AVITA Medical Reports Fourth Quarter and Full Year 2022 Financial Results and Provides 2023 Financial Guidance

February 23, 2023

VALENCIA, Calif. and MELBOURNE, Australia, Feb. 23, 2023 (GLOBE NEWSWIRE) -- 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 fourth quarter and full-year ended December 31, 2022.

Full-Year 2022 and Recent Updates

- Commercial revenue, which excludes BARDA revenue, of $34.1 million, a 36% increase compared to $25.1 million for the same period in 2021
- Total revenue, which includes BARDA revenue, of $34.4 million, a 4% increase compared to $33.0 million for the same period in 2021
- Gross profit margin of 82%
- Food and Drug Administration (FDA) granted Breakthrough Device designations for the RECELL® System for both the soft tissue repair and vitiligo indications
- Premarket Approval (PMA) supplement application submitted to FDA for soft tissue repair indication in December 2022
- PMA application submitted to FDA for vitiligo indication in December 2022
- As of December 31, 2022, $86.3 million in cash, cash equivalents, and marketable securities, with no debt

"We delivered strong fourth quarter and 2022 results, ending the year in a solid financial position," said Jim Corbett, AVITA Medical Chief Executive Officer. "We continue to execute on our growth strategy, with all areas of our business exceeding my expectations. I would like to personally applaud our commercial sales field team for their increased sales volume and our regulatory team for their expeditious submissions to the FDA last quarter."

"Looking ahead, 2023 is our year of inflection," continued Mr. Corbett. "We expect FDA approvals in June 2023 for our soft tissue repair and vitiligo indications, which we believe will be transformative for our company. Soft tissue repair utilizes the same inpatient reimbursement and outpatient codes as burns, thus inpatient and outpatient reimbursement will be effective immediately upon FDA approval, affording us the unique opportunity to prepare for a full commercial launch on July 1, 2023. In anticipation, we expect to more than double our existing field sales organization, which will cover both burn and soft tissue accounts. This strategic expansion sets us on a path of revenue growth for the next three to five years."

Future Milestones

- Expansion of the field sales organization from 30 to approximately 70 professionals in the second quarter of 2023 in anticipation of the launch of soft tissue repair
- Expect FDA approval for soft tissue repair indication in June 2023 followed by the commercial launch on July 1, 2023
- Anticipate FDA submission of automation program by June 30, 2023
- Expect FDA approval for vitiligo indication in June 2023; pursuing site of service reimbursement for the use of RECELL in the physician office setting, which is expected by January 2025

Financial Guidance

- Commercial revenue, which excludes BARDA revenue, for the first quarter 2023 is expected to be in the range of $10 to $11 million
- Commercial revenue, which excludes BARDA revenue, for the full year 2023 is expected to be in the range of $49 to $51 million

Fourth Quarter 2022 Financial Results

Our commercial revenue, which excludes BARDA revenue, increased by 37% to $9.4 million in the three months ended December 31, 2022, compared to $6.8 million in the same period in 2021. Total revenue, which includes BARDA revenue, increased by 36% to $9.5 million compared to $6.9 million in the same period in 2021.

The gross profit margin was 86% compared to 88% for the fourth quarter of 2021.

Total operating expenses for the quarter increased by 2% to $15.0 million, compared to $14.8 million in the same period in 2021.

Net loss decreased by 37% to $5.4 million, or $0.21 per share, compared to a net loss of $8.5 million, or $0.34 per share, in the same period in 2021.

Adjusted EBITDA* loss decreased by 39% to $4.0 million, compared to a loss of $6.5 million in the same period in 2021.

Full Year 2022 Financial Results

Our commercial revenue, which excludes BARDA revenue, increased by 36% to $34.1 million in the full year ended December 31, 2022, compared to $25.1 million in the same period in 2021. Total revenue, which includes BARDA revenue, increased 4% to $34.4 million compared to $33.0 million in the same period in 2021.

Gross profit margin was 82%, flat compared to the same period in 2021.

Total operating expenses increased by 10% to $59.1 million compared to $53.6 million in the same period in 2021.

Net loss was $26.7 million, or $1.07 per share, compared to a net loss of $25.1 million, or $1.03 per share, in the same period in 2021.

Adjusted EBITDA* loss was $19.0 million, compared to a loss of $18.1 million in the same period in 2021. A table reconciling non-GAAP measures is included in this press release for reference.

Webcast and Conference Call Information

The Company will host a conference call to discuss the fourth quarter financial results, full-year 2022 financial results, business highlights, and 2023 revenue guidance on Thursday, February 23, 2023, at 1:30 p.m. Pacific Time (being Friday, February 24, 2023, 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. A simultaneous webcast of the call will be available via the Company's website at https://ir.avitamedical.com.

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

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:

Investors & Media
AVITA Medical, Inc.
Jessica Ekeberg
Phone +1 661 904 9269
investor@avitamedical.com
media@avitamedical.com

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

	December 31, 2022	December 31, 2021
ASSETS		
Cash and cash equivalents	$ 18,164	$ 55,511
Marketable securities	61,178	29,649
Accounts receivable, net	3,515	3,118
BARDA receivables	898	308
Prepaids and other current assets	1,578	1,213
Restricted cash	-	201
Inventory	2,125	2,132
Total current assets	87,458	92,132
Marketable securities long-term	6,930	19,692
Plant and equipment, net	1,200	1,262
Operating lease right-of-use assets	851	1,544
Corporate-owned life insurance asset	1,238	304
Intangible assets, net	465	443
Other long-term assets	122	638
Total assets	$ 98,264	$ 116,015
LIABILITIES AND SHAREHOLDERS' EQUITY		
Accounts payable and accrued liabilities	3,002	2,708
Accrued wages and fringe benefits	6,623	5,363
Other current liabilities	1,068	1,075
Total current liabilities	10,693	9,146
Non-qualified deferred compensation liability	1,270	262
Contract liabilities	698	952
Operating lease liabilities, long term	306	918
Other long-term liabilities	-	113
Total liabilities	12,967	11,391
Non-qualified deferred compensation plan share awards	557	-
Contingencies (Note 12)		
Shareholders' equity:		
Common stock, $0.0001 par value per share,200,000,000 shares authorized, 25,208,436, 24,925,743 and 24,895,864 shares issued and outstanding at December 31, 2022, December 31, 2021 and June 30, 2021, respectively	3	3
Preferred stock, $0.0001 par value per share, 10,000,000 shares authorized, no shares issued or outstanding at December 31, 2022 and December 31, 2021.	-	-
Company common stock held by the non-qualified deferred compensation plan	(127)	-
Additional paid-in capital	339,825	332,484
Accumulated other comprehensive income	7,627	8,060
Accumulated deficit	(262,588)	(235,923)
Total shareholders' equity	84,740	104,624
Total liabilities, non-qualified deferred compensation plan share awards and shareholders' equity	$ 98,264	$ 116,015

Consolidated Statements of Operations
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2022	**2021**	**2022**	**2021**
Revenues	$ 9,455	$ 6,936	$ 34,421	$ 33,025
Cost of sales	(1,347)	(817)	(6,041)	(6,104)
Gross profit	8,108	6,119	28,380	26,921
BARDA income	1,026	206	3,215	1,590
Operating expenses:				
Sales and marketing expenses	(6,342)	(4,954)	(21,913)	(16,267)
General and administrative expenses	(5,321)	(5,647)	(23,330)	(21,693)
Research and development expenses	(3,379)	(4,198)	(13,857)	(15,669)
Total operating expenses	(15,042)	(14,799)	(59,100)	(53,629)
Operating loss	(5,908)	(8,474)	(27,505)	(25,118)
Interest expense	(6)	(8)	(16)	(29)
Other income	585	22	892	47
Loss before income taxes	(5,329)	(8,460)	(26,629)	(25,100)
Provision for income tax	(24)	(19)	(36)	(42)
Net loss	$ (5,353)	$ (8,479)	$ (26,665)	$ (25,142)
Net loss per common share:				
Basic	$ (0.21)	$ (0.34)	$ (1.07)	$ (1.03)
Diluted	$ (0.21)	$ (0.34)	$ (1.07)	$ (1.03)
Weighted-average common shares:				
Basic	25,082,816	24,925,424	25,000,180	24,364,024
Diluted	25,082,816	24,925,424	25,000,180	24,364,024

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

(In thousands)	Three Months Ended December 31,		Year Ended December 31,	
	2022	**2021**	**2022**	**2021**
Sales and marketing expenses	$ 371	$ 372	$ 1,393	$ 964
General and administrative expenses	597	1,067	4,668	4,420
Research and development expenses	248	307	937	947
Total	$ 1,216	$ 1,746	$ 6,998	$ 6,631

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

(In thousands)	Three Months Ended December 31,		Year Ended December 31,	
	2022	**2021**	**2022**	**2021**
Net Loss	$ (5,353)	$ (8,479)	$ (26,665)	$ (25,142)
Depreciation expense	122	127	510	556
Patent Amortization	8	32	58	120
Share-based expense	1,216	1,746	6,998	6,331
Interest Expense	6	8	16	29
Income Tax Expense	24	19	36	42
Adjusted EBITDA (Non-GAAP)	$ (3,977)	$ (6,547)	$ (19,047)	$ (18,064)