

AVITA Medical Reports Fourth Quarter and Fiscal Year 2021 Financial Results

August 26, 2021

VALENCIA, Calif., Aug. 26, 2021 (GLOBE NEWSWIRE) -- AVITA Medical, Inc. (NASDAQ: RCEL, ASX:AVH) (**Company**), a regenerative medicine company that is developing and commercializing a technology platform that enables point-of-care autologous skin restoration for multiple unmet needs, today reported financial results for its fourth quarter of fiscal year 2021, ended June 30, 2021.

Fourth Quarter of Fiscal Year 2021 Highlights

- Total net revenue increased 166% to \$10.3 million compared to \$3.9 million in the fourth quarter of 2020
- Total commercial revenue increased 45% to \$6.7 million compared to the prior quarter ended March 31, 2021 and exceeded revised revenue guidance of \$6.0-6.2 million
- Gross profit margin of 80% compared to 77% in the fourth quarter of 2020
- Net loss of \$4.7 million, or \$0.19 per share compared to a net loss of \$12.9 million, or \$0.60 per share in the fourth quarter of 2020
- As of June 30, 2021, the Company had \$110.7 million in cash and cash equivalents, and no debt
- FDA approved expanded use of the RECELL® System in combination with meshed autografting for the treatment of all sizes of acute full-thickness thermal burn wounds for both pediatric and adult patients

Full-Year of Fiscal 2021 Highlights

- Total net revenue increased 105% to \$29.2 million compared to \$14.3 million in the prior year
- Commercial revenues increased 50% compared to the prior year
- Gross profit margin of 80% compared to 79% in the prior year
- Net loss of \$26.6 million, or \$1.17 per share compared to a net loss of \$42.0 million, or \$2.07 per share, in the prior year

"We are excited to report our substantial progress this quarter. As COVID-related restrictions decreased and people resumed everyday activities, the organization was well-positioned for the marked increase in burn-related accidents," said Dr. Mike Perry, AVITA Medical Chief Executive Officer. "We realized a significant revenue increase primarily from the increase in burn cases but also from our further penetration in burn center accounts. We also realized an acceleration of enrollment into our soft tissue reconstruction trial, which is now over half enrolled at 36 of 65 subjects."

Fourth Quarter of Fiscal 2021 Financial Results

Total net revenue increased 166% to \$10.3 million, compared to \$3.9 million in the corresponding period in the prior year. RECELL[®] commercial revenues increased 72% to \$6.7 million, while RECELL[®] revenues associated with the U.S. Department of Health and Human Services' Biomedical Advanced Research and Development Authority within the Office of the Assistant Secretary for Preparedness and Response (BARDA) were \$3.6 million. Revenues associated with BARDA were attributable to the purchase of RECELL[®] units for emergency preparedness by BARDA.

Gross profit margin improved by 3% to 80% compared to the corresponding period in the prior year. The increase in gross profit margin was driven by lower shipping costs and increased production.

Total operating expenses decreased by 19% to \$13.4 million compared to \$16.5 million in the corresponding period in the prior year. The decrease in operating expenses is primarily attributable to lower stock-based compensation and higher costs in the prior year related to the Avita group's redomiciliation to the United States (**Redomiciliation**), which were partially offset by higher costs in research and development. Lower stock-based compensation was driven by higher share-based compensation expenses in the prior year associated with certain performance milestones being met. Higher research and development expenses have resulted from a ramping up of activities related to clinical trials in vitiligo and soft tissue reconstruction, research in RECELL related cell and gene therapies, and initiatives to further improve the RECELL platform technology.

Net loss decreased by 63% or \$8.1 million to \$4.7 million, or \$0.19 per share, compared to a net loss of \$12.9 million, or \$0.60 per share, in the corresponding period of the prior year.

Full-Year 2021 Financial Results

Total net revenue increased by 105% to \$29.2 million, compared to \$14.3 million in the corresponding period in the prior year. RECELL[®] commercial revenues increased by 50% or \$7.2 million to \$21.5 million, while RECELL[®] revenues associated with BARDA were \$7.7 million. Revenues associated with BARDA were attributable to the purchase of RECELL[®] units for emergency preparedness by BARDA.

Gross profit margin increased by 1% to 80%, compared with 79% in the prior year, driven largely by lower shipping costs, increased production, and lower costs resulting from the extension of RECELL[®] shelf-life.

Total operating expenses decreased by 10% or \$6.0 million to \$51.9 million, compared with \$57.9 million in the corresponding period in the prior year. The decrease in operating costs is primarily attributable to lower stock-based compensation, higher costs in the prior year related to the Redomiciliation along with lower sales and marketing costs in the current year, partially offset by higher costs in research and development in the current year. Lower stock-based compensation was driven by higher share-based compensation expenses in the prior year associated with certain performance milestones being met. The decrease in sales and marketing costs in the current year is primarily due to reduced commercial team travel

to burn centers and industry conferences necessitated by COVID-19 related travel restrictions, and higher prior year costs incurred with the RECELL® product launch. Higher research and development expenses have resulted from a ramping up of clinical trial related activities for the treatment of vitiligo and further improvements to the RECELL platform technology.

Net loss decreased by 37% or \$15.4 million to \$26.6 million or \$1.17 per share, compared to a net loss of \$42.0 million or \$2.07 per share in the corresponding period in the prior year.

First Quarter of Fiscal Year 2022 Revenue Guidance

• Total commercial revenue is expected to be approximately \$7.0 million

Webcast and Conference Call Information

The Company will host a conference call to discuss the fourth quarter financial results after market close on Thursday, August 26, 2021, at 1:30 p.m. Pacific Time / 4:30 p.m. Eastern Time (being 6.30 a.m. Australian Eastern Standard Time on Friday, August 27, 2021). The conference call can be accessed live over the phone for (833) 614-1538 U.S. callers or for (706) 634-6548 international callers, using conference ID:3858364. The live webinar can be accessed at https://ir.avitamedical.com.

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

ABOUT AVITA Medical, INC.

AVITA Medical, Inc. is a regenerative medicine company with a technology platform positioned to address unmet medical needs in burns, chronic wounds, and aesthetics indications. AVITA Medical Inc. patented and proprietary collection and application technology provides innovative treatment solutions derived from the regenerative properties of a patient's own skin. The medical devices work by preparing a RES [®] REGENERATIVE EPIDERMAL SUSPENSION, an autologous suspension comprised of the patient's skin cells necessary to regenerate natural healthy epidermis. This autologous suspension is then sprayed onto the areas of the patient requiring treatment.

AVITA Medicals' 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. 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 8,000 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 marketed under the RECELL[®] System brand to promote skin healing in a wide range of applications including burns, chronic wounds, and aesthetics. The RECELL[®] System is TGA-registered in Australia and received CE-mark approval in Europe. 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 goals. 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 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 including, but not limited to the ongoing COVID-19 pandemic which are 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, 2021		June 30, 2020
ASSETS				
Cash	\$	110,746	\$	73,639
Accounts receivable, net		3,467		2,076
BARDA receivables		3,936		356
Prepaids and other current assets		1,333		990
Restricted cash		201		201
Inventory		1,647		1,125
Total current assets		121,330		78,387
Plant and equipment, net		1,458		1,363
Operating lease right-of-use assets		1,480		2,347
Intangible assets, net		472		364
Other long-term assets		761		1
Total assets	\$	125,501	\$	82,462
LIABILITIES AND SHAREHOLDERS' EQUITY				
Accounts payable and accrued liabilities	\$	3,120	\$	4,333
Accrued wages and fringe benefits		3,321		2,816
Other current liabilities		949		560
Total current liabilities		7,390		7,709
Contract liabilities		1,075		435
Operating lease liabilities, long term		878		1,917
Other long-term liabilities		503		
Total liabilities		9,846		10,061
Contingencies (Note 10)				
Shareholders' Equity:				
Common stock, \$0.0001 par value per share, 200,000,000 shares authorized, 24,895,864 and 21,467,912 shares issued and outstanding at June 30, 2021, and June 30, 2020, respectively		3		3
Preferred stock, \$0.0001 par value per share, 10,000,000 shares authorized, no shares issued or outstanding at June 30, 2021, and June 30, 2020		-		-
Additional paid-in capital		328,889		259,165
Accumulated other comprehensive income		8,259		8,146
Accumulated deficit		(221,496)		(194,913)
Total shareholders' equity		115,655		72,401
Total liabilities and shareholders' equity	\$	125,501	\$	82,462

The accompanying notes form part of the consolidated financial statements

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

	Three months ended June 30.				Year ended June 30,			
		2021		2020		2021		2020
Revenues	\$	10,304	\$	3,877	\$	29,232	\$	14,263
Cost of sales		(2,053)		(874)		(5,949)		(2,973)
Gross profit		8,251		3,003		23,283		11,290
BARDA income		440		481		2,055		3,926
Operating expenses:								
Sales and marketing expenses ⁽¹⁾		(4,146)		(4,260)		(14,660)		(15,706)
General and administrative expenses ⁽¹⁾		(5,275)		(9,709)		(22,400)		(33,025)

Research and development expenses ⁽¹⁾	 (3,974)	 (2,538)	(14,818)	(9,164)
Total operating expenses	 (13,395)	(16,507)	(51,878)	(57,895)
Operating loss	(4,704)	(13,023)	(26,540)	(42,679)
Interest expense	(9)	(8)	(22)	(33)
Other income/(expense)	 2	121	 17	 686
Loss before income taxes	(4,711)	(12,910)	(26,545)	(42,026)
Income tax expense	 (7)	(4)	 (38)	 (4)
Net loss	\$ (4,718)	\$ (12,914)	\$ (26,583)	\$ (42,030)
Net loss per common share:				
Basic	\$ (0.19)	\$ (0.60)	\$ (1.17)	\$ (2.07)
Diluted	\$ (0.19)	\$ (0.60)	\$ (1.17)	\$ (2.07)
Weighted-average common shares:				
Basic	24,860,738	21,372,892	22,674,313	20,290,966
Diluted	24,860,738	21,372,892	22,674,313	20,290,966

 $\hbox{(1) Total operating expenses include impact of share-based compensation as follows:} \\$

		Year Ended June 30,					
		2020	· ·	2021	2020		
Sales and marketing expenses	\$	(63)	\$ (309)	\$	(925)	\$	(893)
General and administrative expenses		(1,173)	(3,348)		(4,095)		(14,890)
Research and development expenses		(175)	(206)		(644)		(703)
Total	\$	(1,411)	\$ (3,863)	\$	(5,664)	\$	(16,486)