Morgans IN ALLIANCE WITH CIMB

Avita Medical

Rejuvenated

ADD

Current price:	A$0.100
Target price:	A$0.57
Previous target:	A$
Up/downside:	471.1%
Reuters:	AVH.AX
Bloomberg:	AVH AU
Market cap:	US$43.94m
	A$57.28m
Average daily turnover:	US$0.06m
	A$0.08m
Current shares o/s	300.5m
Free float:	70.0%

Source: Bloomberg

Price performance	1M	3M	12M
Absolute (%)	-4.8	7.5	58.7
Relative (%)	-7.5	13.3	73

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- AVH is a medical device company focused on regenerative technologies to treat a range of wounds, scars and skin defects, representing a US$5bn+ global market.
- Under new leadership, the strategy has been revamped and the product portfolio rebranded to better exploit its proprietary, safe and efficacious on-site patient cell harvesting and skin regeneration system, which is commercialised in more than 30 countries and has been used by more than 6.5k patients.
- Encouragingly, 1HFY16 regenerative medicine sales increased 17% yoy, with momentum expected to increase on broader international distribution.
- Its recent five-year US defense contract win worth up to cUS$54m validates point-of-care technology, provides non-dilutive capital to support its commercial strategy and underwrites the ongoing FDA burns trial which has received expedited review.
- With sales traction evident and catalysts on the horizon, we initiate coverage with an Add recommendation and A$0.57 blended (DCF/SOTP) price target.

An innovative, proprietary skin healing portfolio…

AVH has developed a unique, single-use, patented cell collection and application technology derived from a patient's own skin (ie autologous). Its three-product portfolio (ReCell®, ReGenerCell™, ReNovaCell™) is based on RES™ (regenerative epithelial suspension), which regenerates natural, healthy skin to address a broad range of applications, including: acute wounds (eg burns/scars), chronic wounds (eg venous leg ulcers and diabetic foot ulcers) and functional and aesthetic outcomes (eg repigmentation, scar revision), respectively.

…but a dysfunctional strategy has impinged the growth trajectory

Over the past five years, regenerative medicines sales growth has been anaemic. We believe a combination of limited clinical data, regulatory delays, a mismatched product portfolio (eg respiratory, cell culturing and regenerative technologies) and an incoherent commercialisation strategy have held growth in check.

New management, new strategy = new growth prospects

Under new leadership and broad renewal, the company has undergone a strategic re-positioning, taking a more incremental transition to wound care, where products complement existing therapies, and the focus is on accumulating clinical studies and clinical/health-economic benefits. We believe this much more structured approach has improved the fundamental outlook for the company, helping to differentiate product characteristics and beginning to grab the attention of physicians worldwide.

Catalysts and cash

We believe a transformed commercial focus and numerous upcoming catalysts should reignite investor interest. While A$7.7m in cash backing exiting 2QFY16 and US government contract revenues should provide sufficient capital for at least the next 12 months, we have incorporated a A$10m equity raise into CY16 to see the company through to profitability.

Financial Summary	Jun-14A	Jun-15A	Jun-16F	Jun-17F	Jun-18F
Revenue (US$m)	3.03	2.76	2.34	5.03	30.08
Operating EBITDA (US$m)	-6.36	-7.97	-10.11	-11.17	7.03
Net Profit (US$m)	-4.87	-7.17	-10.27	-11.09	6.80
Core EPS (US$)	(0.015)	(0.020)	(0.022)	(0.024)	0.012
Core EPS Growth	(38.5%)	35.6%	10.1%	8.0%	
FD Core P/E (x)	NA	NA	NA	NA	6.38
DPS (US$)	-	-	-	-	-
Dividend Yield	0%	0%	0%	0%	0%
EV/EBITDA (x)	NA	NA	NA	NA	5.16
P/FCFE (x)	NA	NA	NA	NA	6.06
Net Gearing	(66.0%)	(70.3%)	(91.4%)	(21.8%)	(80.7%)
P/BV (x)	5.16	7.55	3.26	19.55	4.82
ROE	(64%)	(170%)	(122%)	(143%)	121%

SOURCE: MORGANS, COMPANY REPORTS

Figure 1: Financial summary

Avita Medical					Year end June
Income statement (US$m)	**2014A**	**2015A**	**2016F**	**2017F**	**2018F**
Divisional sales	3	3	2	5	30
Total revenue	3	3	2	5	30
EBITDA	(6.4)	(8.0)	(10.1)	(11.2)	7.0
Associate income	(0.1)	0.2	0.0	0.0	0.0
Depreciation	(0.1)	(0.1)	(0.2)	(0.2)	(0.2)
EBITA	(6.4)	(8.0)	(10.3)	(11.4)	6.8
Amortisation/impairment	0.0	0.0	0.0	0.0	0.0
EBIT	(6.4)	(8.0)	(10.3)	(11.4)	6.8
EBIT(incl associate profit)	(6.5)	(7.9)	(10.3)	(11.4)	6.8
Net interest expense	0.2	0.0	0.1	0.3	0.0
Pre-tax profit	(6.4)	(7.8)	(10.3)	(11.1)	6.8
Income tax expense	1.5	0.7	0.0	0.0	0.0
After-tax profit	(4.9)	(7.2)	(10.3)	(11.1)	6.8
Minority interests	0.0	0.0	0.0	0.0	0.0
NPAT (normalised)	(4.9)	(7.2)	(10.3)	(11.1)	6.8
Significant items	0.0	0.0	0.0	0.0	0.0
NPAT (reported)	(4.9)	(7.2)	(10.3)	(11.1)	6.8

Cash flow (US$m)	**2014A**	**2015A**	**2016F**	**2017F**	**2018F**
EBITDA	(6.4)	(8.0)	(10.1)	(11.2)	7.0
Change in working capital	(1.9)	0.6	0.2	(1.0)	0.4
Net interest (pd)/rec	0.0	0.0	(0.0)	0.3	0.0
Taxes paid	0.0	0.0	0.0	0.0	0.0
Other oper cash items	1.8	0.8	0.0	0.0	0.0
Cash flow from ops (1)	(6.6)	(6.4)	(10.0)	(11.9)	7.5
Capex (2)	(0.1)	(0.0)	(0.2)	(0.2)	(0.3)
Disposals/(acquisitions)	0.0	0.0	0.0	0.0	0.0
Other investing cash flow	0.0	(0.6)	0.0	0.0	0.0
Cash flow from invest (3)	(0.1)	(0.6)	(0.2)	(0.2)	(0.3)
Incr/(decr) in equity	0.0	6.2	20.0	0.0	0.0
Incr/(decr) in debt	0.0	0.0	0.0	0.0	0.0
Ordinary dividend paid	0.0	0.0	0.0	0.0	0.0
Preferred dividends (4)	0.0	0.0	0.0	0.0	0.0
Other financing cash flow	0.0	0.0	0.0	0.0	0.0
Cash flow from fin (5)	0.0	6.2	20.0	0.0	0.0
Forex and disc ops (6)	0.0	0.0	0.0	0.0	0.0
Inc/(decr) cash (1+3+5+6)	(6.7)	(0.8)	9.8	(12.1)	7.2
Equity FCF (1+2+4)	(6.7)	(6.4)	(10.2)	(12.1)	7.2

Balance sheet (US$m)	**2014A**	**2015A**	**2016F**	**2017F**	**2018F**
Cash & deposits	3.6	3.0	12.7	0.6	7.8
Trade debtors	2.5	1.5	1.3	2.7	6.5
Inventory	0.8	0.6	0.5	1.1	6.5
Investments	0.0	0.0	0.0	0.0	0.0
Goodwill	0.0	0.0	0.0	0.0	0.0
Other intangible assets	0.0	0.0	0.1	0.1	0.3
Fixed assets	0.1	0.1	0.1	0.1	0.1
Other assets	0.2	0.2	0.2	0.2	0.2
Total assets	7.3	5.4	15.0	4.9	21.4
Short-term borrowings	0.0	0.0	0.0	0.0	0.0
Trade payables	1.7	1.0	0.9	1.8	11.5
Long-term borrowings	0.0	0.0	0.0	0.0	0.0
Provisions	0.0	0.0	0.0	0.0	0.0
Other liabilities	0.1	0.2	0.2	0.2	0.2
Total liabilities	1.8	1.2	1.1	2.0	11.6
Preference shares	0.0	0.0	0.0	0.0	0.0
Hybrid equity	0.0	0.0	0.0	0.0	0.0
Share capital	111.4	117.0	137.0	137.0	137.0
Other reserves	0.0	0.0	0.0	0.0	0.0
FCTR	0.0	0.0	0.0	0.0	0.0
Unrealised gains/losses	0.0	0.0	0.0	0.0	0.0
Retained earnings	(106.6)	(113.5)	(123.7)	(134.8)	(128.0)
Other equity	0.0	0.0	0.0	0.0	0.0
Total equity	4.8	3.6	13.3	2.2	9.0
Minority interest	0.7	0.6	0.6	0.6	0.6
Total shareholders' equity	5.5	4.2	13.9	2.9	9.6
Total liabilities & SE	7.3	5.4	15.0	4.8	21.3

Closing price (A$)	**0.10**	**Target price (A$)**	**0.57**
Valuation metrics			
Preferred methodology	DCF, EV/EBITDA, PE	Valuation	0.57
DCF valuation inputs			
Rf	6.25%	10-year rate	6.25%
Rm-Rf	6.00%	Margin	1.5%
Beta	2.52	Kd	7.75%
CAPM (Rf+Beta(Rm-Rf))	21.4%	Ke	21.4%
E/EV*Ke+D/EV*Kd(1-t)		NPV cash flow (US$m)	214.0
Equity (E/EV)	60.0%	Minority interest (US$m)	0.6
Debt (D/EV)	40.0%	Net debt (US$m)	-3.0
Interest rate	7.8%	Investments (US$m)	0.0
Tax rate (t)	30.0%	Equity market value (US$m)	216.3
WACC	**15.0%**	Diluted no. of shares (m)	353.1
		DCF Valuation (A$)	**0.47**

Multiples	**2015A**	**2016F**	**2017F**	**2018F**
Enterprise value (US$m)	41.0	41.6	31.8	43.9
EV/Sales (x)	14.9	17.8	6.3	1.5
EV/EBITDA (x)	(5.1)	(4.1)	(2.8)	6.3
EV/EBIT (x)	(5.1)	(4.0)	(2.8)	6.5
PE (normalised) (x)	(4.2)	(2.9)	(3.3)	6.4
PEG (normalised) (x)	(0.2)	(0.1)	0.3	(0.0)
Price/Book (x)	8.37	2.25	19.55	4.82

At target price	**2015A**	**2016F**	**2017F**	**2018F**
EV/EBITDA (x)	(13.2)	(9.5)	(9.6)	14.3
PE (normalised) (x)	(23.9)	(16.7)	(18.9)	36.5

Comparable company data (x)		**2016F**	**2017F**	**2018F**
Nanosonics	EV/EBITDA	-140.5	187.0	43.4
Y/E June	EV/EBIT	-114.5	274.3	47.0
	PE	-164.4	172.2	45.7
	PEG	4.3	-0.9	0.2
SomnoMed	EV/EBITDA	46.6	23.7	13.8
Y/E June	EV/EBIT	61.7	27.2	15.0
	PE	79.7	36.3	21.2
	PEG	0.4	0.3	0.3

Per share data	**2015A**	**2016F**	**2017F**	**2018F**
No. shares	391.2	391.2	566.1	566.1
EPS (normalised) (cps)	(2.0)	(2.2)	(2.4)	1.2
EPS (dil. normalised) (cps)	(1.8)	(2.6)	(2.3)	1.2
Dividend per share (cps)	0.0	0.0	0.0	0.0
Franking (%)	0%	0%	n.a.	n.a.
Dividend payout ratio (%)	0.0%	0.0%	0.0%	0.0%
Dividend yield (%)	0.0%	0.0%	0.0%	0.0%

Growth ratios	**2015A**	**2016F**	**2017F**	**2018F**
Sales growth	-8.9%	-15.1%	114.9%	498.1%
Operating cost growth	10.3%	16.1%	30.1%	42.3%
EBITDA growth	25.3%	26.9%	10.5%	-162.9%
EBITA growth	25.0%	28.8%	10.3%	-159.5%
EBIT growth	25.0%	28.8%	10.3%	-159.5%
Reported NPAT growth	47.2%	43.3%	8.0%	-161.4%
Normalised NPAT growth	47.2%	43.3%	8.0%	-161.4%
Reported EPS growth	22.4%	43.3%	-11.8%	-151.9%
Normalised EPS growth	22.4%	43.3%	-11.8%	-151.9%

Operating performance	**2015A**	**2016F**	**2017F**	**2018F**
Asset turnover	11.9%	6.8%	5.9%	9.6%
EBITDA margin	-289.0%	-432.1%	-222.1%	23.4%
EBIT margin	-291.3%	-442.1%	-226.8%	22.6%
Net profit margin	-260.0%	-439.0%	-220.5%	22.6%
Return on net assets	-190.4%	-74.2%	-400.0%	70.4%
Net debt (US$m)	-3.0	-12.7	-0.6	-7.8
Net debt/equity	-70.3%	-91.4%	-21.8%	-80.7%
Net interest/EBIT cover (x)	181.9	139.5	35.8	-437.3
ROIC	128.2%	248.2%	-986.8%	301.8%

Internal liquidity	**2015A**	**2016F**	**2017F**	**2018F**
Current ratio (x)	4.3	13.8	2.4	1.8
Receivables turnover (x)	1.5	2.0	1.2	1.1
Payables turnover (x)	6.9	11.1	9.2	2.4

Assumptions	**2015A**	**2016F**	**2017F**	**2018F**
USD/USD	0.836	0.730	0.740	0.740

SOURCE: MORGANS RESEARCH, COMPANY

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Investment thesis

Initiating coverage with an ADD rating

Avita Medical is a medical device company focused on the rapidly growing regenerative space with its proprietary skin cell collection and application technology that can be used to treat burns, restart healing in unresponsive wounds and improve functional and aesthetic outcomes of damaged skin. This "spray-on skin" cell suspension technology, which was developed by Professor Fiona Wood, director of the Royal Perth Hospital Burns unit and 2005 Australian of the Year, and used to treat victims of the Bali bombing in 2002, provides treatment solutions derived from a patient's own skin, is applied at the point of care setting and is commercialised in Australia, EU, Canada, China and Taiwan. While arguably having all the markings of a "revolutionary" technology, the company has failed to live up to this claim, with insufficient clinical evidence, regulatory delays, a mismatched product portfolio (eg respiratory, cell culturing products and regenerative technologies) and an incoherent commercialisation strategy conspiring to limit sales growth. Shareholder discontent is evident to us, with shares essentially range bound (between A$0.05-0.20) over the past eight years, a sub-A$100m market cap and far away from its A$12 ASX debut as Clinical Cell Culture more than 20 years ago.

So what has changed and why do we believe investors should be more optimistic about the future? While the core technology remains the same, which we view as sound, backed by a growing body of peer-reviewed, level-one clinical evidence, safely used in more than 6.5k patients and targeting a growing market with unmet medical need, we believe leadership changes have overhauled commercial prospects and thus, the company deserves another look.

Specifically, under the auspices of a new marketing-savvy CEO and commercially-driven renewed board, the marketing mix looks much better positioned to drive uptake across the product portfolio given:

- **Product -** an exclusive focus on regenerative medicine (ie the legacy respiratory business was recently sold for A$2.64m); repositioned as a treatment adjuvant as opposed to replacement therapy and based on the underlying mechanism of action, Regenerative Epithelial Suspension (RES™), allowing for rebranding into multiple product offerings (ie ReCell®, ReGenerCell™ and ReNovaCell™) to address different market segments (acute wounds, chronic wounds and aesthetics, respectively);
- **Price -** seems reasonable at cUS$1,500 per procedure, with good progress on reimbursement efforts across multiple geographies and supportive healtheconomic data;
- **Promotion -** optimised combination of distributors (new contracts inked in UK, France, South Korea, Japan and China) and direct sales (taking footprint to 28 people versus 6 previously), with increased thought leader engagement to better educate surgeons, nurses and wound care specialists end-users; and
- **Place -** multichannel customer base (eg hospitals, burn centres, wound care centres and trauma centres), which focus on the top decile prescribing base.

Management has also sought and secured government contracts, effectively underwriting further clinical development with non-dilutive financing and lowering cash utilisation. The company is also one of the first to be granted eligibility for earlier regulatory approval of ReCell® in burns under the FDA Expedited Access Pathway (EAP) guidelines, a new program aimed at helping patients get more timely access to life-saving medical devices. This program allows for expedited commercial filing for its ongoing US pivotal acute burn trial and should shave considerable time off previously flagged timelines (prior 3Q17).

We initiate coverage with an ADD recommendation and A$0.57 target price, using a combined DCF/SOTP methodology.

Investment highlights

A unique, proprietary regenerative medicine product portfolio

AVH has developed a proprietary skin collection and application technology that provides treatment solutions derived from a patient's own skin (ie autologous). This single-use technology is based on RES™ (regenerative epithelial suspension), an autologous suspension comprising cells and wound healing factors necessary to regenerate natural, healthy skin. AVH's products deploy the same approach, but vary in presentation based on the cause and size of the wound targeted. Three product iterations include: 1) ReCell®, positioned to treat acute wounds (eg burns/scars); 2) ReGenerCell™, targeting chronic wounds (eg venous leg ulcers and diabetic foot ulcers); and 3) ReNovaCell™, aimed at improving functional and aesthetic outcomes (eg repigmentation, scar revision). Thus, the product offering is positioned to address a broad range of applications and targets large market opportunities. While all three products are CE-marked, only ReCell® is TGA-registered in Australia, CFDA-cleared in China and has been used in more than 6.5k patients in more than 30 countries.

New management, new strategy, and new growth prospects

Over the last year, the company has undergone a strategic re-positioning. Under new leadership, the company has taken a more incremental transition to wound care, where products complement existing therapies, and the focus is on accumulating clinical studies and clinical/health-economic benefits when achieving healing and/or improved skin appearance. We believe this much more structured approach improves the fundamental outlook for the company, helping to differentiate product characteristics and beginning to grab the attention of physicians worldwide.

Products underpinned by accumulating clinical data

AVH boasts more than 60 conference presentations and peer-reviewed publications to underpin its product offering in burns, chronic wounds and aesthetics. Admittedly, most of these reports are based on case studies, reviews and retrospective analyses, which have limited strong translation into clinical practice and wider adoption, in our view; however, we note at least five completed randomised controlled trials (RCT) and at least 12 other studies are underway or pending. We believe these data provide strong clinical validation of the company's regenerative medicine technology in triggering healing in burns, helping with scar revision and repigmentation and in cosmetic procedures and should help support a lift the sales trajectory.

Compassionate use IDE program in the US

In April 2014, FDA approved ReCell® for an Investigational Device Exemption (IDE) specifically for compassionate use, limiting its use to treatment of up 12 subjects with life-threatening wounds and who have insufficient healthy skin available for standard skin grafting of their injury. These 12 cases have been conducted with success at several leading institutions, including: Wake Forest Baptist Medical Center, Maricopa Medical Center, Walter Reed National Military Medical Center and MedStar Washington Hospital Center. In October 2015, the FDA expanded the IDE program to 24 subjects, followed by a 50% increase to 36 subjects in March 2016. We believe expanding the number of compassionate use cases and broadening ReCell®'s application will help accelerate educational efforts and support a more rapid uptake.

Well defined regulatory pathway for ReCell® US pivotal acute burn trial…

AVH is currently conducting a randomised, within subject controlled, US pivotal trial to support a PMA application for ReCell® in the US. The trial is evaluating the safety and effectiveness of ReCell® in combination with meshed skin autograft for treatment of a broad range of acute burn injuries in up to 30 patients. The study has co-primary endpoints: 1) non-inferiority of ReCell®/Mesh combo versus graft alone in the incidence of complete wound closure rate at eight weeks (additional procedures aiding wound closure are allowed); and 2) superiority of ReCell®/Mesh combo versus conventional autograft alone on the expansion ratio (donor:treatment area) at time of treatment. In addition, there are three secondary endpoints at 24 weeks: subject preference, blinded observer and patient scar rating. We view these hurdle rates as relatively low implying the trial has a high probability of success. AVH announced complete patient recruitment on 11 January 2016.

…with FDA Expedited Access Pathway (EAP) designation granted

FDA recently ruled ReCell® is eligible for earlier regulatory approval for burns treatment. Notably, the ruling falls under Expedited Access Pathway (EAP) guidance and was given as ReCell® offers 'significant, clinically meaningful advantages' over other current alternatives in the US for burns treatment. Management is in discussions with FDA to determine the specific data required to support an expedited commercial filing. Together with priority review, considerable time would be shaved off prior management guidelines (prior 3Q17).

Chronic venous leg ulcers (VLU) on a healing trajectory

We believe the RES™ technology platform is also amenable to helping promote healing of chronic wounds that are unresponsive to conventional treatments, possibly due to comorbidities such as diabetes, obesity and/or poor circulation. A randomised study compared the addition of RES™, prepared by using ReGenerCell™ device, to conventional medical therapy in 52 adult patients with venous leg ulcers (VLU) across seven centres (one UK; six France) for 14 weeks. Encouragingly, the study showed a statistically significant improvement across multiple metrics including: wound size (closing an average of 9.1 cm^2 vs 1.2 cm^2, p=0.014); pain (c2 point drop on a 10 point scale vs no change; p=0.017); and health-related quality of life (using the Charing Cross Venous Leg Ulcer Questionnaire - improvement seen in social interaction, domestic activity, emotional status and cosmosis, with statistical significance shown on emotional status, p=0.044). Positive trends were also seen in healing time and incidence of closure, particularly in large ulcers (>10 cm^2), which comprise the majority of VLUs. Specifically, complete wound closure was 26.9% vs 15.4%, with large ulcers (>10 to ≤80 cm^2) showing a closure incidence of more than 3x vs control (23.1% vs 7.1%), and mean closure time of large ulcers was 43 days vs 84 days. On the safety front, no differences were noted between the groups. Management plans to incorporate results into discussions with regulatory authorities to determine next steps for ReGenerCell™ in VLU.

Recent BARDA contract win helps mitigate the cash burn

In September 2015, the Biomedical Advanced Research and Development Authority (BARDA), a unit of the United States government responsible for federal disaster preparedness, granted AVH up to US$53.9m in a five-year contract to establish an inventory of more than 5k ReCell® devices that can be deployed to help deal with a mass casualty scenario involving burn injuries. Specifically, BARDA committed an initial US$16.9m to support the company's ongoing US clinical regulatory program towards FDA approval and to establish an initial inventory of over 5k devices. There are additional contract options valued up to US$37m to support additional clinical trials potentially required by the FDA as part of post-market surveillance, or as needed to expand the use of ReCell® to the paediatric population, and provide surge capacity for up to 20k additional ReCell® devices. Management has been invoicing the United States government monthly since last October, with revenue expected 1Q16. We believe this contract not only lends credence to the usefulness of AVH's point-

of-care technology to regenerate healthy skin damaged from burns, highlighting the increased importance of mass casualty preparedness involving burn injuries, but also provides AVH with a significant source of non-dilutive capital.

Strategic divestment of Australian respiratory business adds to cash

AVH operated a respiratory business that sold two products, Breath-A-Tech and Funhaler, both asthma spacers aimed at optimising the use of medicinal puffers in paediatric and adolescent/adult patients, respectively, and are sold in pharmacies throughout Australia. In December 2015, the respiratory business was sold to Medical Developments International (ASX: MVP) for A$2.64m, comprised of A$2.2m cash plus, at MVP's option, either 125k new MVP shares escrowed for six months (adjusted based on the five-day VWAP prior to completion) or A$0.44m cash. We believe deal metrics are reasonable and will not only provide a source of non-dilutive capital, but will also allow management to fully focus on growing its regenerative medicine business.

Healtheconomic benefits emerging

Healtheconomic data is increasingly being used to obtain reimbursement or justify product pricing in an effort to reduce healthcare spending and elevate the economic burden on health care systems globally. In fact, Healtheconomic data currently forms an integral part in shaping the recommendations from the National Institute for Health and Care Excellence (NICE) in the UK to the Affordable Care Act in the US, where there is committed budget spend to carry out comparative effectiveness research on treatments. We also note the trend by health systems to shift towards 'payment for performance' schemes in an effort to promote high quality care and increase the effectiveness of treatments. In this changing environment, we believe providing technologies that deliver value by improving clinical outcomes, simplifying procedures and reducing cost is key for product success and sustainability. Recent findings from 12 cases (eight adults; four children) at Wake Forest Baptist Medical Center's Burn Center showed length of hospital stay for patients with extensive burn injuries decreased by 63% when ReCell® was used in conjunction with autografting compared with published age-matched averages for autografting alone. Specifically, the combination of ReCell® and autograph appears to reduce risks of graft loss, poor functional/aesthetic outcomes and injuries heal earlier, allowing doctors to achieve primary closure of wounds up to 12,000 cm^2 in a single procedure as opposed to requiring multiple, staged operations.

US DoD trial ongoing in trauma wounds

The US Department of Defense (DoD) research program funded trial is underway at Walter Reed National Medical Center. The study is evaluating how ReCell® can be used to treat trauma wounds suffered by civilians and military personnel. While the trial is investigator-initiated, AVH does play a supportive advisory role. Given that physicians are often limited in choice of donor sites for skin grafts when treating injuries associated with severe trauma, AVH believes there is a tangible need for an acceptable alternative to conventional skin autografting.

Strong IP

We believe AVH has a robust intellectual property portfolio for its regenerative technology platform. ReCell®, ReGenerCell™ and ReNovaCell™ are protected by a family of patents and patent applications covering unique composition of final product, method of production, device and automation for methods and apparatus to generate epithelial suspension. Last May, AVH was issued a new US patent covering the methods for producing and using a transplantable cellular suspension of living tissue suitable for grafting to a patient forming an essential component of ReCell®, novel autologous skin regeneration therapy platform. We believe this new patent strengthens and expands AVH's overall patent coverage for ReCell®. AVH's pending worldwide patents and applications will expire in 2022 to 2034.

Pipeline

Figure 2: Products

Product	Description	Indication	Market opportunity	Development stage	Comment
Recell	Regenerative cell therapy	Acute Wounds- repair with less donor skin	US$350m+	CE Marked Phase III- US trial	Selling into hospitals, burn/trauma centres
Regenercell	"	Chronic wounds- restart healing	US$1bn+	CE Marked	Selling into hospitals and wound clinics
Renovacell	"	Aesthetics- restore pigmentation, improve scaring	US$500m+	CE Marked	Selling into private clinics

SOURCES: MORGANS, COMPANY REPORTS

Catalysts

Figure 3: Key inflection points

Product	Indication	Event	Timing	Significance
Recell	Acute wounds-burns	US pivotal trial data	2Q16	+++
"	"	FDA PMA submission (post 52 wk safety data)	1Q17	++
"	"	Potential FDA approval	3Q17	+++
"	"	Potential FDA approval under EAP	1H17	+++
Regenercell	Chronic wounds- VLU	Next steps post- pilot study	1H16	+++
"	"	Start 2nd study	Mid-16	+++
"	Chronic wounds- DFU	Complete feasibility study	3Q16	+++
Renovacell	Aethetics	SNIP Pigmentation defects study	2H16	+++

SOURCES: MORGANS, COMPANY REPORTS

Valuation

We utilise an equally blended risk-adjusted sum-of-the-parts (SOP) and DCF analysis to capture fair value. Using the first approach, peak sales estimates are risk-mitigated based on our assumptions of the probability of commercial success and years to launch, and discounted based on an appropriate cost of capital. We assume ReCell® peak sales of A$200m, with a 75% probability of success. In addition, we include A$750m in potential sales for ReGenerCell™ and A$350m in ReNovaCell™, with a 70% probability of success. Applying a 4x sales multiple and less than A$0.01 in cash per share, we derive a combined value of A$0.67 per share.

Figure 4: SOP valuation

SOTP	Disct Rt	Yrs. to Mkt	% Success	Peak Sales (AUD Mln)	Yrs. to peak sales	Sales multiple	Value (AUD$M)
Recell	15%	0	75%	200	5	4	$780.00
NPV							**A$0.19**
Regenercell	15%	3	70%	750	7	4	$2,775.00
NPV							**A$0.48**
Renovacell	15%	4	70%	350	8	4	$1,295.00
NPV							**A$0.19**
Net Margin							30%
Mln Shrs OS							459.59
Total							**A$0.67**
Cash/Shr (est)							A$0.01
Net value							A$0.67
Target Price							**A$0.67**

SOURCES: MORGANS, COMPANY REPORTS

Our DCF analysis ascribes fair value of A$0.47 per share (WACC of 15%, long-term growth rate of 3%).

Figure 5: DCF valuation

DCF	Disct Rt	Long term growth rate	NPV (AUD$m)	Terminal value (AUD$m)	Firm value (AUD$m)	Per share value
	15%	3%	43	175	218	A$0.47
Net value						A$0.47
Target Price						**A$0.47**

SOURCES: MORGANS, COMPANY REPORTS

Taken together, we arrive at a fair value per share of A$0.57.

Figure 6: Blended valuation

Metric	Weight	Valuation (A$ per share)	Blended Valuation (A$ per share)
DCF	50%	0.47	0.24
SOP	50%	0.67	0.34
Blended Equity Valuation	100%		0.57
Target price			**0.57**

SOURCES: MORGANS, COMPANY REPORTS

Financials and Morgans estimates

Revenues: Over the past five years, AVH has generated A$17.4m in product sales. However, growth throughout this period was stagnant (0.1% CAGR) as we believe the commercialisation strategy wasn't optimal. In FY15, product sales increased 2.5% to A$2.75m, with ReCell® sales improving 25% driven by a new management team focused on a strategy underpinned by continued clinical evidence and focused sales effort in its key markets, including a 28% increase in the UK, 13% in Australia and New Zealand, 81% in Germany and 88% in China.

In 1HFY16, total sales of A$1.6m were flat on the pcp. Importantly, ReCell® sales increased 17% yoy underpinned by strong EU sales in Germany (+213% yoy) and France (+54% yoy). UK sales growth was flat on the pcp, but increased 9% yoy in 2QFY16. Total 2QFY16 sales growth was down 39% to A$629k, impacted by the transition to new distributors. Further distributorships were signed in South Korea and Japan in January 2016 and most recently, in China, with Sinopharm, the largest healthcare group in the region, granted sole rights to AVH's product range. We believe sales can quadruple when all markets come on line.

Manufacturing: AVH has a comprehensive suite of quality, manufacturing and management systems in place as well as certified reviews and control verifications across its portfolio of medical products. The company has maintained ISO 9000, ISO 13485 and medical device directive certification via completing annual ISO Quality Recertification Audits to maintain its CE mark. In addition, AVH has a formal continuous improvement system in place that has yielded improved margins and reductions in operating costs. The manufacture of the proprietary ReCell® Enzyme was relocated to a specialist US-based manufacturer in 2012 to yield significant advances in the manufacturing process and performance.

Cost of goods (COGs) sold have averaged A$790k pa over the past five years. In FY15, COGs were A$755k, an increase of 13% yoy due to manufacturing cost gains, with GP of A$1.99m down 9%. This included the regenerative products and the company's respiratory products, Funhaler and Breath-A-Tech.

Operating expenditures: Annual growth in opex has increased 12% since 2010, comprised of SG&A and R&D growth of 19% and 64%, respectively. In FY15, opex was A$10m (+10.1% yoy), with SG&A of A$3.2m (+22%), R&D of A$2.3m (+8.3%) and general administrative expenses of A$4.4m (+3.7%). The bulk of the expenses were from increased global sales and marketing efforts and to complete clinical trials in Europe, Australia and China.

In 1HFY16, opex was A$7.0m, equating to annualised expenditure of A$14m. We estimate opex growth at a CAGR of 3% through 2020, with SG&A annual growth of 5% and R&D annual growth declining by 10%. Our estimates attempt to account for management's focus on a limited number of key markets, working with select distributors or dedicated sales consultants. Several clinical trials have also commenced to further develop clinical evidence in key indications.

Low tax rate due to NOLs: AVH had an accumulated deficit of around A$113.5m exiting FY15, with an estimated additional A$13.5m through 2018. As such, we believe the company has considerable net operating losses (NOLs) to act as credit against tax expenses when it reaches profitability (we estimate 2019).

Net income: In FY15, AVH reported a net loss after tax of A$7.2m (-38% yoy). We forecast profitability of A$7.6m in 2019 ramping up to more than A$100m over the next four years.

Balance sheet: AVH had A$2.97m in cash and no debt exiting FY15. However, funding doesn't look to be a near-term problem, given the BARDA contract win last September is slated to provide up to US$53.9m (A$73.8m) in funding over a five-year period. In addition, the company completed an A$10m equity raise last October (issuing 107.7m shares at A$0.093) to support its ongoing growth efforts and recently sold its respiratory business for A$2.64m (comprised of A$2.2m cash and A$440k in stock). The company exited 2QFY14 with A$7.7m in cash on hand. While we believe this capital and US government contract revenues should provide sufficient capital for at least the next 12 months, given the ramp-up of commercial activities and ongoing clinical development, we have incorporated an equity raise of A$10m in CY16, which should provide adequate capital to see the company through to profitability.

Risks

Developmental risk – The success of the regenerative medicine technology and lead product candidate ReCell® is reliant upon ongoing evidence of a favourable risk/benefit profile in clinical studies. If products fail to demonstrate the required clinical specifications or cause adverse or unexpected events, the technology may be questioned.

Commercial risk – The success of AVH's regenerative medicine portfolio is dependent upon market acceptance. In most markets throughout the world, expenditure on medical devices is ultimately controlled to a large extent by governments. As such, AVH is largely dependent on future governments providing increased funds commensurate with the increased demand arising from demographic trends, with pricing largely influenced in most developed markets by governmental reimbursement authorities. While we have based our estimates and forecasts on the targeted patient populations and various market penetration rates, we remind investors that uptake for this novel device is difficult to estimate at such an early stage in its life cycle, with changes to our key metrics potentially having a material impact on our projections.

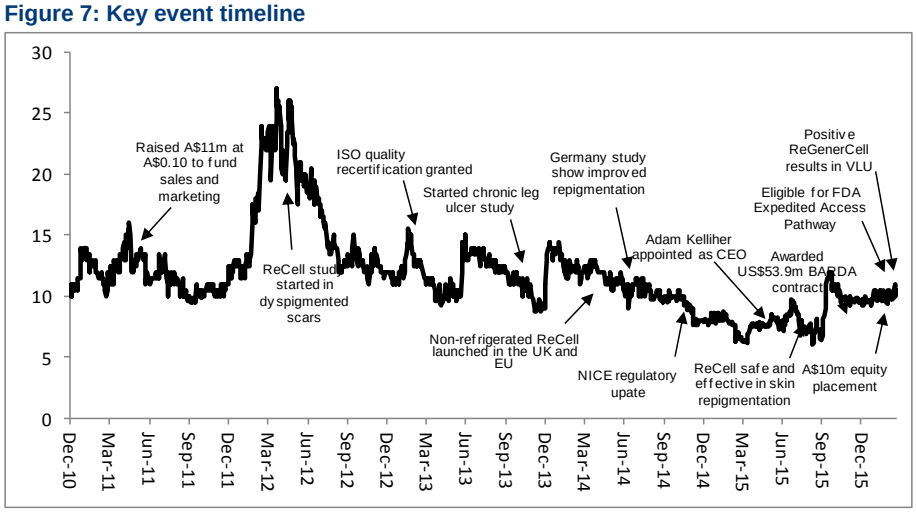
Regulatory risk – The international medical device industry is highly regulated, with a complex series of laws and regulations governing the design, development, approval, manufacture, labelling, marketing and sale of healthcare products. Data supporting safety and efficacy of products are constantly being reviewed by regulatory agencies. Moreover, these bodies are intensifying audits of manufacturing facilities and approval times for new products have lengthened.

Financial risk – While we estimate the company should have sufficient funds post an estimated A$10m capital raise to reach profitability, there is no guarantee additional funds will not be required and shareholders incur substantial dilution.

Company description

Avita Medical (AVH), domiciled in Perth Australia and restructured out of 1993 ASX listed Clinical Cell Culture in June 2008, is a medical device company that develops and sells regenerative medicine-based products for the treatment of a broad range of wounds, scars and skin defects. Three products encompass its competitive offering, which include: ReCell®, positioned to treat acute wounds (eg burns/scars); ReGenerCell™, targeting chronic wounds (eg venous leg ulcers and diabetic foot ulcers); and ReNovaCell™, aimed at improving functional and aesthetic outcomes (eg repigmentation, scar revision). The company's unique, patented, skin cell collection and application technology underpins all products and is based on RES™ (epithelial cell suspension), derived from a patient's own skin (ie autologous). The single-use RES™ application comprises skin cells and wound healing factors necessary to regenerate natural, healthy skin in the point of care setting (approximately 30 minutes). All three products are CE-marked, while only lead product ReCell® is TGA-registered in Australia, CFDA-cleared in China and has been used in more than 6k patients in 32 countries. As of 30 June 2015, the company has 21 FTEs, with clinical, regulatory and financial operations conducted out of Los Angeles, California, and commercial operations in UK and Asia. Shares are also traded as US ADRs (OTC- AVMXY).

Figure 7: Key event timeline



SOURCES: MORGANS, COMPANY REPORTS

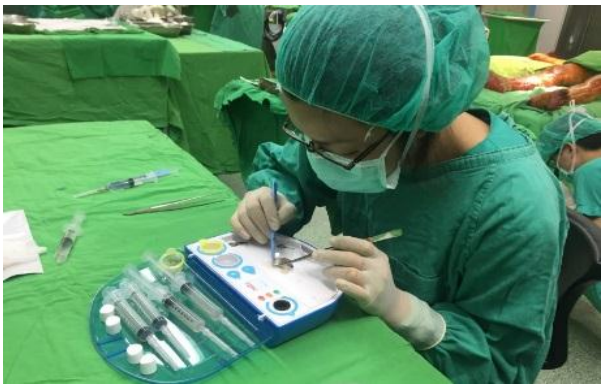
What is ReCell®?

ReCell® is a battery powered skin regeneration system that uses a patient's own skin cells (ie autologous) to treat wounds and skin defects. The device includes sterile enzyme soak-, buffer rinse- and filtering- chambers and a sterile tray for mechanical disaggregation of skin samples. Other components include a proprietary enzyme formulation to disaggregate the cells and a validated set of applicators designed to overlay the wound area with the suspension of healthy cells.

Figure 8: ReCell®

SOURCE: MORGANS RESEARCH, COMPANY

Figure 9: Clinical use



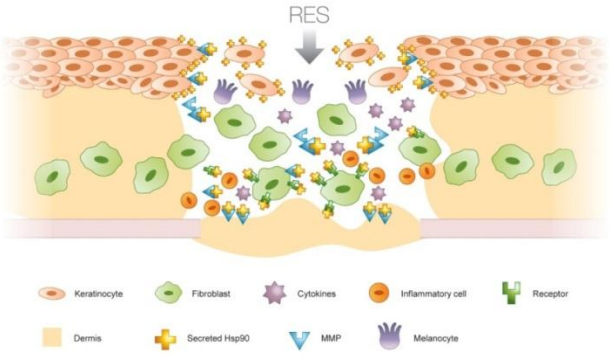
SOURCE: MORGANS RESEARCH, COMPANY

Specifically, healthcare professionals add a 0.15-0.20mm thick piece of skin, measuring up to 2x2 cm from the donor site, to the proprietary enzyme solution in the processing unit and heat for 15-30 minutes to disaggregate the cells. The skin is removed from the solution, scraped with a scalpel to develop a plume of cells and then added to a buffer solution, aspirated and filtered to create a Regenerative Epithelial Suspension (RES™) that contains all key cell types. The RES™ is delivered via a spray applicator or can be dripped directly onto the site.

How does ReCell® work?

RES™ is comprised of multiple cell types (eg keratinocytes, fibroblasts, melanocytes) as well as a myriad of signalling molecules (eg cytokines, chaperones like hsp90, growth factors) that help with the epidermal regenerative healing process upon application to the wound and restore normal pigmentation. Normally, skin cells are part of intact tissue. However, when the skin is disrupted, the cells at the wound edge no longer have neighbouring cells, which changes them into an activated state that initiates migration and proliferation. Without RES™, this effect only happens at the wound edge and is a limitation of sheets or grafts of cells. On the other hand, a RES™ population of disaggregated cells is introduced across the entire surface area of the wound, are highly proliferative and able to survive in a hostile wound environment, overcoming the usual limited resource of the wound edge. The loss of contract inhibition has been referred to in the literature as 'free edge' effect. Thus, introduction of RES™ is a way of creating a free-edge effect over the entire surface of the wound, rather than only at the wound edges to promote healthy cell growth and rapid healing.

Figure 10: RES™ mechanism of action



SOURCE: MORGANS RESEARCH, COMPANY

Value proposition

We believe AVH's treatment platform is competitively positioned as an adjunct to other methods, given its unique ability to offer improved characteristics compared with conventional mesh autograft, micro autograft, cultured epithelial autograft and skin substitute. It is also used on skin graft donor sites, helping to reduce healing time and allowing further grafts to be taken earlier from the same site in the treatment of very large burns. We highlight the key features below that we believe may translate into improved patient benefits.

Figure 11: Competitive attributes

Characteristics	RES	Conventional mesh autograft	Micro autograft	Cultured epithelial autograft	Skin substitute
Autograft sparing	+	-	+	+	+
Single unit capacity	+	-	+	+	+
Short term- healing	+	-	-	-	-
Long term- less scaring	+	-	-	+	-
Ease of use (1 hour training; 30 minute preparation time- sample, process, prepare, deliver)	+	-	-	-	+
Patient cost	+	-	+	-	-
Device price	+	NA	+	-	-
Use limitations	+	+	+	-	-

SOURCES: MORGANS RESEARCH, COMPANY REPORTS

In addition, we believe as a light weight and easily transported device that doesn't require refrigeration and has a two-year shelf life, it is optimally suited for field hospitals and emergency disaster facilities. As such, we expect ongoing interest from governments focused on disaster preparedness, as seen with the US$53.9m, five-year contract with the Biomedical Advanced Research and Development Authority (BARDA) and treatment of trauma wounds as seen with the current US Department of Defense (DoD) sponsored trial.

Wound care management market

Wound healing is a complex, multifactorial process that involves the activation of intracellular and extracellular events leading to tissue remodelling and wound contraction. There have been many strategies employed and products commercialised for the treatment of wounds, from various dressings (eg gauze, foam, films), to devices (eg ultrasound, negative pressure therapy) to biologics (eg skin replacements, collagen therapies), with advancements in the clinical understanding of wounds expanding the treatment landscape.

These dressings and products are used for the management of both acute and chronic wounds, impacting as many as 6.5m patients pa in the US. Acute wounds are defined as sudden skin injuries that tend to heal at predictable and expected rates over time. This wound type tends to be caused by surgical intervention, trauma or burns. Chronic wounds are defined as skin injuries where the normal wound healing process is extensively delayed, possibly due to comorbidities, such as diabetes, obesity and/or poor circulation. Common types of chronic wounds include: diabetic foot ulcers (DFU), venous leg ulcers (VLU), pressure ulcers, arterial ulcers, and infected surgical wounds.

In both acute and chronic wounds, the treatment goal is to heal the wound while allowing natural function in the area of the wound with minimal scarring and infection. If a wound becomes infected, it can lead to the loss of limb or life, so it is paramount to close the wound as quickly as possible to minimise this risk. However, we estimate there are c50m reported cases globally of patients suffering from hard-to-close wounds despite advanced dressings. In the US alone, roughly 30m individuals suffer from diabetes, with c1m of those individuals affected by chronic wounds, with 14-24% eventually requiring amputations and a 45% five-year mortality rate post-amputation higher than that of many cancers.

Numerous and lengthy treatments (averaging 17 prior to closure) required to address patients with chronic wounds also comes at significant cost to the healthcare system. More than US$25bn is spent annually in the US on treatment of chronic wounds, with the average cost per patient with a non-healing wound cUS$4k, chronic DFU cUS$5.4k and with chronic VLU cUS$7.5k. The cost burden to the US healthcare system has been so severe that the Center for Medical and Medicaid Services (CMS) has changed the reimbursement policy for wound care, providing economic incentives for hospitals to improve care and reduce costs.

Aside from application in both acute and chronic wounds, we also believe AVH's tissue platform may have the potential to improve skin aesthetics in a variety of settings, including: repigmentation and scar reduction (eg plastic surgery).

Market size

We estimate the global market for wound care management products is worth cUS$15bn, with annual growth rate of c3.5% through 2020, targeting sales of US$18bn, driven by:

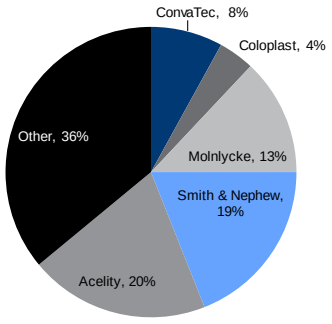
- Rising awareness of new technologies - that decrease healing times and provide cost savings
- A growing focus on special populations - diabetics, obese, smokers
- An aging global population – growing the addresssable market
- Wound care biologics - taking centre stage with new bioactive products
- Emerging markets - targeting emerging economies Brazil, China, India

We segment the wound care management market based on five product types, including: traditional wound care; basic wound care; advanced wound care; bio-active wound care; and therapy devices.

The advanced wound care market

We estimate the cUS$5bn advanced wound care segment represents the largest part of the global market for wound care and is characterised by rapidly evolving technologies and intense competition. Advanced wound care involves numerous products (eg collagen products, hydrocolloids, film dressings, hydrogels, composites, alginate dressings, and hydrofibers) that are used when standard wound care treatments fail. While global competitors vary across product areas and geographies, five large diversified players (eg Kinetic Concept (20%; US), Coloplast (Denmark; 4%), ConvaTec Healthcare (US; 8%), Mölnlycke Health Care (Sweden,13%), Smith & Nephew (19%; UK)) tend to control 60% of the market, with the remainder highly fragmented among "pure plays" private and micro-cap companies.

Figure 12: US$5bn+ advanced wound management revenue market share - 2014



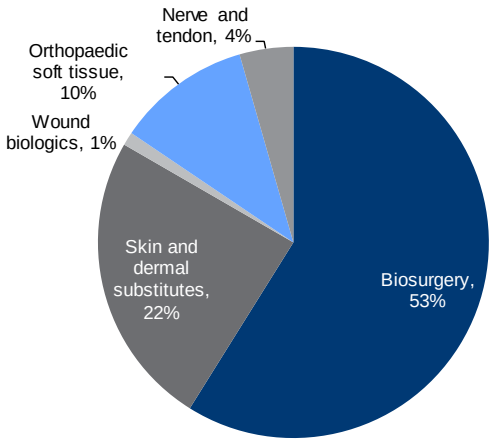
SOURCES: MORGANS RESEARCH, COMPANY REPORTS

Regenerative technologies - the skin substitute market

The advanced wound care segment is also the fastest growing (c5% per annum) across the broader wound care market, not only given the aforementioned drivers increasing the number of addressable wounds, but the clear medical need and market dynamic shift from conventional to more sophisticated, “regenerative” wound care products/technologies.

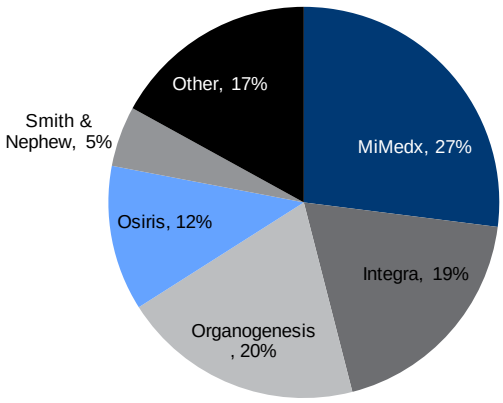
We view the cUS$2.5bn regenerative wound care segment of the advanced wound care market as the key target market for AVH, with the main focus on cUS$600m skin and dermal substitutes segment. In the graphs below, we highlight the main global competitors across this segment, core technologies and specific application of treatment.

Figure 13: Regenerative technologies revenue market share - 2014



SOURCES: MORGANS RESEARCH, COMPANY REPORTS

Figure 14: US skin substitute revenue market share -2014



SOURCES: MORGANS RESEARCH, COMPANY REPORTS

Figure 15: Skin subsititues - competitive positioning

Company	Brand	Technology	Severe Burns	DFU	VLU	Dermatology	Other
Avita Medical	ReCell ReGenerCell ReNovaCell	Autologous cell therapy	+	+	+	+	
Alliqua Biomedical	Biovance	Dehydrated, amniotic-based allografts		+			
Cytori Therapeutics	Cytori cell therapy	Adipose tissue-derived stem cells	+		+	+	+
Derma Sciences	Amnioexcell Amniomatrix	Amnitoic extracellular matrix; cryopreserved placenta-derived liquid		+			
Integra Life Sciences	Dermal regeneration matrix	Silicone film and crosslinked fiber matrix skin substitute	+	+			+
MiMedx Group	AminoFix EpiFix	Dehydrated, amniotic-based allografts		+	+		+
Organogenesis	ApliGraf DermaGraft	Allogenic, bio-engineered, cell-based therapy		+	+		
Osiris Therapeutics	Grafix	Cryo-preserved human placental membrane		+	+		
Vericel	EpiCel	Cultured epidermal autografts	+				+

SOURCES: MORGANS, COMPANY REPORTS

Acute wounds - burns

We believe ReCell® is well-positioned to address the US$350m+ burn market, with clinical data demonstrating comparable healing times with skin grafts, decreased donor skin requirements, reduced scarring and fewer follow-on procedures that should translate into improved healtheconomics. Notably, when a patient has limited available healthy skin (eg after an extensive burn injury), they tend to undergo multiple operations, as the healthy area is harvested, allowed to heal and reharvested repeatedly until enough autograft can be produced to close the burn injury. While expanding meshed autograft has reduced the requirement for donor harvesting, it ordinarily creates risk of graft loss and poor scar outcomes. With RES™, widely meshed autografts achieve closure with less skin, offer better scar outcomes and result in decreased hospital length of stay. These attributes have been described in more than 30 clinical studies and medical conference presentations. While most of these investigations and presentations are based on case series, reviews and retrospective analyses, we highlight in the table below results from three randomised controlled studies (RCT) involving 110 patients providing level-one evidence supportive of these claims.

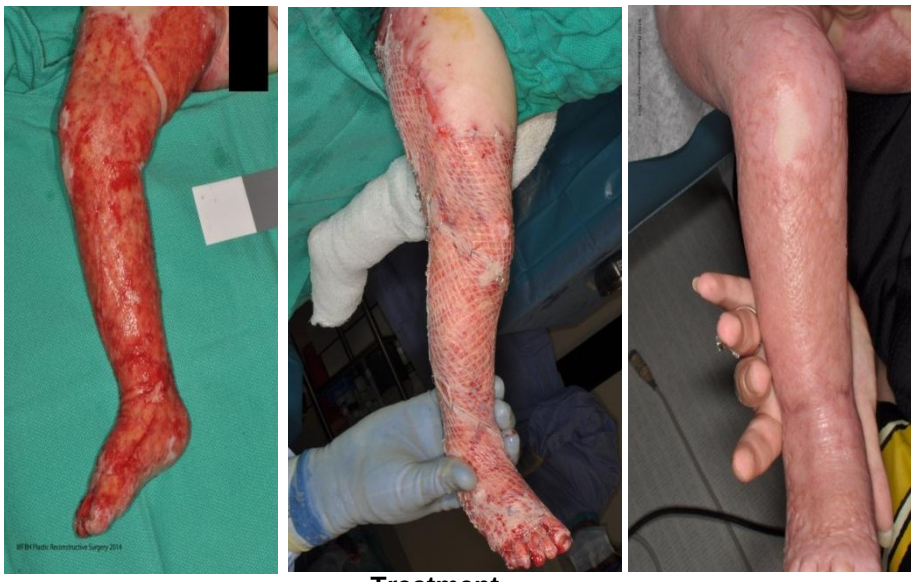
Figure 16: Data in acute wounds

Author	Design	Publication	N	Endpoints	Comment
Campanella SD, et al	RCT comparing silicone net dressing Mepitel and polyamide woven dressing Surfasoft on paediatric donor sites treated with ReCell	Burns 2011; 37(8):1334-42	15 children (1-15 yrs) with acute or reconstructive burns	Rate of epithelialisation and epidermal maturation, pain, and ease of dressing removal on paediatric donor sites treated with ReCell	Mepitel was shown to improve healing of ReCell treated donor sites with less pain at dressing changes No difference was seen in the rate of epidermal maturation between the two groups
Gravante G, et al	RCT comparing ReCell to classic skin grafts for deep partial thickness burns	Burns 2007; 33(8):966-72	82	(i) Time for complete epithelisation (treated and biopsy site) (ii) Aesthetic and functional quality of the epithelisation (color, joint contractures) (iii) Infections, inflammations, adverse effects, medications assumed, postoperative pain	ReCell showed effective healing with reduced donor area and less postoperative pain (p=0.03) vs skin grafting Skin grafting was faster than ReCell for epidermal replacement (p<0.05). Aesthetic and functional outcomes were similar between procedures.
Wood F, et al	RCT comparing standard treatment to biosynthetic skin dressing Biobane with and without RES, paediatric scald injuries	Burns 2012;38(6):830-9	13 paediatric patients with partial thickness scald injury (2% TBSA or more and non-healing within 10 days)	(i) Tissue salvage (ii) Reducing in the incidence of definitive surgery at 10 days following scald injury	Biobrane + RES showed effective healing (no grafting), less pain and better scar outcomes Saved on nursing time, dressing, pain and scar management costs when used within 4 days of injury

SOURCES: MORGANS, COMPANY REPORTS

We also highlight an example below showing the use of ReCell® on a patient with a 30% total body surface area (TBSA) third degree leg burn. ReCell® was used with mesh skin graft and resulting in faster healing, minimal down skin usage and improved appearance than the typically expected mesh shaped scaring seen with skin grafting.

Figure 17: ReCell® with mesh graft before, during and after treatment



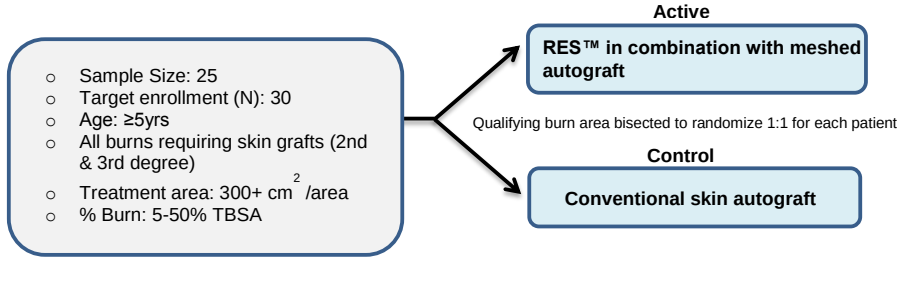
SOURCES: MORGANS,RESEARCH, COMPANY REPORTS

While we view these data as promising, limited patient numbers, anecdotal reports and the lack of additional level-one evidence, make it difficult to assess the clinical utility of ReCell® and to know which patients might benefit the most from its use. In fact, in November 2014 the National Institute for Health and Care Excellence (NICE) recommended further research into ReCell®'s ability for treating skin loss, scarring and depigmentation after burn injury. We view the lack of sufficient evidence on its clinical use as a significant impediment for wider ReCell® adoption.

US FDA pivotal trial

Encouragingly, management aims to address this concern by conducting a randomised, within subject controlled, US pivotal trial to evaluate the safety and efficacy of ReCell® in combination with meshed skin graft for treatment of a broad range of acute burn injuries in up to 30 patients. The trial was designed with two co-primary endpoints: 1) non-inferiority of ReCell®/Mesh combination versus graft alone in the incidence of complete wound closure rate at 8 weeks (additional procedures aiding wound closure are allowed); and 2) superiority of ReCell®/Mesh combination versus graft alone on the expansion ratio (donor:treatment area) at time of treatment. The study also has secondary endpoints at 24 weeks that include: subject preference, blinded observer and patient scar rating. We view these hurdle rates as low indicating that the trial has a high probability of success. We highlight the trial design below.

Figure 18: US burn trial design



SOURCES: MORGANS RESEARCH, COMPANY REPORTS

The burn market

Burns are often extremely painful and highly traumatic as they can lead to permanent scarring, disfigurement or death. The treatment of burns is based on the amount, depth and severity of the skin damage as well as the classification of the injury (ie superficial, partial or full-thickness). Whereas first degree burns are red and sometimes painful and classified as superficial/partial thickness burns, second degree burns are red/blistered, swollen and very painful and classified as partial thickness burns. A third degree or full thickness burn is where the skin is charred/translucent or whitish, with no sensation in the burned area.

There are multiple steps to burn management including: removing dead tissue, promoting healing, preventing wound infection and graft loss to maintaining function of the affected body part, and achieving wound closure as soon as possible. While the standard of care for most burns is silver sulphadiazine (SSD) based treatments, it suffers from a less-than-ideal side effect profile (eg pain, allergic reactions, low white blood cell counts). In the case of partial or full-thickness burns, skin grafting can be used to reduce the course of treatment needed and quickly restore skin integrity and appearance. Skin autografts require the removal of skin from a healthy part of the body (the donor site), the size and depth of which is determined by the original injury, and adhered to the wound via clips, skin glue or staples. A split-thickness skin autograft (STSG), the epidermis and part of the dermis is removed. It is either processed through a skin mesher, allowing it to expand up to nine times its original size, or unmeshed and referred to as sheet graft. The injured donor site heals by skin re-epithelialisation from the dermis and surrounding skin. A full-thickness skin autograft includes the epidermis and the entire dermis, with the donor site either sutured closed or covered by a STSG. Cultured epidermal autografts are also used as an adjunct therapy.

Market size

We estimate the worldwide burn-treatment market at cUS$3bn, growing at a CAGR of c4%. We believe the majority of the market is comprised of conventional, mature therapies (eg anti-infectives, basic burn management medications, and pressure-relief devices). However, we believe novel therapies (eg biologic dressings, artificial skin) that result in decreasing healing times and subsequent cost savings are driving growth.

We believe nearly 2.5m people seek medical care each year for burns in the US. According to the American Burn Association, c50k of these patients are hospitalised and 9.5k die from their injury. Children and elderly adults account for more than two-thirds of all burn fatalities. Specific guidelines exist for patient referrals to one of 121 regional burn centres (eg TBSA >10%; third degree burns; burns with other trauma), with 2012 admittances of 23k.

Figure 19: Burns statistics - 2014

	US	ROW
All burns	2,500,000	27,000,000
Outpatient visits	1,100,000	7,000,000.00
Hospitalisations	50,000	1,000,000
Second-degree burns	40,000	NA
TBSA >25%	20,000	NA
Deaths due to burns	9,500	1,200,000

SOURCES: MORGANS RESEARCH, AMERICAN BURN ASSOCIATION

Chronic wounds

We believe the RES™ technology platform is also amenable to promoting healing of wounds that are unresponsive to conventional treatments, possibly due to comorbidities such as diabetes, obesity and/or poor circulation. As mentioned previously, common types of these chronic wounds include: diabetic foot ulcers, venous leg ulcers, pressure ulcers, arterial ulcers, and infected surgical wounds.

Recently rebranded as ReGenerCell™ in the chronic wound setting, the product has shown encouraging signs of effectiveness in chronic wounds in a handful of published case studies. Improvements have been observed in healing rate and time to complete wound closure, while showing few complications, improved quality of life and enhanced healtheconomics. For example, B De Angelis *et al* (International Wound Journal 2013 February;12(1):32-9) reported to a 70% healing rate within 60 days of treatment in 20 patients with ulcers unresponsive to conventional therapies that averaged 18 months, with 80% healing seen in 20% of patients and three patients with DFU (28-month average duration) healing within 50 days. The author also noted improved pain scores by day seven postprocedure and that the function and aesthetics of the ReGenerCell™-treated patients were good.

We find these data promising and suggestive that ReGenerCell™ provides the regenerative tissue stimulation necessary to heal chronic ulcers, including those not responsive to more traditional methods. However, patient numbers remain modest (a little over 50) and definitive level-one evidence of utility is lacking. That said, a recently published RCT comparing RES™ combined with split-thickness autograft to autograft alone in 88 patients with chronic wounds, showed a statistically significant improvement in healing rates and time to compete healing, along with few complications and improved aesthetic features.

Figure 20: Data in chronic wounds

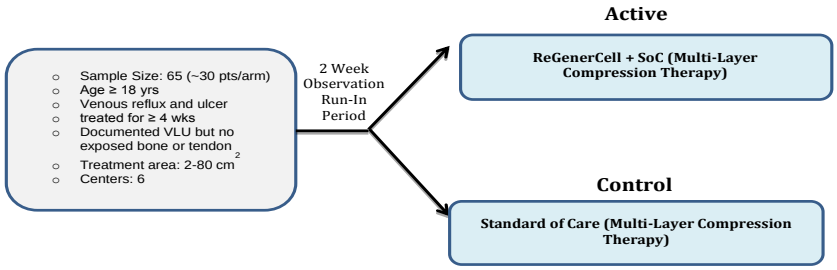
Author	Design	Publication	N	Endpoints	Comment
Hu ZC, et al	RCT comparing split-thickness autograft with and without RES	Br J Surg. 2015 Jan;102(2):e117-23	88 patients with chronic wounds	(i) Rate of complete wound closure by postoperative day 28. (ii) Quality of healing at 6 months	RES + autograft vs autograft alone showed a statistically significant: complete wound closure (41 versus 34 patients; p=0.035); shorter time to complete wound closure (14 days vs 20 days; p=0.001). fewer complications (4 vs 11 patients; p=0.047) better physical attributes reduced tendency for wound recurrence

SOURCES: MORGANS, COMPANY REPORTS

Pilot trial in VLU

Aiming to provide additional evidence to address any uncertainties about the patient and healthsystem benefits of ReGenerCell™, a UK-based randomised, multi-centre pilot study recently reported results in 52 adult patients with VLU. The RESTART study evaluated the efficacy of ReGenerCell™ in combination with standard compression device versus standard of care (SoC) alone for the closure of VLU. Patients were eligible for repeat ReGenerCell™ therapy at week 6-7 if the extent of wound epithelialsation is < 85% and has changed less than 15% from the prior study visit. Trial endpoints include: superiority of ReGenerCell™ over SoC in wound closure (ie complete re-epithelialisation without drainage) at 12 weeks; rate of epithelialisation; treatment costs; safety; and patient reported pain and quality of life data. We highlight the trial design below.

Figure 21: VLU pilot trial



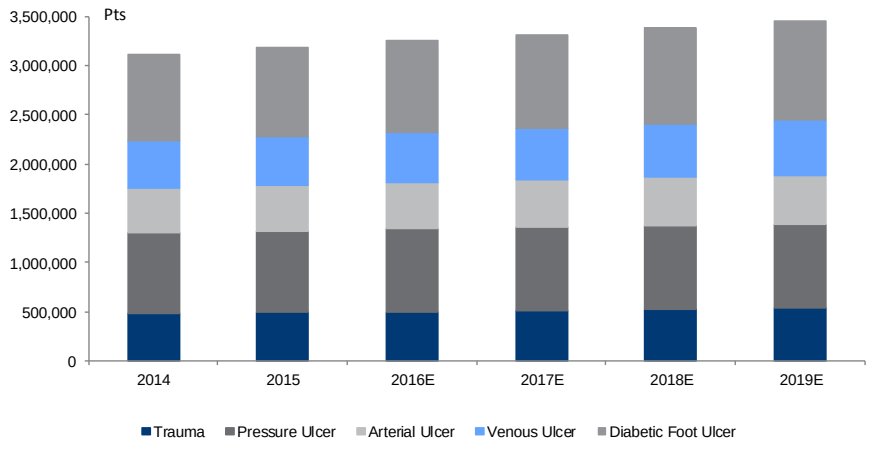
SOURCES: MORGANS RESEARCH, COMPANY REPORTS

The study showed a statistically significant improvement across multiple metrics including: wound size (closing an average of 9.1 cm^2 vs 1.2 cm^2, p=0.014); pain (c2 point drop on a 10 point scale vs no change; p=0.017); and health-related quality of life (using the Charing Cross Venous Leg Ulcer Questionnaire - improvement seen in social interaction, domestic activity, emotional statue and cosmosis, with statistical significance shown on emotional status, p=0.044). Positive trends were also seen in healing time and incidence of closure, particularly in large ulcers (>10 cm^2), which comprise the majority of VLUs. Specifically, complete wound closure was 26.9% vs 15.4%, with large ulcers (>10 to ≤80 cm^2) showing a closure incidence of more than 3x vs control (23.1% vs 7.1%), and mean closure time of large ulcers was 43 days vs 84 days. On the safety front, on difference were noted between the groups. Management plans to incorporate results into discussions with regulatory authorities to determine next steps for ReGenerCell™ in VLU.

Market opportunity

Ulcers of the lower limbs, which include VLU and DFU, are a major health concern, with increasing prevalence and high cost of treatment. In the US, we estimate that more than 3.2m people suffer from chronic wounds, with c45% (c1.4m) inflicted with either VLU (c500k) or DFU (c900k). Total healthcare costs from these aliments is more than US$25bn per annum. We believe treatment of VLU and DFU represents a US$1bn+ market opportunity for ReGenerCell™.

Figure 22: US chronic wounds



SOURCES: MORGANS RESEARCH, COMPANY REPORTS

Aesthetics - Repigmentation, scarring and plastic surgery

RES™ technology has been shown to be safe and effective in aesthetics applications, including skin repigmentation, scar revision and cosmetic procedures. Recently rebranded as ReNovaCell™ in this setting, more than ten case studies involving c100 patients have been published demonstrating improved outcomes to conventional treatments.

Importantly, two RCT provide strong clinical evidence supporting the use of ReNovaCell™ in the treatment of hypopigmented burn scars as well as in vitiligo, a common and incurable skin pigmentation disorder affecting 1-2% of worldwide population, with 18.5m afflicted in OECD countries, and piebaldism, a rare genetic disorder characterised by the absence of pigment containing cells in certain areas of the skin and hair, respectively.

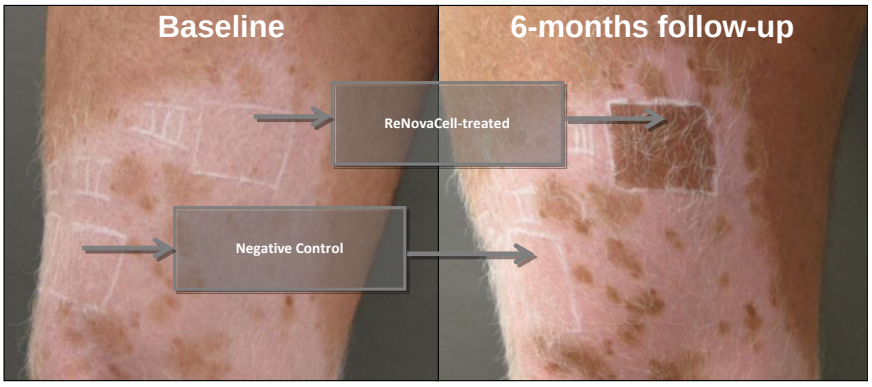
Specifically, in the former German-conducted study found that areas treated with ReNovaCell™, combined with percutaneous collagen induction scar treatment, showed statistically significant repigmentation, compared to areas treated with percutaneous collagen induction alone. A 78% response rate was reported for ReNovaCell™ treated patients compared with no response in the control group. Moreover, 70% of sites treated with ReNovaCell™ showed greater than 73% repigmentation of their depigmented test lesion, the treatment was well tolerated, with no long-term side effects, infections or treatment-area scars reported and 70% of patients reported ReNovaCell™ site repigmentation as good or excellent.

The latter Netherland-conducted study was published in the Journal of the American Academy of Dermatology in July 2015 (Komen L *et al*; 73(1):170-2) showed ReNovaCell™ treatment to be beneficial to patients with segmental vitiligo and piebaldism. Notably, 70% of patients with piebaldism showed repigmentation in over 75% of the transplanted area six months after treatment.

We view the results to data as promising as treating piebaldism is challenging given the condition is not usually responsive to medical therapies or phototherapy. While skin autografts are able to restore pigmentation over a long period of time, most are designed to treat small surface areas and can cause significant scarring.

Interestingly, researchers at the Netherlands Institute for Pigment Disorders (Stichting Nederlands Instituut voor Pigmentstoornissen or SNIP) recently completed enrolment of a 10 patient study to evaluate the optimal use of ReNovaCell™ in patients with pigmentation defects six months post treatment. SNIP is exploring three different approaches: 1) superficial full surface ablation; 2) fractional laser treatment; and 3) conventional (deep) full surface CO_2 laser ablation. We believe this study should provide more insight into which ablation approach is most effective.

Figure 23: Patient with segmental vitiligo for >five-year duration



SOURCES: MORGANS, COMPANY REPORTS

In the plastic surgery setting, a recent report published in the Journal of Cranio-Maxillo-Facial Surgery showed that ReNovaCell™ use in a secondary procedure to repair facial defects resulting from surgical removal of skin cancers, improved pigment, volume, texture and elasticity of tissue transplanted from one body site to the facial region.

Management and board

We believe the management team and board members have a complementary mix of broad experiences across the medical device, technology and broader healthcare industries, with domestic and international experience in capital markets. We view the appointment (13 April 2015) of Adam Kelliher as CEO as well regarded, given Mr Kelliher's entrepreneurial skill and marketing background.

Adam Kelliher (CEO)

Mr. Kelliher joined AVH in April 2015 bringing more than 18 years industry experience as a successful entrepreneur with a strong marketing background and track record of creating and building life science companies. Mr. Kelliher was a global pioneer in the omega-3 space, launching Equateq Limited (2006), a cGMP-certified manufacturer providing super-pure fatty acids for the nutritional, pharmaceutical and research sectors, which was sold to BASF in 2012. He also started Equazen Limited (2000), a leading omega-3 and omega-6 supplement company whose lead product, eye q™ for lipid deficiencies linked to learning conditions, and at sale was marketed in 16 countries. Equazen was sold to Galencia of Switzerland in December, 2007.

Timothy Rooney (CFO/COO)

Mr. Rooney has 20 years of experience in senior finance and operations management, pharmaceutical wholesale distribution and medical device industries. Mr. Rooney joined AVH as CFO/COO in 2012 and has also served the company as the Interim Chief Executive Officer for a 16-month period spanning late 2013 to early 2015. Previously Mr. Rooney was an owner of PDI Enterprises, Inc., a pharmaceutical wholesale distributor, where he served as the CFO/COO. Mr. Rooney spearheaded and managed the growth of PDI from an early-stage regional operator to a market-leading company with national stage presence growing revenues from A$5m to A$430m. Mr. Rooney holds degrees in Finance and Economics.

Andrew Quick (VP Research & Technology)

Mr. Quick has 21 years of experience across the medical device space, with expertise in design, development and clinical Research. Prior to joining AVH in 2010, Mr. Quick headed US clinical Research for investigational devices and post-market research for Advanced Bionics, LLC. Mr. Quick spent 10 years as VP of SonaMed Corporation, developing hearing screening and diagnostic devices. Mr. Quick holds degrees in Biomedical Engineering.

Justin McCann (VP Finance)

Mr. McCann is a Certified Management Accountant with over 20 years finance experience in the tech and biotech sectors. Mr. McCann has extensive experience in several start-up and high-tech enterprises including acquisitions, restructuring and change management. Prior to joining AVH, Mr. McCann was Group Finance Manager and Company Secretary at NextGen Sciences and played a significant role in achieving an Initial Public Offering onto AIM, London. Mr. McCann holds degrees in Biochemistry, Physiology and Marketing & International Trade.

David Fencil (VP Global Operations)

Mr. Fencil has 30 years of experience in the medical device space, with expertise in biomaterials, device design and development, operations, and quality systems. Mr. Fencil came to AVH in a product development role in 2012 and managed the development of a larger ReCell® and the ReGenerCell™ and ReNovaCell™ products. For over 14 years Mr. Fencil held several positions with the Alfred Mann Foundation, a technology incubator in Valencia, CA and related companies where he managed development projects, quality

system revisions and operational departments. Mr. Fencil holds degrees in Polymer Science and Business Administration.

Lorraine Glover (GM, APAC)

Ms. Glover has 22 years of experience in the commercial biotechnology and medical devices industries. Ms. Glover has held various positions during this time, including those of Research scientist, International sales manager, corporate and public/investor affairs and manager regulatory, clinical and quality systems. Ms. Glover joined AVH in 2002 as Sales & Marketing Manager (Visiomed) and holds degrees in Applied Sciences (Biology).

Claire Darby (GM, EMEA)

Ms. Darby has more than 10 years of experience in medical device and regenerative medicine industries, with expertise in acute and chronic wound care markets from both a clinical and commercial perspective. Ms. Darby holds a BSc (Honours) degree in Equine Science and Chartered Institute of Personnel and Development qualification.

The board

Lou Panaccio (Chairman)

Mr. Panaccio has extensive experience in progressing companies from concept to commercialisation and was appointed to the role of Chairman of the Board, effective 1 July 2014. Mr. Panaccio replaced Mr. Ian Macpherson who has served in the interim role since December 2013. Mr. Panaccio possesses more than 30 years' executive leadership experience in healthcare services and life sciences, including approximately 15 years' board-level experience. Mr. Panaccio is currently a Non-Executive Director of ASX50 company and one of the world's largest medical diagnostics companies, Sonic Healthcare Limited, where he has served since 2005. In addition to his Sonic Healthcare Limited role, Mr. Panaccio is the Executive Chairman of Health Networks Australia Group, Non-Executive Director Yarra Community Housing, Non-Executive Director Inner East Community Health Service and Executive Chairman of Genera Biosystems Limited. He was also the Chief Executive Officer and an Executive Director of Melbourne Pathology for 10 years to 2001. Mr. Panaccio has also served in executive and board roles with CPW Group, Monash IVF Group, Primelife Corporation Limited and other private entities.

Jeremy Curnock Cook (Non-Executive Director)

Mr. Cook was appointed to the Board on 19 October 2012 and is currently on a number of boards of International Healthcare and Biotechnology companies. He is the former head of the life science private equity team at Rothschild Asset Management, was responsible for the launch of the first dedicated biotechnology fund for the Australian market and the launch of a joint venture with Johnson & Johnson Development Corporation for the creation of Healthcare Ventures, an investment vehicle dedicated to seed stage investments in Europe, as well as the conception and launch of the International Biotechnology Trust. He is currently the Managing Director of Bioscience Managers Pty Ltd, responsible for the BM Asia Pacific Healthcare Fund.

Dr Michael Perry (Non-Executive Director)

Dr. Perry was appointed to the Board on 6 February 2013 and currently serves as Chief Scientific Officer of Global Cell and Gene Therapy for Novartis Pharmaceuticals Corp. From 2012 – 2014 he served as Vice President and Global Head of Stem Cell Therapy for Novartis Pharmaceuticals Corp, a US affiliate of Switzerland-based Novartis AG. Dr Perry, based in the United States, has previously served as the Global Head of R&D at Baxter Healthcare, President, Cell & Gene Therapy at Novartis affiliates Systemix and Genetic Therapy, Inc., VP Regulatory Affairs at Sandoz Pharmaceuticals Corp., Director of Regulatory Affairs at Schering-Plough Corporation, and Chairman, CEO or CMO at several early stage biotech companies. He also previously served as a Venture Partner with Bay City Capital, LLC based in San Francisco California.

Louis Drapeau (Non-Executive Director)

Mr Drapeau was appointed to the board on 13 January 2016 and brings considerable expertise in both the biotech sector and the financial rigour required of US public companies. Based in the US, Mr Drapeau is an Independent Director at AmphliPhi Biosciences Corporation (NYSE), CFO, Principal Accounting Officer and Vice President at Insite Vision Inc., and Independent Director at Bio-Rad Laboratories, Inc. (NYSE). Mr Drapeau has held senior positions with Nektar Therapeutics and BioMarin Pharmaceutical, Inc., and has been an Audit Partner at Arthur Andersen LLP. Mr Drapeau has formally been an Independent Director at InterMune, Inc. (NASDAQ), Bionovo, Inc. (NASDAQ), and Inflazyme Pharmaceuticals Ltd (TSE). He has an MBA from Stanford University.

Damien McDonald (Non-Executive Director)

Mr McDonald was appointed to the board on 13 January 2016 and has a track record of achieving value in the medical device space. Based in the US, Mr McDonald is a Group Executive and Corporate Vice President at NYSE-listed Danaher Corporation, a multinational science and technology innovation company that acquires and produces life science and industrial products and brands. As Group President, Mr McDonald is responsible for a US$1.2bn group of dental consumables companies, for which he executes group strategic planning with full P&L accountability. He has previously worked for Merck &Co, Johnson & Johnson and Zimmer. He has Bachelor's degrees in both pharmacy and economics from the University of Queensland a Master's degree in International Economics from the University of Wales, and an MBA from IMD of Lausanne, Switzerland.

Professor Suzanne Crowe AM (Non-Executive Director)

Professor Crowe was appointed to the board on 13 January 2016. Australian-based, she is a physician-scientist and company director with extensive expertise in supporting companies with their medical and scientific strategies. Professor Crowe is an Associate Director of the Burnet Institute, and is a Principal Research Fellow of the Australian National Health and Medical Research Council. She is a Principal Specialist in Infectious Diseases at The Alfred Hospital, Melbourne and Adjunct Professor of Medicine and Infectious Diseases at Monash University, Melbourne, and has published more than 200 peer-reviewed papers. Professor Crowe is a member of the Australian Institute of Company Directors, and has served on various company boards. Professor Crowe was appointed as a Member of the Order of Australia (AM) in 2011 to recognise her service to medical research in HIV/AIDS. She has medical and MD degrees from Monash University, an internal medicine specialist qualification in Infectious Diseases from the Royal Australasian College of Physicians, and a Diploma in Medical Laboratory Technology from the Royal Melbourne Institute of Technology.

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