AVITA Medical Reports Third Quarter Financial Results with 51% Revenue Growth over the Same Period the Prior Year

November 9, 2023

VALENCIA, Calif., Nov. 09, 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 third quarter September 30, 2023.

Financial Highlights and Recent Updates

- Commercial revenue of $13.5 million, an approximately 51% increase compared to $9.0 million for the same period in 2022
- Gross margin of 84.5% for the quarter
- Announced international expansion plan; engaged first European distribution partner, PolyMedics Innovations GmbH, to lead expansion into Germany, Austria, and Switzerland
- In October, secured a debt financing facility for up to $90.0 million, of which $40.0 million was borrowed at closing. Together with the cash on hand of $60.1 million as of September 30, 2023, the Company believes it has sufficient capital to meet its goals and to reach profitability during 2025.

"We continue to execute our growth strategy, paving the way to profitability," said Jim Corbett, Chief Executive Officer of AVITA. "We are diligently working through supplemental in-house testing to support the FDA's review of our PMA supplement for RECELL GO. Once complete, we expect to submit a response to the FDA's open questions on February 28, 2024. Under the Breakthrough Device program, we anticipate FDA approval on May 30, 2024, which positions us for a launch the following day."

Future Milestones

- Expect FDA real-time review of the PMA Supplement for RECELL GO ™ to resume on March 1, 2024, day 91 of the 180-day review cycle, with FDA approval anticipated on May 30, 2024
- Reaffirming high growth potential of full-thickness skin defect indication, which presents a market 10 times the size of original burns market
- Plan to actively identify new international distributor partnerships, including Australia, Japan, and European Union, over the next 6 to 12 months
- Expect full enrollment of post-market study, TONE, by end of February 2024
- Initiating health care economics study to capture longitudinal healthcare costs of vitiligo patients
- Expect initial reimbursement coverage for vitiligo in Q3 2025
- Expect to reach profitability in 2025

"We have achieved significant commercial revenue growth rates for the last three quarters of 40%, 42% and 51%, respectively, over the same periods in the previous year," said David O'Toole, Chief Financial Officer of AVITA Medical. "Further, we remain confident that our cash reserves position us to achieve our goals and reach profitability in 2025."

Financial Guidance

- Commercial revenue for the fourth quarter 2023 is expected to be in the range of $15.3 to $16.3 million, reflecting a lower bound of 64% and upper bound of 73% growth over the same period in the prior year
- Commercial revenue for the full year 2023 is expected to be in the range of $51 to $53 million, reflecting a lower bound of 50% and upper bound of 56% growth over the same period in the

prior year
- Gross margin for the full year 2023 expected to be in the range of 83% to 85%

Third Quarter 2023 Financial Results

Our commercial revenue, which excludes Biomedical Advanced Research and Development Authority (BARDA) revenue, increased by 51% to $13.5 million in the three-months ended September 30, 2023, compared to $9.0 million in the same period in 2022. Total revenue, which includes BARDA revenue, increased by 50% to $13.6 million compared to $9.1 million in the same period in 2022.

Gross profit margin increased by 1.3% to 84.5% compared to 83.2% for the third quarter of 2022. The increase was largely driven by higher production associated with our increase in revenues and lower shipping costs.

Total operating expenses for the quarter were $21.0 million, compared to $14.2 million in the same period in 2022. The increase in operating expenses is primarily attributable to an increase of $5.1 million in sales and marketing costs. The increase in sales and marketing costs is a result of the expansion of our commercial organization in preparation of the commercial launch of full-thickness skin defects that happened in the second quarter. In addition, the increase in operating expenses included an increase of $0.6 million in R&D costs, and an increase of $1.1 million in G&A costs, primarily due to an increase in stock compensation expense.

Net loss was $8.7 million, or a loss of $0.34 per basic and diluted share, compared to a net loss of $5.6 million, or a loss of $0.22 per basic and diluted share, in the same period in 2022.

As of September 30, 2023, the Company had approximately $60.1 million in cash, cash equivalents, and marketable securities.

BARDA income consisted of funding from the Biomedical Advanced Research and Development Authority, under the Assistant Secretary for Preparedness and Response, within the U.S. Department of Health and Human Services, under ongoing USG Contract No. HHSO100201500028C.

Webcast and Conference Call Information
The Company will host a conference call to discuss the third quarter financial results and, recent business highlights on Thursday, November 9, 2023, at 1:30 p.m. Pacific 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.

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 thermal burn wounds and full-thickness skin defects and for repigmentation of stable depigmented vitiligo lesions, 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. 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.

In international markets, our products are approved under the RECELL System brand to promote skin healing in a wide range of applications including burns, full-thickness skin defects, and vitiligo. 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.

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.

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

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

	As of	
	September 30, 2023	**December 31, 2022**

ASSETS		
Cash and cash equivalents	$ 50,854	$ 18,164
Marketable securities	9,264	61,178
Accounts receivable, net	5,875	3,515
BARDA receivables	201	898
Prepaids and other current assets	3,356	1,578
Inventory	4,377	2,125
Total current assets	73,927	87,458
Marketable securities long-term	-	6,930
Plant and equipment, net	1,862	1,200
Operating lease right-of-use assets	2,607	851
Corporate-owned life insurance ("COLI") asset	1,923	1,238
Intangible assets, net	459	465
Other long-term assets	236	122
Total assets	$ 81,014	$ 98,264
LIABILITIES, NON-QUALIFIED DEFERRED COMPENSATION PLAN SHARE AWARDS AND STOCKHOLDERS' EQUITY		
Accounts payable and accrued liabilities	3,019	3,002
Accrued wages and fringe benefits	7,143	6,623
Current non-qualified deferred compensation liability	333	78
Other current liabilities	1,341	990
Total current liabilities	11,836	10,693
Non-qualified deferred compensation liability	3,361	1,270
Contract liabilities	365	698
Operating lease liabilities, long term	1,845	306
Total liabilities	17,407	12,967
Non-qualified deferred compensation plan share awards	629	557
Contingencies (Note 12)		
Stockholders' equity:		
Common stock, $0.0001 par value per share, 200,000,000 shares authorized, 25,550,690 and 25,208,436 shares issued and outstanding at September 30, 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 September 30, 2023, and December 31, 2022.	-	-
Company common stock held by the non-qualified deferred compensation plan ("NQDC Plan")	(1,290)	(127)
Additional paid-in capital	347,192	339,825
Accumulated other comprehensive income	7,977	7,627
Accumulated deficit	(290,904)	(262,588)
Total stockholders' equity	62,978	84,740
Total liabilities, non-qualified deferred compensation plan share awards and stockholders' equity	$ 81,014	$ 98,264

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

	Three-Months Ended		Nine-Months Ended	
	September 30, 2023	**September 30, 2022**	**September 30, 2023**	**September 30, 2022**
Revenues	$ 13,645	$ 9,092	$ 35,948	$ 24,966
Cost of sales	(2,113)	(1,530)	(5,984)	(4,694)
Gross profit	11,532	7,562	29,964	20,272
BARDA income	212	904	1,369	2,189
Operating expenses:				
Sales and marketing expenses	(10,532)	(5,411)	(27,075)	(15,571)
General and administrative expenses	(6,124)	(5,004)	(20,584)	(18,009)
Research and development expenses	(4,394)	(3,799)	(14,056)	(10,478)
Total operating expenses	(21,050)	(14,214)	(61,715)	(44,058)
Operating loss	(9,306)	(5,748)	(30,382)	(21,597)
Interest expense	(10)	(6)	(21)	(10)
Other income	615	170	2,141	307
Loss before income taxes	(8,701)	(5,584)	(28,262)	(21,300)
Income tax expense	(11)	(4)	(54)	(12)
Net loss	$ (8,712)	$ (5,588)	$ (28,316)	$ (21,312)
Net loss per common share:				

Basic and Diluted	$ (0.34)	$ (0.22)	$ (1.12)	$ (0.85)
Weighted-average common shares:				
Basic and Diluted	25,401,754	25,006,995	25,281,920	24,972,331