AVITA Medical Reports First Quarter 2022 Financial Results

May 12, 2022

VALENCIA, Calif. and MELBOURNE, Australia, May 12, 2022 (GLOBE NEWSWIRE) -- AVITA Medical, Inc. (NASDAQ: RCEL, ASX: AVH) (the "**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 first quarter ended March 31, 2022.

Financial Highlights and Recent Updates:

- Reported commercial revenue, which excludes BARDA revenue, of $7.4 million a 61% increase compared to $4.6 million in the corresponding period in the prior year
- Reported total revenue, which includes BARDA revenue, of $7.5 million compared to $8.8 million in the corresponding period in the prior year, which included $4.1 million in BARDA revenue
- In February 2022, FDA approved our premarket approval application (PMA) supplement for RECELL® Autologous Cell Harvesting Device, an enhanced RECELL system aimed at providing clinicians a more efficient user experience and simplified workflow
- In February 2022, Japan's Pharmaceuticals and Medical Devices Agency (PMDA) approved our application for commercialization of the RECELL system in burns
- As of March 31, 2022, the Company had $95.0 million in cash, cash equivalents, and marketable securities, with no debt

"Our commercial team performed well this quarter driving further adoption and penetration within burn centers, and our clinical team continued to move the soft tissue reconstruction and vitiligo trials forward," said Dr. Mike Perry, AVITA Medical Chief Executive Officer. "We are well positioned to drive revenue growth ahead and we look forward to topline data readouts from our soft tissue reconstruction and vitiligo clinical trials in the second half of this year."

First Quarter of Year 2022 Financial Results

Our commercial revenue, which excludes BARDA revenue, was $7.4 million in the current year, an increase of $2.8 million or 61%, compared to $4.6 million the corresponding period in the prior year. Total revenue, which includes BARDA revenue, was $8.8 million in the corresponding period in the prior year which included $4.1 million in BARDA related revenue that resulted from our delivery of units to managed inventory for BARDA for emergency response preparedness. The increase in commercial revenue was largely driven by broader utilization among our customer base as well as deeper penetration within individual customer accounts.

Gross profit margin was 76% and is flat compared to the corresponding period in the prior year.

Total operating expenses increased by 21% to $16.0 million compared to $13.2 million in the corresponding period in the prior year. The increase in operating expenses is primarily attributable to higher share-based compensation, salary, and benefits. Higher share-based compensation expenses are associated with acceleration of expense for certain performance milestones being met in the current quarter. Higher salary and benefits are driven by the expansion of our workforce to support the overall operations, an increase in field resources to expand our market coverage and hiring of an executive at the end of March 2021.

Net loss increased by 58% or $3.5 million to $9.5 million, or $0.38 per share, compared to a net loss of $6.0 million, or $0.26 per share, in the corresponding period of the prior year.

Adjusted EBITDA* loss increased by 42%, or $1.9 million to $6.4 million, over the $4.5 million recognized in the corresponding period in the prior year. A table reconciling non-GAAP measures is included in this press release for reference.

Calendar Year 2022 Revenue Guidance

Commercial revenues in calendar year 2022 are projected to be approximately $30 million, excluding BARDA revenues, which represents a 20% increase year-over year. We project BARDA revenues of approximately $0.3 million in calendar year 2022, as compared to $7.9 million in calendar year 2021, since we completed delivery of RECELL units into the national stockpile in 2021.

*Adjusted EBITDA is a non-GAAP financial measure. See the appendix to this release for a discussion of Non-GAAP financial measures, including a reconciliation to the most closely correlated GAAP measure.

Webcast and Conference Call Information

The Company will host a conference call to discuss the first quarter financial results after market close on Thursday May 12, 2022, at 1:30 p.m. Pacific Time / 4:30 p.m. Eastern Time (being 6.30 a.m. Australian Eastern Standard Time on Friday May 13, 2022). The conference call can be accessed live over the phone at (833) 614-1538 for U.S. callers or at (706) 634-6548 international callers, using conference ID:2592487. 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 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 a device that enables healthcare professionals to produce a suspension of Spray-On Skin™ Cells using a small sample of the patient's own skin for the treatment of acute thermal burns

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.

*** 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 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	
	March 31, 2022	**December 31, 2021**
ASSETS		
Cash and cash equivalents	$ 23,535	$ 55,511
Marketable securities	59,835	29,649
Accounts receivable, net	3,481	3,118
BARDA receivables	682	308
Prepaids and other current assets	1,146	1,213
Restricted cash	201	201
Inventory	1,803	2,132
Total current assets	90,683	92,132
Marketable securities, long-term	11,684	19,692
Plant and equipment, net	1,171	1,262
Operating lease right-of-use assets	1,375	1,544
Intangible assets, net	416	443
Other long-term assets	1,162	942
Total assets	$ 106,491	$ 116,015
LIABILITIES AND SHAREHOLDERS' EQUITY		
Accounts payable and accrued liabilities	2,397	2,708
Accrued wages and fringe benefits	2,914	5,363
Other current liabilities	1,186	1,075
Total current liabilities	6,497	9,146
Contract liabilities	882	952
Operating lease liabilities, long-term	726	918
Other long-term liabilities	571	375
Total liabilities	8,676	11,391
Contingencies (Note 12)		
Shareholders' Equity:		
Common stock, $0.0001 par value per share, 200,000,000 shares authorized, 24,955,581 and 24,925,743 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively	3	3
Preferred stock, $0.0001 par value per share, 10,000,000 shares authorized, no shares issued or outstanding at March 31, 2022 and December 31, 2021	-	-
Additional paid-in capital	335,417	332,484
Accumulated other comprehensive income	7,781	8,060
Accumulated deficit	(245,386)	(235,923)
Total shareholders' equity	97,815	104,624
Total liabilities and shareholders' equity	$ 106,491	$ 116,015

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

	Three Months Ended March 31,	
	2022	**2021**
Revenues	$ 7,539	$ 8,765
Cost of sales	(1,778)	(2,146)
Gross profit	5,761	6,619
BARDA income	734	570
Operating expenses:		
Sales and marketing expenses *	(4,828)	(3,649)
General and administrative expenses *	(7,534)	(5,422)
Research and development expenses *	(3,620)	(4,109)
Total operating expenses	(15,982)	(13,180)
Operating loss	(9,487)	(5,991)
Interest expense	-	(3)
Other income	28	7
Loss before income taxes	(9,459)	(5,987)
Income tax expense	(4)	(10)

Net loss	$ (9,463)	$ (5,997)
Net loss per common share:		
Basic	$ (0.38)	$ (0.26)
Diluted	$ (0.38)	$ (0.26)
Weighted-average common shares:		
Basic	24,937,999	22,734,335
Diluted	24,937,999	22,734,335

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

	Three-months ended March 31,	
	2022	**2021**
Sales and marketing expenses	$ 329	$ 238
General and administrative expenses	2,327	930
Research and development expenses	276	165
Total	$ 2,932	$ 1,333

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

	Three months ended March 31,	
	2022	**2021**
Net Loss	$ (9,463)	$ (5,997)
Depreciation expense	129	137
Patent Amortization	34	30
Share-based expense	2,932	1,333
Interest Expense	-	3
Income Tax Expense	4	10
Adjusted EBITDA (Non-GAAP)	$ (6,364)	$ (4,484)