume 75-85% gross margins for OncoSil at launch, alongside SG&A expenses equal to 20-25% of sales. We assume both COGS and SG&A decline by 0.1%-0.2% of revenue annually;
 - We assume an 8% royalty to pSivida for the technology, which OncoSil ceases to pay after the fifth year post product launch due to the introduction of OncoCal;
 - We assume negative terminal growth of 3-5% after 2030, which we think is conservative but allows for the risk of alternative brachytherapies that could reasonably emerge by this time;
 - We assume that \$10m in equity capital needs to be raised in order to fund the field force which would launch OncoSil globally around 2017.
- **MAJOR SHAREHOLDERS:** Neil Frazer (7.4%), Webinvest (Otto Buttula, 5.4%).
- **KEY RISKS:** 1) Delays or slowness in recruitment for the ONC-301 study; 2) Clinical risk for the ONC-301 study; 3) Lack of clinical acceptance for the brachytherapy product; and 4) Lack of reimbursement for the product.

FIG.14: ONCOSIL SHARE PRICE



Source: Iress

²⁶ Previous valuation range from 28 March 2014 was \$0.43 / \$1.10 – new valuation results from lower discount rate.

OncoSil - Financial Summary

Code OSL
Analyst Stuart Roberts
Date 13 June, 2014
Share price \$0.11
Market capitalisation \$39m
Year end 30 June

Rating BUY
Price target \$0.45
Upside/downside 309.1%
Valuation \$0.446 / \$1.135
Valuation method Probability-weighted DCF
Risk Speculative

PROFIT AND LOSS (A\$m)					
Y/e June 30 (A\$m)	FY12A	FY13A	FY14E	FY15E	FY16E
Revenue	0	0	0	0	0
EBITDA	-1	-1	-4	-6	-6
D&A	0	0	0	0	0
EBIT	-1	-1	-4	-6	-6
Net interest	0	0	0	0	0
Pre-tax profit	0	-1	-4	-6	-6
Tax	0	0	0	0	0
NPAT	0	-1	-4	-6	-6
Minority interests	0	0	0	0	0
Net profit after minorities	0	-1	-4	-6	-6

BALANCE SHEET (A\$m)					
Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
Cash	2	4	5	9	3
Current receivables	0	0	0	0	0
Inventories	0	0	0	0	0
Other current assets	0	0	4	4	4
Current assets	3	4	10	13	7
PPE	0	0	0	0	0
Intangible assets	0	3	3	3	3
Other non-current assets	0	0	0	0	0
Non-current assets	0	3	3	3	3
Total assets	3	6	12	16	10
Payables	0	0	0	0	0
Debt	0	0	0	0	0
Other liabilities	0	0	0	0	0
Total liabilities	0	0	0	0	0
Shareholders' equity	2	6	12	16	10
Minorities	0	0	0	0	0
Total shareholders funds	2	6	12	16	10
Total funds employed	3	6	12	16	10
W/A shares on issue	97	126	321	328	346

CASH FLOW (A\$m)					
Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
NPAT plus discontinued ops.	0	-1	-4	-6	-6
Non-cash items	0	0	0	0	0
Working capital	0	0	0	0	0
Other operating cash flow	0	0	0	0	0
Operating cashflow	0	0	-4	-6	-6
Capex	0	0	0	0	0
Investments	0	0	-4	0	0
Other investing cash flow	0	0	0	0	0
Investing cashflow	0	0	-4	0	0
Change in borrowings	0	0	0	0	0
Equity raised	0	2	10	10	0
Dividends paid	0	0	0	0	0
Other financing cash flow	0	0	0	0	0
Financing cashflow	0	2	10	10	0
Net change in cash	0	1	2	4	-6
Cash at end of period	2	4	5	9	3

EARNINGS (A\$m)					
Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
Net profit (\$m)	-0.4	-0.9	-4.1	-6.3	-6.4
EPS (c)	-0.4	-0.7	-1.3	-1.9	-1.8
EPS growth (%)	N/A	N/A	N/A	N/A	N/A
P/E ratio (x)	-24.8	-15.7	-8.7	-5.7	-6.0
CFPS (c)	-0.3	-0.4	-1.2	-1.8	-1.7
Price/CF (x)	-34.9	-29.3	-9.2	-6.1	-6.3
DPS (c)	0.0	0.0	0.0	0.0	0.0
Yield (%)	0.0%	0.0%	0.0%	0.0%	0.0%
Franking (%)	N/A	N/A	N/A	N/A	N/A
EV/EBITDA	-50.4	-29.4	-6.8	-4.6	-4.5
EV/EBIT	-50.4	-29.3	-6.8	-4.6	-4.5

PROFITABILITY RATIOS					
Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
EBITDA/revenue (%)	N/A	N/A	N/A	N/A	N/A
EBIT/revenue (%)	N/A	N/A	N/A	N/A	N/A
Return on assets (%)	-17.1%	-14.1%	-33.0%	-39.4%	-64.0%
Return on equity (%)	-17.4%	-14.5%	-33.6%	-39.9%	-65.4%
Return on funds empl'd (%)	-17.4%	-14.5%	-33.6%	-39.9%	-65.4%
Dividend cover (x)	N/A	N/A	N/A	N/A	N/A
Effective tax rate (%)	0.0%	0.0%	0.0%	0.0%	0.0%

LIQUIDITY AND LEVERAGE RATIOS					
Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
Net debt/(cash) (\$m)	-2	-4	-5	-9	-3
Net debt/equity (%)	-97.1%	-58.0%	-43.9%	-56.7%	-29.9%
Net interest cover (x)	N/A	N/A	N/A	N/A	N/A
Current ratio (x)	61.5	18.6	46.3	63.4	34.7

INTERIMS					
Y/e June 30 (\$m)	1H13A	2H13A	1H14A	2H14F	1H15F
Revenue	0	0	0	0	0
EBITDA	0	-1	-2	-2	-3
D&A	0	0	0	0	0
EBIT	0	-1	-2	-2	-3
Net interest	0	0	0	0	0
Pre-tax profit	0	-1	-2	-2	-3
Tax	0	0	0	0	0
NPAT	0	-1	-2	-2	-3
Minority interests	0	0	0	0	0
Net profit after minorities	0	-1	-2	-2	-3

VALUATION		
	Base	Optim.
OncoSil (A\$m)	174.4	468.8
Value of tax losses	3.3	3.3
Underlying R&D cost	-9.6	-9.6
Cash now (A\$m)	10.3	10.3
Cash from options and cash to be raised	12.4	12.4
Total value (A\$m)	190.7	485.2
Total diluted shares (million)	427.4	427.4
Value per share	\$0.45	\$1.14
Valuation midpoint	\$0.79	
Share price now (A\$ per share)	\$0.110	
Upside to midpoint	618.8%	

Phosphagenics (POH) – Breakthrough drug delivery patches

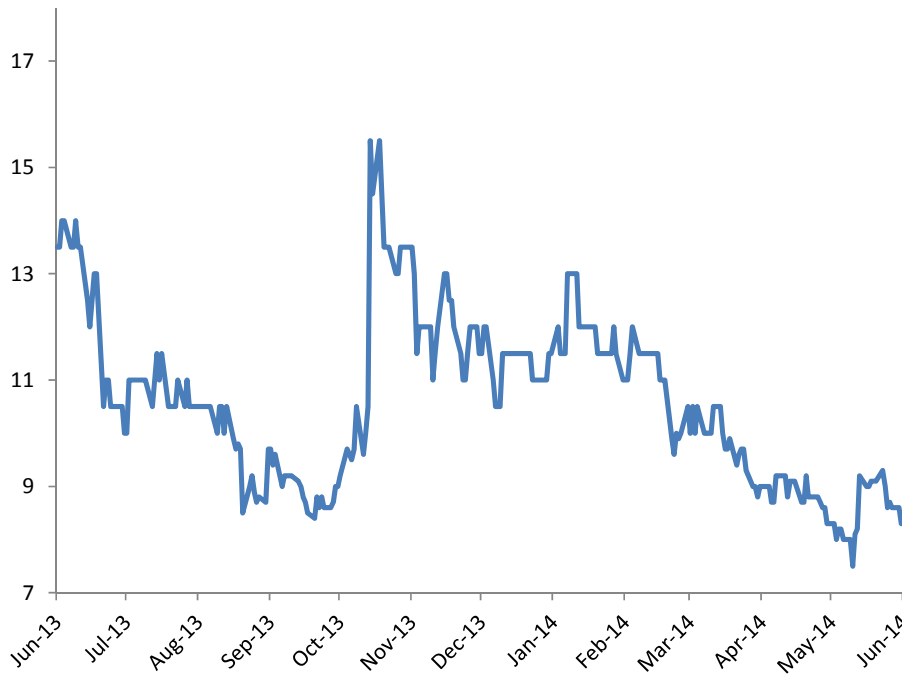
BUY. Target price \$0.26

- **COMPANY DESCRIPTION.** Phosphagenics' has proved in multiple clinical trials over the last decade that its TPM technology, which is based on the ability of phosphorylated Vitamin E to cross the skin, represents an efficient transdermal drug delivery solution. The company's patches, which avoid the traditional 'first pass metabolism' problem of orally available drugs, are notable for the speed and safety of drug delivery and the lack of skin irritation. Importantly, the company has now developed the world's first patches for the delivery of the opioid analgesics oxycodone and oxymorphone. This development opens up a multi-billion dollar market opportunity.
- **A near-term payday from oxycodone and oxymorphone.** Clinical data to date has shown that Phosphagenics has viable patches for the delivery of oxycodone and oxymorphone (see Phosphagenics announcements dated 26 July 2013 and 24 October 2013). The patches are small and can deliver their drug payload either systemically or topically over a 72 hour period for the treatment of chronic moderate-to-severe pain. These opioid analgesics represent a large market opportunity - US\$3bn p.a. just for oxycodone in the US market – that has grown strongly in recent years due to increased clinical need for chronic pain relief. Phosphagenics' oxycodone/oxymorphone breakthrough positions it for a good licensing deal. The record of another painkiller called Fentanyl, from J&J, is that the ability to deliver it via a patch in a product called Duragesic boosted sales eighty-fold over a 15 year period. At its peak J&J sold just over US\$2bn worth of Duragesic.
- **Patch delivery would represent a solution to opioid abuse.** In the last decade oxycodone has emerged as a drug of abuse, particularly in the US, due to ease with which abusers can extract the active pharmaceutical ingredient from tablets and use it to get a high. This has led regulators to look for tamper-resistant formulations. Phosphagenics patches would represent an ideal solution, due to the difficulty the would-be 'street chemists' would face in extracting the active from the patches, as well as the inability of sustained release patches to give the abuser the high he or she is looking for.
- **Phase II in 2014.** Phosphagenics has indicated that it intends to go to Phase II with its oxycodone and oxymorphone patches this year. After this there is potential for Phase II/III studies ahead of 505(b)(2) filings, which could take place in 2016 or 2017.
- **TPM has been deployed across a range of drug delivery indications.** Phosphagenics currently has programmes with various collaborators ongoing in pain, dermatology, various injectable drugs and animal health. These collaborations have potential to pay off in a big way. Consider diclofenac. This non-steroidal anti-inflammatory drug, known globally as Voltaren gel for the treatment of osteoarthritis and other inflammatory conditions, is a US\$700m global opportunity which is now being tapped via collaborations in India and Japan. Phosphagenics has shown that TPM allows better dermal absorption of diclofenac than Voltaren, while maintaining similar levels of systemic exposure.
- **Phosphagenics earns revenue from cosmeceuticals.** The company has created some Vitamin E-based cosmeceuticals which sells through various channels around the world. While these products only net Phosphagenics A\$1-2m p.a. it does show the ability of the Phosphagenics to realise commercial value from TPM.
- **Capable leadership.** Phosphagenics's CEO, Harry Rosen, already has a track record of success in the Life Sciences thanks to Betatene, which became the world's largest producer of natural beta carotene before it was sold in 1995 to the German company Henkel. While 2013 has seen the company experience a scandal in which various insiders were found to have misappropriated funds, under Rosen Phosphagenics has recovered much of the lost funds, enabling the company to move forward in 2014.
- **POH is undervalued on our numbers.** We value Phosphagenics at 25 cents base case and 60 cents optimistic case using a probability-weighted DCF valuation. We believe Phosphagenics stock is undervalued because of the long time it has taken to get here – the company has been developing TPM since 2002. We look for a re-rating of the stock as the company initiates the next Phase II trials for oxycodone and oxymorphone.

Phosphagenics has early revenues from cosmeceuticals

- **VALUATION METHODOLOGY.** Our probability-weighted DCF of Phosphagenics²⁷ was built as follows:
 - Our WACC was 14.2% (High risk);
 - We modelled payoffs mainly for oxycodone and oxymorphone patches, allowing a small amount of extra value for tretinoin and ketoconazole and other products as a proxy for the value of the TPM platform;
 - We used a 32% risk weighting for the patches for base case and 38% for optimistic case, to reflect the fact that the patches are moving into Phase II and have elements of both small and large molecule risk associated with them. We assigned different risk weights to the other pipeline products modelled;
 - The main part of our valuation is our assumption that the oxycodone and oxymorphone patches license together in 2015-2016, for US\$100-150m upfront, US\$250-350m milestones and 10-14% royalties. We assume that the products launch by 2017-2018 and model peak sales of US\$3.9-\$5.2bn;
 - We assume that \$15m in equity capital needs to be raised in order to fund the Phase II clinical work on oxycodone and oxymorphone.
- **MAJOR SHAREHOLDERS.** Allan Gray Australia (13.1%) and Harry Rosen (6.3%).
- **KEY RISKS.** 1) Delays in recruitment for the opioid patch clinical trials; 2) Clinical failure; 3) Regulatory risk related to the politics of opioid drugs; 4) Funding risk.

FIG.15: PHOSPHAGENICS SHARE PRICE



Source: Iress

²⁷ Previous valuation range from 7 March 2014 was \$0.26 / \$0.63 – new valuation results from lower discount rate and changed capital raising assumptions.

Phosphagenics - Financial Summary

Code	POH
Analyst	Stuart Roberts
Date	13 June, 2014
Share price	\$0.09
Market capitalisation	\$87m
Year end	31 December

Rating	BUY
Price target	\$0.26
Upside/downside	205.9%
Valuation	\$0.252 / \$0.596
Valuation method	Probability-weighted DCF
Risk	High

PROFIT AND LOSS (A\$m)					
Y/e June 30 (A\$m)	FY12A	FY13A	FY14E	FY15E	FY16E
Revenue	5	5	1	48	81
EBITDA	-7	-9	-15	28	62
D&A	-5	-4	-4	-4	-4
EBIT	-12	-13	-19	24	58
Net interest	1	1	0	1	3
Pre-tax profit	-11	-13	-18	25	61
Tax	0	0	0	0	0
NPAT	-11	-13	-18	25	61
Minority interests	0	0	0	0	0
Net profit after minorities	-11	-13	-18	25	61

BALANCE SHEET (A\$m)					
Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
Cash	17	9	9	36	100
Current receivables	5	4	4	6	7
Inventories	1	1	1	2	3
Other current assets	0	0	0	0	0
Current assets	23	14	14	45	110
PPE	1	1	1	1	1
Intangible assets	40	28	24	21	17
Other non-current assets	0	0	0	0	0
Non-current assets	41	29	25	21	18
Total assets	64	43	39	66	128
Payables	1	2	2	3	3
Debt	0	0	0	0	0
Other liabilities	0	0	0	0	0
Total liabilities	2	2	2	3	4
Shareholders' equity	63	41	37	63	124
Minorities	0	0	0	0	0
Total shareholders funds	63	41	37	63	124
Total funds employed	64	43	39	66	128
W/A shares on issue	1,049	1,042	1,074	1,235	1,235

CASH FLOW (A\$m)					
Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
NPAT plus discontinued ops.	-11	-13	-18	25	61
Non-cash items	5	4	4	4	4
Working capital	-5	0	0	-2	-1
Other operating cash flow	0	0	0	0	0
Operating cashflow	-10	-8	-14	27	64
Capex	0	0	0	0	0
Investments	0	0	0	0	0
Other investing cash flow	0	0	0	0	0
Investing cashflow	0	0	0	0	0
Change in borrowings	0	0	0	0	0
Equity raised	0	0	14	0	0
Dividends paid	0	0	0	0	0
Other financing cash flow	0	0	0	0	0
Financing cashflow	0	0	14	0	0
Net change in cash	-10	-8	0	27	64
Cash at end of period	17	9	9	36	100

EARNINGS (A\$m)					
Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
Net profit (\$m)	-10.5	-12.7	-18.2	25.1	60.9
EPS (c)	-1.0	-1.2	-1.7	2.0	4.9
EPS growth (%)	N/A	N/A	N/A	N/A	143%
P/E ratio (x)	-8.5	-7.0	-5.0	4.2	1.7
CFPS (c)	-1.0	-0.8	-1.3	2.2	5.2
Price/CF (x)	-8.6	-11.1	-6.5	3.9	1.6
DPS (c)	0.0	0.0	0.0	0.0	0.0
Yield (%)	0.0%	0.0%	0.0%	0.0%	0.0%
Franking (%)	N/A	N/A	N/A	N/A	N/A
EV/EBITDA	-11.6	-8.3	-5.3	2.8	1.3
EV/EBIT	-6.7	-5.9	-4.2	3.2	1.3

PROFITABILITY RATIOS					
Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
EBITDA/revenue (%)	-132.2%	-201.6%	-1013.3%	59.1%	75.8%
EBIT/revenue (%)	-230.0%	-285.4%	-1275.2%	51.1%	71.1%
Return on assets (%)	-16.4%	-29.5%	-46.3%	38.0%	47.6%
Return on equity (%)	-16.8%	-31.1%	-49.0%	40.0%	49.1%
Return on funds empl'd (%)	-16.8%	-31.1%	-49.0%	40.0%	49.1%
Dividend cover (x)	N/A	N/A	N/A	0%	0%
Effective tax rate (%)	0.0%	0.0%	0.0%	0.0%	0.0%

LIQUIDITY AND LEVERAGE RATIOS					
Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
Net debt/(cash) (\$m)	-17	-9	-9	-9	-100
Net debt/equity (%)	-27.0%	-21.6%	-24.2%	-57.1%	-80.3%
Net interest cover (x)	N/A	N/A	N/A	N/A	N/A
Current ratio (x)	15.9	6.7	6.8	13.5	28.3

INTERIMS					
Y/e June 30 (\$m)	2H12A	1H13A	2H13A	1H14F	2H14F
Revenue	3	3	2	1	1
EBITDA	-2	-4	-5	-7	-8
D&A	-3	-2	-2	-2	-2
EBIT	-5	-6	-7	-9	-10
Net interest	0	0	0	0	0
Pre-tax profit	-5	-6	-7	-9	-10
Tax	0	0	0	0	0
NPAT	-5	-6	-7	-9	-10
Minority interests	0	0	0	0	0
Net profit after minorities	-5	-6	-7	-9	-10

VALUATION	
	Base Optim.
Opioid patches (A\$m)	198.0 525.8
Dermatology gels (A\$m)	11.7 46.5
Other programmes (A\$m)	27.7 91.0
Total value for technology (A\$m)	237.4 663.4
Value of tax losses	59.7 59.7
Underlying R&D cost	-9.6 -9.6
Cash now (A\$m)	8.8 8.8
Cash to be raised (A\$m)	15.5 15.5
Total value (A\$m)	311.9 737.8
Total diluted shares (million)	1237.8 1237.8
Value per share	\$0.25 \$0.60
Valuation midpoint	\$0.42
Share price now (A\$ per share)	\$0.085
Upside to midpoint	398.9%

Rhinomed (RNO) – Breathtaking early stage opportunity

BUY. Target price \$0.12

- **Note:** Baillieu Holst Ltd has raised funds for Rhinomed Ltd and earned fees in relation to those activities in the past 12 months.
- **COMPANY DESCRIPTION.** Rhinomed is commercialising an internal nasal dilation platform called BreatheAssist. The initial BreatheAssist product called Turbine, was launched into the sports performance market in January 2014. Other applications in the works for BreatheAssist include its use in snoring reduction and drug delivery.
- **Rhinomed has its first commercial product.** The BreatheAssist platform technology's first product is Turbine, a nasal dilation device designed to improve breathing in sports, launched commercially in January 2014.
- **Turbine may represent the Next Big Thing in sports medicine.** There are clear advantages for users based on a 38% increase in air delivery to the lungs. We see potential for Turbine to be used across a range of sports, beginning with cycling.
- **The clinical data on Turbine in cycling is compelling.** Rhinomed announced in May 2003 the results of the 'Ridewiser' trial, which was conducted at a clinic run by the Melbourne-based cycling coach Rob Crowe. This study showed that Turbine could increase a cyclist's power and distance:
 - A total of nine A and B grade qualified racing cyclists were tested while riding at endurance levels of racing (65-75% of maximum heart rate) as well as threshold levels (80-90% of maximum heart rate) with and without Turbine. This was a 'crossover' study, so study participants were in all cohorts;
 - When riders used Turbine during threshold exertion they increased their wattage²⁸, by an average 3.7%. The average for the best six riders was 6.5%; and
 - When riders used Turbine during threshold exertion they increased their 40-minute ride distance by 143 metres, a 1.2% improvement.
- **Is Rhinomed the 'Next CNS Inc.'?** CNS Inc. built a US\$100m business out of Breathe Right nasal strips which ultimately allowed it to be sold to GSK for US\$566m in 2006. We see potential for Rhinomed to follow a similar pathway given the superiority of its product.
- **BreatheAssist may represent a new product in sleep disorders.** Work is planned to show that it can treat snoring and mild-to-moderate sleep apnoea. The company expects to conduct user trials of a BreatheAssist device suitable for snoring later in 2014 ahead of a 510(k) filing in the US, after which social media can be used to promote usage in this space, targeting the partner who is kept awake by the snoring. For sleep apnoea Rhinomed will explore whether a BreatheAssist device has clinical effectiveness, either as a stand-alone or in conjunction with CPAP; this will be undertaken in 2015.
- **BreatheAssist has potential to be a serious drug delivery technology.** There is evidence that it can be used for nasal delivery of a range of drugs. Rhinomed is currently working on BreatheAssist delivery of the migraine drug Sumatriptan, where dissatisfaction with current delivery modalities is high. Around 16% of US adults will experience a migraine over any three month period, and around 80% of all patients prescribed an anti-migraine drug will get a triptan, half of them Sumatriptan²⁹. The high incidence of migraines fuelled blockbuster status for the innovator brand for Sumatriptan GSK's Imitrex after it gained FDA approval in 1991, with peak sales of US\$1.37bn in 2007.
- **Rhinomed has strong leadership.** CEO, Michael Johnson brings to Rhinomed a marketing background with experience in positioning new medical therapies. His skills have proved instrumental in bringing Turbine to market. Backing Johnson is a board Chaired by Martin Rogers which includes Brett Scrimshaw, formerly Vice President & Chief Executive Western Europe for Nike.

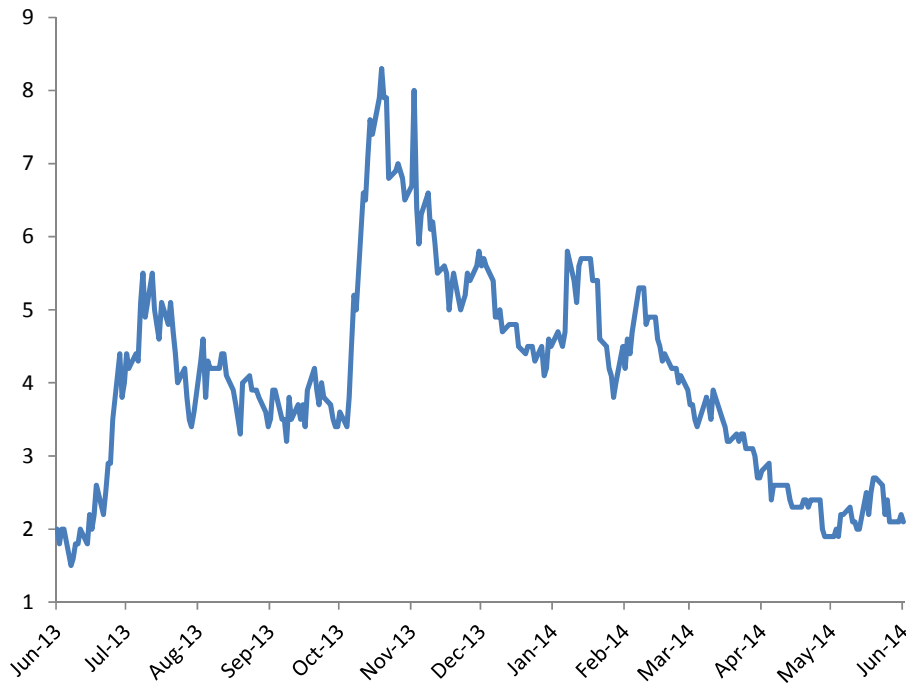
BreatheAssist could be a good drug delivery tool.

²⁸ In cycling a rider's wattage is the power his effort at the pedals is generating. It is a function of his velocity and all the resisting forces (ie wind, gravity and friction).

²⁹ See Headache. 2013 Mar;53(3):427-36.Epub 2013 Mar 7.

- **Rhinomed is undervalued on our numbers.** We value Rhinomed at \$0.12 per share base case and \$0.38 per share optimistic case on a probability-weighted DCF valuation. Our target price sits at our base case valuation.
- **VALUATION METHODOLOGY.** Our probability-weighted DCF of Rhinomed was built using various assumptions:
 - Our WACC was 14.2% (High risk);
 - We modelled payoffs for Turbine, for a BreatheAssist product targeted at snoring and sleep apnoea, and for a Sumatriptan delivery product;
 - We used a 20% probability of success for the Sumatriptan project, and a 100% probability to Turbine and BreatheAssist, taking the view that there was little technology development risk remaining;
 - We assumed that Turbine can reach US\$10-20m in net sales within five years of launch, while for BreatheAssist in snoring/apnoea the comparable figures are US\$20-40m; and
 - We assumed a further \$2m in equity capital needs to be raised before Rhinomed becomes break-even from sales of Turbine and BreatheAssist in snoring/apnoea.
- **MAJOR SHAREHOLDERS:** None.
- **KEY RISKS:** 1) Sales risk; 2) Development risk; 3) Funding risk; and 4) Competitor risk.

FIG.16: RHINOMED SHARE PRICE



Source: Iress

Rhinomed - Financial Summary

Code RNO
Analyst Stuart Roberts
Date 13 June, 2014
Share price \$0.02
Market capitalisation \$8m
Year end 30 June

Rating BUY
Price target \$0.12
Upside/downside 471.4%
Valuation \$0.116 / \$0.385
Valuation method Probability-weighted DCF
Risk High

PROFIT AND LOSS (A\$m)					
Y/e June 30 (A\$m)	FY12A	FY13A	FY14E	FY15E	FY16E
Revenue	5	0	0	1	4
EBITDA	-1	-16	-1	-1	0
D&A	0	0	0	0	0
EBIT	-1	-16	-1	-1	0
Net interest	0	0	0	0	0
Pre-tax profit	-1	-16	-1	-1	0
Tax	0	1	0	0	0
NPAT	-1	-15	-1	-1	0
Minority interests	0	0	0	0	0
Net profit after minorities	-1	-15	-1	-1	0

BALANCE SHEET (A\$m)					
Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
Cash	0	0	1	1	2
Current receivables	0	1	1	1	1
Inventories	0	0	0	0	0
Other current assets	3	0	0	0	0
Current assets	3	1	1	2	3
PPE	0	0	0	0	0
Intangible assets	22	5	5	5	5
Other non-current assets	0	0	0	0	0
Non-current assets	22	5	5	5	5
Total assets	26	6	7	8	8
Payables	1	1	1	1	1
Debt	0	0	0	0	0
Other liabilities	4	0	0	0	0
Total liabilities	5	1	1	1	1
Shareholders' equity	20	6	6	7	8
Minorities	0	0	0	0	0
Total shareholders funds	20	6	6	7	8
Total funds employed	26	6	7	8	8
W/A shares on issue	147	239	333	458	458

CASH FLOW (A\$m)					
Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
NPAT plus discontinued ops.	-1	-15	-1	-1	0
Non-cash items	2	12	0	0	0
Working capital	-4	1	0	0	0
Other operating cash flow	0	0	0	0	0
Operating cashflow	-3	-2	-1	-1	1
Capex	0	0	0	0	0
Investments	0	0	0	0	0
Other investing cash flow	0	0	0	0	0
Investing cashflow	-1	0	0	0	0
Change in borrowings	0	0	0	0	0
Equity raised	3	2	1	2	0
Dividends paid	0	0	0	0	0
Other financing cash flow	0	0	0	0	0
Financing cashflow	3	2	1	2	0
Net change in cash	-1	0	0	1	1
Cash at end of period	0	0	1	1	2

EARNINGS (A\$m)					
Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
Net profit (\$m)	-0.8	-15.0	-1.1	-1.3	0.3
EPS (c)	-0.5	-6.3	-0.3	-0.3	0.1
EPS growth (%)	N/A	N/A	N/A	N/A	N/A
P/E ratio (x)	-4.1	-0.3	-6.6	-7.6	28.9
CFPS (c)	-2.0	-0.7	-0.3	-0.2	0.1
Price/CF (x)	-1.1	-2.9	-6.8	-10.0	17.1
DPS (c)	0.0	0.0	0.0	0.0	0.0
Yield (%)	0.0%	0.0%	0.0%	0.0%	0.0%
Franking (%)	N/A	N/A	N/A	N/A	N/A
EV/EBITDA	-6.8	-0.4	-3.9	-4.5	17.4
EV/EBIT	-6.7	-0.4	-3.9	-4.5	17.5

PROFITABILITY RATIOS					
Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
EBITDA/revenue (%)	-15.6%	-5373.2%	-1713.6%	-114.6%	8.8%
EBIT/revenue (%)	-15.8%	-5375.6%	-1718.3%	-114.8%	8.7%
Return on assets (%)	-2.9%	-232.5%	-16.1%	-16.8%	4.0%
Return on equity (%)	-3.7%	-263.7%	-17.6%	-18.2%	4.3%
Return on funds empl'd (%)	-3.7%	-253.5%	-17.6%	-18.2%	4.3%
Dividend cover (x)	N/A	N/A	N/A	N/A	0%
Effective tax rate (%)	7.2%	4.3%	26.9%	0.0%	0.0%

LIQUIDITY AND LEVERAGE RATIOS					
Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
Net debt/(cash) (\$m)	0	0	0	-1	-2
Net debt/equity (%)	-2.0%	-1.7%	-8.0%	-20.4%	-25.9%
Net interest cover (x)	N/A	N/A	N/A	N/A	N/A
Current ratio (x)	0.7	1.4	2.0	3.7	4.5

INTERIMS					
Y/e June 30 (\$m)	1H13A	2H13A	1H14A	2H14F	1H15F
Revenue	0	0	0	0	0
EBITDA	-12	-4	-1	0	-1
D&A	0	0	0	0	0
EBIT	-12	-4	-1	0	-1
Net interest	0	0	0	0	0
Pre-tax profit	-12	-4	-1	0	-1
Tax	0	1	0	0	0
NPAT	-12	-3	-1	0	-1
Minority interests	0	0	0	0	0
Net profit after minorities	-12	-3	-1	0	-1

VALUATION		
	Base	Optim.
Turbine (A\$m)	20.8	80.0
Snoring / apnea (A\$m)	30.5	140.3
Sumatriptan (A\$m)	16.8	61.5
Value of Rhinomed technology	68.1	281.8
Value of tax losses	8.2	8.2
Underlying R&D cost	-9.6	-9.6
Cash now (A\$m)	2.6	2.6
Cash from options and cash to be raised	23.3	23.3
Total value (A\$m)	92.5	306.3
Total diluted shares (million)	796.6	796.6
Value per share	\$0.12	\$0.38
Valuation midpoint	\$0.25	
Share price now (A\$ per share)	\$0.021	
Upside to midpoint	1092.2%	

Sirtex Medical (SRX) – Moving up the usage curve

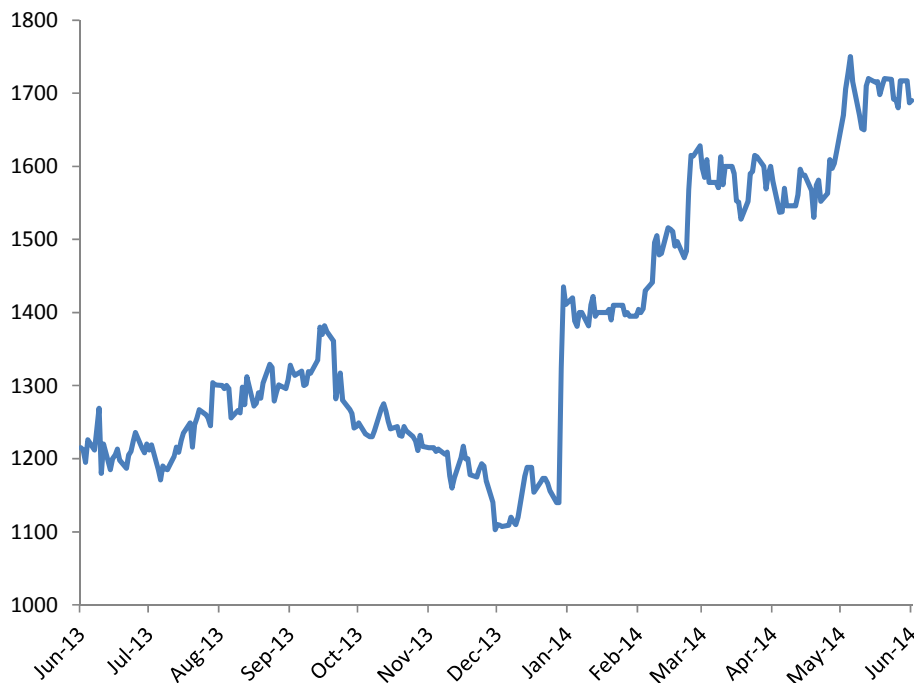
BUY. Target price \$21.00

- **COMPANY DESCRIPTION.** Sirtex Medical has built a great business over the last decade out of SIR-Spheres, which are radioactive Yttrium 90 microspheres used in the treatment of liver cancer. SIR-Spheres enhance the survival of patients with liver cancer by Selective Internal Radiation Therapy (SIRT), meaning that the radiation is placed close enough to the tumours to make a meaningful difference but only expose healthy tissues to low doses of radiation. Sirtex's business has been booming in recent years, from just 581 dose units in FY04 to 7,299 doses in FY13. In the latter year total revenue increased 16% over the previous corresponding period to \$100m while NPAT rose 7% to A\$18m. As at 31 March 2014 Sirtex had registered 39 consecutive quarters of sales growth.
- **SIR-Spheres are a great product.** A number of studies have suggested that, for colorectal cancer patients where their tumour has metastasised to the liver, which is the primary market for SIR-Spheres, the therapy may help the patient live another 10-18 months on top of an average life expectancy of just over two years. For primary liver cancer patients the comparable figures are 3-6 months extra life on top of an 11 month life expectancy pre-treatment. At around US\$14,000 per dose all the evidence suggests that SIR-Spheres represent a highly cost effective treatment option for patients with either primary or secondary liver cancer.
- **Acceptance of SIR-Spheres is increasing.** SIR-Spheres are now administered at in excess of 600 hospitals worldwide, with data on patient survival having increased the credibility of the product at leading cancer treatment centres.
- **Even with increased usage Sirtex has only just begun to penetrate the market.** Sirtex reckons that market penetration for its product is only around 1% penetrated. There's a simple reason for this. Up until now all the clinical studies on SIR-Spheres, including those that allowed marketing approval to be obtained, were only conducted with 50 patients or less. Without large studies with hundreds of patients the product can't 'mainstream' and move from 'salvage therapy' as at present to a first line treatment which is where Sirtex would like it to go. Sirtex is now rectifying this situation, with five large studies ongoing. The first of these, called SIRFLOX, reads out data in late 2014. We think that this and subsequent studies will lay the groundwork for a step-change in SIR-Spheres usage.
- **Sirtex has invested heavily in its growth, with a marketing budget consistently greater than 30% of sales.** We have a high regard for this willingness of Sirtex leadership under CEO Gilman Wong to defer their company's 'payday' while they build the true potential of SIR-Spheres.
- **SIRFLOX has potential to unlock significant value from early 2015.** The 518-patient SIRFLOX study, for which recruitment completed in April 2013 (around five years after the study started), randomised metastatic colorectal cancer patients 1:1 to either SIR-Spheres plus FOLFOX (5-fluorouracil, leucovorin and oxaliplatin) with or without Avastin as a first line treatment versus FOLFOX±Avastin alone. The primary endpoint of the trial is Progression-Free Survival (PFS). Data from this trial alone may propel substantial first-line usage.
- **Other studies are enjoying accelerated recruitment.** As word has gotten out about the effectiveness of SIR-Spheres, it is becoming easier to recruit patients into the other large-scale clinical trials. As at May 2014 the SARAH study was 85% complete, FOXFIRE 83%, SIRveNIB 68% and SORAMIC 59%.
- **Sirtex is debt-free, with A\$48m net cash as at December 2013.** This clean balance sheet gives the company flexibility in terms of planning for long-term growth.
- **The stock remains undervalued.** We value Sirtex using a DCF valuation model at \$15.98 base case / \$28.62 optimistic case. Our \$21.00 price target sits at around the midpoint of this DCF range. We see the potential for a continued rerating on the back of good quarterly numbers, particularly as the SIRFLOX data draws near.

The SIRFLOX trial data become available in early 2015

- **VALUATION METHODOLOGY.** Our DCF of Sirtex³⁰ was built as follows:
 - Our WACC was 12% (Medium risk, to reflect the momentum behind SIR-Spheres at a >US\$100m pa revenue run rate);
 - As with Nanosonics we modelled revenue out to FY23 and then used FY24 as a terminal year.
 - After our FY14-16 forecast we used a population model for both primary and secondary liver cancer in the jurisdictions in which SIR-Spheres is approved to model revenue. The population model suggested around 570,000 cases p.a. currently rising to 680,000 in 2023. For our revenue numbers we assumed 10% (base case) and 14% (optimistic) market penetration for SIR-Spheres by 2023. Penetration is current 1%;
 - We assume 2-4% p.a. average selling price increases for SIR-Spheres;
 - We assume no margin improvement for our base case but lowered COGS and SG&A expenses by 0.1% of revenue annually for our optimistic case;
 - We use a 3% FY24 terminal growth assumption for our base case and 4% for our optimistic case, with EBITDA margins falling back to 25% for the terminal measure;
 - We assume no further equity capital needs to be raised.
- **MAJOR SHAREHOLDERS.** Hunter Hall (20.5%), Bruce Gray (founder, no longer involved, 12.6%), Perpetual (6.9%).
- **KEY RISKS.** 1) Clinical risk with SIRFLOX and the other trials; 2) Competitor risk, where new drug therapies slow sales of SIR-Spheres.

FIG.17: SIRTEX SHARE PRICE



Source: Iress

³⁰ Previous valuation range from 18 February 2014 was \$15.11 / \$26.86 – new valuation results from lower discount rate.

Sirtex Medical - Financial Summary

Code SRX
Analyst Stuart Roberts
Date 13 June, 2014
Share price \$16.21
Market capitalisation \$910m
Year end 30 June

Rating BUY
Price target \$21.00
Upside/downside 29.5%
Valuation \$15.976 / \$28.62
Valuation method DCF
Risk Medium

PROFIT AND LOSS (A\$m)					
Y/e June 30 (A\$m)	FY12A	FY13A	FY14E	FY15E	FY16E
Total revenue	83	97	123	144	169
EBITDA	21	23	29	43	50
D&A	-1	-1	-2	-3	-4
EBIT	20	22	27	40	46
Net interest	2	2	2	2	2
Pre-tax profit	22	25	29	42	48
Tax	-5	-6	-7	-10	-12
NPAT	17	18	22	32	37
Minority interests	0	1	0	0	0
Net profit after minorities	17	19	23	32	37

BALANCE SHEET (A\$m)					
Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
Cash	49	52	49	52	60
Current receivables	18	21	21	22	23
Inventories	1	2	2	3	4
Other current assets	2	3	5	5	5
Current assets	71	77	77	82	91
PPE	7	9	14	19	19
Intangible assets	16	28	45	60	75
Other non-current assets	3	3	4	4	4
Non-current assets	26	40	62	82	98
Total assets	97	118	140	164	189
Payables	9	11	13	13	13
Debt	0	0	0	0	0
Other liabilities	14	19	21	21	21
Total liabilities	23	30	34	34	34

Shareholders' equity	74	88	105	130	155
Minorities	0	0	0	0	0
Total shareholders funds	74	88	105	130	155
Total funds employed	97	118	140	164	189
W/A shares on issue	56	56	56	56	56

CASH FLOW (A\$m)					
Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
NPAT plus discontinued ops.	17	18	22	32	37
Non-cash items	1	4	3	3	4
Working capital	2	2	2	-2	-2
Other operating cash flow	0	0	0	0	0
Operating cashflow	20	24	27	34	39
Capex	-1	-4	-7	-8	-4
Investments	0	0	0	0	0
Other investing cash flow	-9	-13	-17	-15	-15
Investing cashflow	-10	-16	-24	-23	-20
Change in borrowings	0	0	0	0	0
Equity raised	0	0	0	0	0
Dividends paid	-4	-5	-7	-8	-11
Other financing cash flow	0	0	0	0	0
Financing cashflow	-4	-5	-7	-8	-11
Net change in cash	7	3	-3	3	8
Cash at end of period	49	52	49	52	60

EARNINGS (A\$m)					
Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
Net profit (\$m)	16.7	18.9	22.6	32.2	36.5
EPS (c)	29.9	33.9	40.4	57.4	65.2
EPS growth (%)	49%	13%	19%	42%	14%
P/E ratio (x)	54.2	47.8	40.1	28.3	24.9
CFPS (c)	35.8	43.6	49.0	60.2	69.2
Price/CF (x)	45.2	37.2	33.1	26.9	23.4
DPS (c)	10.0	12.0	14.0	20.0	23.0
Yield (%)	0.6%	0.7%	0.9%	1.2%	1.4%
Franking (%)	100%	100%	100%	100%	100%
EV/EBITDA	42.9	38.7	31.4	21.1	18.3
EV/EBIT	45.9	41.2	33.8	22.8	20.0

PROFITABILITY RATIOS					
Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
EBITDA/revenue (%)	25.7%	24.3%	23.5%	30.0%	29.5%
EBIT/revenue (%)	24.0%	22.8%	21.9%	27.7%	27.0%
Return on assets (%)	17.3%	16.1%	16.2%	19.6%	19.3%
Return on equity (%)	22.7%	21.5%	21.5%	24.8%	23.6%
Return on funds empl'd (%)	22.7%	21.5%	21.5%	24.8%	23.6%
Dividend cover (x)	3.0	2.8	2.9	2.9	2.8
Effective tax rate (%)	22.7%	25.4%	23.7%	24.0%	24.0%

LIQUIDITY AND LEVERAGE RATIOS					
Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
Net debt/(cash) (\$m)	-49	-52	-49	-52	-60
Net debt/equity (%)	-67.2%	-59.1%	-46.8%	-40.3%	-38.8%
Net interest cover (x)	N/A	N/A	N/A	N/A	N/A
Current ratio (x)	4.3	3.9	3.6	3.8	4.3

INTERIMS					
Y/e June 30 (\$m)	1H13A	2H13A	1H14A	2H14F	1H15F
Revenue	46	52	59	65	69
EBITDA	10	13	14	15	21
D&A	-1	-1	-1	-1	-2
EBIT	10	13	13	14	19
Net interest	1	1	1	1	1
Pre-tax profit	11	14	15	15	20
Tax	-3	-3	-3	-4	-5
NPAT	8	10	11	11	15
Minority interests	0	1	0	0	0
Net profit after minorities	8	11	11	11	15

VALUATION		
	Base	Optim.
Business (A\$m)	848.5	1558.0
Cash as at Dec 2013 (A\$m)	47.9	47.9
Cash from options (A\$m)	0.0	0.0
Total value (A\$m)	896.4	1605.8
Diluted shares on issue (million)	56.1	56.1
Value per share	\$15.98	\$28.62
Valuation midpoint	\$22.30	
Share price now	\$16.210	
Upside	37.6%	

Tissue Therapies (TIS) – Marked upside once the regulatory issues are dealt with

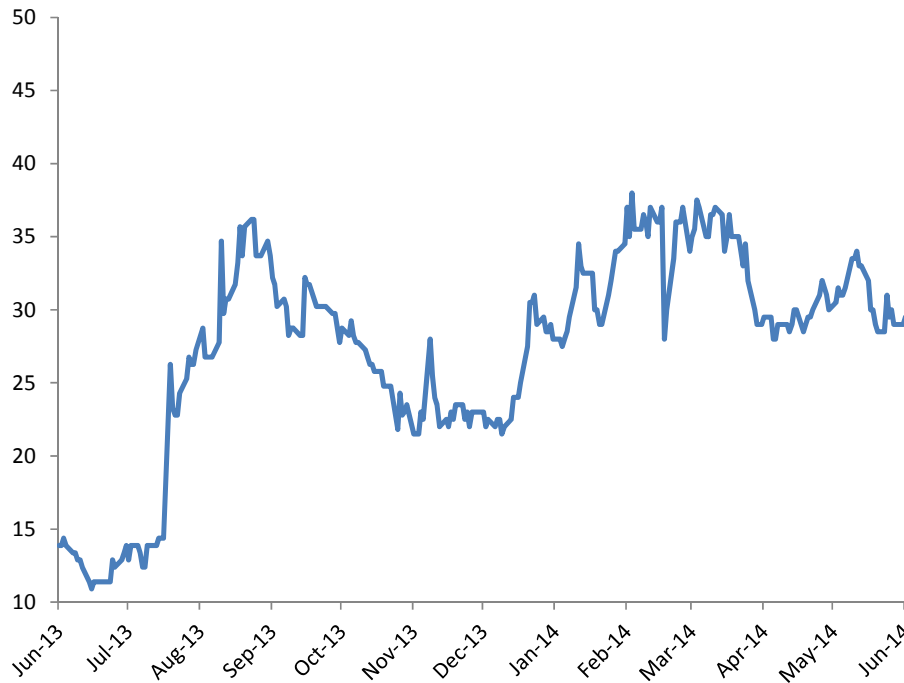
BUY. Target price \$0.65.

- **Company description.** Tissue Therapies has completed its clinical work for CE Mark approval of its VitroGro ECM wound-healing solution. VitroGro ECM can be used in the treatment of diabetic, venous and pressure ulcers, with outstanding outcomes compared to existing therapies. Tissue Therapies argues that VitroGro ECM can be a billion dollar product in the US\$30-40bn global market for chronic wound care. However the product has yet to be approved in Europe due to a disagreement between the UK health regulator, the MHRA, and the EMA as to the appropriate final review. This has been resolved and the final review of quality data is now underway with CE Mark expected to be granted during the second half of calendar 2014.
- **A wonderful solution to diabetic foot ulcers and venous ulcers.** Around 6~12% of US diabetics have foot ulcers, many of which prove difficult to heal and some of which can lead to expensive and often life-shortening amputations. With ~19 million diagnosed adult diabetics in the US alone any wound healing product with efficacy in diabetic foot ulcers can sell into a market of more than a million people. Another ~2 million Americans probably have venous ulcers today as a result of poor circulation. VitroGro ECM, a combination the two human skin matrix proteins vitronectin and IGF-I, is an elegant solution to venous and diabetic ulcers. In the CE Mark trial of 44 patients, 34% had complete healing and 43% had >90% healing after 12 weeks in wounds that had ulcerated for years.
- **There has been a hold-up on the regulatory front.** Tissue Therapies has been working since 2011 on CE Mark approval of VitroGro ECM. In March 2013 these efforts hit a road block when the European Commission Medical Devices Group, which advises the EMA, voted that VitroGro ECM should be regulated as a drug and not as a device. Tissue Therapies and its Notified Body had previously received confirmation of the classification of VitroGro ECM as a device from the MHRA (because it acts as a scaffold that promotes wound healing but doesn't cause therapeutic protein to go into the bloodstream). The difference between drug and device is important - a device is something that doesn't ordinarily go into the bloodstream whereas a drug has that potential. This classification issue has now been resolved but it has resulted in a delay of the launch of VitroGro ECM in spite of good safety and efficacy data.
- **Things seem to have gone Tissue Therapies' way since July last year.** In late July 2013 Tissue Therapies advised the market that the EMA would now proceed to review manufacturing quality data. This was because the regulator had had legal advice that the only competent body to classify products was the MHRA, which had classified VitroGro ECM as a device. This appears to be a reversal of the previous EMA decision. A clear pathway to approval has now been set and this was confirmed by the September 2013 announcement of the start of the final approval review. Any progress on the European regulatory front can be regarded as highly positive for Tissue Therapies stock, given that arrangements have already been made with Quintiles (~US\$3.0bn p.a. in revenue) for that company to provide a contract sales force.
- **Tissue Therapies is moving towards gaining US approval for VitroGro ECM.** In the US VitroGro ECM clinical work is expected to initiate this year, with an IND for a venous ulcer trial having been filed in late October 2013. This trial, which will be double-blinded and placebo-controlled (unusual for wound care products) puts Tissue Therapies on track for US approval in 2016, subject to funds of approximately US\$10m being available to conduct the clinical trial. The US market has a large patient population and favourable pricing.
- **Tissue Therapies has good management.** CEO, Dr Steve Mercer has an intimate knowledge of the wound care space, gained as a long-time executive at Smith & Nephew. With Steve having guided Tissue Therapies through the creation of VitroGro ECM from beginning to end, we think he has the commercial smarts to take VitroGro ECM all the way.
- **Tissue Therapies is undervalued on our numbers.** We value Tissue Therapies at \$0.65 per share base case and \$1.44 per share optimistic case using a DCF valuation of VitroGro ECM. Our target price of \$0.65 per share sits at around the low point of our DCF range. We see a Tissue Therapies re-rating to our target price on the back of any progress towards resolution of the European regulatory issues.

Tissue Therapies seems to be on the path to CE Mark.

- **VALUATION METHODOLOGY.** Our probability-weighted DCF of Tissue Therapies³¹ was built as follows:
 - Our WACC was 16.4% (Speculative);
 - We assumed that Tissue Therapies self-distributes VitroGro ECM with the help of the Quintiles sales force in Europe once it gains approval. We assume launch in either FY15 (optimistic case) or FY16 (base case). We model peak sales of US\$380-540m;
 - We assume launch late in calendar 2014;
 - We used a 91% chance of clinical/regulatory success in the current approval process with the EMA;
 - We assumed 75-85% gross margins for the product, and SG&A costs of 20-25% of revenue, with a 0.1%-0.2% p.a. increase in gross margins and reductions in SG&A as a percentage of revenue; and
 - We assume another A\$10m in equity capital needs to be raised at 20 cents per share to fund US clinical work.
- **MAJOR SHAREHOLDERS:** Allan Gray Australia (15.8%) and Asia Union Investments (Chris Abbott, Maple-Brown Abbott founder, 7.8%).
- **KEY RISKS:** 1) Regulatory risk, as per our remarks above; and 2) Funding risk, which could slow initiation of the US trial.

FIG.18: TISSUE THERAPIES SHARE PRICE



Source: Iress

³¹ Previous valuation range from 28 November 2013 was \$0.61 / \$1.34 – new valuation results from lower discount rate.

Tissue Therapies - Financial Summary

Code TIS
Analyst Stuart Roberts
Date 13 June, 2014
Share price \$0.30
Market capitalisation \$78m
Year end 30 June

Rating BUY
Price target \$0.65
Upside/downside 120.3%
Valuation \$0.648 / \$1.442
Valuation method Probability-weighted DCF
Risk Speculative

PROFIT AND LOSS (A\$m)					
Y/e June 30 (A\$m)	FY12A	FY13A	FY14E	FY15E	FY16E
Revenue	0	0	0	2	6
EBITDA	-7	-6	-8	-10	-5
D&A	-1	0	0	0	0
EBIT	-8	-6	-8	-10	-5
Net interest	1	0	0	0	0
Pre-tax profit	-7	-6	-8	-10	-5
Tax	0	0	0	0	0
NPAT	-7	-6	-8	-10	-5
Minority interests	0	0	0	0	0
Net profit after minorities	-7	-6	-8	-10	-5

BALANCE SHEET (A\$m)					
Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
Cash	5	5	6	6	1
Current receivables	0	0	0	0	0
Inventories	6	9	9	10	10
Other current assets	1	1	1	1	1
Current assets	12	15	16	16	12
PPE	0	0	0	0	0
Intangible assets	0	0	0	0	0
Other non-current assets	0	0	0	0	0
Non-current assets	1	1	1	1	1
Total assets	13	16	17	17	12
Payables	2	1	1	1	1
Debt	0	0	0	0	0
Other liabilities	0	0	1	1	1
Total liabilities	2	2	1	1	2
Shareholders' equity	10	14	16	16	11
Minorities	0	0	0	0	0
Total shareholders funds	10	14	16	16	11
Total funds employed	13	16	17	17	12
W/A shares on issue	169	186	262	312	312

CASH FLOW (A\$m)					
Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
NPAT plus discontinued ops.	-7	-6	-8	-10	-5
Non-cash items	1	0	0	0	0
Working capital	-4	-4	-1	0	0
Other operating cash flow	0	0	0	0	0
Operating cashflow	-10	-9	-8	-10	-5
Capex	0	0	0	0	0
Investments	0	0	0	0	0
Other investing cash flow	0	0	0	0	0
Investing cashflow	0	0	0	0	0
Change in borrowings	0	0	0	0	0
Equity raised	0	9	9	10	0
Dividends paid	0	0	0	0	0
Other financing cash flow	0	0	0	0	0
Financing cashflow	0	9	9	10	0
Net change in cash	-10	0	1	0	-5
Cash at end of period	5	5	6	6	1

EARNINGS (A\$m)					
Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
Net profit (\$m)	-6.8	-5.7	-7.9	-9.7	-5.0
EPS (c)	-4.0	-3.1	-3.0	-3.1	-1.6
EPS growth (%)	N/A	N/A	N/A	N/A	N/A
P/E ratio (x)	-7.4	-9.6	-9.9	-9.5	-18.6
CFPS (c)	-6.1	-5.0	-3.2	-3.1	-1.6
Price/CF (x)	-4.9	-5.9	-9.2	-9.6	-18.4
DPS (c)	0.0	0.0	0.0	0.0	0.0
Yield (%)	0.0%	0.0%	0.0%	0.0%	0.0%
Franking (%)	N/A	N/A	N/A	N/A	N/A
EV/EBITDA	-9.9	-11.3	-8.4	-7.1	-13.9
EV/EBIT	-8.9	-11.0	-8.3	-7.1	-13.8

PROFITABILITY RATIOS					
Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
EBITDA/revenue (%)	-2069.4%	-6406.3%	N/A	-547.3%	-81.9%
EBIT/revenue (%)	-2296.7%	-6565.3%	N/A	-549.5%	-82.5%
Return on assets (%)	-52.3%	-36.3%	-45.9%	-56.7%	-39.8%
Return on equity (%)	-64.7%	-41.1%	-50.0%	-61.9%	-45.6%
Return on funds empl'd (%)	-64.5%	-41.1%	-50.0%	-61.9%	-45.6%
Dividend cover (x)	N/A	N/A	N/A	N/A	N/A
Effective tax rate (%)	6.1%	5.1%	3.7%	0.0%	0.0%

LIQUIDITY AND LEVERAGE RATIOS					
Y/e June 30	FY12A	FY13A	FY14E	FY15E	FY16E
Net debt/(cash) (\$m)	-5	-5	-6	-6	-1
Net debt/equity (%)	-49.0%	-34.8%	-37.2%	-36.6%	-6.8%
Net interest cover (x)	N/A	N/A	N/A	N/A	N/A
Current ratio (x)	5.2	9.2	13.6	13.1	8.6

INTERIMS					
Y/e June 30 (\$m)	1H13A	2H13A	1H14A	2H14F	1H15F
Revenue	0	0	0	0	1
EBITDA	-3	-3	-4	-5	-6
D&A	0	0	0	0	0
EBIT	-3	-3	-4	-5	-6
Net interest	0	0	0	0	0
Pre-tax profit	-3	-3	-4	-5	-6
Tax	0	0	0	0	0
NPAT	-3	-3	-3	-5	-6
Minority interests	0	0	0	0	0
Net profit after minorities	-3	-3	-3	-5	-6

VALUATION	
	Base Optim.
VitroGro (A\$m)	183.8 435.0
Value of tax losses	11.5 11.5
Underlying R&D cost	-9.6 -9.6
Cash now (A\$m)	8.8 8.8
Cash to be raised (A\$m)	10.7 10.7
Total value (A\$m)	205.1 456.3
Total diluted shares (million)	316.4 316.4
Value per share	\$0.65 \$1.44
Valuation midpoint	\$1.05
Share price now (A\$ per share)	\$0.295
Upside to midpoint	254.4%

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