Baillieu Holst
Since 1889

# Australian Life Sciences

**SECTOR REPORT - INITIATION**

## Good performances so far, more to come

- **The Australian Life Sciences sector** has performed well since 2008 and we believe that this outperformance will continue, with many companies still having good clinical or commercial news to come. The US biotechnology sector is booming at the moment. Our three top picks are: Alchemia (ACL) expecting Phase III data next year on a new cancer drug formation; Neuren (NEU) with its potential blockbuster CNS drug NNZ-2566; and Bionomics (BNO) also expecting data early next year on its BNC105 cancer drug.
- **Alchemia (ACL)** is in Phase III with HA-Irinotecan, a new formulation of an old cancer drug. Data from this metastatic colorectal cancer trial is due in the first half of calendar 2014. Phase II suggested a strong improvement in Progression-Free Survival for these patients. BUY. Target price $1.10.
- **Admedus (AHZ)** has gained CE Mark approval for its first product, a cardiovascular tissue patch called CardioCel. Admedus is also seeking to be a player in the emerging field of DNA vaccines, backing the Gardasil inventor, UQ's Professor Ian Frazer. BUY. Target price $0.25.
- **Bionomics (BNO)** licensed the anxiety drug BNC210 to America's Ironwood in 2012 for a massive US$345m in upfront and milestone payments. Bionomics's BNC105 cancer drug reads out important Phase II data early next year. 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. An important partnership with Teva, one of the world's largest pharma companies, is moving forward. BUY. Target price $8.50.
- **Nanosonics (NAN)** is now earning revenue from trophon EPR, which disinfects ultrasound probes. This product has potential to become a healthcare industry standard, helped by GE, which is trophon EPR's North American distributor. BUY. Target price $1.15.
- **Neuren (NEU)** is developing NNZ-2566, now in Phase II in Traumatic Brain Injury (TBI) and in a rare condition called Rett Syndrome. Clinical success in either indication makes a potential blockbuster. The US government is funding the TBI trial. BUY. Target price $0.26.
- **Phosphagenics (POH)** has developed the world's first patches delivering the painkilling drugs oxycodone and oxymorphone. These products go to Phase II next year. Various potentially valuable collaborations related to transdermal drug delivery are ongoing. BUY. Target price $0.27.
- **REVA Medical (RVA)** has developed one of the world's first bioresorbable stents. This polymer-based product, called ReZolve, is now in a pivotal trial for potential CE Mark approval in 2015. We expect the product can help double a US$4-5bn global market for stents. BUY. Target price $1.50.
- **Sirtex Medical (SRX)** now has a $100m-a-year business in its SIR-Spheres radioactive beads for the treatment of liver cancer. We foresee a big jump in sales from 2015 once data from the first of a number of large clinical trials of SIR-Spheres is released. BUY. Target price $15.00.
- **Tissue Therapies (TIS)** has, in VitroGro ECM, a compelling wound healing product for the treatment of venous and diabetic foot ulcers, but European launch has been delayed by regulatory issues. Resolution of these issues could substantially re-rate the stock. BUY. Target price $0.65.

### STOCKS COVERED IN THIS REPORT



***Disclosure***
The author owns no shares in ACL, AHZ, BNO, MSB, NAN, NEU, POH, RVA, SRX or TIS.

### RESEARCH ANALYST

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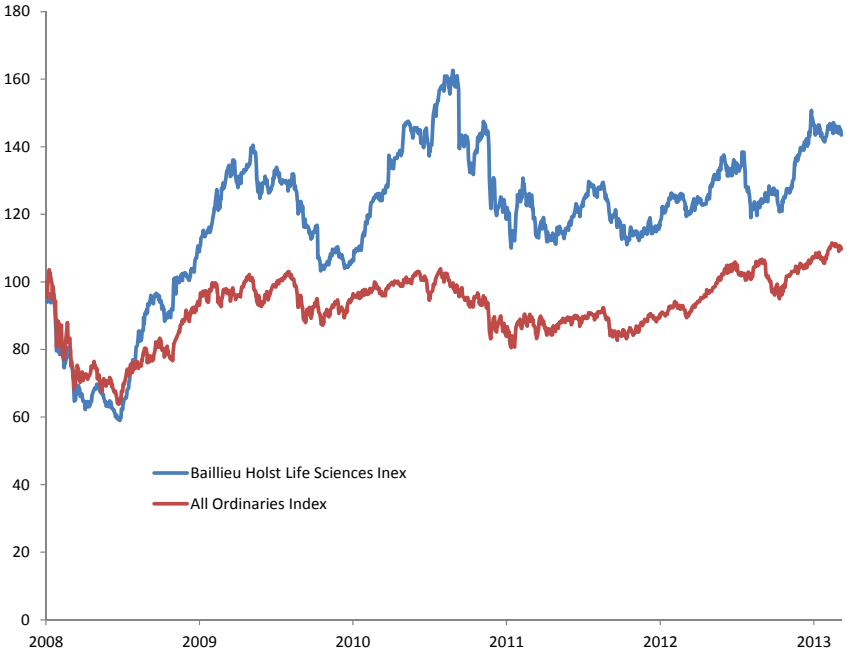
***Recommendations***
**Buy:** The stock's total return is expected to increase by at least 10-15% from the current share price over the next 12 months.
**Hold:** The stock's total return is expected to trade within a range of ±10-15% from the current share price over the next 12 months.
**Sell:** The 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 secret success story of the post-GFC era

- Since 2008 the Life Sciences sector in Australia has generated good returns for shareholders. We calculated an equally-weighted index of 67 Life Sciences stocks and plotted them against the All Ordinaries Index for the period since September 2008. Life Sciences is the clear winner in this comparison, with the sector up 43% since 2008 versus only 9% for the All Ordinaries Index.

**FIG.1: PERFORMANCE OF THE BAILLIEU HOLST LIFE SCIENCES INDEX SINCE SEPTEMBER 2008**



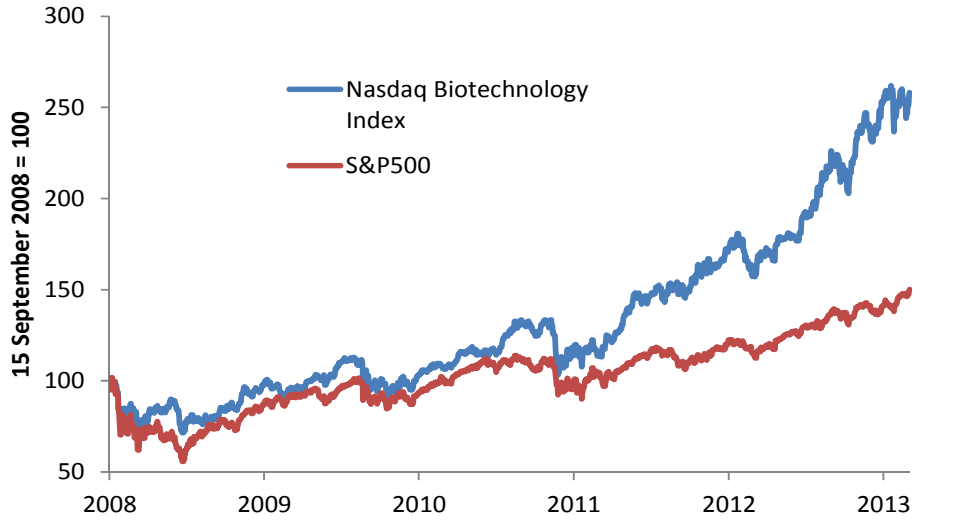

*Source: Baillieu Holst*

- **We see five main reasons why the Life Sciences Sector has performed so well**:
  - The sector is more mature, with later stage opportunities now on offer, and companies better managed than was the case a decade ago;
  - There have been some big commercial winners, most notably, Mesoblast (MSB), where a partnering deal in late 2010 vaulted that stem cell company above the billion dollar capitalisation level;
  - A number of companies have generated good Phase II data;
  - The sector is better understood than in the past by investors, with a number of Australian broking houses employing analysts with expertise in the space, including Baillieu Holst;
  - There has been strong performance by the US biotech and medical device sector (see next page) which is beginning to spill into our market.
- In this note we look at ten ASX-listed Life Sciences companies which we believe are worthy of investor's attention.

# Biotechnology is booming in the US

- The US biotech sector has created significant value for investors for five years now. Since the start of the Global Financial Crisis in September 2008 the US biotech sector has exploded upwards, with the benchmark Nasdaq Biotechnology Index gaining 21% p.a. for the next five years versus 8% for the S&P500. This boom, which has taken 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. Big ticket transactions this year have included Amgen buying Onyx for US$10bn and Perrigo buying Elan for US$8.6bn.
- **Clinical and regulatory success by many companies.** A lot of companies that went public during the last 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 that usual. 2012 saw 39 new drugs, the biggest number in a decade.
- **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.

**FIG.2: PERFORMANCE OF THE NASDAQ BIOTECHNOLOGY INDEX SINCE SEPTEMBER 2008**




*Source: Nasdaq*

# 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. 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 in this note.
- **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 Phase[1] 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 12.5% and 17% depending on the risk. This is derived from a RFR of 4.2%; a MRP of 7.5%[2] for 'medium risk' companies rising to 11.5% for 'speculative' companies; and an ungeared beta of 1.1[3]. 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 REVA Medical is $1.50 whereas the market is currently $0.51. Our valuation is based on an 85% probability of success in the current pivotal trial for the ReZolve stent. We think this probability is reasonable given what we know about REVA's stent. At $0.51 the market is, in effect, saying that the stent has around a 29% chance of success (i.e. 51/200*85%). The difference lies in the fact that Australia, unlike 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 successful[4]. 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 10 companies we think are worthy of inclusion in such a portfolio. Mesoblast is already capitalised at more than a billion dollars. We're reasonably confident predict that, on the probabilities alone, at least two more will join Mesoblast at this lofty level by 2018, if they haven't been acquired beforehand.
- **We nominate three top picks.** We like all the stocks covered here, but readers ought to pay particular attention to three. **Alchemia (ACL)** reads out Phase III data next year on a new cancer drug formation. We like this one because the formulation performed very well at Phase II. **Neuren (NEU)** will know next year if its potential blockbuster CNS drug, NNZ-2566, will work to treat the underlying biology of Rett Syndrome. We think this drug can easily become a blockbuster based on unmet medical need and Orphan drug pricing. **Bionomics (BNO)** reads out data early next year on its BNC105 cancer drug. We believe success here can unlock a significant partnering deal given the ability of BNC105 to deal with many different types of solid tumours.

[1] See Di Masi et. al., Clinical Pharmacology & Therapeutics (2010) 87 3, 272–277.
[2] 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.
[3] 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.
[4] Large molecules are closer to 40%.

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

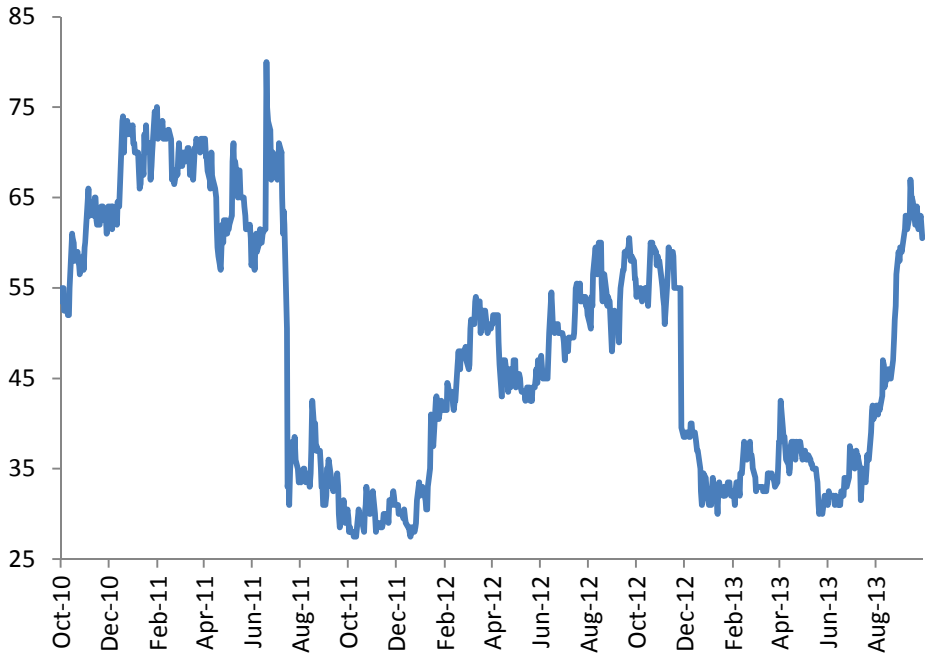
## BUY. Target price $1.10

- **COMPANY DESCRIPTION.** Alchemia is a Brisbane-based company that 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 conclude in the first half of calendar 2014. Phase II data suggested a strong interest in Progression-Free Survival (PFS) for these patients.
- **Riding on Reddy's coat-tails.** Alchemia enjoys a 60% 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$6.6bn[5] 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 25-30% 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, providing near-term upside for shareholders.
- **Phase III data coming soon.** HA-Irinotecan is an off-patent cancer drug called Irinotecan (Pfizer's old Camptosar drug, peak sales US$970m) 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, reported in May 2007, HA-Irinotecan was able to more than double PFS, from 2.4 months in the control group to 5.2 months in the HA-Irinotecan ground (p=0.016). HA-Irinotecan's 415-patient Phase III trial in metastatic colorectal cancer completed enrolment in February 2013 and results are expected to be available in the first half 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 second half of 2014. Alchemia has powered the study to show an 8-12 week improvement in PFS. The company believes HA-Irinotecan's sales potential is between US$0.5bn and US$1.7bn and it is currently looking at partnering options. The US has ~143,000 new colorectal cancer cases every year.
- **A valuable platform technology**. Alchemia calls it's 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 cells[6]. There has been a boom on Wall Street in companies going after cancer stem cells in recent days, featuring companies such as Verastem (Nasdaq VSTM, market capitalisation US$268m), Oncomed (Nasdaq OMED, US$364m) and Stemline (Nasdaq STML, US$257m)[7].
- **Alchemia has good management.** CEO Charlie Walker and his colleagues have taken 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 $1.06 base case and $1.99 optimistic case. Our $1.10 price target sits at the low point of this range. With Alchemia having sufficient funds to complete the colorectal cancer Phase III, we anticipate the stock being re-rated by the market as completion of this trial draws near.

[5] 14 November 2013 close on National Stock Exchange of India, code DRREDDY.
[6] CD44 is well known as a cancer stem cell market. See Cancer Res. 2013 Jul 1;73(13):4112-22. Epub 2013 Apr 30.
[7] 27 November 2013 close on Nasdaq.

- **VALUATION METHOLOGY**. Our probability-weighted DCF of Alchemia was built as follows:
  - Our WACC was 14.7% (High risk);
  - HA-Irinotecan was modelled using 56% probability of clinical and regulatory success[8], 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 is currently buying 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.
- **MAJOR SHAREHOLDERS.** Allan Gray Australia (18.2%) and 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.3: ALCHEMIA SHARE PRICE**




*Source: Iress*

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

# Alchemia - Financial Summary

| | |
|---|---|
| Code | ACL |
| Analyst | Stuart Roberts |
| Date | 27 November, 2013 |
| Share price | $0.60 |
| Market capitalisation | $195m |
| Year end | 30 June |

| | |
|---|---|
| Rating | BUY |
| Price target | $1.10 |
| Upside/downside | 83.3% |
| Valuation | $1.055 / $1.99 |
| 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 | 18 | 65 | 112 |
| **EBITDA** | **-14** | **-4** | **-1** | **45** | **92** |
| D&A | -2 | -2 | -1 | -1 | -1 |
| **EBIT** | **-16** | **-5** | **-2** | **44** | **91** |
| Net interest | 0 | 0 | 1 | 1 | 5 |
| Pre-tax profit | **-15** | **-5** | **-2** | **45** | **95** |
| Tax | 0 | 0 | 0 | 0 | -5 |
| NPAT | -15 | -5 | -2 | 45 | 91 |
| Minority interests | 0 | 0 | 0 | 0 | 0 |
| Net profit after minorities | -15 | -5 | -2 | 45 | 91 |

**BALANCE SHEET (A$m)**

| Y/e June 30 | FY12A | FY13A | FY14E | FY15E | FY16E |
|---|---|---|---|---|---|
| Cash | 12 | 5 | 5 | 51 | 143 |
| Current receivables | 0 | 12 | 13 | 14 | 15 |
| Inventories | 0 | 0 | 0 | 0 | 0 |
| Other current assets | 3 | 9 | 9 | 9 | 9 |
| **Current assets** | **16** | **26** | **26** | **73** | **166** |
| 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 | 13 | 11 |
| **Total assets** | 32 | 41 | 41 | 86 | 178 |
| Payables | 3 | 5 | 5 | 6 | 6 |
| Debt | 0 | 0 | 0 | 0 | 0 |
| Other liabilities | 5 | 4 | 4 | 4 | 4 |
| **Total liabilities** | 8 | 9 | 10 | 10 | 10 |
| Shareholders' equity | 24 | 32 | 31 | 76 | 168 |
| Minorities | 0 | 0 | 0 | 0 | 0 |
| **Total shareholders funds** | **24** | **32** | **31** | **76** | **168** |
| **Total funds employed** | **32** | **41** | **41** | **86** | **178** |
| **W/A shares on issue** | 242 | 292 | 324 | 324 | 324 |

**CASH FLOW (A$m)**

| Y/e June 30 | FY12A | FY13A | FY14E | FY15E | FY16E |
|---|---|---|---|---|---|
| NPAT plus discontinued ops. | -15 | -5 | -2 | 45 | 91 |
| Non-cash items | 2 | 2 | 2 | 2 | 2 |
| Working capital | 1 | -10 | 0 | 0 | 0 |
| Other operating cash flow | 0 | 0 | 0 | 0 | 0 |
| **Operating cashflow** | **-12** | **-13** | **0** | **46** | **92** |
| 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** | **0** | **46** | **92** |
| **Cash at end of period** | 12 | 5 | 5 | 51 | 143 |

**EARNINGS (A$m)**

| Y/e June 30 | FY12A | FY13A | FY14E | FY15E | FY16E |
|---|---|---|---|---|---|
| Net profit ($m) | -15.1 | -4.8 | -1.6 | 44.9 | 90.7 |
| EPS (c) | -6.2 | -1.6 | -0.5 | 13.8 | 28.0 |
| *EPS growth (%)* | N/A | N/A | N/A | N/A | 102% |
| P/E ratio (x) | -9.6 | -36.8 | -118.9 | 4.3 | 2.1 |
| CFPS (c) | -4.9 | -4.5 | -0.1 | 14.3 | 28.4 |
| Price/CF (x) | -12.3 | -13.2 | -510.7 | 4.2 | 2.1 |
| 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 | -13.0 | -13.0 | -13.0 | -13.0 | -13.0 |
| EV/EBIT | -11.6 | -35.1 | -76.9 | 4.2 | 2.0 |

**PROFITABILITY RATIOS**

| Y/e June 30 | FY12A | FY13A | FY14E | FY15E | FY16E |
|---|---|---|---|---|---|
| EBITDA/revenue (%) | -4195.8% | -15.2% | -5.5% | 69.5% | 82.0% |
| **EBIT/revenue (%)** | -4709.2% | -21.8% | -13.1% | 67.3% | 80.8% |
| Return on assets (%) | -46.6% | -11.5% | -4.0% | 52.1% | 51.0% |
| Return on equity (%) | -62.2% | -14.7% | -5.3% | 58.9% | 54.1% |
| Return on funds empl'd (%) | -62.2% | -14.7% | -5.3% | 58.9% | 54.1% |
| Dividend cover (x) | N/A | N/A | N/A | 0% | 0% |
| Effective tax rate (%) | 2.6% | 5.4% | 0.0% | 0.0% | 5.0% |

**LIQUIDITY AND LEVERAGE RATIOS**

| Y/e June 30 | FY12A | FY13A | FY14E | FY15E | FY16E |
|---|---|---|---|---|---|
| Net debt/(cash) ($m) | -12 | -5 | -5 | -51 | -143 |
| **Net debt/equity (%)** | -50.9% | -15.6% | -15.0% | -66.8% | -85.5% |
| Net interest cover (x) | N/A | N/A | N/A | 0.0 | -0.1 |
| Current ratio (x) | 3.3 | 4.4 | 4.2 | 11.0 | 23.8 |

**INTERIMS**

| Y/e June 30 ($m) | 2H12A | 1H13A | 2H13A | 1H14F | 2H14F |
|---|---|---|---|---|---|
| Revenue | 0 | 9 | 15 | 9 | 9 |
| **EBITDA** | **-9** | **-5** | **2** | **-1** | **0** |
| D&A | **-1** | **-1** | **-1** | **-1** | **-1** |
| **EBIT** | **-10** | **-6** | **1** | **-1** | **-1** |
| Net interest | **0** | **0** | **0** | **0** | **0** |
| Pre-tax profit | -9 | -6 | 1 | -1 | -1 |
| Tax | **0** | **0** | **0** | **0** | **0** |
| NPAT | -9 | -6 | 1 | -1 | -1 |
| Minority interests | **0** | **0** | **0** | **0** | **0** |
| Net profit after minorities | -9 | -6 | 1 | -1 | -1 |

**VALUATION**

| | Base | Optim. |
|---|---|---|
| HA-Irinotecan (A$m) | 265.7 | 571.9 |
| Fondaparinux (A$m) | 48.6 | 63.5 |
| VAST (A$m) | 20.0 | 40.0 |
| Total value for technology (A$m) | 334.3 | 675.4 |
| Value of tax losses | 36.9 | 36.9 |
| Underlying R&D cost | -19.2 | -19.2 |
| Cash now (A$m) | 10.2 | 10.2 |
| Cash to be raised (A$m) | 22.8 | 22.8 |
| Total value (A$m) | 384.9 | 726.0 |
| Total diluted shares (million) | 364.8 | 364.8 |
| Value per share | $1.06 | $1.99 |
| Valuation midpoint | $1.52 | |
| Share price now (A$ per share) | $0.600 | |
| Upside to midpoint | 153.8% | |

# Admedus (AHZ) – New generation vaccines

## BUY. Target price $0.25

- **COMPANY DESCRIPTION.** Admedus has gained CE Mark approval for its first product, a cardiovascular tissue patch called CardioCel. First sales were made in Europe in November 2013. 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 Coridon, 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's 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, following on from favourable long-term clinical data (i.e. out to four years) 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.
- **There are many commercial opportunities coming for ADAPT.** ~US$700m pa gets spent in the US on tissue repair solutions for hernia and pelvic floor repair, 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$448m) and Vical (Nasdaq: VICL, US$100m)[9]. While its work in the field is still at an early stage, Admedus's Coridon venture has generated encouraging pre-clinical data.
- **Admedus is backing Ian Frazer.** Professor Ian Frazer, who was Australian of the Year in 2006, is world famous as the inventor of Gardasil, a vaccine for Human Papilloma Virus, which is the causative agent in cervical cancer. Merck & Co. gained FDA approval for this Australian invention in mid-2006. The Frazer laboratory's track record of success suggests the potential for favourable outcomes from their work on Coridon's DNA vaccines.
- **Coridon has generated impressive pre-clinical results for its vaccines.** Coridon has created a DNA vaccine for HSV-2 infection in order to prevent genital herpes as well as a therapeutic vaccine 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 50 million Americans are infected. Coridon expects to have interim data from an HSV-2 Phase I clinical study in late 2013 or early 2014. Positive preclinical results for the HPV vaccine were reported in late 2012.
- **Admedus is undervalued on our numbers.** We value Admedus at $0.25 per share base case and $0.55 per share optimistic case. Our target price of $0.25 sits in the low point of our valuation range. We expect the market to re-rate Admedus as further clinical and pre-clinical data emerges during 2014.

[9] 27 November 2013 close on Nasdaq.

- **VALUATION METHOLOGY**. Our probability-weighted DCF of Admedus was built as follows:
  - Our WACC was 14.7% (High risk);
  - We modelled payoffs from CardioCel (self-distributed) and the HSV-2 and HPV vaccine candidates (partnered, 21% probability of clinical and regulatory success[10]);
  - 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.
- **MAJOR SHAREHOLDER.** Minderoo Group (Andrew Forrest, 17.7%).
- **KEY RISKS**. 1) Commercial risk for CardioCel; 2) Clinical risk for HSV-2 vaccine; 3) Clinical risk for HPV vaccine; 4) Funding risk.

**FIG.4: ADMEDUS SHARE PRICE**


*Source: Iress*

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

# Admedus - Financial Summary

| | |
|---|---|
| Code | AHZ |
| Analyst | Stuart Roberts |
| Date | 27 November, 2013 |
| Share price | $0.155 |
| Market capitalisation | $195m |
| Year end | 30 June |

| | |
|---|---|
| Rating | BUY |
| Price target | $0.25 |
| Upside/downside | 61.3% |
| Valuation | $0.251 / $0.547 |
| 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 | 33 | 60 |
| **EBITDA** | **-10** | **-3** | **1** | **9** | **21** |
| D&A | 0 | 0 | 0 | 0 | 0 |
| **EBIT** | **-10** | **-3** | **0** | **9** | **20** |
| Net interest | 0 | 0 | 0 | 1 | 1 |
| Pre-tax profit | **-10** | **-3** | **1** | **9** | **22** |
| Tax | 0 | 1 | 0 | 0 | -6 |
| NPAT | -10 | -2 | 1 | 9 | 16 |
| Minority interests | 0 | 0 | 0 | 0 | 0 |
| Net profit after minorities | -10 | -2 | 1 | 9 | 16 |

**BALANCE SHEET (A$m)**

| Y/e June 30 | FY12A | FY13A | FY14E | FY15E | FY16E |
|---|---|---|---|---|---|
| Cash | 2 | 2 | 13 | 21 | 36 |
| Current receivables | 1 | 2 | 2 | 2 | 2 |
| Inventories | 2 | 2 | 2 | 2 | 2 |
| Other current assets | 0 | 0 | 0 | 0 | 0 |
| **Current assets** | **5** | **6** | **16** | **25** | **40** |
| | | | | | |
| PPE | 0 | 0 | 0 | 0 | 0 |
| Intangible assets | 3 | 10 | 10 | 9 | 9 |
| Other non-current assets | 3 | 1 | 2 | 3 | 5 |
| **Non-current assets** | 6 | 11 | 12 | 13 | 14 |
| | | | | | |
| **Total assets** | 11 | 17 | 28 | 38 | 54 |
| | | | | | |
| Payables | 0 | 1 | 1 | 1 | 1 |
| Debt | 0 | 0 | 0 | 0 | 0 |
| Other liabilities | 0 | 1 | 1 | 1 | 1 |
| **Total liabilities** | 1 | 1 | 2 | 2 | 2 |
| | | | | | |
| Shareholders' equity | 10 | 13 | 25 | 34 | 50 |
| Minorities | 0 | 2 | 2 | 2 | 2 |
| **Total shareholders funds** | **10** | **15** | **27** | **36** | **52** |
| | | | | | |
| **Total funds employed** | **11** | **17** | **28** | **38** | **54** |
| | | | | | |
| **W/A shares on issue** | 663 | 908 | 1,244 | 1,249 | 1,249 |

**CASH FLOW (A$m)**

| Y/e June 30 | FY12A | FY13A | FY14E | FY15E | FY16E |
|---|---|---|---|---|---|
| NPAT plus discontinued ops. | -10 | -2 | 1 | 9 | 16 |
| Non-cash items | 7 | -1 | 0 | 0 | 0 |
| Working capital | -1 | -1 | 0 | 0 | 0 |
| Other operating cash flow | 0 | 0 | 0 | 0 | 0 |
| **Operating cashflow** | **-4** | **-4** | **1** | **10** | **16** |
| | | | | | |
| Capex | 0 | 0 | 0 | 0 | 0 |
| Investments | -2 | -1 | -1 | -1 | -1 |
| Other investing cash flow | 0 | 0 | 0 | 0 | 0 |
| **Investing cashflow** | **-2** | **-1** | **-1** | **-1** | **-2** |
| | | | | | |
| Change in borrowings | 0 | 0 | 0 | 0 | 0 |
| Equity raised | 6 | 4 | 10 | 0 | 0 |
| Dividends paid | 0 | 0 | 0 | 0 | 0 |
| Other financing cash flow | 0 | 0 | 0 | 0 | 0 |
| **Financing cashflow** | **7** | **5** | **10** | **0** | **0** |
| | | | | | |
| **Net change in cash** | **1** | **0** | **10** | **8** | **15** |
| | | | | | |
| **Cash at end of period** | 2 | 2 | 13 | 21 | 36 |

**EARNINGS (A$m)**

| Y/e June 30 | FY12A | FY13A | FY14E | FY15E | FY16E |
|---|---|---|---|---|---|
| Net profit ($m) | -10.2 | -2.4 | 0.9 | 9.5 | 16.0 |
| EPS (c) | -1.5 | -0.3 | 0.1 | 0.8 | 1.3 |
| *EPS growth (%)* | N/A | N/A | N/A | 941% | 70% |
| P/E ratio (x) | -10.1 | -58.2 | 213.0 | 20.5 | 12.1 |
| CFPS (c) | -0.5 | -0.4 | 0.1 | 0.8 | 1.3 |
| Price/CF (x) | -29.1 | -38.1 | 158.0 | 19.8 | 11.8 |
| DPS ( c ) | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| *Yield (%)* | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% |
| Franking (%) | 0% | 0% | 0% | 0% | 0% |
| EV/EBITDA | -18.1 | -18.1 | -18.1 | -18.1 | -18.1 |
| EV/EBIT | -17.6 | -60.1 | 392.1 | 21.1 | 8.9 |

**PROFITABILITY RATIOS**

| Y/e June 30 | FY12A | FY13A | FY14E | FY15E | FY16E |
|---|---|---|---|---|---|
| EBITDA/revenue (%) | -157.1% | -37.3% | 5.3% | 27.2% | 34.7% |
| **EBIT/revenue (%)** | -161.3% | -41.0% | 3.3% | 26.4% | 34.1% |
| Return on assets (%) | -91.3% | -14.6% | 3.2% | 25.1% | 29.8% |
| Return on equity (%) | -98.0% | -16.0% | 3.4% | 26.2% | 30.7% |
| Return on funds empl'd (%) | -97.8% | -16.0% | 3.4% | 26.2% | 30.7% |
| Dividend cover (x) | N/A | N/A | 0% | 0% | 0% |
| Effective tax rate (%) | 1.3% | 20.0% | 0.0% | 0.0% | 26.9% |

**LIQUIDITY AND LEVERAGE RATIOS**

| Y/e June 30 | FY12A | FY13A | FY14E | FY15E | FY16E |
|---|---|---|---|---|---|
| Net debt/(cash) ($m) | -2 | -2 | -13 | -21 | -36 |
| **Net debt/equity (%)** | -19.6% | -16.2% | -47.5% | -58.4% | -68.8% |
| Net interest cover (x) | N/A | N/A | -0.9 | -0.1 | -0.1 |
| Current ratio (x) | 7.8 | 6.7 | 17.6 | 25.8 | 39.6 |

**INTERIMS**

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

**VALUATION**

| | Base | Optim. |
|---|---|---|
| CardioCel (A$m) | 334.3 | 782.0 |
| HSV-2 vaccine (A$m) | 27.3 | 54.5 |
| HPV vaccine (A$m) | 15.6 | 40.3 |
| Total value for technology (A$m) | 377.2 | 876.9 |
| Value of tax losses | 3.8 | 3.8 |
| Underlying R&D cost | -9.6 | -9.6 |
| Cash now (A$m) | 12.1 | 12.1 |
| Cash from options and cash to be rai | 40.7 | 40.7 |
| Total value (A$m) | 424.2 | 923.9 |
| Total diluted shares (million) | 1690.1 | 1690.1 |
| Value per share | $0.25 | $0.55 |
| Valuation midpoint | $0.40 | |
| Share price now (A$ per share) | $0.155 | |
| Upside to midpoint | 157.3% | |

# Bionomics (BNO) – Drug discovery powerhouse

## BUY. Target price $0.90

- **COMPANY DESCRIPTION.** Bionomics is an Adelaide-based 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 which feed tumours. Both drugs have performed well in pre-clinical and clinical work. Bionomics licensed BNC210 to the US biotech company Ironwood Pharmaceuticals (Nasdaq IRWD) in January 2012 for a deal package worth a massive US$345m, and the drug is now in Phase I. BNC105 is in Phase II in Renal Cell Carcinoma (RCC) and in ovarian cancer. The RCC trial is expected to read out data in early 2014 and we expect a favourable outcome given what we know about the dose escalation part of the trial. 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$1.37bn[11], 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's directly cytotoxic for cancer cells. And it induces cancer cell killing via apoptosis. BNC105 seems to be highly effective in treating all solid tumours. This ability points to a strong payoff in the cancer space given the large global sales of Avastin, a US$6bn pa bestseller for Roche. Of the first 12 patients recruited into the RCC Phase II trial, which is a combination study with Novartis' Afinitor drug, eight patients achieved stable disease at the 12 mg/m$^2$ and 16 mg/m$^2$ doses, where the drug is understood to prevent new tumour blood vessels from being constructed. Moreover, at these doses the drug was safe and well-tolerated. This suggests a good outcome for the enlarged 139 patient study, which completed enrolment in June 2013. Since the primary endpoint is six months Progression-Free Survival, top-line data is expected to be available around the end of this calendar year.
- **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 next 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 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. Deborah 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 $0.90 base case and $2.30 optimistic case. Our $0.90 price target sits at the low point of this range. We anticipate Bionomics being re-rated by the market on the basis of Phase II data from BNC105. We see $1.60 – the DCF midpoint - as a feasible target for Bionomics to reach in the medium term on the back of this data and a potential licensing.

[11] 27 November 2013 close on Nasdaq.

- **VALUATION METHOLOGY**. Our probability-weighted DCF of Bionomics was built as follows:
  - Our WACC was 16.9% (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;
  - We assume average peak sales for a typical Bionomics licensed product of US$2.1bn to US$3bn.
- **MAJOR SHAREHOLDERS.** Link Traders (Laurence Freedman, 8.4%), John Leaver (5.9%), Ausbil Dexia (5.8%) and Australian National University (5.3%).
- **KEY RISKS.** 1) Failure of the Phase II for BNC105 in RCC; 2) Ironwood's commitment to BNC210; 3) Funding risk.

**FIG.5: BIONOMICS SHARE PRICE**


*Source: Iress*

# Bionomics - Financial Summary

| | |
|---|---|
| Code | BNO |
| Analyst | Stuart Roberts |
| Date | 27 November, 2013 |
| Share price | $0.81 |
| Market capitalisation | $334m |
| Year end | 30 June |

| | |
|---|---|
| Rating | BUY |
| Price target | $0.90 |
| Upside/downside | 11.1% |
| Valuation | $0.903 / $2.303 |
| 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 | 39 | 102 | 107 |
| **EBITDA** | **-4** | **-9** | **18** | **81** | **86** |
| D&A | -1 | -1 | -2 | -6 | -16 |
| **EBIT** | **-4** | **-11** | **16** | **75** | **70** |
| Net interest | 1 | 1 | 1 | 2 | 4 |
| Pre-tax profit | **-3** | **-10** | **18** | **77** | **74** |
| Tax | 0 | 0 | 0 | -7 | -22 |
| NPAT | -3 | -10 | 18 | 71 | 52 |
| Minority interests | 0 | 0 | 0 | 0 | 0 |
| Net profit after minorities | -3 | -10 | 18 | 71 | 52 |

**BALANCE SHEET (A$m)**

| Y/e June 30 | FY12A | FY13A | FY14E | FY15E | FY16E |
|---|---|---|---|---|---|
| Cash | 17 | 22 | 29 | 66 | 91 |
| Current receivables | 0 | 1 | 1 | 1 | 1 |
| Inventories | 0 | 0 | 0 | 0 | 0 |
| Other current assets | 4 | 7 | 7 | 7 | 7 |
| **Current assets** | **22** | **31** | **37** | **74** | **100** |
| PPE | 1 | 1 | 13 | 47 | 74 |
| Intangible assets | 9 | 22 | 21 | 20 | 19 |
| Other non-current assets | 0 | 0 | 1 | 1 | 2 |
| **Non-current assets** | 9 | 23 | 34 | 69 | 95 |
| **Total assets** | 31 | 54 | 72 | 143 | 195 |
| Payables | 3 | 4 | 4 | 4 | 4 |
| Debt | 1 | 1 | 1 | 1 | 1 |
| Other liabilities | 1 | 7 | 7 | 7 | 7 |
| **Total liabilities** | 5 | 12 | 12 | 12 | 12 |
| Shareholders' equity | 26 | 41 | 59 | 130 | 183 |
| Minorities | 0 | 0 | 0 | 0 | 0 |
| **Total shareholders funds** | **26** | **41** | **59** | **130** | **183** |
| **Total funds employed** | **31** | **54** | **72** | **143** | **195** |
| **W/A shares on issue** | 345 | 374 | 417 | 418 | 419 |

**CASH FLOW (A$m)**

| Y/e June 30 | FY12A | FY13A | FY14E | FY15E | FY16E |
|---|---|---|---|---|---|
| NPAT plus discontinued ops. | -3 | -10 | 18 | 71 | 52 |
| Non-cash items | 0 | -5 | 2 | 6 | 16 |
| Working capital | 0 | 6 | 0 | 0 | 0 |
| Other operating cash flow | 0 | 0 | 0 | 0 | 0 |
| **Operating cashflow** | **-3** | **-9** | **20** | **77** | **68** |
| Capex | 6 | 0 | -13 | -40 | -42 |
| Investments | 0 | -1 | -1 | -1 | -1 |
| Other investing cash flow | 0 | 0 | 0 | 0 | 0 |
| **Investing cashflow** | **6** | **-1** | **-13** | **-41** | **-42** |
| 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** | **7** | **37** | **26** |
| **Cash at end of period** | 17 | 22 | 29 | 66 | 91 |

**EARNINGS (A$m)**

| Y/e June 30 | FY12A | FY13A | FY14E | FY15E | FY16E |
|---|---|---|---|---|---|
| Net profit ($m) | -3.1 | -10.0 | 17.5 | 70.7 | 51.9 |
| EPS (c) | -0.9 | -2.7 | 4.2 | 16.9 | 12.4 |
| *EPS growth (%)* | N/A | N/A | N/A | 303% | -27% |
| P/E ratio (x) | -89.1 | -30.3 | 19.3 | 4.8 | 6.5 |
| CFPS (c) | -0.8 | -2.5 | 4.7 | 18.4 | 16.2 |
| Price/CF (x) | -96.6 | -32.2 | 17.3 | 4.4 | 5.0 |
| DPS ( c ) | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| *Yield (%)* | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% |
| Franking (%) | 0% | 0% | 0% | 0% | 0% |
| EV/EBITDA | -88.0 | -88.0 | -88.0 | -88.0 | -88.0 |
| EV/EBIT | -73.7 | -30.1 | 19.6 | 4.2 | 4.5 |

**PROFITABILITY RATIOS**

| Y/e June 30 | FY12A | FY13A | FY14E | FY15E | FY16E |
|---|---|---|---|---|---|
| EBITDA/revenue (%) | -40.5% | -83.0% | 46.9% | 79.7% | 80.3% |
| **EBIT/revenue (%)** | -48.3% | -94.2% | 42.0% | 73.6% | 65.5% |
| Return on assets (%) | -10.1% | -18.7% | 24.4% | 49.5% | 26.6% |
| Return on equity (%) | -12.1% | -24.2% | 29.5% | 54.2% | 28.4% |
| Return on funds empl'd (%) | -11.6% | -23.5% | 28.9% | 53.7% | 28.2% |
| Dividend cover (x) | N/A | N/A | 0% | 0% | 0% |
| Effective tax rate (%) | 5.8% | -0.4% | 0.0% | 8.5% | 30.0% |

**LIQUIDITY AND LEVERAGE RATIOS**

| Y/e June 30 | FY12A | FY13A | FY14E | FY15E | FY16E |
|---|---|---|---|---|---|
| Net debt/(cash) ($m) | -16 | -21 | -28 | -65 | -90 |
| **Net debt/equity (%)** | -62.4% | -51.6% | -47.0% | -49.4% | -49.4% |
| Net interest cover (x) | N/A | N/A | -0.1 | 0.0 | -0.1 |
| Current ratio (x) | 4.9 | 5.1 | 6.1 | 12.1 | 16.3 |

**INTERIMS**

| Y/e June 30 ($m) | 2H12A | 1H13A | 2H13A | 1H14F | 2H14F |
|---|---|---|---|---|---|
| Revenue | 7 | 4 | 7 | 15 | 23 |
| **EBITDA** | **0** | **-3** | **-6** | **5** | **13** |
| D&A | **0** | **-1** | **-1** | **-1** | **-1** |
| **EBIT** | **0** | **-4** | **-7** | **5** | **11** |
| Net interest | **0** | **0** | **0** | **1** | **1** |
| Pre-tax profit | 0 | -3 | -7 | 5 | 12 |
| Tax | **0** | **0** | **0** | **0** | **0** |
| NPAT | 0 | -3 | -7 | 5 | 12 |
| Minority interests | **0** | **0** | **0** | **0** | **0** |
| Net profit after minorities | 0 | -3 | -7 | 5 | 12 |

**VALUATION**

| | Base | Optim. |
|---|---|---|
| BNC210 (A$m) | 124.3 | 229.2 |
| BNC105 (A$m) | 114.4 | 270.1 |
| Other products A($m) | 119.5 | 495.7 |
| Total value for technology (A$m) | 358.1 | 995.0 |
| Value of tax losses | 21.8 | 21.8 |
| Underlying R&D cost | -9.6 | -9.6 |
| Cash now (A$m) | 16.8 | 16.8 |
| Cash from options and casg to be rai | 23.9 | 23.9 |
| Total value (A$m) | 411.0 | 1048.0 |
| Total diluted shares (million) | 454.9 | 454.9 |
| Value per share | $0.90 | $2.30 |
| Valuation midpoint | $1.60 | |
| Share price now (A$ per share) | $0.810 | |
| Upside to midpoint | 98.0% | |

# 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, a Melbourne-based company, 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 September 2013 Mesoblast held $292m in cash with a burn rate in that quarter of ~A$9m 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 $8.22 / optimistic case $21.93 per share probability-weighted DCF valuation.

- **VALUATION METHOLOGY**. Our probability-weighted DCF of Mesoblast was built as follows:
  - Our WACC was 12.5% (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.
- **MAJOR SHAREHOLDERS.** Silviu Itescu (21.5%), Teva Pharmaceuticals (17.6%), M&G (10.1%) 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.6: MESOBLAST SHARE PRICE**


*Source: Iress*

# Mesoblast - Financial Summary

| | |
|---|---|
| Code | MSB |
| Analyst | Stuart Roberts |
| Date | 27 November, 2013 |
| Share price | $6.15 |
| Market capitalisation | $1952m |
| Year end | 30 June |

| | |
|---|---|
| Rating | BUY |
| Price target | $8.50 |
| Upside/downside | 38.2% |
| Valuation | $8.218 / $21.93 |
| 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 | 51 | 376 | 571 |
| **EBITDA** | **-59** | **-70** | **-53** | **270** | **463** |
| D&A | 0 | -1 | -2 | -3 | -10 |
| **EBIT** | **-59** | **-71** | **-55** | **267** | **453** |
| Net interest | 10 | 11 | 18 | 19 | 35 |
| Pre-tax profit | **-49** | **-60** | **-36** | **286** | **487** |
| Tax | -22 | -2 | 0 | -45 | -146 |
| NPAT | -71 | -62 | -36 | 240 | 341 |
| Minority interests | 0 | 0 | 0 | 0 | 0 |
| Net profit after minorities | -71 | -62 | -36 | 240 | 341 |

**BALANCE SHEET (A$m)**

| Y/e June 30 | FY12A | FY13A | FY14E | FY15E | FY16E |
|---|---|---|---|---|---|
| Cash | 206 | 315 | 274 | 489 | 826 |
| Current receivables | 11 | 12 | 12 | 12 | 12 |
| Inventories | 0 | 0 | 0 | 0 | 0 |
| Other current assets | 0 | 4 | 4 | 4 | 4 |
| **Current assets** | **217** | **332** | **291** | **506** | **844** |
| PPE | 2 | 3 | 5 | 29 | 58 |
| Intangible assets | 497 | 548 | 548 | 549 | 549 |
| Other non-current assets | 5 | 1 | 4 | 6 | 8 |
| **Non-current assets** | 504 | 552 | 557 | 583 | 615 |
| **Total assets** | 720 | 884 | 848 | 1,090 | 1,459 |
| Payables | 12 | 21 | 21 | 21 | 22 |
| Debt | 0 | 0 | 0 | 0 | 0 |
| Other liabilities | 230 | 232 | 232 | 232 | 232 |
| **Total liabilities** | 242 | 253 | 254 | 254 | 254 |
| Shareholders' equity | 479 | 630 | 594 | 836 | 1,205 |
| Minorities | 0 | 0 | 0 | 0 | 0 |
| **Total shareholders funds** | **479** | **630** | **594** | **836** | **1,205** |
| **Total funds employed** | **720** | **884** | **848** | **1,090** | **1,459** |
| **W/A shares on issue** | 283 | 293 | 316 | 317 | 321 |

**CASH FLOW (A$m)**

| Y/e June 30 | FY12A | FY13A | FY14E | FY15E | FY16E |
|---|---|---|---|---|---|
| NPAT plus discontinued ops. | -71 | -62 | -36 | 240 | 341 |
| Non-cash items | 10 | 15 | 2 | 3 | 10 |
| Working capital | -1 | -7 | 0 | 0 | 0 |
| Other operating cash flow | 0 | 0 | 0 | 0 | 0 |
| **Operating cashflow** | **-63** | **-54** | **-35** | **243** | **351** |
| Capex | -2 | -1 | -3 | -26 | -38 |
| Investments | -2 | -2 | -3 | -2 | -2 |
| Other investing cash flow | -1 | -2 | -1 | -2 | -2 |
| **Investing cashflow** | **-5** | **-5** | **-7** | **-29** | **-42** |
| Change in borrowings | 0 | 0 | 0 | 0 | 0 |
| Equity raised | 5 | 169 | 0 | 2 | 28 |
| Dividends paid | 0 | 0 | 0 | 0 | 0 |
| Other financing cash flow | 0 | 0 | 0 | 0 | 0 |
| **Financing cashflow** | **5** | **169** | **0** | **2** | **28** |
| **Net change in cash** | **-63** | **110** | **-42** | **216** | **337** |
| **Cash at end of period** | 206 | 315 | 274 | 489 | 826 |

**EARNINGS (A$m)**

| Y/e June 30 | FY12A | FY13A | FY14E | FY15E | FY16E |
|---|---|---|---|---|---|
| Net profit ($m) | -71.1 | -61.7 | -36.3 | 240.2 | 341.2 |
| EPS (c) | -25.2 | -21.1 | -11.5 | 75.7 | 106.4 |
| *EPS growth (%)* | N/A | N/A | N/A | N/A | 41% |
| P/E ratio (x) | -24.5 | -29.2 | -53.6 | 8.1 | 5.8 |
| CFPS (c) | -22.2 | -18.5 | -10.9 | 76.7 | 109.5 |
| Price/CF (x) | -27.7 | -33.3 | -56.3 | 8.0 | 5.6 |
| DPS ( c ) | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| *Yield (%)* | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% |
| Franking (%) | 0% | 0% | 0% | 0% | 0% |
| EV/EBITDA | -28.2 | -28.2 | -28.2 | -28.2 | -28.2 |
| EV/EBIT | -28.0 | -23.5 | -30.4 | 6.2 | 3.7 |

**PROFITABILITY RATIOS**

| Y/e June 30 | FY12A | FY13A | FY14E | FY15E | FY16E |
|---|---|---|---|---|---|
| EBITDA/revenue (%) | -211.5% | -288.8% | -104.3% | 71.8% | 80.9% |
| **EBIT/revenue (%)** | -212.9% | -291.9% | -107.8% | 70.9% | 79.2% |
| Return on assets (%) | -9.9% | -7.0% | -4.3% | 22.0% | 23.4% |
| Return on equity (%) | -14.9% | -9.8% | -6.1% | 28.7% | 28.3% |
| Return on funds empl'd (%) | -14.9% | -9.8% | -6.1% | 28.7% | 28.3% |
| Dividend cover (x) | N/A | N/A | N/A | 0% | 0% |
| Effective tax rate (%) | -46.0% | -2.6% | 0.0% | 15.9% | 30.0% |

**LIQUIDITY AND LEVERAGE RATIOS**

| Y/e June 30 | FY12A | FY13A | FY14E | FY15E | FY16E |
|---|---|---|---|---|---|
| Net debt/(cash) ($m) | -206 | -315 | -274 | -489 | -826 |
| **Net debt/equity (%)** | -42.9% | -50.0% | -46.1% | -58.5% | -68.6% |
| Net interest cover (x) | N/A | N/A | N/A | -0.1 | -0.1 |
| Current ratio (x) | 4.9 | 6.6 | 5.7 | 10.0 | 16.6 |

**INTERIMS**

| Y/e June 30 ($m) | 2H12A | 1H13A | 2H13A | 1H14F | 2H14F |
|---|---|---|---|---|---|
| Revenue | 14 | 10 | 14 | 20 | 30 |
| **EBITDA** | **-37** | **-32** | **-38** | **-26** | **-27** |
| D&A | **0** | **0** | **0** | **-1** | **-1** |
| **EBIT** | **-37** | **-33** | **-38** | **-27** | **-28** |
| Net interest | **6** | **5** | **6** | **9** | **9** |
| Pre-tax profit | -31 | -28 | -32 | -18 | -19 |
| Tax | **4** | **0** | **-2** | **0** | **0** |
| NPAT | -27 | -28 | -34 | -18 | -19 |
| Minority interests | **0** | **0** | **0** | **0** | **0** |
| Net profit after minorities | -27 | -28 | -34 | -18 | -19 |

**VALUATION**

| | Base | Optim. |
|---|---|---|
| GVHD (A$m) | 589.4 | 1606.6 |
| Crohn's (A$m) | 210.2 | 664.8 |
| Other programmes (A$m) | 1542.0 | 4607.5 |
| Total value for technology (A$m) | 2341.5 | 6879.0 |
| Value of tax losses | 29.3 | 29.3 |
| Underlying R&D cost | -9.6 | -9.6 |
| Cash now (A$m) | 292.1 | 292.1 |
| Cash from options and to be raised (. | 65.7 | 65.7 |
| Total value (A$m) | 2719.2 | 7256.6 |
| Total diluted shares (million) | 330.9 | 330.9 |
| Value per share | $8.22 | $21.93 |
| Valuation midpoint | $15.07 | |
| Share price now (A$ per share) | $6.150 | |
| Upside to midpoint | 145.1% | |

# Nanosonics (NAN) – Cleaning up

## BUY. Target price $1.15

- **COMPANY DESCRIPTION.** Nanosonics is a Sydney-based company whose lead product, 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 July 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 (i.e. in just seven minutes), does not damage the probes, is able to achieve high-level disinfection (i.e. 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 October 2013, 35 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 June 2013 the company had $24m 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 $1.13 / optimistic case $1.66. Our target price of $1.15 sits at 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.

- **VALUATION METHOLOGY**. Our DCF of Nanosonics was built as follows:
  - Our WACC was 12.5% (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, from >40% previously.
- **MAJOR SHAREHOLDERS.** Maurie Stang (10.8%), Allan Gray Australia (10.8%), Bernie Stang (10.5%) and Steve Kritzler (7.5%).
- **KEY RISKS.** 1) GE's commitment to trophon EPR; 2) Cost saving efforts in hospitals; 3) Funding risk.

**FIG.7: NANOSONICS SHARE PRICE**


*Source: Iress*

# Nanosonics - Financial Summary

| | |
|---|---|
| Code | NAN |
| Analyst | Stuart Roberts |
| Date | 27 November, 2013 |
| Share price | $0.84 |
| Market capitalisation | $221m |
| Year end | 30 June |

| | |
|---|---|
| Rating | BUY |
| Price target | $1.15 |
| Upside/downside | 36.9% |
| Valuation | $1.128 / $1.658 |
| Valuation method | DCF |
| Risk | Medium |

**PROFIT AND LOSS (A$m)**

| Y/e June 30 (A$m) | FY12A | FY13A | FY14E | FY15E | FY16E |
|---|---|---|---|---|---|
| Revenue | 12 | 16 | 24 | 45 | 63 |
| **EBITDA** | **-5** | **-5** | **0** | **13** | **24** |
| D&A | -1 | -1 | 0 | 0 | 0 |
| **EBIT** | **-6** | **-6** | **-1** | **12** | **24** |
| Net interest | 1 | 1 | 1 | 2 | 3 |
| Pre-tax profit | **-5** | **-6** | **1** | **14** | **26** |
| Tax | 1 | 0 | 0 | 0 | 0 |
| NPAT | -5 | -6 | 1 | 14 | 26 |
| Minority interests | 0 | 0 | 0 | 0 | 0 |
| Net profit after minorities | -5 | -6 | 1 | 14 | 26 |

**BALANCE SHEET (A$m)**

| Y/e June 30 | FY12A | FY13A | FY14E | FY15E | FY16E |
|---|---|---|---|---|---|
| Cash | 29 | 24 | 24 | 42 | 68 |
| Current receivables | 3 | 4 | 5 | 6 | 6 |
| Inventories | 2 | 3 | 3 | 4 | 5 |
| Other current assets | 0 | 0 | 0 | 0 | 0 |
| **Current assets** | **35** | **32** | **33** | **52** | **80** |
| PPE | 1 | 2 | 2 | 3 | 3 |
| Intangible assets | 0 | 0 | 0 | 0 | 0 |
| Other non-current assets | 0 | 0 | 0 | 0 | 0 |
| **Non-current assets** | 2 | 2 | 3 | 3 | 4 |
| **Total assets** | 37 | 34 | 35 | 55 | 83 |
| Payables | 2 | 3 | 3 | 4 | 4 |
| Debt | 0 | 0 | 0 | 0 | 0 |
| Other liabilities | 8 | 9 | 9 | 9 | 9 |
| **Total liabilities** | 11 | 12 | 12 | 13 | 13 |
| Shareholders' equity | 26 | 22 | 23 | 43 | 70 |
| Minorities | 0 | 0 | 0 | 0 | 0 |
| **Total shareholders funds** | **26** | **22** | **23** | **43** | **70** |
| **Total funds employed** | **37** | **34** | **35** | **55** | **83** |
| **W/A shares on issue** | 235 | 261 | 262 | 263 | 265 |

**CASH FLOW (A$m)**

| Y/e June 30 | FY12A | FY13A | FY14E | FY15E | FY16E |
|---|---|---|---|---|---|
| NPAT plus discontinued ops. | -5 | -6 | 1 | 14 | 26 |
| Non-cash items | 2 | 2 | 1 | 1 | 1 |
| Working capital | -2 | -1 | -1 | -1 | -1 |
| Other operating cash flow | 0 | 0 | 0 | 0 | 0 |
| **Operating cashflow** | **-5** | **-5** | **1** | **13** | **26** |
| 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 | 5 | 0 |
| Dividends paid | 0 | 0 | 0 | 0 | 0 |
| Other financing cash flow | 7 | 0 | 0 | 0 | 0 |
| **Financing cashflow** | **23** | **1** | **0** | **5** | **0** |
| **Net change in cash** | **17** | **-5** | **0** | **18** | **26** |
| **Cash at end of period** | 29 | 24 | 24 | 42 | 68 |

**EARNINGS (A$m)**

| Y/e June 30 | FY12A | FY13A | FY14E | FY15E | FY16E |
|---|---|---|---|---|---|
| Net profit ($m) | -4.7 | -5.8 | 0.7 | 13.9 | 26.3 |
| EPS (c) | -2.0 | -2.2 | 0.3 | 5.3 | 9.9 |
| *EPS growth (%)* | N/A | N/A | N/A | 1885% | 88% |
| P/E ratio (x) | -42.1 | -38.0 | 316.1 | 15.9 | 8.5 |
| CFPS (c) | -2.1 | -1.7 | 0.4 | 5.1 | 9.8 |
| Price/CF (x) | -39.2 | -48.7 | 238.0 | 16.4 | 8.5 |
| 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 | -39.9 | -39.9 | -39.9 | -39.9 | -39.9 |
| EV/EBIT | -33.7 | -31.0 | -314.5 | 16.1 | 8.4 |

**PROFITABILITY RATIOS**

| Y/e June 30 | FY12A | FY13A | FY14E | FY15E | FY16E |
|---|---|---|---|---|---|
| EBITDA/revenue (%) | -40.0% | -32.7% | -1.8% | 27.9% | 37.8% |
| **EBIT/revenue (%)** | -47.4% | -39.1% | -2.6% | 27.3% | 37.4% |
| Return on assets (%) | -12.8% | -17.1% | 2.0% | 25.0% | 31.5% |
| Return on equity (%) | -18.0% | -26.6% | 3.0% | 32.6% | 37.5% |
| Return on funds empl'd (%) | -18.0% | -26.5% | 3.0% | 32.5% | 37.5% |
| Dividend cover (x) | N/A | N/A | 0% | 0% | 0% |
| Effective tax rate (%) | 11.9% | -0.6% | 0.0% | 0.0% | 0.0% |

**LIQUIDITY AND LEVERAGE RATIOS**

| Y/e June 30 | FY12A | FY13A | FY14E | FY15E | FY16E |
|---|---|---|---|---|---|
| Net debt/(cash) ($m) | -29 | -24 | -24 | -42 | -68 |
| **Net debt/equity (%)** | -112.6% | -110.7% | -105.0% | -98.6% | -96.9% |
| Net interest cover (x) | N/A | N/A | N/A | -0.1 | -0.1 |
| Current ratio (x) | 10.1 | 7.5 | 7.3 | 10.2 | 14.1 |

**INTERIMS**

| Y/e June 30 ($m) | 2H12A | 1H13A | 2H13A | 1H14F | 2H14F |
|---|---|---|---|---|---|
| Revenue | 7 | 4 | 12 | 7 | 17 |
| **EBITDA** | **-2** | **-6** | **1** | **-5** | **4** |
| D&A | **0** | **0** | **-1** | **0** | **0** |
| **EBIT** | **-3** | **-6** | **0** | **-5** | **4** |
| Net interest | **0** | **0** | **0** | **1** | **1** |
| Pre-tax profit | -2 | -6 | 0 | -4 | 5 |
| Tax | **1** | **0** | **0** | **0** | **0** |
| NPAT | -2 | -6 | 0 | -4 | 5 |
| Minority interests | **0** | **0** | **0** | **0** | **0** |
| Net profit after minorities | -2 | -6 | 0 | -4 | 5 |

**VALUATION**

| | Base | Optim. |
|---|---|---|
| Business (A$m) | 261.7 | 404.0 |
| Value of tax losses | 16.6 | 16.6 |
| Cash as at Sep 2013 (A$m) | 22.1 | 22.1 |
| Cash from options plus cash to be ra | 1.9 | 1.9 |
| Total value (A$m) | 302.4 | 444.7 |
| Diluted shares on issue (million) | 268.1 | 268.2 |
| Value per share | $1.13 | $1.66 |
| Valuation midpoint | $1.39 | |
| Share price now | $0.840 | |
| Upside | 65.8% | |

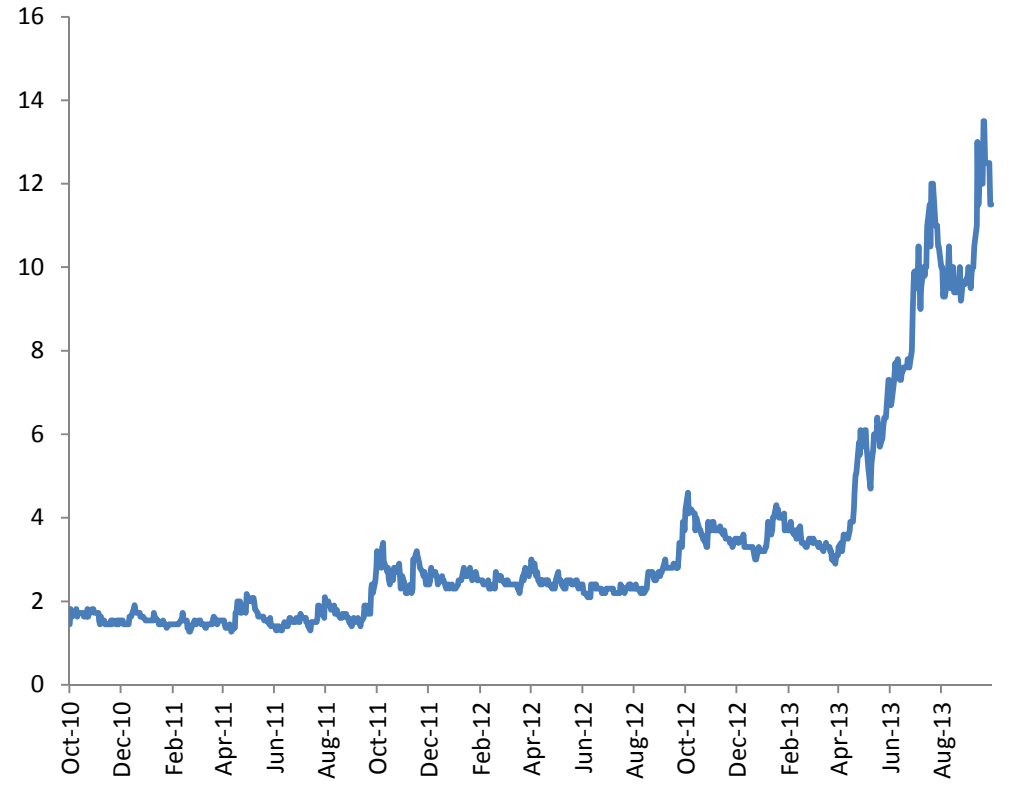
# Neuren Pharmaceuticals (NEU) – Undervalued Orphan Drug play

## 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 next year with the TBI results coming in 2015. There are currently no drugs on the market that can treat TBI or autism, 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 previously built Acrux by licensing the testosterone replacement product Axiron to 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. Neuren intends to initiate a Phase II clinical trial in Fragile X and read out top-line data from that trial in 2015. Fragile X, with an estimated US patient population of ~70,000, will be another Orphan indication for NNZ-2566.
- **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.
- **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 64 cents optimistic case. We regard the re-rating of the stock from ~2-3 cents in August 2012 to the current share price as the market accepting as valid the pre-clinical data for NNZ-2566.

- **VALUATION METHOLOGY**. Our probability-weighted DCF of Neuren was built as follows:
  - Our WACC was 16.9% (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 2014 (US$100-200m in upfronts, US$300-500m in milestones, 16-20% royalties) and NNZ-2591 in 2015 (US$40-70m upfronts, US$120-150m milestones, 10-14% royalties);
  - 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 2016 and NNZ-2591 by 2019.
- **MAJOR SHAREHOLDER.** Lang Walker (~18%[12])
- **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.8: NEUREN SHARE PRICE**




*Source: Iress*

[12] The correct number will likely be reported once Neuren completes its current SPP.

# Neuren Pharmaceuticals - Financial Summary

| | | | |
|---|---|---|---|
| Code | NEU | Rating | BUY |
| Analyst | Stuart Roberts | Price target | $0.26 |
| Date | 27 November, 2013 | Upside/downside | 92.6% |
| Share price | $0.14 | Valuation | $0.258 / $0.643 |
| Market capitalisation | $198m | Valuation method | Probability-weighted DCF |
| Year end | 31 December | Risk | Speculative |

**PROFIT AND LOSS (NZ$m)**

| Y/e June 30 | FY11A | FY12A | FY13E | FY14E | FY15E |
|---|---|---|---|---|---|
| Revenue | 4 | 5 | 6 | 95 | 211 |
| **EBITDA** | **-6** | **-6** | **-7** | **83** | **199** |
| D&A | 0 | 0 | 0 | 0 | 0 |
| **EBIT** | **-6** | **-7** | **-7** | **82** | **198** |
| Net interest | 0 | 0 | 0 | 4 | 10 |
| Pre-tax profit | **-6** | **-7** | **-7** | **86** | **209** |
| Tax | 0 | 0 | 0 | 0 | -61 |
| NPAT | -6 | -7 | -7 | 86 | 147 |
| Minority interests | 0 | 0 | 0 | 0 | 0 |
| Net profit after minorities | -6 | -7 | -7 | 86 | 147 |

**BALANCE SHEET (NZ$m)**

| Y/e June 30 | FY11A | FY12A | FY13E | FY14E | FY15E |
|---|---|---|---|---|---|
| Cash | 10 | 6 | 39 | 136 | 288 |
| Current receivables | 0 | 0 | 0 | 0 | 0 |
| Inventories | 0 | 0 | 0 | 0 | 0 |
| Other current assets | 0 | 0 | 0 | 0 | 0 |
| **Current assets** | **10** | **7** | **39** | **135** | **287** |
| PPE | 0 | 0 | 0 | 0 | 0 |
| Intangible assets | 5 | 4 | 4 | 3 | 3 |
| Other non-current assets | 0 | 0 | 0 | 0 | 0 |
| **Non-current assets** | 5 | 4 | 4 | 3 | 3 |
| **Total assets** | 15 | 11 | 43 | 139 | 290 |
| Payables | 2 | 3 | 2 | 2 | 2 |
| Debt | 0 | 0 | 0 | 0 | 0 |
| Other liabilities | 0 | 0 | 0 | 0 | 0 |
| **Total liabilities** | 2 | 3 | 3 | 2 | 2 |
| Shareholders' equity | 12 | 8 | 41 | 137 | 288 |
| Minorities | 0 | 0 | 0 | 0 | 0 |
| **Total shareholders funds** | **12** | **8** | **40** | **136** | **287** |
| **Total funds employed** | **15** | **11** | **43** | **139** | **290** |
| **W/A shares on issue** | 765 | 1,174 | 1,463 | 1,663 | 1,724 |

**CASH FLOW (NZ$m)**

| Y/e June 30 | FY11A | FY12A | FY13E | FY14E | FY15E |
|---|---|---|---|---|---|
| NPAT plus discontinued ops. | -6 | -7 | -7 | 86 | 147 |
| Non-cash items | 2 | 2 | 2 | 2 | 2 |
| Working capital | 0 | 0 | 0 | 0 | 0 |
| Other operating cash flow | 0 | 0 | 0 | 0 | 0 |
| **Operating cashflow** | **-4** | **-4** | **-6** | **88** | **149** |
| 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 | 38 | 9 | 3 |
| Dividends paid | 0 | 0 | 0 | 0 | 0 |
| Other financing cash flow | 0 | 0 | 0 | 0 | 0 |
| **Financing cashflow** | **12** | **1** | **38** | **9** | **3** |
| **Net change in cash** | **8** | **-3** | **33** | **97** | **152** |
| **Cash at end of period** | 10 | 6 | 39 | 136 | 288 |

**EARNINGS (NZ$m)**

| Y/e June 30 | FY11A | FY12A | FY13E | FY14E | FY15E |
|---|---|---|---|---|---|
| Net profit ($m) | -6.2 | -6.5 | -7.3 | 85.9 | 147.2 |
| EPS (c) | -0.8 | -0.6 | -0.5 | 5.2 | 8.5 |
| *EPS growth (%)* | N/A | N/A | N/A | N/A | 65% |
| P/E ratio (x) | -21.6 | -31.0 | -32.0 | 2.9 | 1.7 |
| CFPS (c) | -0.5 | -0.3 | -0.4 | 5.3 | 8.6 |
| Price/CF (x) | -32.8 | -54.5 | -42.5 | 2.9 | 1.7 |
| DPS ( c ) | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| *Yield (%)* | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% |
| Franking (%) | 0% | 0% | 0% | 0% | 0% |
| EV/EBITDA | -38.3 | -35.1 | -29.3 | 2.4 | 1.0 |
| EV/EBIT | -35.5 | -32.8 | -27.5 | 2.4 | 1.0 |

**PROFITABILITY RATIOS**

| Y/e June 30 | FY11A | FY12A | FY13E | FY14E | FY15E |
|---|---|---|---|---|---|
| EBITDA/revenue (%) | -133.4% | -123.0% | -113.8% | 86.8% | 94.0% |
| **EBIT/revenue (%)** | -143.8% | -131.9% | -121.3% | 86.3% | 93.8% |
| Return on assets (%) | -42.6% | -61.2% | -17.1% | 61.9% | 50.8% |
| Return on equity (%) | -50.2% | -81.9% | -18.2% | 63.0% | 51.2% |
| Return on funds empl'd (%) | -50.2% | -81.9% | -18.2% | 63.0% | 51.2% |
| Dividend cover (x) | N/A | N/A | N/A | 0% | 0% |
| Effective tax rate (%) | 0.0% | 0.0% | 0.0% | 0.0% | 29.4% |

**LIQUIDITY AND LEVERAGE RATIOS**

| Y/e June 30 | FY11A | FY12A | FY13E | FY14E | FY15E |
|---|---|---|---|---|---|
| Net debt/(cash) ($m) | -10 | -6 | -39 | -136 | -288 |
| **Net debt/equity (%)** | -79.2% | -81.0% | -97.3% | -99.8% | -100.1% |
| Net interest cover (x) | N/A | N/A | N/A | 0.0 | -0.1 |
| Current ratio (x) | 4.5 | 2.5 | 15.2 | 56.4 | 120.8 |

**INTERIMS**

| Y/e June 30 (NZ$m) | 1H12A | 2H12A | 1H13A | 2H13F | 1H14F |
|---|---|---|---|---|---|
| Revenue | 3 | 3 | 3 | 3 | 39 |
| **EBITDA** | **-3** | **-3** | **-4** | **-3** | **32** |
| D&A | **0** | **0** | **0** | **0** | **0** |
| **EBIT** | **-3** | **-4** | **-4** | **-4** | **32** |
| Net interest | **0** | **0** | **0** | **0** | **1** |
| Pre-tax profit | -3 | -3 | -4 | -4 | 33 |
| Tax | **0** | **0** | **0** | **0** | **0** |
| NPAT | -3 | -3 | -4 | -4 | 33 |
| Minority interests | **0** | **0** | **0** | **0** | **0** |
| Net profit after minorities | -3 | -3 | -4 | -4 | 33 |

**VALUATION**

| | Base | Optim. |
|---|---|---|
| NNZ2566 (A$m) | 298.7 | 822.8 |
| NNZ2591 (A$m) | 94.6 | 223.0 |
| Total value for technology (A$m) | 393.2 | 1045.8 |
| Value of tax losses | 23.1 | 23.1 |
| Underlying R&D cost | -9.6 | -9.6 |
| Cash now (A$m) | 24.2 | 24.2 |
| Cash from options and to be raised ( | 5.6 | 5.6 |
| Total value (A$m) | 436.5 | 1089.1 |
| Total diluted shares (million) | 1693.3 | 1693.3 |
| Value per share | $0.26 | $0.64 |
| Valuation midpoint | $0.45 | |
| Share price now (A$ per share) | $0.135 | |
| Upside to midpoint | 233.7% | |

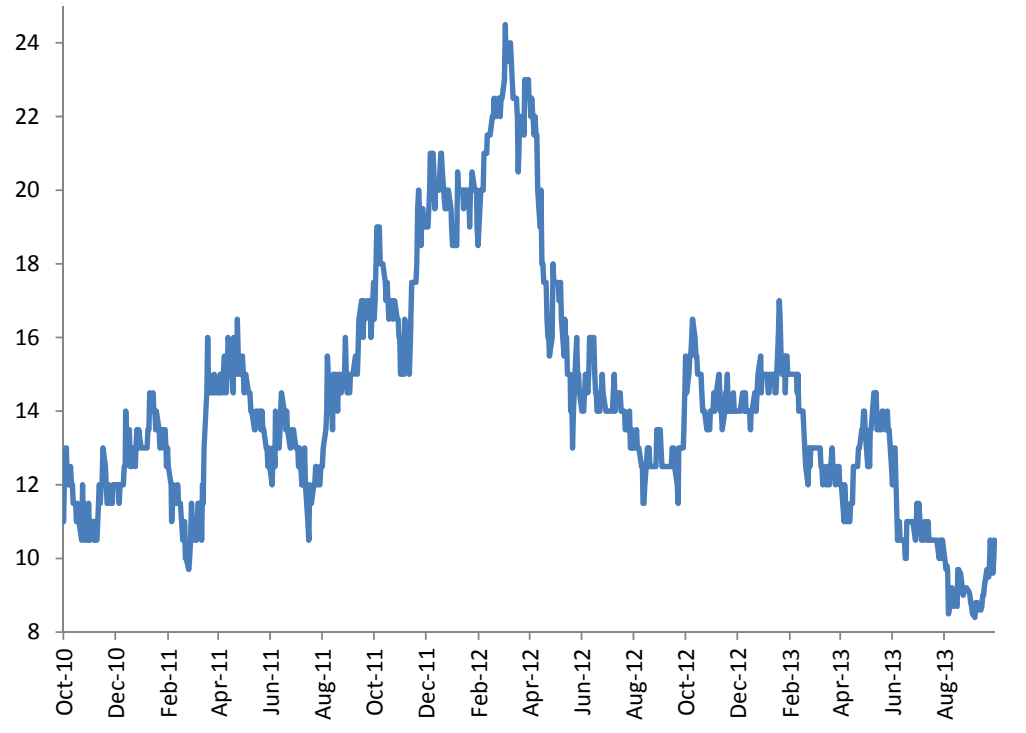
# Phosphagenics (POH) – Breakthrough drug delivery patches

**BUY. Target price $0.27**

- **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 next 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 27 cents base case and 64 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.

- **VALUATION METHOLOGY**. Our probability-weighted DCF of Phosphagenics was built as follows:
  - Our WACC was 14.7% (High risk);
  - We modelled payoffs for oxycodone and oxymorphone patches only. For conservatism we allowed no value for other products like tretinoin or diclofenac, as well as revenue from the company's cosmetics suite;
  - 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 at Phase II and have elements of both small and large molecule risk associated with them;
  - We assume partnering deals for both patches, in 2014-2015 for oxycodone (US$40-70m upfront, US$120-150m milestones and 8-12% royalties) and in 2015-2016 for oxymorphone (US$50-100m upfront, US$150-200m milestones and 10-14% royalties). We have modelled the oxymorphone deal as larger on the assumption that an oxycodone deal heightens interests by Phosphagenics' initial licensee.
  - We assume oxycodone launch by 2017-2018 and oxymorphone launch by 2019-2020.
  - We model peak sales of US$2.3-3.2bn for oxycodone and US$3.9-4.9bn for 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.9: PHOSPHAGENICS SHARE PRICE**




*Source: Iress*

# Phosphagenics - Financial Summary

| | |
|---|---|
| Code | POH |
| Analyst | Stuart Roberts |
| Date | 27 November, 2013 |
| Share price | $0.13 |
| Market capitalisation | $128m |
| Year end | 31 December |

| | |
|---|---|
| Rating | BUY |
| Price target | $0.27 |
| Upside/downside | 116.0% |
| Valuation | $0.268 / $0.642 |
| Valuation method | Probability-weighted DCF |
| Risk | High |

**PROFIT AND LOSS (A$m)**

| Y/e June 30 (A$m) | FY11A | FY12A | FY13E | FY14E | FY15E |
|---|---|---|---|---|---|
| Revenue | 4 | 5 | 4 | 40 | 86 |
| **EBITDA** | **-11** | **-7** | **-9** | **18** | **62** |
| D&A | -3 | -5 | -4 | -4 | -4 |
| **EBIT** | **-13** | **-12** | **-13** | **14** | **59** |
| Net interest | 0 | 1 | 1 | 1 | 3 |
| Pre-tax profit | **-13** | **-11** | **-12** | **15** | **62** |
| Tax | 14 | 0 | 0 | 0 | 0 |
| NPAT | 1 | -11 | -12 | 15 | 62 |
| Minority interests | 0 | 0 | 0 | 0 | 0 |
| Net profit after minorities | 1 | -11 | -12 | 15 | 62 |

**BALANCE SHEET (A$m)**

| Y/e June 30 | FY11A | FY12A | FY13E | FY14E | FY15E |
|---|---|---|---|---|---|
| Cash | 27 | 17 | 14 | 33 | 97 |
| Current receivables | 2 | 5 | 3 | 4 | 6 |
| Inventories | 1 | 1 | 1 | 2 | 4 |
| Other current assets | 0 | 0 | 1 | 1 | 1 |
| **Current assets** | **31** | **23** | **18** | **41** | **107** |
| | | | | | |
| PPE | 1 | 1 | 1 | 1 | 1 |
| Intangible assets | 45 | 40 | 28 | 24 | 21 |
| Other non-current assets | 0 | 0 | 0 | 0 | 0 |
| **Non-current assets** | 46 | 41 | 29 | 25 | 21 |
| | | | | | |
| **Total assets** | 77 | 64 | 47 | 66 | 129 |
| | | | | | |
| Payables | 3 | 1 | 2 | 3 | 4 |
| Debt | 0 | 0 | 0 | 0 | 0 |
| Other liabilities | 0 | 0 | 1 | 1 | 1 |
| **Total liabilities** | 4 | 2 | 2 | 3 | 4 |
| | | | | | |
| Shareholders' equity | 73 | 63 | 45 | 63 | 124 |
| Minorities | 0 | 0 | 0 | 0 | 0 |
| **Total shareholders funds** | **73** | **63** | **45** | **63** | **124** |
| | | | | | |
| **Total funds employed** | **77** | **64** | **47** | **66** | **129** |
| | | | | | |
| **W/A shares on issue** | 853 | 1,049 | 1,021 | 1,025 | 1,025 |

**CASH FLOW (A$m)**

| Y/e June 30 | FY11A | FY12A | FY13E | FY14E | FY15E |
|---|---|---|---|---|---|
| NPAT plus discontinued ops. | 1 | -11 | -12 | 15 | 62 |
| Non-cash items | 4 | 5 | 4 | 4 | 4 |
| Working capital | -14 | -5 | 1 | -2 | -2 |
| Other operating cash flow | 0 | 0 | 0 | 0 | 0 |
| **Operating cashflow** | **-9** | **-10** | **-7** | **17** | **64** |
| | | | | | |
| Capex | 0 | 0 | 0 | 0 | 0 |
| Investments | 1 | 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 | 33 | 0 | 3 | 3 | 0 |
| Dividends paid | 0 | 0 | 0 | 0 | 0 |
| Other financing cash flow | 0 | 0 | 0 | 0 | 0 |
| **Financing cashflow** | **33** | **0** | **3** | **3** | **0** |
| | | | | | |
| **Net change in cash** | **24** | **-10** | **-3** | **20** | **64** |
| | | | | | |
| **Cash at end of period** | 27 | 17 | 14 | 33 | 97 |

**EARNINGS (A$m)**

| Y/e June 30 | FY11A | FY12A | FY13E | FY14E | FY15E |
|---|---|---|---|---|---|
| Net profit ($m) | 1.1 | -11.1 | -12.0 | 14.7 | 61.5 |
| EPS (c) | 0.1 | -1.1 | -1.2 | 1.4 | 6.0 |
| *EPS growth (%)* | N/A | N/A | N/A | N/A | 319% |
| P/E ratio (x) | 96.4 | -11.9 | -10.7 | 8.7 | 2.1 |
| CFPS (c) | -1.1 | -1.0 | -0.6 | 1.6 | 6.2 |
| Price/CF (x) | -11.7 | -12.6 | -19.3 | 7.6 | 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 (%) | 0% | 0% | 0% | 0% | 0% |
| EV/EBITDA | -10.8 | -10.8 | -10.8 | -10.8 | -10.8 |
| EV/EBIT | -8.6 | -9.3 | -8.9 | 8.3 | 1.9 |

**PROFITABILITY RATIOS**

| Y/e June 30 | FY11A | FY12A | FY13E | FY14E | FY15E |
|---|---|---|---|---|---|
| EBITDA/revenue (%) | -250.3% | -142.9% | -230.3% | 43.3% | 72.9% |
| **EBIT/revenue (%)** | -313.5% | -240.7% | -329.8% | 33.9% | 68.5% |
| Return on assets (%) | 1.4% | -17.2% | -25.5% | 22.3% | 47.8% |
| Return on equity (%) | 1.5% | -17.7% | -26.8% | 23.5% | 49.4% |
| Return on funds empl'd (%) | 1.5% | -17.7% | -26.8% | 23.5% | 49.4% |
| Dividend cover (x) | 0% | N/A | N/A | 0% | 0% |
| Effective tax rate (%) | 108.7% | 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) | -27 | -17 | -14 | -33 | -97 |
| **Net debt/equity (%)** | -37.3% | -27.0% | -30.4% | -53.1% | -77.9% |
| Net interest cover (x) | N/A | N/A | N/A | -0.1 | 0.0 |
| Current ratio (x) | 8.5 | 15.9 | 8.1 | 12.6 | 26.0 |

**INTERIMS**

| Y/e June 30 ($m) | 1H12A | 2H12A | 1H13A | 2H13F | 1H14F |
|---|---|---|---|---|---|
| Revenue | 2 | 3 | 3 | 1 | 16 |
| **EBITDA** | **-5** | **-3** | **-4** | **-4** | **4** |
| D&A | **-2** | **-3** | **-2** | **-2** | **-2** |
| **EBIT** | **-7** | **-6** | **-6** | **-6** | **2** |
| Net interest | **1** | **0** | **0** | **0** | **0** |
| Pre-tax profit | -6 | -5 | -6 | -6 | 2 |
| Tax | **0** | **0** | **0** | **0** | **0** |
| NPAT | -6 | -5 | -6 | -6 | 2 |
| Minority interests | **0** | **0** | **0** | **0** | **0** |
| Net profit after minorities | -6 | -5 | -6 | -6 | 2 |

**VALUATION**

| | Base | Optim. |
|---|---|---|
| TPM Oxycodone (A$m) | 86.8 | 256.3 |
| TPM Oxymorphone (A$m) | 125.0 | 339.0 |
| Total value for technology (A$m) | 211.8 | 595.3 |
| Value of tax losses | 57.8 | 57.8 |
| Underlying R&D cost | -9.6 | -9.6 |
| Cash now (A$m) | 14.1 | 14.1 |
| Cash to be raised (A$m) | 0.6 | 0.6 |
| Total value (A$m) | 274.7 | 658.2 |
| Total diluted shares (million) | 1024.7 | 1024.7 |
| Value per share | $0.27 | $0.64 |
| Valuation midpoint | $0.46 | |
| Share price now (A$ per share) | $0.125 | |
| Upside to midpoint | 264.1% | |

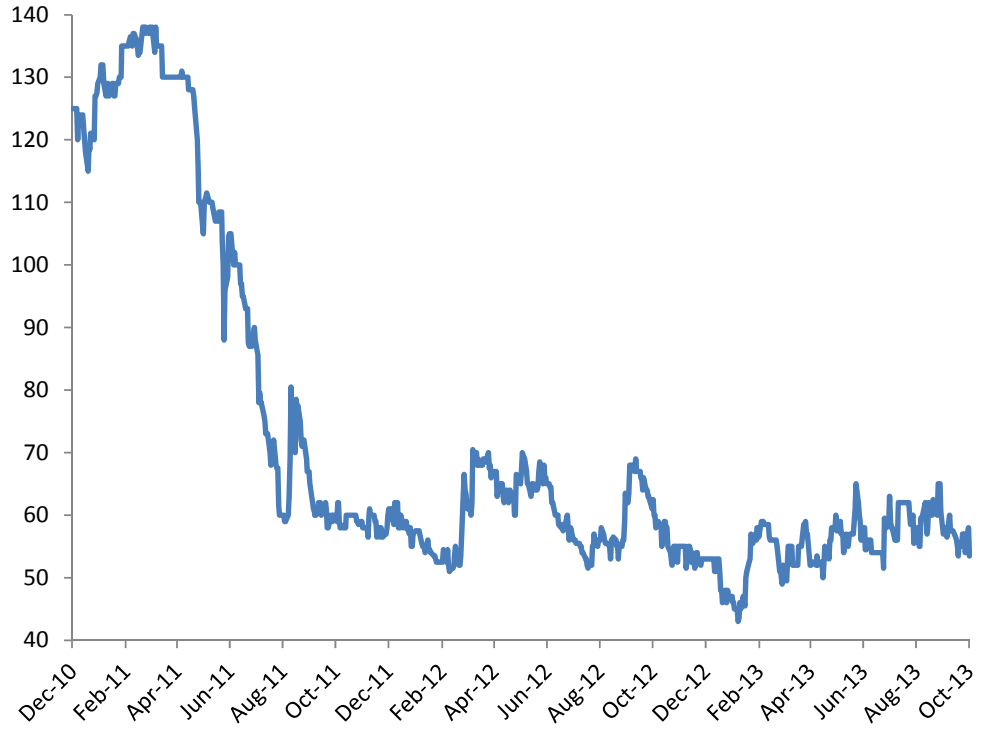
# REVA Medical (RVA) – Bioresorbable stents are real

## BUY. Target price $1.50

- **COMPANY DESCRIPTION**. REVA Medical is developing one of the world's first bioresorbable stents. A stent is a mesh tube designed to keep open coronary arteries that have become clogged due to fatty deposits of plaque. Up until recently stents have all been made of metal, leading in some cases to 'late stent thrombosis' where a blood clot forms on a stent after it has been in place for 30 days or more. In 2011 Abbott gained CE Mark approval for the world's first bioresorbable stent, called Absorb. This product is a big improvement over metal stents because it props open the artery and then, being plastic, gradually erodes away. Consequently it's not really a stent but a vascular 'scaffold'. We believe that widespread use of bioresorbable scaffolds beginning with Absorb will invigorate the stent category, worth US$4-5bn p.a., and potentially double the market. REVA Medical is currently in CE Mark trial for its scaffold, called ReZolve2, which has a number of advantages over Absorb. We see the potential for REVA to build a strong business from its stent from 2015, or alternately be acquired by one the major companies in the stent field.
- **REVA's scaffold concept works.** ReZolve is based on a unique stent geometry called 'Slide-and-Lock', which is a ratchet system in which a series of teeth slide through brackets in the scaffold as the product is expanded, and then lock into place. This system allows a clinically-relevant expansion range. ReZolve was tested clinically in 2011 and 2012 in a study called RESTORE. While the majority of patients in the study had satisfactory outcomes, the number of clinical events in this trial was higher than desired. However what the study did show is outstanding 'late loss'. Ordinarily metal stents see some late loss, which is shrinkage in blood vessel diameter over time. In RESTORE, late loss of 0.29mm of the non-TLR patients was in line with the 0.2-0.4mm usually registered for metal stents, which is a good indicator of positive long-term outcomes.
- **REVA will complete a CE Mark trial with a better scaffold next year.** In 2012 REVA developed a better scaffold than ReZolve, called ReZolve2. This scaffold is 20% thinner than ReZolve, meaning that it doesn't have to be sheathed before delivery and can be delivered using a smaller diameter catheter. REVA took this stent into a 125-patient trial for CE Marking in March 2013. As at late October 2013, 87 patients had been enrolled in this 30-site trial. Enrolment is expected to complete in early 2014, allowing REVA to file for CE Mark approval of ReZolve2 by late 2014. REVA has reported that for the first 65 ReZolve2 patients there were no major coronary events. Following on from ReZolve 2, we also expect to follow the clinical evaluation of REVA's next generation device, which has not yet been named.
- **REVA has a product that has advantages over Abbott's**. Absorb is widely considered by cardiologists to be a great product, with a MACE rate of only 10% over three years, comparable to metal stents (see Abbott press release dated 11/3/2013). REVA reckons it can go one better. Its scaffold is completely visible using X-ray fluoroscopy, while Abbott's isn't. Also, it has a bigger expansion range than the Abbott product.
- **Large companies may like the REVA story.** With Abbott now in the market with its bioresorbable scaffold, we see potential for Abbott's competitors – Medtronic and Boston Scientific, or even J&J (which left the stent business in 2011 but still has a $3bn interventional cardiology business) – to acquire REVA so as to have a competitive offering in this new field. Boston Scientific already holds an option to negotiate terms for worldwide distribution of ReZolve, at a negotiated transfer price to REVA of 50% of average selling price. Medtronic already holds 8% of REVA.
- **Management with a track record of success.** We have a high regard for REVA's management led by Bob Stockman (Chairman and CEO), a medical device entrepreneur with a strong track record of commercial success, and Dr Bob Schultz (President and COO), a pharma industry veteran. REVA's team has worked together for around a decade.
- **REVA remains undervalued.** REVA stock performed poorly after the late 2010 IPO, when the company delayed its clinical programme by a year in order to optimise its manufacturing process. Consequently, we think that REVA is trading way below what a medical device company should be valued at when it is in a pivotal trial. We value REVA at $1.50 per CDI base case and $2.45 per CDI optimistic case using a probability-weighted DCF valuation. Our target price of $1.50 per CDI sits at the low point of our DCF range. We expect that REVA can re-rate as completion of its European pivotal trial nears.

- **VALUATION METHOLOGY**. Our probability-weighted DCF of REVA was built as follows:
  - Our WACC was 16.9% (Speculative);
  - We assumed that REVA self-distributes ReZolve2 once it gains approval, launching in Europe in 2015-2016 and in the US in 2017-2018. We model peak sales of US$1.7-2bn;
  - We used an 85% chance of clinical/regulatory success, which is reasonable for medical devices in pivotal trials;
  - We assumed 70-80% gross margins for the product, and assume that distribution costs roughly 20% of revenue going forward, with modest (i.e. 0.1-0.2%) annual margin improvements in our optimistic case;
  - REVA is fully funded to complete the CE Mark trial of RerZolve2. We modelled another A$85m raise at A$0.55 to fund US clinical work as well as the initial European sales force.
- **MAJOR SHAREHOLDERS.** Domain Partners (11.1%), Elliott Associates (9.7%), Saints Capital (9.7%), Brookside Capital Partners (8.9%), Cerberus (8.7%), Medtronic (6.8%) and Bob Stockman (5.0%).
- **KEY RISKS.** 1) Clinical risk with ReZolve 2; Pricing risk, where REVA isn't able to charge what it thinks ReZolve2 is worth.

**FIG.10: REVA SHARE PRICE**




*Source: Iress*

# REVA Medical - Financial Summary

| | |
|---|---|
| Code | RVA |
| Analyst | Stuart Roberts |
| Date | 27 November, 2013 |
| Share price | $0.51 |
| Market capitalisation | $170m |
| Year end | "31 December" |

| | |
|---|---|
| Rating | BUY |
| Price target | $1.50 |
| Upside/downside | 194.1% |
| Valuation | $1.499 / $2.454 |
| Valuation method | Probability-weighted DCF |
| Risk | Speculative |

**PROFIT AND LOSS (US$m)**

| Y/e June 30 (A$m) | FY11A | FY12A | FY13E | FY14E | FY15E |
|---|---|---|---|---|---|
| Revenue | 0 | 0 | 0 | 0 | 6 |
| **EBITDA** | **-21** | **-23** | **-25** | **-25** | **-22** |
| D&A | 0 | -1 | -1 | -1 | -1 |
| **EBIT** | **-21** | **-24** | **-26** | **-26** | **-23** |
| Net interest | 0 | 0 | 0 | 0 | 0 |
| Pre-tax profit | **-21** | **-24** | **-26** | **-26** | **-23** |
| Tax | 0 | 0 | 0 | 0 | 0 |
| NPAT | -21 | -24 | -26 | -26 | -23 |
| Minority interests | 0 | 0 | 0 | 0 | 0 |
| Net profit after minorities | -21 | -24 | -26 | -26 | -23 |

**BALANCE SHEET (US$m)**

| Y/e June 30 | FY11A | FY12A | FY13E | FY14E | FY15E |
|---|---|---|---|---|---|
| Cash | 59 | 39 | 20 | 77 | 57 |
| Current receivables | 1 | 0 | 0 | 0 | 1 |
| Inventories | 0 | 0 | 0 | 0 | 0 |
| Other current assets | 2 | 5 | 2 | 2 | 2 |
| **Current assets** | **62** | **45** | **22** | **79** | **60** |
| PPE | 2 | 3 | 3 | 3 | 3 |
| Intangible assets | 0 | 0 | 0 | 0 | 0 |
| Other non-current assets | 3 | 0 | 0 | 0 | 0 |
| **Non-current assets** | 5 | 3 | 3 | 3 | 3 |
| **Total assets** | 67 | 47 | 25 | 83 | 63 |
| Payables | 1 | 1 | 1 | 1 | 1 |
| Debt | 0 | 0 | 0 | 0 | 0 |
| Other liabilities | 1 | 2 | 2 | 2 | 2 |
| **Total liabilities** | 3 | 3 | 3 | 3 | 3 |
| Shareholders' equity | 65 | 45 | 22 | 80 | 60 |
| Minorities | 0 | 0 | 0 | 0 | 0 |
| **Total shareholders funds** | **65** | **45** | **22** | **80** | **60** |
| **Total funds employed** | **67** | **47** | **25** | **83** | **63** |
| **W/A shares on issue** | 328 | 331 | 333 | 352 | 410 |

**CASH FLOW (US$m)**

| Y/e June 30 | FY11A | FY12A | FY13E | FY14E | FY15E |
|---|---|---|---|---|---|
| NPAT plus discontinued ops. | -21 | -24 | -26 | -26 | -23 |
| Non-cash items | 4 | 4 | 4 | 4 | 4 |
| Working capital | 0 | 1 | 0 | 0 | 0 |
| Other operating cash flow | 0 | 0 | 0 | 0 | 0 |
| **Operating cashflow** | **-17** | **-19** | **-22** | **-22** | **-19** |
| Capex | -1 | -2 | -1 | -1 | -1 |
| Investments | -5 | 0 | 3 | 0 | 0 |
| Other investing cash flow | 0 | 0 | 0 | 0 | 0 |
| **Investing cashflow** | **-6** | **-2** | **2** | **-1** | **-1** |
| Change in borrowings | 0 | 0 | 0 | 0 | 0 |
| Equity raised | 0 | 0 | 0 | 81 | 0 |
| Dividends paid | 0 | 0 | 0 | 0 | 0 |
| Other financing cash flow | 0 | 0 | 0 | 0 | 0 |
| **Financing cashflow** | **0** | **0** | **0** | **81** | **0** |
| **Net change in cash** | **-23** | **-20** | **-19** | **57** | **-20** |
| **Cash at end of period** | 59 | 39 | 20 | 77 | 57 |

**EARNINGS (US$m)**

| Y/e June 30 | FY11A | FY12A | FY13E | FY14E | FY15E |
|---|---|---|---|---|---|
| Net profit ($m) | -20.9 | -23.8 | -26.0 | -26.3 | -22.7 |
| EPS (c) | -6.4 | -7.2 | -7.8 | -7.5 | -5.5 |
| *EPS growth (%)* | N/A | N/A | N/A | N/A | N/A |
| P/E ratio (x) | -8.3 | -7.4 | -6.3 | -6.1 | -7.8 |
| CFPS (c) | -5.1 | -5.6 | -6.5 | -6.4 | -4.7 |
| Price/CF (x) | -10.2 | -9.4 | -7.6 | -7.2 | -9.3 |
| DPS ( c ) | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| *Yield (%)* | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% |
| Franking (%) | 0% | 0% | 0% | 0% | 0% |
| EV/EBITDA | -7.1 | -6.3 | -5.5 | -5.0 | -5.5 |
| EV/EBIT | -6.9 | -6.2 | -5.3 | -4.8 | -5.2 |

**PROFITABILITY RATIOS**

| Y/e June 30 | FY11A | FY12A | FY13E | FY14E | FY15E |
|---|---|---|---|---|---|
| EBITDA/revenue (%) | N/A | N/A | N/A | N/A | -355.0% |
| **EBIT/revenue (%)** | N/A | N/A | N/A | N/A | -370.0% |
| Return on assets (%) | -31.1% | -50.2% | -103.0% | -31.8% | -36.0% |
| Return on equity (%) | -32.4% | -53.3% | -117.1% | -33.0% | -37.9% |
| Return on funds empl'd (%) | -32.4% | -53.3% | -117.1% | -33.0% | -37.9% |
| 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 | FY11A | FY12A | FY13E | FY14E | FY15E |
|---|---|---|---|---|---|
| Net debt/(cash) ($m) | -59 | -39 | -20 | -77 | -57 |
| **Net debt/equity (%)** | -91.6% | -87.1% | -88.1% | -96.7% | -95.1% |
| Net interest cover (x) | N/A | N/A | N/A | N/A | N/A |
| Current ratio (x) | 28.0 | 20.3 | 8.7 | 31.6 | 22.4 |

**INTERIMS**

| Y/e June 30 (US$m) | 1H12A | 2H12A | 1H13A | 2H13F | 1H14F |
|---|---|---|---|---|---|
| Revenue | 0 | 0 | 0 | 0 | 0 |
| **EBITDA** | **-11** | **-12** | **-13** | **-13** | **-13** |
| D&A | **0** | **0** | **0** | **0** | **0** |
| **EBIT** | **-12** | **-12** | **-13** | **-13** | **-13** |
| Net interest | **0** | **0** | **0** | **0** | **0** |
| Pre-tax profit | -12 | -12 | -13 | -13 | -13 |
| Tax | **0** | **0** | **0** | **0** | **0** |
| NPAT | -12 | -12 | -13 | -13 | -13 |
| Minority interests | **0** | **0** | **0** | **0** | **0** |
| Net profit after minorities | -12 | -12 | -13 | -13 | -13 |

**VALUATION**

| | Base | Optim. |
|---|---|---|
| ReZolve (A$m) | 594.7 | 1,097.5 |
| Value of tax losses | 61.0 | 61.0 |
| Underlying R&D cost | -9.6 | -9.6 |
| Cash now (A$m) | 27.7 | 27.7 |
| Cash to be raised (A$m) | 115.9 | 115.9 |
| Total value (A$m) | 789.8 | 1292.5 |
| Total diluted shares (million) | 526.7 | 526.7 |
| Value per share | $1.50 | $2.45 |
| Valuation midpoint | $1.98 | |
| Share price now (A$ per share) | $0.510 | |
| Upside to midpoint | 287.6% | |

# Sirtex Medical (SRX) – Moving up the usage curve

**BUY. Target price $15.00**

- **COMPANY DESCRIPTION.** The Sydney-based 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. Sirtex has now registered 36 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 of 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 late 2014.** 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 September 2013 the SARAH study was 53.5% complete, FOXFIRE 56%, SORAMIC 47.5% and SIRveNIB 54%.
- **Sirtex is debt-free, with A$52m net cash as at December 2012.** 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 $14.95 base case / $26.26 optimistic case. Our $15.00 price target sits at around the low point 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.

- **VALUATION METHOLOGY**. Our DCF of Sirtex was built as follows:
  - Our WACC was 12.5% (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, from ~30% previously.
- **MAJOR SHAREHOLDERS.** Hunter Hall (22.7%), Bruce Gray (founder, no longer involved, 12.6%), Perpetual (12.4%)
- **KEY RISKS.** 1) Clinical risk with SIRFLOX and the other trials; 2) Competitor risk, where new drug therapies slow sales of SIR-Spheres.

**FIG.11: SIRTEX SHARE PRICE**


*Source: Iress*

# Sirtex Medical - Financial Summary

| | |
|---|---|
| Code | SRX |
| Analyst | Stuart Roberts |
| Date | 27 November, 2013 |
| Share price | $12.00 |
| Market capitalisation | $673m |
| Year end | 30 June |

| | |
|---|---|
| Rating | BUY |
| Price target | $15.00 |
| Upside/downside | 25.0% |
| Valuation | $14.952 / $26.261 |
| Valuation method | DCF |
| Risk | Medium |

**PROFIT AND LOSS (A$m)**

| Y/e June 30 (A$m) | FY12A | FY13A | FY14E | FY15E | FY16E |
|---|---|---|---|---|---|
| Revenue | 84 | 99 | 120 | 140 | 163 |
| **EBITDA** | **21** | **23** | **32** | **42** | **47** |
| D&A | -1 | -1 | -2 | -2 | -2 |
| **EBIT** | **20** | **22** | **30** | **40** | **46** |
| Net interest | 2 | 2 | 3 | 3 | 3 |
| Pre-tax profit | **22** | **25** | **33** | **43** | **49** |
| Tax | -5 | -6 | -8 | -10 | -12 |
| NPAT | 17 | 18 | 25 | 32 | 37 |
| Minority interests | 0 | 1 | 0 | 0 | 0 |
| Net profit after minorities | 17 | 19 | 25 | 32 | 37 |

**BALANCE SHEET (A$m)**

| Y/e June 30 | FY12A | FY13A | FY14E | FY15E | FY16E |
|---|---|---|---|---|---|
| Cash | 49 | 52 | 59 | 69 | 83 |
| Current receivables | 18 | 21 | 21 | 22 | 23 |
| Inventories | 1 | 2 | 3 | 3 | 4 |
| Other current assets | 2 | 3 | 3 | 3 | 3 |
| **Current assets** | **71** | **77** | **86** | **97** | **113** |
| PPE | 7 | 9 | 8 | 8 | 7 |
| Intangible assets | 16 | 28 | 39 | 51 | 62 |
| Other non-current assets | 3 | 3 | 3 | 3 | 3 |
| **Non-current assets** | 26 | 40 | 50 | 62 | 72 |
| **Total assets** | 97 | 118 | 136 | 159 | 186 |
| Payables | 9 | 11 | 11 | 11 | 11 |
| Debt | 0 | 0 | 0 | 0 | 0 |
| Other liabilities | 14 | 19 | 19 | 19 | 19 |
| **Total liabilities** | 23 | 30 | 30 | 30 | 30 |
| Shareholders' equity | 74 | 88 | 106 | 130 | 156 |
| Minorities | 0 | 0 | 0 | 0 | 0 |
| **Total shareholders funds** | **74** | **88** | **106** | **130** | **156** |
| **Total funds employed** | **97** | **118** | **136** | **159** | **186** |
| **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 | 25 | 32 | 37 |
| Non-cash items | 1 | 4 | 2 | 2 | 2 |
| Working capital | 2 | 2 | -2 | -2 | -2 |
| Other operating cash flow | 0 | 0 | 0 | 0 | 0 |
| **Operating cashflow** | **20** | **24** | **25** | **33** | **37** |
| Capex | -1 | -4 | -1 | -1 | -1 |
| Investments | 0 | 0 | 0 | 0 | 0 |
| Other investing cash flow | -9 | -13 | -11 | -12 | -11 |
| **Investing cashflow** | **-10** | **-16** | **-12** | **-13** | **-12** |
| Change in borrowings | 0 | 0 | 0 | 0 | 0 |
| Equity raised | 0 | 0 | 0 | 0 | 0 |
| Dividends paid | -4 | -5 | -7 | -9 | -11 |
| Other financing cash flow | 0 | 0 | 0 | 0 | 0 |
| **Financing cashflow** | **-4** | **-5** | **-7** | **-9** | **-11** |
| **Net change in cash** | **7** | **3** | **6** | **10** | **14** |
| **Cash at end of period** | 49 | 52 | 59 | 69 | 83 |

**EARNINGS (A$m)**

| Y/e June 30 | FY12A | FY13A | FY14E | FY15E | FY16E |
|---|---|---|---|---|---|
| Net profit ($m) | 16.7 | 18.9 | 24.9 | 32.4 | 37.3 |
| EPS (c) | 29.9 | 33.9 | 44.6 | 58.1 | 66.8 |
| *EPS growth (%)* | 49% | 13% | 32% | 30% | 15% |
| P/E ratio (x) | 40.1 | 35.4 | 26.9 | 20.6 | 18.0 |
| CFPS (c) | 35.8 | 43.6 | 45.2 | 58.6 | 66.8 |
| Price/CF (x) | 33.5 | 27.5 | 26.6 | 20.5 | 18.0 |
| DPS ( c ) | 10.0 | 12.0 | 16.0 | 20.0 | 23.0 |
| *Yield (%)* | 0.8% | 1.0% | 1.3% | 1.7% | 1.9% |
| Franking (%) | 100% | 100% | 0% | 0% | 0% |
| EV/EBITDA | 29.3 | 29.3 | 29.3 | 29.3 | 29.3 |
| EV/EBIT | 31.4 | 28.1 | 20.6 | 15.6 | 13.6 |

**PROFITABILITY RATIOS**

| Y/e June 30 | FY12A | FY13A | FY14E | FY15E | FY16E |
|---|---|---|---|---|---|
| EBITDA/revenue (%) | 25.3% | 23.8% | 26.9% | 29.8% | 29.0% |
| **EBIT/revenue (%)** | 23.6% | 22.4% | 25.2% | 28.5% | 27.9% |
| Return on assets (%) | 17.3% | 16.1% | 18.3% | 20.3% | 20.1% |
| Return on equity (%) | 22.7% | 21.5% | 23.4% | 25.0% | 23.9% |
| Return on funds empl'd (%) | 22.7% | 21.5% | 23.4% | 25.0% | 23.9% |
| Dividend cover (x) | 3.0 | 2.8 | 2.8 | 2.9 | 2.9 |
| Effective tax rate (%) | 22.7% | 25.4% | 24.0% | 24.0% | 24.0% |

**LIQUIDITY AND LEVERAGE RATIOS**

| Y/e June 30 | FY12A | FY13A | FY14E | FY15E | FY16E |
|---|---|---|---|---|---|
| Net debt/(cash) ($m) | -49 | -52 | -59 | -69 | -83 |
| **Net debt/equity (%)** | -67.2% | -59.1% | -55.1% | -53.1% | -53.1% |
| Net interest cover (x) | -0.1 | -0.1 | -0.1 | -0.1 | -0.1 |
| Current ratio (x) | 4.3 | 3.9 | 4.3 | 4.9 | 5.7 |

**INTERIMS**

| Y/e June 30 ($m) | 2H12A | 1H13A | 2H13A | 1H14F | 2H14F |
|---|---|---|---|---|---|
| Revenue | 46 | 46 | 52 | 57 | 63 |
| **EBITDA** | **13** | **11** | **13** | **15** | **17** |
| D&A | **-1** | **-1** | **-1** | **-1** | **-1** |
| **EBIT** | **13** | **10** | **12** | **14** | **17** |
| Net interest | **1** | **1** | **1** | **1** | **1** |
| Pre-tax profit | 14 | 11 | 13 | 15 | 18 |
| Tax | **-3** | **-3** | **-3** | **-4** | **-4** |
| NPAT | 11 | 8 | 10 | 11 | 14 |
| Minority interests | **0** | **0** | **1** | **0** | **0** |
| Net profit after minorities | 11 | 8 | 11 | 11 | 14 |

**VALUATION**

| | Base | Optim. |
|---|---|---|
| Business (A$m) | 786.8 | 1421.2 |
| Cash as at Jun 2013 (A$m) | 52.1 | 52.1 |
| Cash from options (A$m) | 0.0 | 0.0 |
| Total value (A$m) | 838.9 | 1473.3 |
| Diluted shares on issue (million) | 56.1 | 56.1 |
| Value per share | $14.95 | $26.26 |
| Valuation midpoint | $20.61 | |
| Share price now | $12.000 | |
| Upside | 71.7% | |

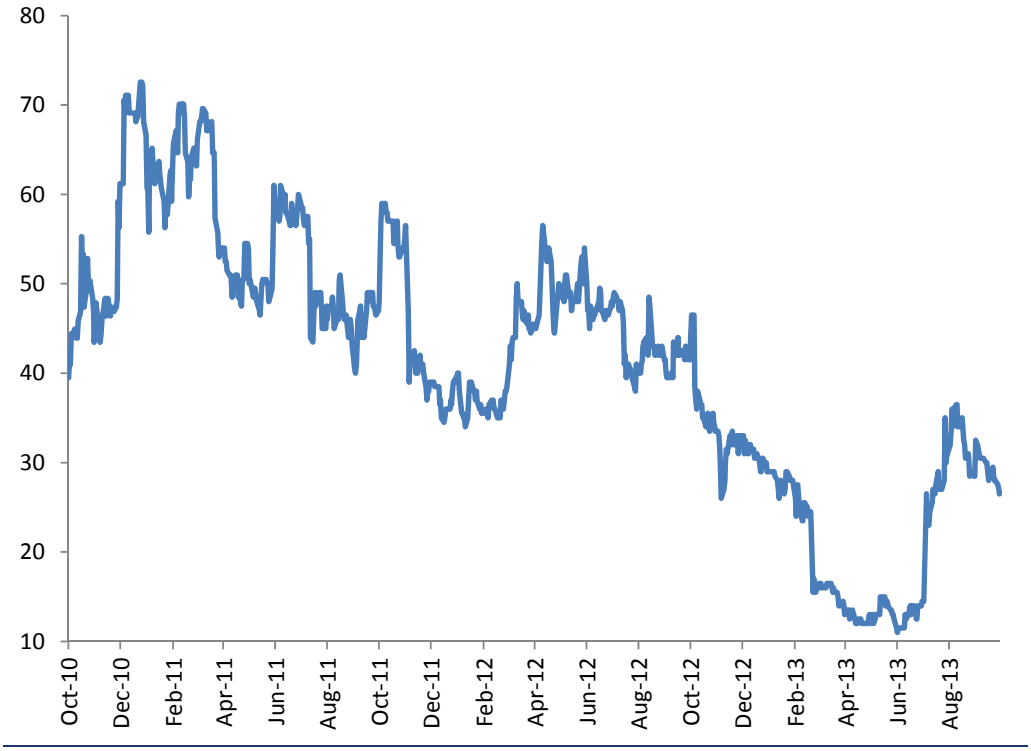
# Tissue Therapies (TIS) – Marked upside once the regulatory issues are dealt with

**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 around mid-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.** In late July 2013 Tissue Therapies advised the market that the EMA would now proceed to review of 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 pa 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 next 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 soup to nuts 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 $0.61 per share base case and $1.34 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 Tissue Therapies re-rating to our target price on the back of any progress towards resolution of the European regulatory issues.

- **VALUATION METHOLOGY**. Our probability-weighted DCF of Tissue Therapies was built as follows:
  - Our WACC was 16.9% (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 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;
  - We assume another A$10m being raised at 20 cents to fund US clinical work.
- **MAJOR SHAREHOLDERS.** Allan Gray Australia (10.9%) and Asia Union Investments (Chris Abbott, Maple-Brown Abbott founder, 9%).
- **KEY RISKS.** 1) Regulatory risk, as per our remarks above; 2) Funding risk, which could slow initiation of the US trial. Competitor risk,

**FIG.12: TISSUE THERAPIES SHARE PRICE**




*Source: Iress*

# Tissue Therapies - Financial Summary

| | |
|---|---|
| Code | TIS |
| Analyst | Stuart Roberts |
| Date | 27 November, 2013 |
| Share price | $0.23 |
| Market capitalisation | $53m |
| Year end | 30 June |

| | |
|---|---|
| Rating | BUY |
| Price target | $0.65 |
| Upside/downside | 182.6% |
| Valuation | $0.609 / $1.335 |
| 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** | **-4** | **-5** | **-3** |
| D&A | -1 | 0 | 0 | 0 | 0 |
| **EBIT** | **-8** | **-6** | **-4** | **-6** | **-3** |
| Net interest | 1 | 0 | 0 | 0 | 0 |
| Pre-tax profit | **-7** | **-6** | **-4** | **-6** | **-3** |
| Tax | 0 | 0 | 0 | 0 | 0 |
| NPAT | -7 | -6 | -4 | -6 | -3 |
| Minority interests | 0 | 0 | 0 | 0 | 0 |
| Net profit after minorities | -7 | -6 | -4 | -6 | -3 |

**BALANCE SHEET (A$m)**

| Y/e June 30 | FY12A | FY13A | FY14E | FY15E | FY16E |
|---|---|---|---|---|---|
| Cash | 5 | 5 | 4 | 8 | 5 |
| Current receivables | 0 | 0 | 0 | 0 | 0 |
| Inventories | 6 | 9 | 9 | 9 | 9 |
| Other current assets | 1 | 1 | 1 | 1 | 1 |
| **Current assets** | **12** | **15** | **14** | **18** | **15** |
| 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 | 15 | 19 | 16 |
| Payables | 2 | 1 | 1 | 1 | 2 |
| Debt | 0 | 0 | 0 | 0 | 0 |
| Other liabilities | 0 | 0 | 0 | 0 | 0 |
| **Total liabilities** | 2 | 2 | 2 | 2 | 2 |
| Shareholders' equity | 10 | 14 | 13 | 17 | 14 |
| Minorities | 0 | 0 | 0 | 0 | 0 |
| **Total shareholders funds** | **10** | **14** | **13** | **17** | **14** |
| **Total funds employed** | **13** | **16** | **15** | **19** | **16** |
| **W/A shares on issue** | 169 | 186 | 229 | 276 | 276 |

**CASH FLOW (A$m)**

| Y/e June 30 | FY12A | FY13A | FY14E | FY15E | FY16E |
|---|---|---|---|---|---|
| NPAT plus discontinued ops. | -7 | -6 | -4 | -6 | -3 |
| Non-cash items | 1 | 0 | 0 | 0 | 0 |
| Working capital | -4 | -4 | 0 | 0 | 0 |
| Other operating cash flow | 0 | 0 | 0 | 0 | 0 |
| **Operating cashflow** | **-10** | **-9** | **-4** | **-5** | **-3** |
| 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 | 3 | 10 | 0 |
| Dividends paid | 0 | 0 | 0 | 0 | 0 |
| Other financing cash flow | 0 | 0 | 0 | 0 | 0 |
| **Financing cashflow** | **0** | **9** | **3** | **10** | **0** |
| **Net change in cash** | **-10** | **0** | **-1** | **4** | **-3** |
| **Cash at end of period** | 5 | 5 | 4 | 8 | 5 |

**EARNINGS (A$m)**

| Y/e June 30 | FY12A | FY13A | FY14E | FY15E | FY16E |
|---|---|---|---|---|---|
| Net profit ($m) | -6.8 | -5.7 | -4.1 | -5.5 | -3.1 |
| EPS (c) | -4.0 | -3.1 | -1.8 | -2.0 | -1.1 |
| *EPS growth (%)* | N/A | N/A | N/A | N/A | N/A |
| P/E ratio (x) | -5.7 | -7.4 | -12.8 | -11.5 | -20.6 |
| CFPS (c) | -6.1 | -5.0 | -1.7 | -1.9 | -1.1 |
| Price/CF (x) | -3.8 | -4.6 | -13.8 | -12.0 | -20.7 |
| DPS ( c ) | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| *Yield (%)* | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% |
| Franking (%) | 0% | 0% | 0% | 0% | 0% |
| EV/EBITDA | -6.7 | -6.7 | -6.7 | -6.7 | -6.7 |
| EV/EBIT | -6.1 | -7.5 | -11.3 | -8.5 | -15.0 |

**PROFITABILITY RATIOS**

| Y/e June 30 | FY12A | FY13A | FY14E | FY15E | FY16E |
|---|---|---|---|---|---|
| EBITDA/revenue (%) | -2069.4% | -6406.3% | N/A | -302.6% | -49.3% |
| **EBIT/revenue (%)** | -2296.7% | -6565.3% | N/A | -308.3% | -50.8% |
| Return on assets (%) | -52.3% | -36.3% | -28.0% | -29.1% | -19.1% |
| Return on equity (%) | -64.7% | -41.1% | -31.9% | -32.3% | -21.8% |
| Return on funds empl'd (%) | -64.5% | -41.1% | -31.9% | -32.3% | -21.8% |
| Dividend cover (x) | N/A | N/A | N/A | N/A | N/A |
| Effective tax rate (%) | 6.1% | 5.1% | 0.0% | 0.0% | 0.0% |

**LIQUIDITY AND LEVERAGE RATIOS**

| Y/e June 30 | FY12A | FY13A | FY14E | FY15E | FY16E |
|---|---|---|---|---|---|
| Net debt/(cash) ($m) | -5 | -5 | -4 | -8 | -5 |
| **Net debt/equity (%)** | -49.0% | -34.8% | -29.9% | -46.9% | -34.7% |
| Net interest cover (x) | N/A | N/A | N/A | N/A | N/A |
| Current ratio (x) | 5.2 | 9.2 | 8.6 | 11.0 | 8.6 |

**INTERIMS**

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

**VALUATION**

| | Base | Optim. |
|---|---|---|
| VitroGro (A$m) | 175.3 | 416.4 |
| Value of tax losses | 10.5 | 10.5 |
| Underlying R&D cost | -9.6 | -9.6 |
| Cash now (A$m) | 5.6 | 5.6 |
| Cash to be raised (A$m) | 20.0 | 20.0 |
| Total value (A$m) | 201.9 | 442.9 |
| Total diluted shares (million) | 331.8 | 331.8 |
| Value per share | $0.61 | $1.34 |
| Valuation midpoint | $0.97 | |
| Share price now (A$ per share) | $0.230 | |
| Upside to midpoint | 322.5% | |

# Glossary - **Note: A larger, 53 page glossary of Life Sciences terms is available on request.**

**Big Pharma** – A collective term referring to the world's largest pharmaceutical companies such as Eli Lilly, J&J, Merck & Co., Novartis and Pfizer.

**Blockbuster** – A pharmaceutical drug with more than US$1bn in global annual sales.

**Cancer stem cell** – A cell that can give rise to a tumour. Cancer stem cells traditionally have been difficult to kill with conventional chemotherapy and radiotherapy.

**CE Marking** – The process of gaining European approval for a medical device. CE stands for *Conformité Européenne.*

**EMA** – The European Medicines Agency, Europe's answer to the FDA.

**FDA -** The Food and Drug Administration, the American government body which regulates the pharmaceutical industry and from whom approval must be received before a drug can be marketed in the US.

**HSV-2** – The Herpes Simplex Virus 2, the virus most commonly responsible for genital herpes.

**IND** – Short for Investigational New Drug, an application to the FDA to begin clinical work on an experimental drug.

**Mesenchymal Precursor Cells (MPCs)** – Mesoblast's adult stem cells.

**Metastatic cancer** – Cancer that has spread from the site of the original tumour to another part of the body.

**Neuroprotection** – The ability to keep brain cells from dying when stressed.

**Opioids** – Pain killing drugs based on opium. The best-known opioid analgesic is morphine.

**Orphan Drug** – A drug that benefits a very small patient population. Orphan Drugs are often valuable for drug companies because they can sell at very high prices.

**Partnering** – A deal in which a drug or medical device developer licenses a product to another company, generally in return for upfront payments, milestone payments as the product develops in a clinical or regulatory sense, and royalties on sales.

**Phase** – A stage of the clinical trialling process for a drug candidate. Phase I tests for safety. Phase II tests for efficacy in a small sample. Phase III tests for efficacy in a large sample.

**Platform technology** – A technology with multiple uses.

**Progression-Free Survival** (PFS) – The length of time a cancer patient undergoing treatment can see no worsening of his or her cancer.

**Rett Syndrome** – A severe Autism Spectrum Disorder that affects only girls.

**Small molecules** – Drugs that have a low molecular weight, making them easy to administer in pill form.

**Soft tissue -** Tissues of the body that are not bone.

**Solid tumour** – In cancer, a tumour that is a localised mass of tissue rather than a blood cancer like leukaemia.

**Stem cells** – Cells that can differentiate into many different cell types when subjected to the right biochemical signals.

# Baillieu Holst Life Sciences Index composition

**The following stocks were included in our Index on an equally-weighted basis:**

Acrux (ACR)
Admedus (AHZ)
Agenix (AGX)
Alchemia (ACL)
Analytica (ALT)
Anteo Diagnostics (ADO)
Antisense Therapeutics (ANP)
AtCor Medical (ACG)
Avexa (AVX)
Avita Medical (AVH)
Benitec (BLT)
Bioniche Life Sciences (BNC)
Bionomics (BNO)
Biotron (BIT)
Brain Resource (BRC)
Calzada (CZD)
Cellmid (CDY)
Circadian Technologies (CIR)
Clinuvel Pharmaceuticals (CUV)
Clover Corporation (CLV)
Cogstate (CGS)
Compumedics (CMP)
Consegna Group (CGP)
Cordlife (CBB)
Ellex Medical Lasers (ELX)
Genera Biosystems (GBI)
Genetic Technologies (GTG)
GI Dynamics (GID)
Holista CollTech (HCT)
IDT Australia (IDT)
Immuron (IMC)
Impedimed (IPD)
Invion (IVX)
iSonea (ISN)
Living Cell Technologies (LCT)
Mayne Pharma (MYX)
Medical Australia (MLA)
Medical Developments (MVP)
Mesoblast (MSB)
Nanosonics (NAN)
Neuren Pharmaceuticals (NEU)
Novogen (NRT)
NuSep (NSP)
OBJ Ltd (OBJ)
Osprey Medical (OSP)
Patrys (PAB)
Pharmaxis (PXS)
Phosphagenics (POH)
Phylogica (PYC)
Prana Biotechnology (PBT)
Prima Biomed (PRR)
Probiotec (PBP)
pSivida Corp (PVA)
QRXPharma (QRX)
REVA Medical (RVA)
Sirtex Medical (SRX)
Solagran (SLA)
SomnoMed (SOM)
Starpharma (SPL)
SUDA (SUD)
Tissue Therapies (TIS)
Unilife (UNS)
Universal Biosensors (UBI)
Uscom (UCM)
Viralytics (VLA)
Vita Life Sciences (VSC)

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

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