AVITA Medical Reports Second Quarter Financial Results

August 10, 2023

VALENCIA, Calif., Aug. 10, 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 second quarter June 30, 2023.

Financial Highlights and Recent Updates

- Commercial revenue of $11.7 million, a 42% increase compared to $8.2 million for the same period in 2022
- Received Food and Drug Administration (FDA) approval of premarket approval (PMA) supplement for the use of RECELL to treat full-thickness skin defects on June 7
- Initiated commercial launch of full-thickness skin defects, along with additional eligible burn procedures, with expanded U.S. commercial organization on June 8
- Received FDA approval of PMA application to use RECELL for repigmentation of stable depigmented vitiligo lesions on June 16
- Submitted PMA supplement for automated cell disaggregation device, RECELL GO™, which maintains the FDA Breakthrough Device designation
- As of June 30, 2023, $68.8 million in cash, cash equivalents, and marketable securities, with no debt

"We had an extraordinary second quarter with significant revenue growth, two landmark FDA approvals, and a pivotal FDA submission," said Jim Corbett, AVITA Medical Chief Executive Officer. "As anticipated, our expanded U.S. commercial organization was fully prepared for the FDA approval of full-thickness skin defects. Our proactive preparation enabled us to initiate the commercial launch the day after receiving FDA approval. Additionally, our PMA supplement for RECELL GO is on track, and we expect approval before the end of the year. Collectively, these approvals and submission mark significant advancement of our platform, empowering us to continue to unlock our growth potential."

Future Milestones

- Anticipate FDA approval of RECELL GO by December 27, 2023
- Conducting post-market study with vitiligo patients to demonstrate the repigmentation and mental health benefits of treatment with RECELL, and reduction of associated health care costs
- Pursuing site of service reimbursement for the use of RECELL in the physician office setting, which is expected in 2025

Financial Guidance

- Commercial revenue for the third quarter 2023 is expected to be in the range of $13 to $14 million
- Raising commercial revenue for the full year 2023 from $49 to $51 million to an expected range of $51 to $53 million
- Gross margin for the full year 2023 expected to be in the range of 83% to 85%

Second Quarter 2023 Financial Results

Our commercial revenue, which excludes Biomedical Advanced Research and Development Authority (BARDA) revenue, increased by 42% to $11.7 million in the three-months ended June 30, 2023, compared to $8.2 million in the same period in 2022. Total revenue, which includes BARDA revenue, increased by 41% to $11.8 million compared to $8.3 million in the same period in 2022.

Gross profit margin decreased by 2% to 81% compared to 83% for the second quarter of 2022. The decrease was largely driven by lower production in one month of the quarter caused by the need to qualify new vendors for certain manufacturing components.

Total operating expenses for the quarter increased by 53% to $21.1 million, compared to $13.9 million in the same period in 2022, primarily due to the significant increase of the commercial organization in preparation of the full-thickness skin defect launch. Additionally, our research and development expenses increased by approximately $2.0 million due to ongoing development of the RECELL GO device and costs associated with our Medical Science Liaison team.

Net loss was $10.4 million, or a loss of $0.41 per share, compared to a net loss of $6.3 million, or a loss of $0.25 per share, in the same period in 2022.

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 second quarter financial results and, recent business highlights on Thursday, August 10, 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, 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.

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	
	June 30, 2023	December 31, 2022
ASSETS		
Cash and cash equivalents	$ 37,485	$ 18,164
Marketable securities	28,562	61,178
Accounts receivable, net	5,754	3,515
BARDA receivables	442	898
Prepaids and other current assets	2,194	1,578
Inventory	3,058	2,125
Total current assets	77,495	87,458
Marketable securities long-term	2,754	6,930
Plant and equipment, net	1,598	1,200

Operating lease right-of-use assets	1,651	851
Corporate-owned life insurance asset	2,091	1,238
Intangible assets, net	456	465
Other long-term assets	285	122
Total assets	$ 86,330	$ 98,264
LIABILITIES, NON-QUALIFIED DEFERRED COMPENSATION PLAN SHARE AWARDS AND STOCKHOLDERS' EQUITY		
Accounts payable and accrued liabilities	3,837	3,002
Accrued wages and fringe benefits	6,200	6,623
Current non-qualified deferred compensation liability	2,572	78
Other current liabilities	1,201	990
Total current liabilities	13,810	10,693
Non-qualified deferred compensation liability	1,224	1,270
Contract liabilities	374	698
Operating lease liabilities, long term	1,047	306
Total liabilities	16,455	12,967
Non-qualified deferred compensation plan share awards	1,228	557
Contingencies (Note 13)		
Stockholders' equity:		
Common stock, $0.0001 par value per share, 200,000,000 shares authorized, 25,447,615 and 25,208,436 shares issued and outstanding at June 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 March 31, 2023 and December 31, 2022.	-	-
Company common stock held by the non-qualified deferred compensation plan ("NQDC Plan")	(892)	(127)
Additional paid-in capital	343,769	339,825
Accumulated other comprehensive income	7,959	7,627
Accumulated deficit	(282,192)	(262,588)
Total stockholders' equity	68,647	84,740
Total liabilities, non-qualified deferred compensation plan share awards and stockholders' equity	$ 86,330	$ 98,264

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

	Three-Months Ended		Six-Months Ended	
	June 30, 2023	June 30, 2022	June 30, 2023	June 30, 2022
Revenues	$ 11,753	$ 8,335	$ 22,303	$ 15,874
Cost of sales	(2,204)	(1,386)	(3,871)	(3,164)
Gross profit	9,549	6,949	18,432	12,710
BARDA income	530	551	1,157	1,285
Operating expenses:				
Sales and marketing expenses	(10,003)	(5,332)	(16,543)	(10,160)
General and administrative expenses	(6,165)	(5,471)	(14,460)	(13,005)
Research and development expenses	(5,076)	(3,059)	(9,662)	(6,679)
Total operating expenses	(21,244)	(13,862)	(40,665)	(29,844)
Operating loss	(11,165)	(6,362)	(21,076)	(15,849)
Interest expense	(7)	(4)	(11)	(4)
Other income	801	109	1,526	137
Loss before income taxes	(10,371)	(6,257)	(19,561)	(15,716)
Provision for income tax	(13)	(4)	(43)	(8)
Net loss	$ (10,384)	$ (6,261)	$ (19,604)	$ (15,724)
Net loss per common share:				
Basic and Diluted	$ (0.41)	$ (0.25)	$ (0.78)	$ (0.63)
Weighted-average common shares:				
Basic and Diluted	25,239,723	24,971,243	25,221,009	24,954,712