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Avita Medical (AVH)

Outpatient Reimbursement Approved

Recommendation
Buy (unchanged)
Price
$5.13
Target (12 months)
$9.80 (unchanged)

GICS Sector

Pharmaceuticals & Biotechnology

Expected Return	
Capital growth	**91.0%**
Dividend yield	**0.0%**
Total expected return	**91.0%**

Company Data & Ratios	
Enterprise value	**US$336m**
Market cap	**US$446m**
Issued capital	**24.9m**
Free float	**99%**
Avg. daily val. (52wk)	**$3.1m**
12 month price range	**A$4.39 - $7.40**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	4.89	5.06	5.93
Absolute (%)	1.84	-1.58	-16.02
Rel market (%)	-1.53	-2.19	-41.79

CMS Approves Transitional Pass-Through Payment

The company announced that the Centre for Medicare/Medicaid (CMS) has approved a new reimbursement code that will provide separate payment for Recell devices used in the outpatient setting. The Transitional Pass-Through Payment (TPT) is expect to reimburse hospitals for approximately US$6,200 related to the use of the device. The event represents an important breakthrough for the company and further validation of the clinical benefit of the Recell technology. TPT's are reserved for devices that offer substantial clinical improvement over the standard of care and are made available where the cost of the device would otherwise represent an obstacle to patient benefit.

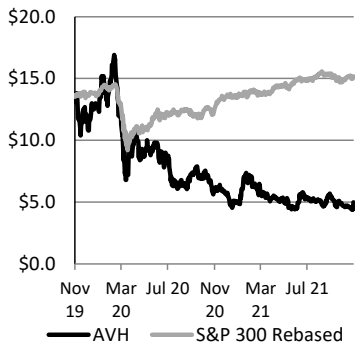
The TPT comes into effect from 1 January 2022. The company plans a launch amongst a small number of existing hospital clients to ensure commercial payers follow suite with the CMS. A larger scale roll out will follow in the back half of CY22 (1H FY23) to specialist burns hospitals. The serviceable market in burns is estimated at US$260m of which small burns with total body surface area is in the range of 5-10% comprises ~US$60m. The TPT will be appropriate for treatment of these wounds.

Today's announcement had been foreshadowed in numerous company updates and represents the first in a series of high profile news flow. Recell is expected to gain a broad label approval from the Japanese PMDA this quarter that may include Vitiligo in addition to burns, trauma and paediatric use. In the clinic the company expects to enrol the final patient in the Vitiligo trial this quarter. Initial proof of concept data is also expected in Epidermolysis Bullosa and facial rejuvenation.

Investment View: Maintain Buy Rating, Price Target $9.80

1Q22 results are due next week. Guidance is for commercial revenues of US$7m relative to US$6.8m from 4Q21. FY22/FY23 revenues are upgraded by 5% and 12% respectively related to the TPT code. The FY22 EBIT loss is reduced by ~$8m to ($22.4m) largely attributable to the rationalisation of the expected scrip based remuneration which has now been adjusted to be more consistent with the prior year charge. We maintain our Buy rating and price target of $9.80.

Absolute Price



SOURCE: IRESS

Earnings Forecast

June Year End US$m	FY21	FY22e	FY23e	FY24e
Revenue (product sales)	21.7	34.7	47.7	83.8
EBITDA $m	-26.3	-22.0	-15.8	11.9
NPAT (underlying) $m	-26.4	-22.4	-16.2	11.5
NPAT (reported) $m	-26.4	-22.4	-16.2	11.5
EPS underlying (cps)	-116.7	-89.3	-64.1	44.8
EPS growth %	nm	nm	-28%	-170%
PER (x)	nm	nm	nm	11
FCF yield (%)	nm	nm	nm	3%
EV/EBITDA (x)	nm	nm	nm	28
Dividend (cps)	-	-	-	-
Franking	0%	0%	0%	0%
Yield %	0%	0%	0%	0%
ROE %	-23%	-23%	-19%	11%

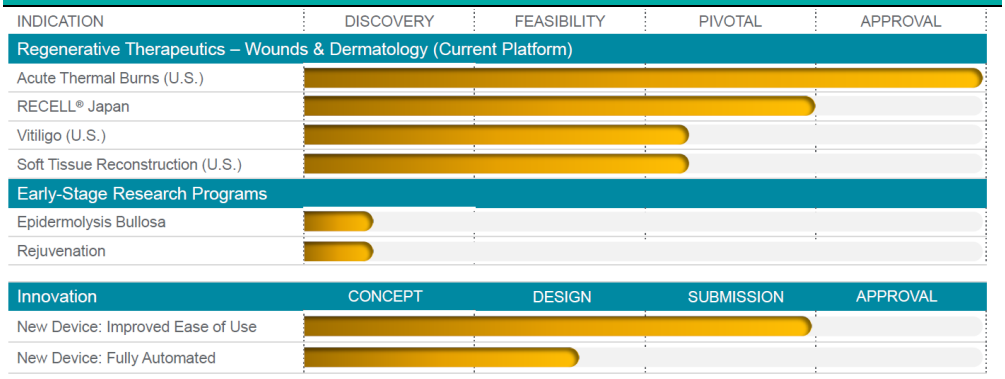
SOURCE: BELL POTTER SECURITIES ESTIMATES

Material Catalysts Ahead

Overview

Figure 1 provides the over view of the addressable universe for Recell.

Figure 1 - Pipeline overview



SOURCE: COMPANY DATA

Today's announcement concerning the transitional pass through payment (TPT) will initially expand AVH's serviceable market within the acute thermal burns category.

The new Healthcare Common Procedure Coding System (HCPCS) device category C code applies to any procedure performed in the hospital outpatient setting, hence it is not specific to a particular type of injury i.e. the reimbursement will apply equally to any episode where the physician deems Recell is appropriate.

The TPT is a temporary code provided by the Centre for Medicare and Medicaid Services (CMS) in the United States. TPTs are specific to patients who receive treatment with certain products in hospital outpatient departments and ambulatory service centres. Medicare makes the additional TPT payment for devices where cost considerations are likely to interfere with patient access. It allows for CMS to collect necessary data and assign appropriate permanent codes and rates, paving the way for routine Medicare reimbursement later. In about three years the treatment and the associated services are bundled into a single payment.

WHAT DOES THE TPT MEAN FOR HOSPITALS

We expect the TPT for Recell will be at least US$6,200 which covers the cost of the kit alone. Hospitals also receive a separate payment (being an APC or ambulatory payment classification) which represents the hospitals revenues in relation to the treatment episode.

Recell has a broad indication for the treatment of burns and the awarding of the TPT does not affect the indication. To this point however, the cost of the kits has been far too high to justify use in the outpatient setting.

Patient's with small burns and trauma injuries treated in the emergency room or who return to the hospital for treatment in an outpatient setting may now benefit from Recell. We include soft tissue trauma injuries as potential beneficiaries as we believe physician's will continue to use the product off label for some of these wounds – despite not yet being approved in this indication.

Physicians will continue to receive payment under the Medicare Physican fee schedule, hence their incomes are not impacted though the use of Recell in this setting.

COMMERCIALISATION

Initial roll out will be to current hospital clients focussing on the highest volume users of Recell kits (25 – 30 sites). This limited roll out will serve the dual purposes of:

- Ensuring commercial coverage is in place amongst commercial payers; and
- To identify any clinical issues with outpatient treatment. Here, post operative care is crucial. Patients need to avoid interfering with the wound following treatment. Compliance may be more difficult when the patient is not in the care of the hospital.

Once commercial reimbursement is established a broader roll out to all Value Analysis Committee (VAC) approved burns centres will take place, most likely over the second half of calendar 2022.

As indicated in figure 1, the company has submitted the dossier for the Improved Ease Of Use device. This second generation device contains no substantive changes to the mechanism of action for Recell. The kits will come complete with all the necessary consumables required for use (thereby reducing the risk of infection) and will reduce the steps involved for use. Roll out to the ER's and ambulatory services centres does not have to wait for the approval of these new format devices, however, it is likely the timing of the new kits and the broader roll out will co-incide.

A full nationwide launch to level 1 and level 2 trauma centres will wait until the trauma wounds indication is approved by the FDA. In this regard, the trauma wounds trial is recruiting well. Target enrolment is 65 patients of which 43 had been enrolled as at mid August 2021. We expect FDA approval in soft tissue repair in mid CY23.

The serviceable market in burns is estimated at US$260m of which burns in the 5-10% total body surface area (TBSA) are estimated at ~$60m.

The normal adoption path for Recell in a new hospitals is to treat patients with very large TBSA burns first. This is somewhat counter intuitive - as these patients are likely to have multiple injuries not just confined to burns and are hardest to treat. Nevertheless the treatment of smaller wounds tends to be at the end of the adoption curve.

The majority of these smaller burns are treated in the outpatient setting, hence we expect this market to make a meaningful contribution to revenue growth from FY23 onwards.

EARNINGS ADJUSTMENTS

Figure 2 - Earnings Adjustments

	2022			2023			2024		
	New	Old	% change	New	Old	% change	New	Old	% change
Revenues - products sales	34.7	33.0	5%	47.7	42.8	12%	83.8	81.3	3%
EBIT	-22.4	-30.5	36%	-16.2	-27.7	71%	11.5	4.3	167%
NPAT	-22.4	-30.9	38%	-16.2	-27.7	71%	11.5	4.3	167%
EPS	-89	-122	37%	-64	-107	67%	45	22	102%

SOURCE: BELL POTTER SECURITIES ESTIMATES

Revenues are upgraded by 5% ($1.7m) in FY22 allowing for expected revenue growth attributable to the TPT code. The loss at EBIT in FY22 reduces from $30.5m to $22.4m in part due to the revenue adjustment. Most of the EBIT adjustment relates to a rationalisation of the non cash scrip based remuneration. We have had previously allowed $13m for this item, now reduced to $4m and closer the FY21 charge of $3.2m. The entire amounts of scrip based remuneration is expected to be incurred in 1Q22 and represents bonuses in respect of the year ended 30 June 2021.

Avita Therapeutics

Avita Therapeutics (Avita) is a one technology company – being Recell, also known as autologous skin cell suspension. Recell is a medical device used for the reconstruction of skin in patients with severe (2nd and 3rd degree) burns. Adjacent markets for the product includes trauma wounds, Vitiligo and potentially aesthetic use.

The common shares of the company trade on the Nasdaq. The CDI's trade on the ASX. One share of common stock is worth 5 CDI's.

Severe burns are treated in hospital where autograft surgery has been the standard of care for decades. The Avita technology is a class III medical device intended for use by trained healthcare providers in the hospital setting. It is not disruptive to the broad manner in which severe burns are treated and does not threaten the income stream of the hospital or the physician whose income is dependent upon treating these patients.

Recell is arguably the most important innovation in the treatment of severe burns in several decades. The process uses a small autologous sample of unaffected skin. The proprietary enzyme formulation within the Recell device disaggregates the sample, allowing for the isolation of key cell types responsible for the regrowth of the dermis and epidermis. Once harvested the cells are sprayed onto the wound in a solution.

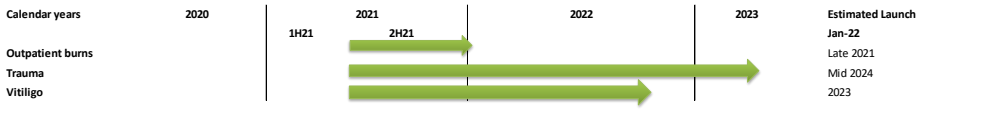
The results from more than 7,000 commercial sales of the device along with new data from randomised clinical trials provide compelling evidence for wider commercial adoption. The four key points from the US clinical trials are:

- The size of the donor site (for the graft) is vastly reduced (30% for 3rd degree and 97% for 2nd degree burns) versus standard of care autografting;
- Non inferiority in healing of the wound site compared to autografting;
- Non inferiority on aesthetic outcomes (i.e. scars at the wound site); and
- Significant reductions (up to 42%) in length of stay for hospitalised patients leading to cost savings for the treating hospital and compelling health economics data to support high levels of reimbursement.

Recell's safety record is outstanding with no device related serious adverse events recorded. The US FDA approved the PMA in September 2018. The products was launched in January 2019. The label was extended to include paediatric use in June 2021.

Figure 3 - Summary Clinical Trial Program

Location	Indication	Patient Numbers	Status	Design	Total Estimated	Fiscal Years 1H21	2H21	1H22	2H22
Japan	Burns and Wounds		Planning	Not yet announced	0.0				
United States	Trauma/Soft Tissue	65	Enrolling patients	Multicentre, Randomised clinical trial	9.0		3.0	3.0	3.0
United States	Re-pigmentation/Vitiligo	23	Enrolling patients	Single Arm Study	14.0	6.0	4.0	2.0	2.0
Total					**23.0**	**6.0**	**7.0**	**5.0**	**5.0**
United States	Rejuvenation		Research collaboration with Houston Methodist		3.0	1.0	1.0	1.0	1.0
United States	Genetic skin disease		Research collaboration with Gates Centre/u. Colorado		3.0	1.0	1.0	1.0	1.0
US	Chronic Wounds		Conceptual		2.0	0.5	0.5	0.5	1.0
Total					31.0	8.5	9.5	7.5	8.0



SOURCE: COMPANY DATA AND BELL POTTER SECURITIES ESTIMATES

Avita also has a long term contract with the Biomedical Advanced Research and Development Authority (BARDA) in the US. BARDA has so far provided several million

dollars for R&D funding and has now placed a multi-million dollar procurement order for Recell devices.

Key Risk Areas

INTELLECTUAL PROPERTY RISK

Key patents for the US, Australia and Europe expire in 2022 although there are undisclosed trade secrets in the IP portfolio providing additional protection. In the event that a competing product were to emerge, it is likely that the competitor would also require a PMA in the US. Trade Secrets have no time frame.

MANUFACTURING AND PRODUCT QUALITY RISK

The single use Recell kits are manufactured in California. Manufacturers of medical devices are subject to ongoing audit and regulatory requirements including inspections by regulatory authorities. Failure by the company or its suppliers to continuously comply with applicable regulatory requirements or failure to take satisfactory corrective action in response to adverse inspection, could result in enforcement actions, including a public warning letter, a shutdown of, or restrictions on, its manufacturing operations, delays in approving or clearing products, refusal to permit the import or export of its products or other enforcement action..

RESEARCH AND DEVELOPMENT

Avita is now exploring label expansions for Recell into the treatment of vitiligo, trauma wounds and facial rejuvenation. The company is recruiting clinical trials in these indications. These trials must be successfully completed in order to commence treatment of these patients, hence there is an element of clinical trial risk. The company has on ongoing research and development program investigating several other uses of the Recell product, however, none of these are yet the subject of clinical trials. The company expenses 100% of its clinical trial and R&D expense.

Avita Medical
as at 4 November 2021

Recommendation	Buy
Price	$5.13
Target (12 months)	$9.80

Table 1 - Financial summary

Profit & Loss (US$m)	FY20	FY21	1Q22e	2Q22e	3Q22e	4Q22e	FY22e	FY23e	FY24e	FY25e
Year Ending June										
Net revenue - Commercial sales	14.3	21.7	7.1	8.7	9.0	9.9	34.7	47.7	83.8	110.5
Growth	160%	52%	*40%*	*70%*	*93%*	*45%*	*60%*	*37%*	*75%*	*32%*
Net revenue - BARDA sales	-	7.6	-	-	-	-	-	-	-	-
Total Revenues	14.3	29.3	7.1	8.7	9.0	9.9	34.7	47.7	83.8	110.5
COGS	(3.0)	(6.0)	(1.1)	(1.3)	(0.4)	(0.7)	(3.5)	(4.8)	(8.4)	(11.1)
Gross profit	**11.3**	**23.3**	**6.1**	**7.4**	**8.5**	**9.3**	**31.2**	**43.0**	**75.4**	**99.5**
GP margin	**79%**	**80%**	**85%**	**85%**	**95%**	**95%**	**90%**	**90%**	**90%**	**90%**
BARDA revenues (non procurement)	3.9	2.1	0.3	0.3	0.3	0.3	1.0	-	-	-
Total revenues	18.2	31.4	7.4	8.9	9.2	10.2	35.7	47.7	83.8	110.5
R&D (clinical trials)	8.5	14.6	4.0	4.0	4.0	4.0	16.0	16.0	16.0	10.0
G&A	18.1	19.7	4.8	4.8	4.8	4.7	19.0	20.0	21.0	21.0
Sales and marketing	14.8	14.2	3.9	3.9	3.9	3.9	15.6	17.2	18.9	20.8
Share based payments (non cash)	16.5	3.2	4.0	-	-	-	4.0	6.0	8.0	17.0
EBIT	(42.7)	(26.3)	(10.3)	(5.1)	(3.9)	(3.0)	(22.4)	(16.2)	11.5	30.7
Interest expense	0.7	-	-	-	-	-	-	-	-	-
Pre tax profit	(42.0)	(26.3)	(10.3)	(5.1)	(3.9)	(3.0)	(22.4)	(16.2)	11.5	30.7
Tax expense	-	(0.0)	-	-	-	-	-	-	-	-
NPAT	(42.0)	(26.4)	(10.3)	(5.1)	(3.9)	(3.0)	(22.4)	(16.2)	11.5	30.7
Earnings per share (cps)	-207	-117	-42	-20	-16	-12	-89	-64	45	117
Weighted avg Diluted shares (m)	20.3	22.6	24.9	24.9	24.9	24.9	25.1	25.3	25.6	26.3

Cashflow (US$m)	FY20	FY21	FY22e	FY23e	FY24e
Gross cashflow	-22.7	-25.9	-20.1	-11.6	14.4
Net interest	0.0	0.0	0.0	0.0	0.0
R&D tax refund	0.0	0.0	0.0	0.0	0.0
Operating cash flow	-22.7	-26.0	-20.1	-11.6	14.4
Maintenance capex	-0.6	-0.9	-0.5	-0.5	-0.5
Proceeds from asset sales	0.0	0.0	0.0	0.0	0.0
Free cash flow	-23.3	-26.9	-20.6	-12.1	13.9
Business acquistions	0.0	0.0	0.0	0.0	0.0
Proceeds from issuance	77.0	64.0	0.0	0.0	0.0
Movement in borrow ings	0.0	0.0	0.0	0.0	0.0
Other	0.0	0.0	0.0	0.0	0.0
Change in cash held	53.7	37.1	-20.6	-12.1	13.9
Cash at beginning of period	20.2	73.7	110.7	90.0	78.0
FX adjustment	0.0	0.2	0.0	0.0	0.0
Cash at year end	**73.7**	**110.7**	**90.0**	**78.0**	**91.9**

Balance Sheet (US$m)	FY20	FY21	FY22e	FY23e	FY24e
Cash	73.7	110.7	90.0	78.0	91.9
Receivables	2.1	3.5	5.6	7.7	13.5
Short term investments	1.1	1.6	1.6	1.6	1.6
Other current assets	1.4	5.4	5.4	5.4	5.4
Property, Plant and Equipment	1.4	1.5	1.6	1.7	1.8
Intangible assets	0.4	0.5	0.5	0.5	0.5
Other assets	2.6	2.3	2.3	2.3	2.3
Total assets	82.7	125.5	107.1	97.2	117.0
Trade payables	4.3	3.1	3.1	3.1	3.1
Other liabilities	2.4	2.3	2.4	2.5	2.7
Debt	-	-	-	-	-
Other provisions	3.3	4.4	4.6	4.9	5.1
Total Liabilities	10.0	9.8	10.1	10.5	10.9
Net Assets	72.7	115.7	96.9	86.7	106.2
Share capital	259.2	329.0	333.0	339.0	347.0
Retained earnings	(194.8)	(221.2)	(243.5)	(259.8)	(248.3)
Reserves	8.3	8.2	7.5	7.5	7.5
Shareholders Equity	72.7	116.0	97.0	86.7	106.2

Valuation Ratios	FY20	FY21	FY22e	FY23e	FY24e
PE(x)	**nm**	**nm**	**nm**	**11.4**	**4**
EV/EBITDA (x)	nm	nm	nm	28.9	11
EV/EBIT (x)	nm	nm	-21.2	29.9	11
NTA (cps)	464.0	384.9	340.9	412.7	583.4
P/NTA (x)	1.1	1.3	1.5	1.2	0.9
Book Value (cps)	466.0	386.9	342.9	414.7	585.3
Price/Book (x)	1.1	1.3	1.5	1.2	0.9
DPS (cps)	-	-	-	-	-
Payout ratio %	0%	0%	0%	0%	0%
Dividend Yield %	0.0%	0.0%	0.0%	0.0%	0.0%
Franking %	0%	0%	0%	0%	0%
FCF yield %	nm	nm	nm	3%	9%
Net debt/Equity	0%	0%	0%	0%	0%
Net debt/Assets	0%	0%	0%	0%	0%
Gearing	net cash	net cash	net cash	net cash	net cash
Net debt/EBITDA (x)	n/a	n/a	n/a	n/a	n/a
Interest cover (x)	n/a	n/a	n/a	n/a	n/a

Recell Unit sales estimates	FY21	FY22e	FY23e	FY24e
US Unit sales ex BARDA	3,491	5,600	7,600	14,400
BARDA procurement order	-	-	-	-
Estimated sales (units) US	**3,491**	**5,600**	**7,600**	**14,400**

SOURCE: BELL POTTER SECURITIES ESTIMATES

Recommendation structure

Buy: Expect >15% total return on a 12 month view. For stocks regarded as 'Speculative' a return of >30% is expected.

Hold: Expect total return between -5% and 15% on a 12 month view

Sell: Expect <-5% total return on a 12 month view

Speculative Investments are either start-up enterprises with nil or only prospective operations or recently commenced operations with only forecast cash flows, or companies that have commenced operations or have been in operation for some time but have only forecast cash flows and/or a stressed balance sheet.

Such investments may carry an exceptionally high level of capital risk and volatility of returns.

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