AVITA Medical Reports Third Quarter 2021 Financial Results

May 13, 2021

VALENCIA, Calif. and MELBOURNE, Australia, May 13, 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 third quarter of fiscal year 2021, ended March 31, 2021.

Third Quarter Highlights

- Reported RECELL® revenue of $8.8 million in the third quarter of 2021, a 126% increase over the same quarter in the prior year.
- Commercial metrics:
  - Procedural volumes were 492 in the third quarter of 2021, compared with 408 in the same period last year, and 487 in the prior quarter ended December 31, 2020;
  - Added 6 new burn center accounts in the third quarter 2021 for a total of 99 accounts, or a penetration rate of 73% of the 136 total U.S. burn centers;
  - Of the approximate 300 total U.S. burn surgeons:
    - 244 U.S. burn surgeons have been trained and certified with RECELL® through the third quarter of 2021, for a penetration rate of 81%; and
    - 147 burn surgeons used RECELL® in the third quarter of 2021, for a penetration rate of nearly 50%.

“We made steady progress over the last quarter as we continued to drive RECELL® usage in our established hospital burn center base with an increasing focus on smaller burns, and we continued to expand our physician training and outreach programs. As pandemic headwinds abate, we plan to leverage our highly experienced burns sales force and strong relationships built to date with the burn practitioner community to increase hospital access and to penetrate deeper into our existing accounts, resulting in additional procedures and engaging more burn practitioners,” said Dr. Mike Perry, AVITA Medical Chief Executive Officer. “Our three pivotal clinical trials in vitiligo, trauma, and pediatric burns are continuing on schedule and we expect to see expanded indications for RECELL® coming online, allowing us to serve an ever-growing population of patients.”

Third Quarter 2021 Financial Results

Revenue in the third quarter ended March 31, 2021 was $8.8 million, compared to $3.9 million in the corresponding period ended March 31, 2020, and compared to $5.1 million in the prior quarter ended December 31, 2020. In the third quarter ended March 2021, RECELL® commercial revenues were $4.6 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 $4.1 million. Revenues associated with BARDA were attributable to the purchase of RECELL® units for emergency preparedness by BARDA. RECELL® commercial revenues in the third quarter ended March 31, 2021 compared to the corresponding period ended March 31, 2020, increased $0.7 million, or 19%.

Gross margin was 76% for the third quarter of 2021, compared with 84% in the same quarter last year. Lower third quarter gross margins resulted from a lower RECELL® price point for units that were purchased under contract with BARDA. AVITA’s contract with BARDA was negotiated prior to the establishment of a higher price point achieved in the RECELL® commercialization in the United States.

Operating expenses were $13.2 million for the third quarter of 2021, compared with $19.7 million in the same quarter last year. The decrease in quarter over quarter expenses is primarily attributable to lower stock-based compensation along with lower sales and marketing expenses, 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. The decrease in sales and marketing expense in the current quarter is primarily due to reduced travel to burn centers and industry conferences necessitated by COVID-19 related travel restrictions, partially offset by 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 treatment of vitiligo as well as other research and developments costs to further expand the Company’s pipeline.

Net loss was $6.0 million for the third quarter of 2021 and net loss per share was $0.26 on a weighted-average basic and diluted share count of 22.7 million, compared to $15.0 million and a net loss per share of $0.71 on a weighted-average basic and diluted share count of 21.2 million in the same period of the prior year.

Cash was $114.9 million as of March 31, 2021, which includes $64.0M net proceeds from our capital issuance closed in the third quarter of 2021.

Fourth Quarter 2021 Revenue Guidance

- Total revenue expected to be in the range of $8.2-$8.6 million, consisting of $5.0-5.3 million of commercial RECELL® revenue and $3.2-3.3 million of RECELL® revenue associated with BARDA.

Webcast and Conference Call Information
The Company will host a conference call to discuss the third quarter financial results after market close on Thursday, May 13, 2021 at 1:30 p.m. Pacific Time / 4:30 p.m. Eastern Time (being 6.30 a.m. Australian Eastern Daylight Time on Friday, May 14, 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:5490156. The live webinar can be accessed at https://ir.avitamedical.com.

Authorized for release by the Chief Executive 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 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 indicated for use in the treatment of acute thermal burns in patients 18 years and older. 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 letter 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 letter 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 letter 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 letter. 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 letter 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, 2021	June 30, 2020
ASSETS		
Cash	$ 114,879	$ 73,639
Accounts receivable, net	2,230	2,076
BARDA receivables	3,250	356
Prepaids and other current assets	1,357	990
Restricted cash	201	201
Inventory	1,794	1,125
Total current assets	123,711	78,387
Plant and equipment, net	1,643	1,363
Operating lease right-of-use assets	1,639	2,347
Intangible assets, net	463	364
Other long-term assets	631	1
Total assets	$ 128,087	$ 82,462
LIABILITIES AND SHAREHOLDERS' EQUITY		
Accounts payable and accrued liabilities	$ 3,638	$ 4,333
Accrued wages and fringe benefits	2,472	2,816
Other current liabilities	956	560
Total current liabilities	7,066	7,709
Contract liabilities	999	435
Operating lease liabilities, long term	1,060	1,917
Other long-term liabilities	19	-
Total liabilities	9,144	10,061
Contingencies (Note 10)		
Shareholders' Equity:		
Common stock, $0.0001 par value per share, 200,000,000 shares authorized, 24,842,883 and 21,467,912 shares issued and outstanding at March 31, 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 March 31, 2021 and June 30, 2020	—	—
Additional paid-in capital	327,447	259,165
Accumulated other comprehensive income	8,271	8,146
Accumulated deficit	(216,778)	(194,913)
Total shareholders' equity	118,943	72,401
Total liabilities and shareholders' equity	$ 128,087	$ 82,462

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

	Three months ended March 31,		Nine months ended March 31,	
	2021	2020	2021	2020
Revenues	$ 8,765	$ 3,877	$ 18,928	$ 10,386
Cost of sales	(2,146)	(634)	(3,896)	(2,099)
Gross profit	6,619	3,243	15,032	8,287
BARDA income	570	1,008	1,615	3,445
Operating expenses:				
Sales and marketing expenses[(1)]	(3,649)	(4,375)	(10,514)	(11,446)
General and administrative expenses[(1)]	(5,422)	(12,787)	(17,125)	(23,316)
Research and development expenses[(1)]	(4,109)	(2,495)	(10,844)	(6,626)
Total operating expenses	(13,180)	(19,657)	(38,483)	(41,338)
Operating loss	(5,991)	(15,406)	(21,836)	(29,656)
Interest expense	(3)	(5)	(13)	(25)
Other income/(expense)	7	363	15	565
Loss before income taxes	(5,987)	(15,048)	(21,834)	(29,116)
Income tax expense	(10)	—	(31)	—
Net loss	$ (5,997)	$ (15,048)	$ (21,865)	$ (29,116)
Net loss per common share:				
Basic	$ (0.26)	$ (0.71)	$ (1.00)	$ (1.46)
Diluted	$ (0.26)	$ (0.71)	$ (1.00)	$ (1.46)
Weighted-average common shares:				

Basic	22,734,335	21,215,246	21,948,132	19,932,947
Diluted	22,734,335	21,215,246	21,948,132	19,932,947

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

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2021	2020	2021	2020
Sales and marketing expenses	$ (238)	$ (214)	$ (862)	$ (584)
General and administrative expenses	(930)	(8,641)	(2,922)	(11,541)
Research and development expenses	(165)	(193)	(469)	(498)
Total	$ (1,333)	$ (9,048)	$ (4,253)	$ (12,623)