

avita^{medical}

Pitched By: Anna Marsden

Avita Medical Ltd

Company Profile

Avita



Information

Current price	\$0.445 (13/05)	Market cap	\$981.38 m
52 week range	\$0.325 - \$0.865	Enterprise value	\$952.397

- Avita is listed on the ASX and is a global regenerative medicine company focused on skin regeneration
- Avita's main product for skin regeneration is its patented RECELL system
- The current market focus is on burn treatment, with expansion areas into traumatic wounds, scar revision and vitiligo
- Avita intends to change its primary listing to the US and maintaining a secondary listing on the ASX
- Avita's primary operations and revenue sources are in the US

Investment Thesis

Avita Investment Thesis

Global approval for burn treatment

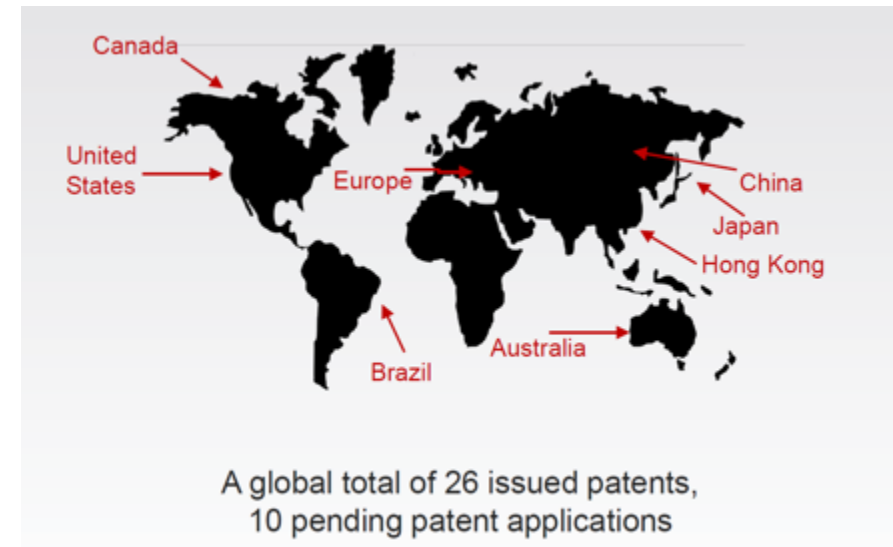
- In 2018, Avita received FDA approval for the RECELL system to treat 2nd and 3rd degree burns on adults
- RECELL is also approved in Europe, China and Australia, though it is not currently selling into these markets due to its US focus

Huge Growth Opportunities

- RECELL technology can be applied to a range of skin applications including wounds, scar revision, vitiligo and potentially rejuvenation
- This range of applications open Avita up to profitable markets such as aesthetic procedures (worth US\$16.5 B)

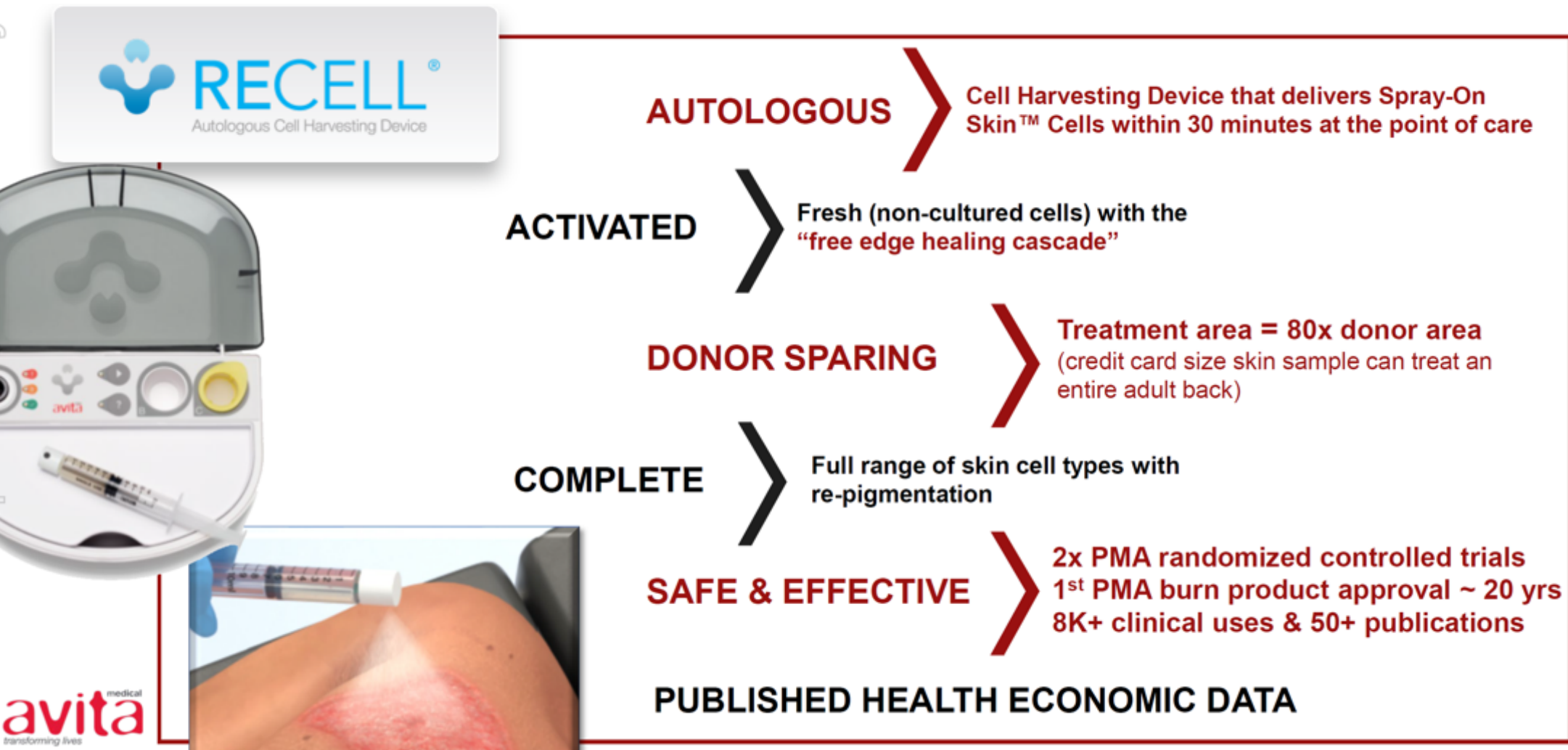
Change in Primary Listing

- Avita will change its primary listing to NASDAQ and maintain a secondary listing on the ASX
- This will grow Avita's visibility and presence while reducing costs

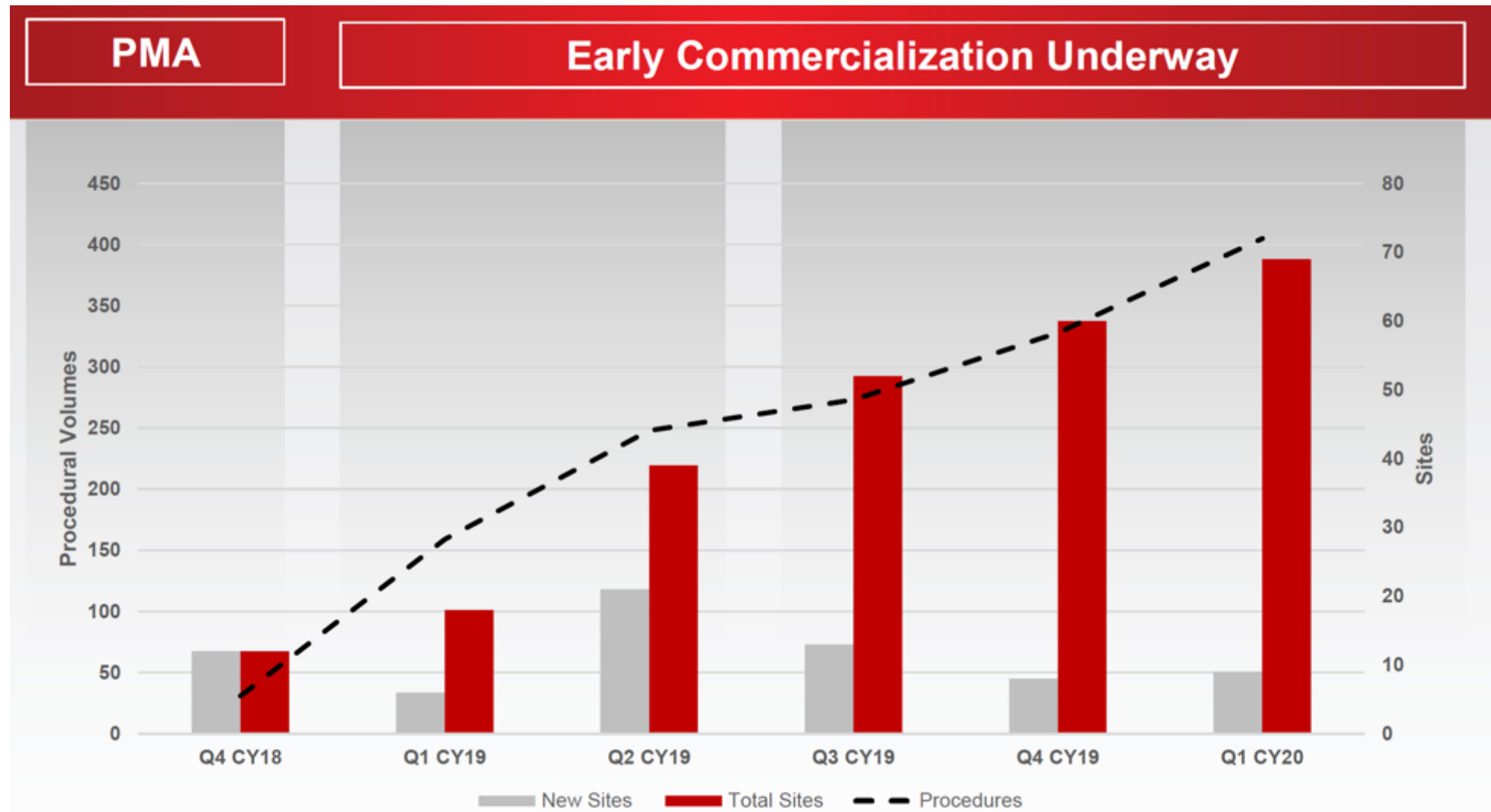


Avita Medical Ltd

The RECELL system



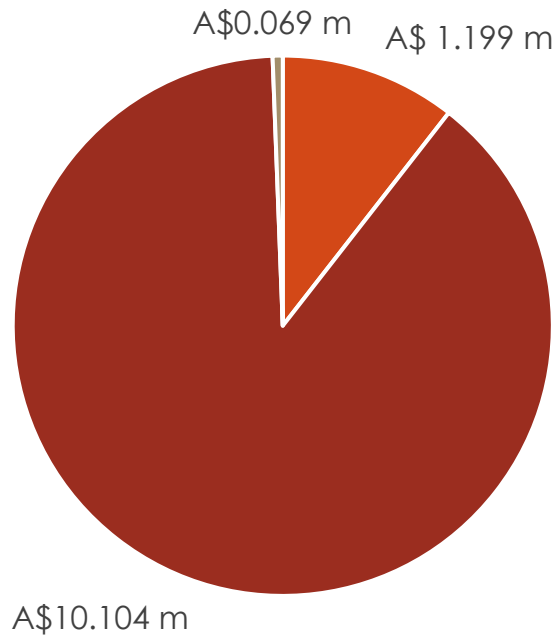
Large uptake of RECELL across 2019



Funds from both Revenue and BARDA funding

2018

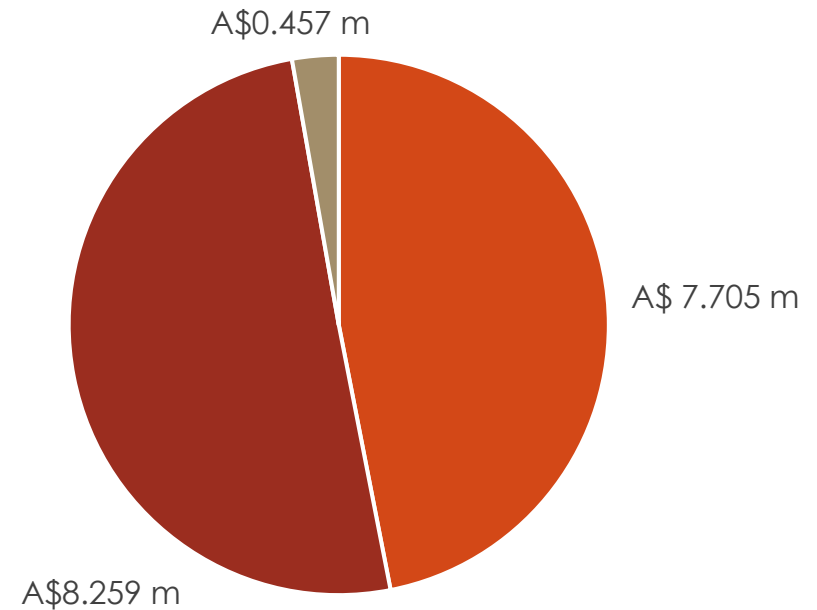
Income Streams



sale of goods BARDA income Interest Income

2019

Income Streams



sale of goods BARDA income Interest Income

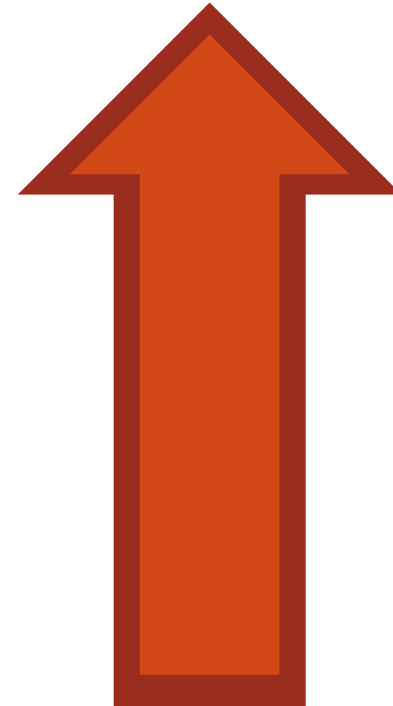
Currently the only revenue stream is in the form of in-patient burn centers

A close-up photograph of a doctor's torso. The doctor is wearing a white lab coat over a light blue shirt and a grey tie. A silver stethoscope is draped around their neck, with the chest piece resting on their left breast. The doctor's hands are clasped in front of them. A semi-transparent grey rectangular box is centered over the image, containing the word "Industry" in a bold, red, sans-serif font.

Industry

The burn industry is growing

- Over 1200 burns in US per day
- Total of 486,000 burns in US per year
- 14,000 adults treated in US burn centers each year
- Burn industry is predicted to be worth USD 3 billion globally by 2026



Current Split-Thickness Skin Grafting method outdated



Dermatome skin harvesting from new donor site



New (second) donor wound created via skin harvesting

- Large donor area required
- Pain associated with donor site
- Prolonged hospitalization plus high costs
- Multiple complex, costly, surgical procedures
- Risk of infection
- Scarring

Epicel[®]
(cultured epidermal autografts)



 **Mallinckrodt**
Pharmaceuticals
StrataGraft

 **PolyNovo**[®]
NovoSorb BTM

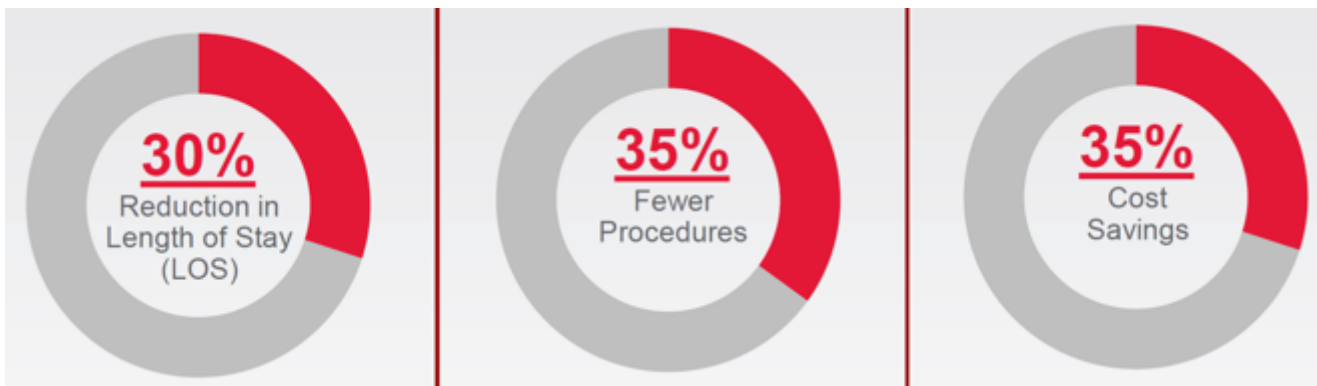
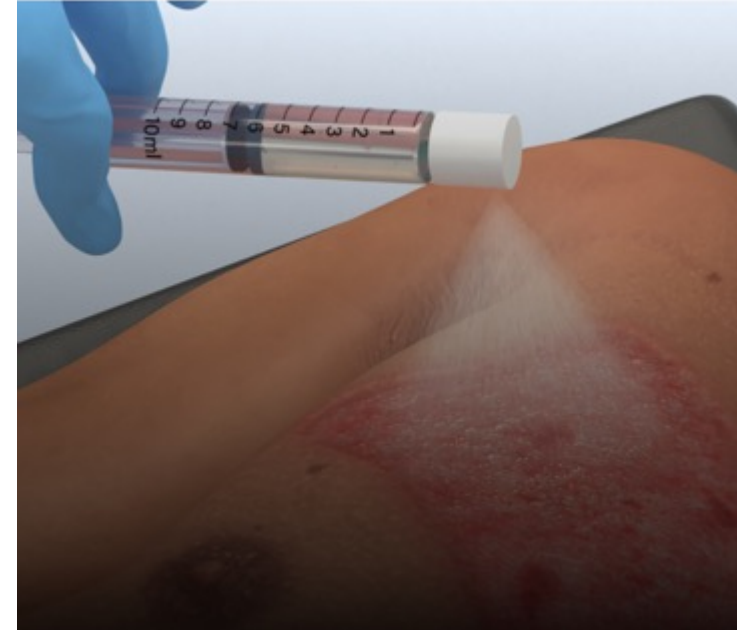
- Similar to Avita's RECELL
 - Require offsite preparing
 - Take 2-3 weeks for product (skin) manufacturing
 - High cost products
- Yet to receive FDA approval
 - Higher cost
- Can be used in conjunction with RECELL to produce better outcomes, therefore making it a complementary product
 - Approved in overlapping markets to RECELL



Strategy and CA

Avita's RECELL has strong Competitive Advantages

- **Cheap** - Comparatively cheap with respect to competitors and skin grafts at USD \$6,500 per unit
- **Quick** - RECELL takes only 30 minutes to manufacture
- **Simple** - Simple to use and therefore carries no switching costs associated with training and adoption by surgeons
- **Efficient** - RECELL has a large treatment area for a small donor area (treatment area = 80 x donor area)
- **Expandable** - The above points mean that rollout to other markets such as outpatient burns, and pediatric scalds will be smoother

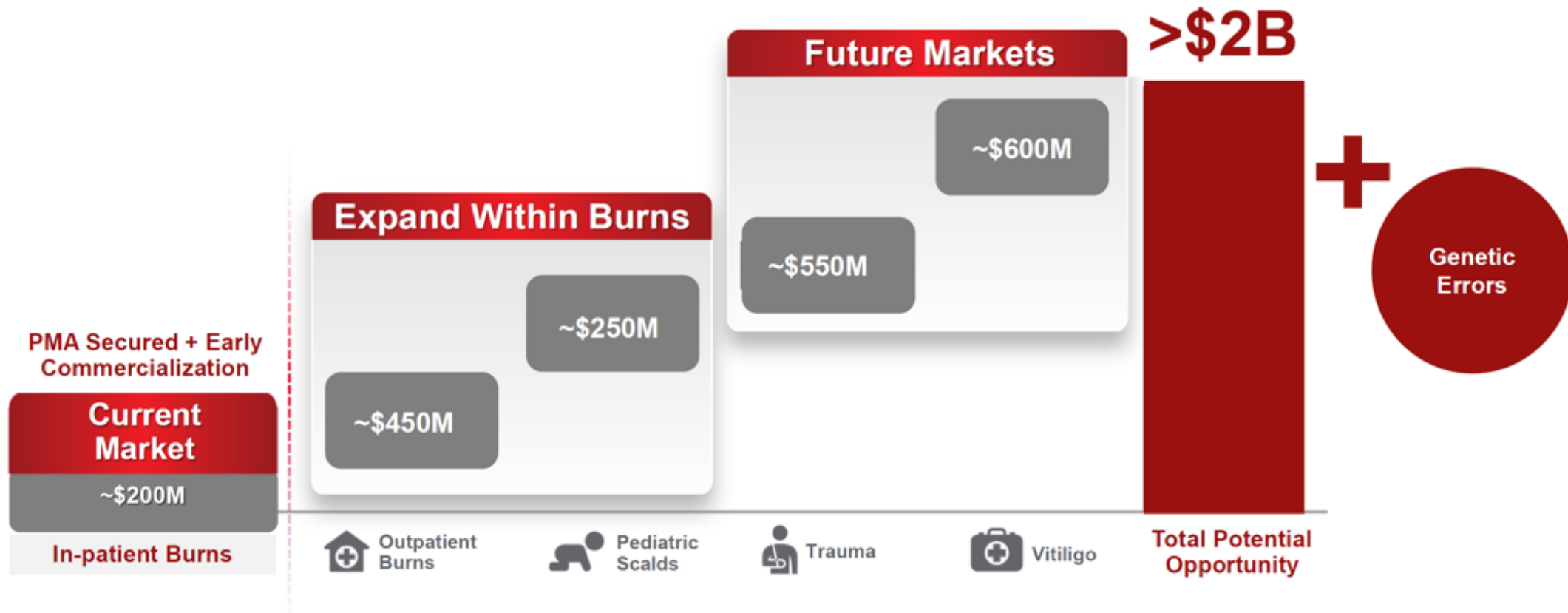


Uptake of RECELL in past year proves high growth

(United States \$'s)

	Quarter Ended				
	31 March 2019	30 June 2019	30 Sept 2019	31 Dec 2019	31 March 2020
US RECELL Sales	\$1,577,341	\$2,036,270	\$3,183,030	\$3,178,160	\$3,861,530
Cumulative. U.S. RECELL Sales	\$1,577,341	\$3,613,611	\$6,796,641	\$9,974,801	\$13,836,331
New Accounts	9	21	13	8	9
Cumulative Accounts	18	39	52	60	69
Physicians Certified	32	39	21	27	21
Cumulative Physicians	97	136	157	184	205

Expansion Strategy into other markets



Steps to reaching target markets

- **Pursue more favorable reimbursement** – This will allow patients outside of burn centers to be able to afford to use RECELL
- **RECELL “2.0” approval for market access** – RECELL 2.0 focuses on improved efficiencies and ease of use
- **Enrolling in US pivotal studies to gain FDA approval for a range of RECELL uses** – Avita is currenting enrolled varying pivotal studies in the US. This includes phase three trials for paediatric use and enrolling patients in a soft tissue reconstruction study.





Risks

There are three main risks Avita face

Risks	Mitigations
<ul style="list-style-type: none">Roll-out success	<ul style="list-style-type: none">Creation of RECELL 2.0 to increase ease and efficiency for use outside of burn centers.Seeking approval for outpatient funding
<ul style="list-style-type: none">FDA approval for uses outside of adult burns	<ul style="list-style-type: none">Continued BARDA funding suggests high likelihood of ultimate approvalHas already reached stage three for clinical trials for paediatrics
<ul style="list-style-type: none">Patent expiry	<ul style="list-style-type: none">Filed applications to prevent copy-cat device approval without undergoing clinical trials

The background of the slide is a collage of various microscopic cells. There are several pink, oval-shaped cells with prominent red nuclei. Some cells are purple and star-shaped, possibly representing specialized cells or microorganisms. One cell at the bottom center is green and elongated with a dark nucleus. The cells are scattered across the slide, creating a scientific and biological theme.

Financial Statements

AVITA MEDICAL LIMITED
CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME
FOR THE YEAR ENDED 30 JUNE 2019

	Notes	2019	2018
Continuing operations			
Sale of goods	2a	A\$ 7,705,398	A\$ 1,198,861
Cost of sales	2e	(1,697,823)	(511,646)
Gross profit		6,007,575	687,215
BARDA income	2b	8,259,152	10,104,081
Other income	2b	456,895	68,617
Total other income		8,715,847	10,172,698
Operating costs			
Sales and marketing expenses		(17,576,754)	(8,936,441)
Corporate and administrative expenses		(15,398,177)	(5,360,553)
Product development expenses		(14,361,995)	(12,606,127)
Share based payment expenses	2g	(2,688,817)	(1,835,157)
Finance costs	2c	(37,769)	(26,586)
Total operating costs		(50,063,512)	(28,764,864)
Loss from continuing operations before income tax benefit		(35,340,090)	(17,904,951)
Income tax benefit		179,863	1,385,796
Loss for the period	3	(35,160,227)	(16,519,155)
Other comprehensive income			
<i>Items that may be reclassified subsequently to profit and loss:</i>			
Foreign currency translation		1,783,222	563,279
Other comprehensive income for the period, net of tax		1,783,222	563,279
Total other comprehensive loss for the period		A\$ (33,377,005)	A\$ (15,955,876)
Loss for the period attributable to owners of the parent		(35,160,227)	(16,519,155)
Total comprehensive loss attributable to owners of the parent		A\$ (33,377,005)	A\$ (15,955,876)
Basic loss per share attributable to ordinary equity holders of the parent		A\$ (2.78) cents	A\$ (1.77) cents
Diluted loss per share attributable to ordinary equity holders of the parent		A\$ (2.78) cents	A\$ (1.77) cents

AVITA MEDICAL LIMITED
CONSOLIDATED STATEMENT OF FINANCIAL POSITION
AS AT 30 JUNE 2019

	2019	2018
ASSETS		
Current Assets		
Cash and cash equivalents	A\$ 28,983,491	A\$ 14,825,532
Trade and other receivables	2,980,102	5,437,357
Prepayments and other assets	1,557,525	855,716
Inventories	1,057,764	1,155,826
Total Current Assets	34,578,882	22,274,431
Non-Current Assets		
Plant and equipment	1,838,515	742,583
Patents-in-progress	320,676	-
Total Non-Current Assets	2,159,191	742,583
TOTAL ASSETS	A\$ 36,738,073	A\$ 23,017,014
LIABILITIES		
Current Liabilities		
Trade and other payables	5,633,562	3,487,582
Provisions	650,359	395,535
Total Current Liabilities	6,283,921	3,883,117
Non-Current liabilities		
Contract liability	610,674	-
Finance lease	54,057	134,338
Total Non-Current liabilities	664,731	134,338
TOTAL LIABILITIES	A\$ 6,948,652	A\$ 4,017,455
NET ASSETS	A\$ 29,789,421	A\$ 18,999,559
EQUITY		
Equity attributable to equity holders of the parent:		
Contributed equity	204,279,078	162,801,028
Accumulated losses	(183,753,106)	(148,592,879)
Reserves	9,263,449	4,791,410
TOTAL EQUITY	A\$ 29,789,421	A\$ 18,999,559

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Appendices

Impact of Covid-19

BURN BUSINESS

Non-Elective Procedure

- Patients suffering acute thermal burns require immediate treatment
- Burn procedures are not elective, and cannot be deferred
- Burn patients take up hospital beds, including ICU beds

Commercial Implications

- No material negative impact to revenue / procedural volumes through March 31st
- Difficult to assess longer-term impact of travel restrictions and social distancing
- New site ramp expected to slow given “movement restrictions”

OPERATIONS

Employees

- Implemented comprehensive work from home and social distancing policy
- Travel limited to essential travel
- Manufacturing continuing

Supply and Distribution

- No anticipated disruptions to supply chain or distribution network
- Sufficient raw materials to meet expected demand

Business “idling” and Well Capitalized

- Tightly focused on existing objectives and managing expenses

STUDIES & SUPPORT

Field Participation and Support

- Comprehensive digital and audio outreach program implemented
- Virtual case support and site training implemented
- Clinical onsite hospital support provided in a minority of territories but limited to urgent cases

Clinical Studies

- Investigational studies have been de-prioritized at all institutions
- Enrollment in all studies expected to be delayed