AVITA Medical Reports Third Quarter 2022 Financial Results

VALENCIA, California, November 10, 2022 and MELBOURNE, Australia, November 11, 2022 — AVITA Medical, Inc. (NASDAQ: RCEL, ASX: AVH) (the "**Company**"), a regenerative medicine company leading the development and commercialization of first-in-class devices and autologous cellular therapies for skin restoration, today reported financial results for the third quarter ended September 30, 2022.

Third Quarter Highlights and Recent Updates:

- Reported commercial revenue, which excludes BARDA revenue, of $9.0 million, a 30% increase compared to $6.9 million in the corresponding period in the prior year
- Reported total revenue, which includes BARDA revenue, of $9.1 million compared to $7.0 million in the corresponding period in the prior year
- Gross profit margin was 83%
- Topline results from its pivotal randomized controlled trial evaluating the safety and effectiveness of the RECELL® System for healing of soft tissue repair with reduced donor skin
    - Co-primary endpoints were met for superiority relative to donor skin sparing and for non-inferiority relative to healing
- Topline results from its pivotal randomized controlled trial evaluating the safety and effectiveness of the RECELL® System for repigmentation for stable vitiligo
    - Super-superiority was established for the primary endpoint
- The Company plans U.S. Food and Drug Administration (FDA) submissions for soft tissue repair and vitiligo indications in December 2022
- Breakthrough Device designation provided by the FDA for the RECELL System for soft tissue repair and vitiligo
- The Japanese MHLW (Ministry of Health, Labor, and Welfare) granted the RECELL System marketing approval with pricing to end-customers equivalent to our U.S. pricing. Our partner in Japan, COSMOTEC, an M3 Company, will launch commercial RECELL in Japan in Q4 2022
- As of September 30, 2022, the Company had $88.2 million in cash, cash equivalents, and marketable securities, with no debt

"Over the next 24 to 36 months, our growth is expected to be driven by the burns and soft tissue repair markets," said Jim Corbett, AVITA Medical Chief Executive Officer. "Soft tissue repair will expand our hospital and treating physician call points by nearly three times. We are prepared to make the necessary investment in our commercial organization to support this expansion. This market opportunity expansion and the related revenue growth is the number one priority of AVITA Medical."

Three Months Ended September 30, 2022 Financial Results

Our commercial revenue, which excludes BARDA revenue, increased by 30% or $2.1 million to $9.0 million in the three months ended September 30, 2022, compared to $6.9 million in the corresponding period in the prior year. Total revenue, which includes BARDA revenue, increased 30% or $2.1 million to $9.1 million compared to $7.0 million in the corresponding period in the prior year. The growth in commercial revenues was largely driven by deeper penetration within individual customer accounts along with the commencement of commercial sales with our partner COSMOTEC in Japan.

Gross profit margin decreased by 2% to 83% compared to the corresponding period in the prior year.

Total operating expenses increased by 16% or $2.0 million to $14.2 million compared to $12.3 million in the corresponding period in the prior year. The increase in operating expenses is attributable to higher compensation costs, pre-commercialization costs, research and development expenses, partially offset by lower share-based compensation expenses. Higher compensation costs were primarily a result of an expansion of our commercial team along with an increase in commissions which resulted from an increase in commercial revenues. In addition, we incurred severance costs in the current quarter associated with the termination of a former executive employee. Higher pre-commercialization costs are driven by activities related to future RECELL launches in soft tissue reconstruction and vitiligo. Increased research and development expenses resulted from ongoing development of next generation devices for an automated preparation of Spray-On Skin™ Cells. Higher research and development expenses were partially offset by lower clinical trial expenses for soft tissue reconstruction and vitiligo as trial participants were in less costly follow-up phases this period compared to more costly recruitment and treatment phases in the prior period. Share-based compensation expense was lower in the current period as certain performance milestones were met in the prior period, and there was a reversal in the current period of previously recognized expense for unvested awards related to the termination of an executive officer.

Net loss decreased by 6% or $0.4 million to $5.6 million, or $0.22 per share, compared to a net loss of $5.9 million, or $0.24 per share, in the corresponding period of the prior year.

Adjusted EBITDA* loss increased by 2% or $84 thousand to $4.0 million, compared to a loss of $3.9 million in the corresponding period in the prior year. A table reconciling non-GAAP measures is included in this press release for reference.

2022 Revenue Guidance

Turning to guidance, full year 2022 commercial revenue (excluding BARDA revenues) is expected to be $33.0-34.0 million, an increase from our prior guidance of $30 million, and an approximate 33% increase year-over-year. We continue to project BARDA revenues of approximately $0.3 million in calendar year 2022.

*Adjusted EBITDA is a non-GAAP financial measure. See the appendix to this release for a discussion of non-GAAP financial measures, including a reconciliation to the most closely correlated GAAP measure.

Webcast and Conference Call Information

The Company will host a conference call to discuss the third quarter financial results after NASDAQ market close on Thursday, November 10, 2022, at 1:30 p.m. Pacific Time (being Friday, November 11, 2022, at 8:30 a.m. Australian Eastern Daylight Time). To access the live call via telephone, please register in advance using the link here. Upon registering, each participant will receive an email confirmation with dial-in numbers and a unique personal PIN that can be used to join the call. The live webinar can be accessed at https://ir.avitamedical.com.

Authorized for release by the Chief Financial Officer of AVITA Medical, Inc.

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ABOUT AVITA MEDICAL, INC.
AVITA Medical is a regenerative medicine company leading the development and commercialization of devices and autologous cellular therapies for skin restoration. The RECELL® System technology platform, approved by the FDA for the treatment of acute thermal burns in both adults and children, harnesses the regenerative properties of a patient's own skin to create Spray-On Skin™ cells. Delivered at the point-of-care, RECELL enables improved clinical outcomes and validated cost savings. RECELL is the catalyst of a new treatment paradigm and AVITA Medical is leveraging its proven and differentiated capabilities to develop first-in-class cellular therapies for multiple indications, including soft tissue repair and repigmentation of stable vitiligo lesions.

AVITA Medical's first U.S. product, the RECELL System, was approved by the U.S. Food and Drug Administration (FDA) in September 2018. The RECELL System is approved for acute partial-thickness thermal burn wounds in patients 18 years of age and older or application in combination with meshed autografting for acute full-thickness thermal burn wounds in pediatric and adult patients. In February 2022, the FDA reviewed and approved the PMA supplement for RECELL Autologous Cell Harvesting Device, an enhanced RECELL System aimed at providing clinicians a more efficient user experience and simplified workflow.

The RECELL System is used to prepare Spray-On Skin™ Cells using a small amount of a patient's own skin, providing a new way to treat severe burns, while significantly reducing the amount of donor skin required. The RECELL System is designed to be used at the point of care alone or in combination with autografts depending on the depth of the burn injury. Compelling data from randomized, controlled clinical trials conducted at major U.S. burn centers and real-world use in more than 15,000 patients globally, reinforce that the RECELL System is a significant advancement over the current standard of care for burn patients and offers benefits in clinical outcomes and cost savings. Healthcare professionals should read the INSTRUCTIONS FOR USE - RECELL Autologous Cell Harvesting Device (https://recellsystem.com) for a full description of indications for use and important safety information including contraindications, warnings, and precautions.

In international markets, our products are approved under the RECELL System brand to promote skin healing in a wide range of applications including burns, soft tissue repair, vitiligo, and aesthetics. The RECELL System is TGA-registered in Australia, received CE-mark approval in Europe and has PMDA approval in Japan.

To learn more, visit www.avitamedical.com.

*** Use of non-GAAP Measure**

AVITA Medical's reported earnings are prepared in accordance with generally accepted accounting principles in the United States, or GAAP, and represent earnings as reported to the Securities and Exchange Commission. AVITA Medical has provided in this release certain financial information that has not been prepared in accordance with GAAP. AVITA Medical's management believes that the non-GAAP adjusted EBITDA described in the release, which includes adjustments for specific items that are generally not indicative of our core operations, provides additional information that is useful to investors in understanding AVITA Medical's underlying performance, business and performance trends, and helps facilitate period-to-period comparisons and comparisons of its financial measures with other companies in AVITA Medical's industry. However, the non-GAAP financial measures that AVITA Medical uses may differ from measures that other companies may use. Non-GAAP financial measures are not required to be uniformly applied, are not audited and should not be considered in isolation or as substitutes for results prepared in accordance with GAAP.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This press release includes forward-looking statements. These forward-looking statements generally can be identified by the use of words such as "anticipate," "expect," "intend," "could," "may," "will," "believe," "estimate," "look forward," "forecast," "goal," "target," "project," "continue," "outlook," "guidance," "future," other words of similar meaning and the use of future dates. Forward-looking statements in this press release include, but are not limited to, statements concerning, among other things, our ongoing clinical trials and product development activities, regulatory approval of our products, the potential for future growth in our business, and our ability to achieve our key strategic, operational, and financial goal. Forward-looking statements by their nature address matters that are, to different degrees, uncertain. Each forward-looking statement contained in this press release is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statement. Applicable risks and uncertainties include, among others, the timing and realization of regulatory approvals of our products; physician acceptance, endorsement, and use of our products; failure to achieve the anticipated benefits from approval of our products; the effect of regulatory actions; product liability claims; risks associated with international operations and expansion; and other business effects, including the effects of industry, economic or political conditions outside of the company's control. Investors should not place considerable reliance on the forward-looking statements contained in this press release. Investors are encouraged to read our publicly available filings for a discussion of these and other risks and uncertainties. The forward-looking statements in this

press release speak only as of the date of this release, and we undertake no obligation to update or revise any of these statements.

FOR FURTHER INFORMATION:

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AVITA MEDICAL, INC.
Consolidated Balance Sheets
(In thousands, except share and per share data)
(Unaudited)

	As of	
	September 30, 2022	**December 31, 2021**
ASSETS		
Cash and cash equivalents	$ 23,613	$ 55,511
Marketable securities	60,559	29,649
Accounts receivable, net	3,553	3,118
BARDA receivables	792	308
Prepaids and other current assets	1,041	1,213
Restricted cash	202	201
Inventory	1,960	2,132
Total current assets	91,720	92,132
Marketable securities, long-term	4,012	19,692
Plant and equipment, net	1,226	1,262
Operating lease right-of-use assets	1,029	1,544
Corporate-owned life insurance asset	948	304
Intangible assets, net	449	443
Other long-term assets	548	638
Total assets	$ 99,932	$ 116,015
LIABILITIES AND SHAREHOLDERS' EQUITY		
Accounts payable and accrued liabilities	3,118	2,708
Accrued wages and fringe benefits	4,776	5,363
Other current liabilities	1,619	1,075
Total current liabilities	9,513	9,146
Non-qualified deferred compensation plan liability	1,016	262
Contract liabilities	740	952
Operating lease liabilities, long-term	405	918
Other long-term liabilities	-	113
Total liabilities	$ 11,674	$ 11,391
Non-qualified deferred compensation plan share awards	272	-
Contingencies (Note 12)		
Shareholders' Equity:		
Common stock, $0.0001 par value per share, 200,000,000 shares authorized, 25,030,902 and 24,925,743 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	3	3
Preferred stock, $0.0001 par value per share, 10,000,000 shares authorized, no shares issued or outstanding at September 30, 2022 and December 31, 2021	-	-
Company common stock held by the non-qualified deferred compensation plan	(127)	-
Additional paid-in capital	337,995	332,484
Accumulated other comprehensive income	7,350	8,060
Accumulated deficit	(257,235)	(235,923)
Total shareholders' equity	$ 87,986	$ 104,624
Total liabilities and shareholders' equity	$ 99,932	$ 116,015

AVITA MEDICAL, INC.
Consolidated Statements of Operations
(In thousands, except share and per share data)
(Unaudited)

	Three-Months Ended September 30,		Nine-Months Ended September 30,	
	2022	2021	2022	2021
Revenues	$ 9,092	$ 7,020	$ 24,966	$ 26,089
Cost of sales	(1,530)	(1,088)	(4,694)	(5,287)
Gross profit	7,562	5,932	20,272	20,802
BARDA income	904	374	2,189	1,384
Operating expenses:				
Sales and marketing expenses*	(5,411)	(3,518)	(15,571)	(11,313)
General and administrative expenses*	(5,004)	(5,349)	(18,009)	(16,046)
Research and development expenses*	(3,799)	(3,388)	(10,478)	(11,471)
Total operating expenses	(14,214)	(12,255)	(44,058)	(38,830)
Operating loss	(5,748)	(5,949)	(21,597)	(16,644)
Interest expense	(6)	(9)	(10)	(21)
Other income	170	16	307	25
Loss before income taxes	(5,584)	(5,942)	(21,300)	(16,640)
Income tax expense	(4)	(6)	(12)	(23)
Net loss	$ (5,588)	$ (5,948)	$ (21,312)	$ (16,663)
Net loss per common share:				
Basic	$ (0.22)	$ (0.24)	$ (0.85)	$ (0.69)
Diluted	$ (0.22)	$ (0.24)	$ (0.85)	$ (0.69)
Weighted-average common shares:				
Basic	25,006,995	24,905,403	24,972,331	24,174,811
Diluted	25,006,995	24,905,403	24,972,331	24,174,811

* Total operating expenses include impact of share-based compensation as follows:

(In thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Sales and marketing expenses	$ 408	$ 291	$ 1,022	$ 592
General and administrative expenses	761	1,251	4,071	3,353
Research and development expenses	267	300	689	640
Total	$ 1,436	$ 1,842	$ 5,782	$ 4,585

Reconciliation of reported Net Loss (GAAP) to Adjusted EBIDTA (NON-GAAP) Measure – Unaudited

(In thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Net Loss	$ (5,588)	$ (5,948)	$ (21,312)	$ (16,663)
Depreciation expense	130	147	388	429
Patent Amortization	8	27	50	88
Share-based expense	1,436	1,842	5,782	4,585
Interest Expense	6	9	10	21
Income Tax Expense	4	6	12	23
Adjusted EBITDA (Non-GAAP)	$ (4,004)	$ (3,917)	$ (15,070)	$ (11,517)