# AVITA Medical Reports First Quarter Financial Results and Affirms Full Year Guidance

May 11, 2023

VALENCIA, Calif. and MELBOURNE, Australia, May 11, 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 first quarter March 31, 2023.

**Financial Highlights and Recent Updates**

- Commercial revenue, which excludes BARDA revenue, of $10.5 million, a 40% increase compared to $7.4 million for the same period in 2022
- Total revenue, which includes BARDA revenue, of $10.6 million, a 40% increase compared to $7.5 million for the same period in 2022
- Gross profit margin was 84% compared to 76% in the same period in 2022
- Expanded field sales organization from 30 to 69, towards our goal of 70
- Automated disaggregation device, RECELL GO™, maintains the Food and Drug Administration (FDA) Breakthrough Device designation
- Appointed two independent members to the Board of Directors, Cary Vance and Robert McNamara
- As of March 31, 2023, $77.6 million in cash, cash equivalents, and marketable securities, with no debt

"With a solid first quarter, we are on track to deliver a year of significant growth revenue," said Jim Corbett, AVITA Medical Chief Executive Officer. "The onboarding and training of our expanded U.S. field sales organization is underway, and we believe we will be fully prepared for the commercial launch of the soft tissue repair indication following expected FDA approval in June. Further, we are on track to submit our PMA supplement to the FDA for RECELL GO by the end of the second quarter. We believe RECELL GO is a critical component of our platform and has the potential to significantly accelerate our growth trajectory."

**Future Milestones**

- Expect FDA approval for soft tissue repair indication in June 2023 followed by the commercial launch on July 1, 2023
- Anticipate FDA submission of RECELL GO 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 2025

**Financial Guidance**

- Commercial revenue, which excludes BARDA revenue, for the second quarter 2023 is expected to be in the range of $10.7 to $11.7 million
- Commercial revenue, which excludes BARDA revenue, for the full year 2023, remains unchanged, and is expected to be in the range of $49 to $51 million

**Organizational Update**

Mr. Terry Bromley has been promoted to Senior Vice President of Global Sales and Ms. Debbie Garner has been promoted to Senior Vice President of Global Marketing and Strategy. Mr. Bromley and Ms. Garner will report directly to Jim Corbett, Chief Executive Officer of AVITA Medical.

On May 11, 2023, Ms. Erin Liberto resigned from her position as Chief Commercial Officer to accept a role with a privately held, non-competing business.

**First Quarter 2023 Financial Results**

Our commercial revenue, which excludes BARDA revenue, increased by 40% to $10.5 million in the three-months ended March 31, 2023, compared to $7.4 million in the same period in 2022. Total revenue, which includes BARDA revenue, increased by 40% to $10.6 million compared to $7.5 million in the same period in 2022.

The gross profit margin was increased by 8% to 84% compared to 76% for the first quarter of 2022.

Total operating expenses for the quarter increased by 22% to $19.4 million, compared to $16.0 million in the same period in 2022, primarily due to increased field expansion and continued development of the RECELL GO device for the planned submission in June 2023.

Net loss decreased by 3% to $9.2 million, or $0.37 per share, compared to a net loss of $9.5 million, or $0.38 per share, in the same period in 2022.

Adjusted EBITDA* loss remained flat at $6.4 million.

**Webcast and Conference Call Information**

The Company will host a conference call to discuss the first quarter financial results and, recent business highlights on Thursday, May 11, 2023, at 1:30 p.m. Pacific Time (being Friday, May 12, 2023, at 6:30 a.m. Australian Eastern Daylight Standard 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 statements. 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 March 31, 2023 | As of December 31, 2022 |
|---|---|---|
| **ASSETS** | | |
| Cash and cash equivalents | $ 28,050 | $ 18,164 |
| Marketable securities | 45,401 | 61,178 |
| Accounts receivable, net | 4,502 | 3,515 |
| BARDA receivables | 516 | 898 |
| Prepaids and other current assets | 1,481 | 1,578 |
| Inventory | 2,811 | 2,125 |
| Total current assets | 82,761 | 87,458 |
| Marketable securities long-term | 4,189 | 6,930 |
| Plant and equipment, net | 1,333 | 1,200 |
| Operating lease right-of-use assets | 1,815 | 851 |
| Corporate-owned life insurance asset | 1,833 | 1,238 |
| Intangible assets, net | 461 | 465 |
| Other long-term assets | 230 | 122 |
| Total assets | $ 92,622 | $ 98,264 |
| **LIABILITIES, NON-QUALIFIED DEFERRED COMPENSATION PLAN SHARE AWARDS AND STOCKHOLDERS' EQUITY** | | |
| Accounts payable and accrued liabilities | 3,752 | 3,002 |
| Accrued wages and fringe benefits | 3,665 | 6,623 |
| Current non-qualified deferred compensation liability | 2,140 | 78 |
| Other current liabilities | 1,929 | 990 |
| Total current liabilities | 11,486 | 10,693 |
| Non-qualified deferred compensation liability | 1,165 | 1,270 |
| Contract liabilities | 382 | 698 |
| Operating lease liabilities, long term | 1,235 | 306 |
| Total liabilities | 14,268 | 12,967 |
| Non-qualified deferred compensation plan share awards | 793 | 557 |
| Contingencies (Note 12) | | |
| Stockholders' equity: | | |
| Common stock, $0.0001 par value per share, 200,000,000 shares authorized, 25,327,761 and 25,208,436 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively | 3 | 3 |
| Preferred stock, $0.0001 par value per share, 10,000,000 shares authorized, no shares issued or outstanding at March 31, 2023 and December 31, 2022. | - | - |
| Company common stock held by the non-qualified deferred compensation plan | (892) | (127) |
| Additional paid-in capital | 342,400 | 339,825 |
| Accumulated other comprehensive income | 7,858 | 7,627 |
| Accumulated deficit | (271,808) | (262,588) |
| Total stockholders' equity | 77,561 | 84,740 |
| Total liabilities, non-qualified deferred compensation plan share awards and stockholders' equity | $ 92,622 | $ 98,264 |

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

| | Three- Months Ended | |
|---|---|---|
| | March 31, 2023 | March 31, 2022 |
| Revenues | $ 10,550 | $ 7,539 |
| Cost of sales | (1,667) | (1,778) |
| Gross profit | 8,883 | 5,761 |
| BARDA income | 627 | 734 |
| Operating expenses: | | |
| Sales and marketing expenses | (6,540) | (4,828) |
| General and administrative expenses | (8,295) | (7,534) |

| | | |
|---|---|---|
| Research and development expenses | (4,586) | (3,620) |
| Total operating expenses | (19,421) | (15,982) |
| Operating loss | (9,911) | (9,487) |
| Interest expense | (4) | - |
| Other income | 725 | 28 |
| Loss before income taxes | (9,190) | (9,459) |
| Provision for income tax | (30) | (4) |
| Net loss | $ (9,220) | $ (9,463) |
| | | |
| Net loss per common share: | | |
| Basic | $ (0.37) | $ (0.38) |
| Diluted | $ (0.37) | $ (0.38) |
| | | |
| Weighted-average common shares: | | |
| Basic | 25,202,088 | 24,937,999 |
| Diluted | 25,202,088 | 24,937,999 |

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

| | Three-Months Ended | |
|---|---|---|
| (In thousands) | **March 31, 2023** | **March 31, 2022** |
| Sales and marketing expenses | $ 325 | $ 329 |
| General and administrative expenses | 2,090 | 2,327 |
| Research and development expenses | 225 | 276 |
| Total | $ 2,640 | $ 2,932 |

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

| | Three-Months Ended | |
|---|---|---|
| (In thousands) | **March 31, 2023** | **March 31, 2022** |
| Net Loss | $ (9,220) | $ (9,463) |
| Depreciation expense | 126 | 129 |
| Patent Amortization | 9 | 34 |
| Share-based expense | 2,640 | 2,932 |
| Interest Expense | 4 | - |
| Income Tax Expense | 30 | 4 |
| **Adjusted EBITDA (Non-GAAP)** | $ (6,411) | $ (6,364) |