



AVITA Therapeutics Reports First Quarter 2021 Financial Results

November 10, 2020

VALENCIA, Calif., Nov. 10, 2020 (GLOBE NEWSWIRE) – AVITA Therapeutics, Inc. (NASDAQ: RCEL, ASX:AVH), 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 fiscal first quarter of 2021, ended September 30, 2020.

First Quarter Highlights

- Reported U.S based RECELL[®] revenue of \$5.0 million in the first quarter of 2021, a 59% increase over the same quarter prior year
- Total global revenue of \$5.1 million in the first quarter of 2021, a 56% increase over the same quarter prior year
- Commercial metrics:
 - Procedural volumes were 496 in the first quarter of 2021, an increase of 27.2% over the prior quarter
 - Added 9 new accounts in the first quarter 2021 for a total of 86 accounts
- Enrolled first patient in the pivotal study assessing the use of the RECELL[®] System to treat stable vitiligo

“We saw a very encouraging recovery in procedure volumes and new account openings in our fiscal first quarter, and while we still expect to see some impacts due to the pandemic, we think our sales trajectory within burns is back on track,” said Dr. Mike Perry, AVITA Therapeutics Chief Executive Officer. “Looking ahead, we are driving forth our efforts to leverage the RECELL system in other markets and have been particularly encouraged by the patient and physician interest and enrollment levels we’ve experienced in our vitiligo trial.”

First Quarter 2021 Financial Results

Revenue was \$5.1 million in the first quarter of 2021, compared to \$3.3 million for the same quarter last year and \$3.9 million for the prior quarter.

Gross margin was 82% for the first quarter of 2021, compared with 81% in the same quarter last year.

Operating expenses were \$14.9 million for the first quarter of 2021, compared with \$8.3 million in the same quarter last year. The increase was primarily driven by the additional costs of the Company’s status as a dual listed entity on NASDAQ and the ASX, along with commencement of pivotal clinical trials for the treatment of pediatric scald injuries, soft tissue reconstruction, vitiligo and other research and development activities to further promote the RECELL System.

Net loss was \$10.2 million for the first quarter of 2021 and net loss per share was \$0.48 on a weighted-average basic and diluted share count of 21.5 million, compared to \$3.6 million and a net loss per share of \$0.19 on a weighted-average basic and diluted share count of 18.7 million in the same period of the prior year.

Cash was \$65.8 million as of September 30, 2020.

Outlook and COVID-19

Due to uncertainty surrounding the COVID-19 pandemic, AVITA Therapeutics will not provide financial guidance at this time. Management will continue to evaluate its guidance policies and anticipates providing an update at the time of its second quarter earnings announcement, to the extent practicable, based on available information at that time.

Webcast and Conference Call Information

AVITA Therapeutics will host a conference call to discuss the first quarter financial results after market close on Tuesday, November 10, 2020 at 1:30 p.m. Pacific Time / 4:30 p.m. Eastern Time. The conference call can be accessed live over the phone (833) 614-1538 for U.S. callers or (706) 634-6548 for international callers, using conference ID: 2688929. The live webinar can be accessed at <https://ir.avitamedical.com>.

Authorized for release by the Chief Executive Officer of AVITA Therapeutics, Inc.

ABOUT AVITA THERAPEUTICS, INC.

AVITA Therapeutics is a regenerative medicine company with a technology platform positioned to address unmet medical needs in burns, chronic wounds, and aesthetics indications. AVITA Therapeutics’ 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 Therapeutics’ 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 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:

<p>U.S. Media Sam Brown, Inc. Christy Curran Phone +1 615 414 8668 christycurran@sambrown.com</p> <p>O.U.S Media Monsoon Communications Rudi Michelson Phone +61 (0)3 9620 3333 Mobile +61 (0)411 402 737 rudim@monsoon.com.au</p>	<p>Investors Westwicke Partners Caroline Corner Phone +1 415 202 5678 caroline.corner@westwicke.com</p>
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AVITA THERAPEUTICS, INC.
Consolidated Statements of Operations
(In thousands, except share and per share data)

	Three months ended September 30,	
	2020	2019
Revenues	\$ 5,060	\$ 3,250
Cost of sales	929	619
Gross profit	4,131	2,631
BARDA income	596	2,051
Operating expenses:		
Sales and marketing expenses	2,935	2,962
General and administrative expenses	5,536	3,071
Research and development expenses	3,204	1,635
Share-based compensation	3,266	672
Total operating expenses	14,941	8,340
Operating loss	(10,214)	(3,658)
Interest expense	7	11
Other income	4	103
Loss before income taxes	(10,217)	(3,566)
Income tax expense	10	-
Net loss	\$ (10,227)	\$ (3,566)
Net loss per common share:		
Basic	\$ 0.48	\$ 0.19
Diluted	\$ 0.48	\$ 0.19

Weighted-average common shares:

Basic	21,503,643	18,719,857
Diluted	21,503,643	18,719,857

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

	As of	
	September 30, 2020	June 30, 2020
ASSETS		
Cash	\$ 65,753	\$ 73,639
Accounts receivable, net	2,360	2,076
BARDA receivables	371	356
Prepays and other current assets	1,054	990
Restricted cash	201	201
Inventory	1,657	1,125
Total current assets	71,396	78,387
Plant and equipment, net	1,349	1,363
Operating lease right-of-use assets	2,216	2,347
Intangible assets	403	364
Other long term assets	55	1
Total assets	<u>\$ 75,419</u>	<u>\$ 82,462</u>
LIABILITIES AND SHAREHOLDERS' EQUITY		
Accounts payable and accrued liabilities	\$ 3,570	\$ 4,333
Accrued wages and fringe benefits	3,589	2,816
Other current liabilities	561	560
Total current liabilities	7,720	7,709
Contract liabilities	435	435
Operating lease liabilities, long term	1,776	1,917
Total liabilities	9,931	10,061
Contingencies (Note 10)		
Shareholders' Equity:		
Common stock, \$0.0001 par value per share, 200,000,000 shares authorized, 21,623,287 and 21,467,912 shares issued and outstanding at September 30, 2020 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 September 30, 2020 and June 30, 2020	-	-
Additional paid-in capital	262,431	259,165
Accumulated other comprehensive income	8,194	8,146
Accumulated deficit	(205,140)	(194,913)
Total shareholders' equity	65,488	72,401
Total liabilities and shareholders' equity	<u>\$ 75,419</u>	<u>\$ 82,462</u>