

AVITA Medical, Inc Half-Year Financial Report for Fiscal Year 2022

Valencia, Calif., and MELBOURNE, Australia, August 12, 2022 — AVITA Medical, Inc. (NASDAQ: RCEL, ASX: AVH), filed the attached Form 10-Q for the three- and six-month periods ended 30 June 2022. A copy of the filing is attached and it can be accessed on the SEC filings at <https://www.sec.gov/edgar/searchedgar/companysearch.html>.

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.'s patented, and proprietary collection and application technology provides innovative treatment solutions derived from the regenerative properties of a patient's own skin. The Company's lead product is the RECELL® System, a device that enables healthcare professionals to Spray-On Skin™ Cells using a small sample of the patient's own skin to create an autologous suspension. The RES® Regenerative Epidermal Suspension™ is then sprayed onto the areas of the patient requiring treatment to regenerate natural healthy epidermis.

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 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. 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 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 15,000 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 approved 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, received CE-mark approval in Europe, and received Japan's Pharmaceuticals and Medical Devices Act (PMDA) approval for burns 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 statement. 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:

<p>U.S. Media Sam Brown, Inc. Christy Curran Phone +1-615-414-8668 christycurran@sambrown.com</p> <p>O.U.S. Media Rudi Michelson Phone +61 (0)3 9620 3333 Mobile +61 (0)411 402 737 rudim@monsoon.com.au</p>	<p>Investors ICR Westwicke Caroline Corner Phone +1-415-202-5678 caroline.corner@westwicke.com</p>
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Results for announcement to the market

Financial Results (in thousands)				June 2022	June 2021
Sale of goods	Down	17%	to	\$ 15,874	\$ 19,069
Other income	Up	40%	to	1,422	1,019
Net loss	Up	47%	to	15,724	10,714
Total other comprehensive loss for the period	Up	51%	to	16,248	10,745

Dividends	Amount per ordinary security	Franked amount per security
2022 interim dividend	Nil	Nil
2021 interim dividend	Nil	Nil

Record date for determining entitlements to the 2022 interim dividends	N/A
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Net Tangible Asset Backing	June 2022	June 2021
Net tangible asset backing per ordinary security	\$ 3.6432	\$ 4.5671

Other explanatory notes		
	June 2022	June 2021
<i>Net Tangible Assets:</i>		
Net assets	\$ 92,721,479	\$ 115,654,225
Right of use assets	(1,203,190)	(1,480,145)
Intangibles	(428,037)	(471,525)
Total net tangible assets	<u>\$ 91,090,252</u>	<u>\$ 113,702,555</u>
<i>Number of ordinary shares on issue</i>	<u>25,003,088</u>	<u>24,895,864</u>
Net tangible asset backing per ordinary security	<u>\$ 3.6432</u>	<u>\$ 4.5671</u>

Additional information

Additional disclosure and further commentary on these results is contained in the attached Form 10-Q for the three months and six months ended June 30, 2022.

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended June 30, 2022

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number: 001-39059



AVITA MEDICAL, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

85-1021707
(IRS Employer
Identification No.)

28159 Avenue Stanford
Suite 220

Valencia, CA 91355

(Address of principal executive offices and Zip Code)

Registrant's telephone number, including area code: (661) 367-9170

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	RCEL	The NASDAQ Stock Market LLC

Securities registered pursuant to section 12(g) of the Act:

None

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer", "accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has selected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

The number of shares of the registrant's \$0.0001 par value common stock outstanding as of August 2, 2022 was 25,003,088

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

FORWARD-LOOKING STATEMENT

This Quarterly Report on Form 10-Q contains forward-looking statements. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q, including statements regarding our future revenues; solvency; future industry market conditions; future changes in our capacity and operations; future operating and overhead costs; intellectual property; regulatory and related approvals; the conduct or outcome of pre-clinical or clinical (human) studies; operational and management restructuring activities (including implementation of methodologies and changes in the board of directors); future employment and contributions of personnel; effects on the global economy of the ongoing COVID-19 pandemic, including effects on the economy of existing and future variants on the original COVID-19 strain; including the highly contagious Omicron BA.5 variant; tax and interest rates; productivity, business process, rationalization, investment, acquisition and acquisition integrations, consulting, operational, tax, financial and capital projects and initiatives; inflationary pressures on the U.S. and global economy; changes in the legal or regulatory environment; and future working capital, costs, revenues, business opportunities, cash flows, margins, earnings and growth. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplate,” “believe,” “estimate,” “predict,” “potential”, or “continue” or the negative of these terms or other similar expressions.

The forward-looking statements in this Quarterly Report on Form 10-Q are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition, and results of operations. These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q and are subject to a number of important factors that could cause actual results to differ materially from those in the forward-looking statements, including the factors described under the sections in this Quarterly Report on Form 10-Q titled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for our management to predict all risk factors and uncertainties.

You should read this Quarterly Report on Form 10-Q and the documents that we reference in this Quarterly Report on Form 10-Q completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Shareholders
Avita Medical, Inc.

Results of review of interim financial statements

We have reviewed the accompanying consolidated balance sheet of Avita Medical, Inc. (a Delaware corporation) and subsidiaries (the “Company”) as of June 30, 2022 and the related consolidated statements of operations, comprehensive loss, and shareholders’ equity for the three-month and six-month periods ended June 30, 2022 and 2021, cash flows for the six-month periods ended June 30, 2022 and 2021, and the related notes (collectively referred to as the “interim financial statements”). Based on our reviews, we are not aware of any material modifications that should be made to the accompanying interim financial statements for them to be in conformity with accounting principles generally accepted in the United States of America.

We have previously audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (“PCAOB”), the consolidated balance sheet of the Company as of December 31, 2021, and the related consolidated statements of operations, comprehensive loss, shareholders’ equity, and cash flows for the year then ended (not presented herein); and in our report dated February 28, 2022, we expressed an unqualified opinion on those consolidated financial statements. In our opinion, the information set forth in the accompanying consolidated balance sheet as of December 31, 2021, is fairly stated, in all material respects, in relation to the consolidated balance sheet from which it has been derived.

Basis for review results

These interim financial statements are the responsibility of the Company’s management. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB. We conducted our reviews in accordance with the standards of the PCAOB. A review of interim financial information consists principally of applying analytical procedures and making inquiries of persons responsible for financial and accounting matters. It is substantially less in scope than an audit conducted in accordance with the standards of the PCAOB, the objective of which is the expression of an opinion regarding the financial statements taken as a whole. Accordingly, we do not express such an opinion.

/s/ GRANT THORNTON LLP

Los Angeles, California
August 11, 2022

PART I – Financial Information

Item 1. FINANCIAL STATEMENTS

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

	As of	
	June 30, 2022	December 31, 2021
ASSETS		
Cash and cash equivalents	\$ 34,737	\$ 55,511
Marketable securities	49,618	29,649
Accounts receivable, net	3,884	3,118
BARDA receivables	338	308
Prepays and other current assets	1,005	1,213
Restricted cash	202	201
Inventory	2,022	2,132
Total current assets	91,806	92,132
Marketable securities, long-term	6,743	19,692
Plant and equipment, net	1,249	1,262
Operating lease right-of-use assets	1,203	1,544
Intangible assets, net	428	443
Other long-term assets	1,240	942
Total assets	\$ 102,669	\$ 116,015
LIABILITIES AND SHAREHOLDERS' EQUITY		
Accounts payable and accrued liabilities	2,495	2,708
Accrued wages and fringe benefits	4,174	5,363
Other current liabilities	1,217	1,075
Total current liabilities	7,886	9,146
Contract liabilities	813	952
Operating lease liabilities, long-term	532	918
Other long-term liabilities	715	375
Total liabilities	9,946	11,391
Non-qualified deferred compensation share awards	163	-
Contingencies (Note 12)		
Shareholders' Equity:		
Common stock, \$0.0001 par value per share, 200,000,000 shares authorized, 25,003,088 and 24,925,743 shares issued and outstanding at June 30, 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 June 30, 2022 and December 31, 2021	-	-
Additional paid-in capital	336,668	332,484
Accumulated other comprehensive income	7,536	8,060
Accumulated deficit	(251,647)	(235,923)
Total shareholders' equity	92,560	104,624
Total liabilities and shareholders' equity	\$ 102,669	\$ 116,015

The accompanying notes form part of the unaudited consolidated financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Revenues	\$ 8,335	\$ 10,304	\$ 15,874	\$ 19,069
Cost of sales	(1,386)	(2,053)	(3,164)	(4,199)
Gross profit	6,949	8,251	12,710	14,870
BARDA income	551	440	1,285	1,010
Operating expenses:				
Sales and marketing expenses	(5,332)	(4,146)	(10,160)	(7,795)
General and administrative expenses	(5,471)	(5,275)	(13,005)	(10,697)
Research and development expenses	(3,059)	(3,974)	(6,679)	(8,083)
Total operating expenses	(13,862)	(13,395)	(29,844)	(26,575)
Operating loss	(6,362)	(4,704)	(15,849)	(10,695)
Interest expense	(4)	(9)	(4)	(12)
Other income	109	2	137	9
Loss before income taxes	(6,257)	(4,711)	(15,716)	(10,698)
Income tax expense	(4)	(7)	(8)	(17)
Net loss	<u>\$ (6,261)</u>	<u>\$ (4,718)</u>	<u>\$ (15,724)</u>	<u>\$ (10,715)</u>
Net loss per common share:				
Basic	\$ (0.25)	\$ (0.19)	\$ (0.63)	\$ (0.45)
Diluted	\$ (0.25)	\$ (0.19)	\$ (0.63)	\$ (0.45)
Weighted-average common shares:				
Basic	24,971,243	24,860,738	24,954,712	23,803,460
Diluted	24,971,243	24,860,738	24,954,712	23,803,460

The accompanying notes form part of the unaudited consolidated financial statements.

AVITA MEDICAL, INC.
Consolidated Statements of Comprehensive Loss
(In thousands)
(Unaudited)

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	2022	2021	2022	2021
Net loss	\$ (6,261)	\$ (4,718)	\$ (15,724)	\$ (10,715)
Change in foreign currency translation loss	(110)	(12)	(92)	(30)
Change in net unrealized loss on marketable securities, net of tax	(135)	-	(432)	-
Comprehensive loss	<u>\$ (6,506)</u>	<u>\$ (4,730)</u>	<u>\$ (16,248)</u>	<u>\$ (10,745)</u>

The accompanying notes form part of the unaudited consolidated financial statements.

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AVITA MEDICAL, INC.
Consolidated Statements of Shareholders' Equity
(In thousands, except shares)
(Unaudited)

Three Months Ended June 30, 2022

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount				
Balance at March 31, 2022	24,955,581	\$ 3	\$ 335,417	\$ 7,781	\$ (245,386)	\$ 97,815
Net loss	-	-	-	-	(6,261)	(6,261)
Share-based compensation	-	-	1,414	-	-	1,414
Vesting of restricted stock units	47,507	-	-	-	-	-
Change in classification of deferred compensation share awards	-	-	(192)	-	-	(192)
Change in redemption value of share awards in NQDC plan	-	-	29	-	-	29
Other comprehensive loss	-	-	-	(245)	-	(245)
Balance at June 30, 2022	25,003,088	\$ 3	\$ 336,668	\$ 7,536	\$ (251,647)	\$ 92,560

Three Months Ended June 30, 2021

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount				
Balance at March 31, 2021	24,842,883	\$ 3	\$ 327,447	\$ 8,271	\$ (216,778)	\$ 118,943
Net loss	-	-	-	-	(4,718)	(4,718)
Share-based compensation	-	-	1,410	-	-	1,410
Exercise of stock options	5,475	-	32	-	-	32
Vesting of restricted stock units	47,506	-	-	-	-	-
Translation loss	-	-	-	(12)	-	(12)
Balance at June 30, 2021	24,895,864	\$ 3	\$ 328,889	\$ 8,259	\$ (221,496)	\$ 115,655

Six Months Ended June 30, 2022

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount				
Balance at December 31, 2021	24,925,743	\$ 3	\$ 332,484	\$ 8,060	\$ (235,923)	\$ 104,624
Net loss	-	-	-	-	(15,724)	(15,724)
Share-based compensation	-	-	4,346	-	-	4,346
Exercise of stock options	125	-	1	-	-	1
Vesting of restricted stock units	77,220	-	-	-	-	-
Change in classification of deferred compensation share awards	-	-	(192)	-	-	(192)
Change in redemption value of share awards in NQDC plan	-	-	29	-	-	29
Other comprehensive loss	-	-	-	(524)	-	(524)
Balance at June 30, 2022	25,003,088	\$ 3	\$ 336,668	\$ 7,536	\$ (251,647)	\$ 92,560

Six Months Ended June 30, 2021

	<u>Common Stock</u>		<u>Additional Paid-in Capital</u>	<u>Accumulated Other Comprehensive Gain (Loss)</u>	<u>Accumulated Deficit</u>	<u>Total Shareholders' Equity</u>
	<u>Shares</u>	<u>Amount</u>				
Balance at December 31, 2020	<u>21,625,058</u>	<u>\$ 3</u>	<u>\$ 262,086</u>	<u>\$ 8,289</u>	<u>\$ (210,781)</u>	<u>\$ 59,597</u>
Net loss	-	-	-	-	(10,715)	(10,715)
Issuance of common stock under direct placement	3,214,250	-	69,106	-	-	69,106
Issuance costs associated with direct placement	-	-	(5,109)	-	-	(5,109)
Share-based compensation	-	-	2,743	-	-	2,743
Exercise of stock options	9,050	-	63	-	-	63
Vesting of RSU awards	47,506	-	-	-	-	-
Translation loss	-	-	-	(30)	-	(30)
Balance at June 30, 2021	<u>24,895,864</u>	<u>\$ 3</u>	<u>\$ 328,889</u>	<u>\$ 8,259</u>	<u>\$ (221,496)</u>	<u>\$ 115,655</u>

The accompanying notes form part of the unaudited consolidated financial statements.

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AVITA Medical, Inc.
Consolidated Statements of Cash Flows
(In thousands)
(Unaudited)

	Six-Months Ended	
	June 30, 2022	June 30, 2021
Cash flow from operating activities:		
Net loss	\$ (15,724)	\$ (10,715)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	300	343
Share-based compensation	4,346	2,743
Non-cash lease expense	341	315
Loss on fixed asset disposal	-	130
Remeasurement and foreign currency transaction gain	(39)	(1)
Excess and obsolete inventory related charges	158	255
BARDA deferred costs	(64)	343
Contract cost amortization	169	129
Provision for doubtful accounts	10	18
Amortization of premium of marketable securities	83	-
Changes in operating assets and liabilities:		
Trade and other receivables	(777)	(1,543)
BARDA receivables	(29)	(3,496)
Prepays and other current assets	205	(520)
Inventory	(52)	386
Operating lease liability	(349)	(326)
Other long-term assets	(467)	(738)
Accounts payable and accrued expenses	(179)	343
Accrued wages and fringe benefits	(1,178)	(983)
Other current liabilities	105	64
Contract liabilities	(139)	479
Other long-term liabilities	403	238
Net cash used in operations	(12,877)	(12,536)
Cash flows from investing activities:		
Purchase of marketable securities	(32,975)	-
Maturities of marketable securities	25,440	-
Cash paid for property and equipment	(278)	(422)
Cash paid for patent filing fees	(32)	(104)
Net cash used in investing activities	(7,845)	(526)
Cash flow from financing activities:		
Proceeds from direct placement of common stock	-	69,106
Issuance cost associated with direct placement	-	(5,109)
Principal repayment of finance lease	-	(2)
Proceeds from exercise of stock options	1	63
Net cash provided by financing activities	1	64,058
Effect of foreign exchange rate on cash and restricted cash	(52)	(15)
Net increase/(decrease) in cash and cash equivalents and restricted cash	(20,773)	50,981
Cash and cash equivalents and restricted cash beginning of the period	55,712	59,966
Cash and cash equivalents and restricted cash end of the period	\$ 34,939	\$ 110,947
Supplemental Disclosure of Cash Flow Information		
Cash paid for income taxes	\$ 17	\$ -
Cash paid for interest	\$ 4	\$ 12
Plant and equipment purchases not yet paid	\$ -	\$ 20

The accompanying notes form part of the unaudited consolidated financial statements.

AVITA MEDICAL, INC.
Notes to Consolidated Financial Statements
(Unaudited)

1. The Company

Nature of the Business

The AVITA group of companies (comprising AVITA Medical, Inc. (“AVITA” or the “Company”) and its subsidiaries, including AVITA Medical Pty Limited, previously known as AVITA Medical Limited (“AVITA Medical”)) (collectively, “AVITA Group” or “we”, “us”, or “our”), is a commercial-stage regenerative medicine company focused on the treatment of burns, trauma and other acute injuries, together with skin defects like vitiligo. The Company’s lead product is the RECELL® System, 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. In September 2018, the United States Food & Drug Administration (“FDA”) granted premarket approval (“PMA”) to the RECELL System for use in the treatment of acute thermal burns in patients eighteen years and older. Following receipt of our original PMA, we commenced commercializing the RECELL System in January 2019 in the United States. In June 2021 the FDA approved an expanded indication to include treatment of pediatric acute full-thickness thermal burns. In February 2022, the FDA approved a PMA supplement for the RECELL® Autologous Cell Harvesting Device with enhanced ease-of-use, aimed at providing clinicians a more efficient user experience and simplified workflow. In addition, the FDA has granted the Company Investigational Device Exemptions (“IDES”) which have enabled the Company to initiate pivotal clinical trials to further expand the approval of the RECELL System for soft tissue reconstruction and vitiligo. Enrollment of those clinical trials is complete, with topline results recently announced for the soft tissue reconstruction trial. Results from those studies are intended to support the Company’s pursuit of FDA approval to market the RECELL System in the United States for those indications.

In February 2019 we entered into a collaboration with COSMOTEC, an M3 Group company, to market and distribute the RECELL System in Japan. We worked with COSMOTEC to advance our application for approval of the RECELL System in Japan pursuant to Japan’s Pharmaceuticals and Medical Devices Act (“PMDA”). In February 2022, COSMOTEC’s application for regulatory approval was approved by the PMDA initially with labelling for burns only. COSMOTEC plans to commercially launch RECELL in Japan following Japan’s Ministry of Health, Labour, and Welfare approval of reimbursement pricing. Once soft tissue and vitiligo data are available from the Company’s related U.S. clinical trials, COSMOTEC plans to submit a further application for soft tissue and vitiligo indications.

In March 2020, the World Health Organization declared the outbreak of a novel strain of the coronavirus (“COVID-19”) a pandemic. We continue to closely monitor the recent developments surrounding the continued spread and potential resurgence of COVID-19 due to existing and future variants. As a result of the pandemic, our customers (primarily hospitals) are experiencing disruptions with respect to a shortage in operating room personnel. Although the number of U.S. hospitalizations due to COVID-19 has generally decreased in 2022 and many government imposed restrictions have been lifted, we continue to be unable to predict the full impact that the ongoing COVID-19 pandemic will have on our future results of operations, liquidity and financial condition due to numerous uncertainties, including the duration of the pandemic and the actions that may be taken in the future by government authorities across the United States in response to new variants. The Company has assessed the potential impact of COVID-19 on certain accounting matters including, but not limited to, the allowance for doubtful accounts, inventory reserves and return reserves, and impairment considerations for long-lived assets, marketable securities and intangibles, as of June 30, 2022 and through the date of this report. With respect to future operating results, it is not possible at this time to predict, with any degree of precision, the effects of COVID-19. Consequently, actual results for accounting estimates and assumptions, particularly those relating to the recoverability of certain intangible assets and estimates of expected credit losses on accounts receivable could differ from these estimates. However, we do not currently believe that COVID-19 will result in any significant changes in costs going forward. We will continue to monitor the performance of our business and reassess the impacts of COVID-19 and its variants.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited consolidated financial statements of the Company have been prepared in accordance with generally accepted accounting principles in the United States of America (“GAAP”) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X of the Securities and Exchange Commission (the “SEC”). Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. The information included in this quarterly report on Form 10-Q should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company’s Transition Report on Form 10-KT for the transition period ended December 31, 2021 filed

with the SEC on February 28, 2022 (United States) and the Australian Securities Exchange ("ASX") on March 01, 2022 (Australia) (the "Transition Report").

There have been no changes to the Company's significant accounting policies as described in the Transition Report on Form 10-KT that have had a material impact on the Company's consolidated financial statements. See the summary of the Company's significant accounting policies set forth in the notes to its consolidated financial statements included in the Transition Report.

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany transactions and balances have been eliminated upon consolidation.

Use of Estimates

The preparation of the accompanying consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts (including doubtful accounts, carrying value of long-lived assets, the useful lives of long-lived assets, accounting for marketable securities, income taxes, stock-based compensation, and the stand-alone selling price for the BARDA contract) and related disclosures. Estimates have been prepared on the basis of the current and available information. However, actual results could differ from estimated amounts.

Foreign Currency Translation and Foreign Currency Transactions

The financial position and results of operations of the Company's operating non-U.S. subsidiaries are generally determined using the respective local currency as the functional currency of that subsidiary. Assets and liabilities of these subsidiaries are translated at the exchange rate in effect at each period end. Income statement accounts are translated at the average rate of exchange prevailing during the period. Adjustments arising from the use of differing exchange rates from period to period are included in accumulated other comprehensive gain (loss) in shareholders' equity. Gains and losses resulting from foreign currency transactions are included in general and administrative expenses and were a gain of \$69,000 and \$9,000 for the three months ended June 30, 2022 and 2021, respectively. Foreign currency transactions were a gain of \$47,000 and \$17,000 for the six months ended June 30, 2022 and 2021, respectively.

The Company's non-operating subsidiaries that use the U.S. dollar as their functional currency remeasure monetary assets and liabilities at exchange rates in effect at the end of each period and nonmonetary assets and liabilities at historical rates. Gains and losses resulting from these remeasurements and foreign currency transactions are included in general and administrative expenses. During the three months ended June 30, 2022 and 2021, the Company recorded gains of \$7,000 and \$0, respectively. The Company recorded losses of \$8,000 and \$16,000 for the six months ended June 30, 2022 and 2021, respectively.

Comprehensive Loss

The components of comprehensive loss consist of net loss, foreign currency translation adjustments from its subsidiaries not using the U.S. dollar as their functional currency and unrealized gains and losses in investments available for sale. The Company did not have reclassifications from other comprehensive loss to net loss during the three and six-months ended June 30, 2022.

Revenue Recognition

The Company recognizes revenue when its customers obtain control of promised goods or services, in an amount that reflects the consideration which the Company expects to be entitled in exchange for those goods or services.

To determine revenue recognition for arrangements that are within the scope of Accounting Standard Codification ("ASC") Topic 606, Revenue Recognition, the Company performs the following five steps:

1. Identify the contract with a customer
2. Identify the performance obligations
3. Determine the transaction price
4. Allocate the transaction price to the performance obligations
5. Recognize revenue when/as performance obligation(s) are satisfied

In order for an arrangement to be considered a contract, it must be probable that the Company will collect the consideration to which it is entitled for goods or services to be transferred. Once the contract is determined to be within the scope of ASC 606, the

Company assesses the goods or services promised with each contract, determines whether those are performance obligations and the related transaction price. The Company then recognizes the sale of goods based on the transaction price that is allocated to the respective performance obligation when the performance obligation is satisfied.

The Company's revenue consists primarily of the sale of the RECELL System to hospitals or other treatment centers and to BARDA (collectively, "customers"), predominately in the United States. The Company evaluated the BARDA contract and concluded that a portion of the arrangement, such as the procurement of the RECELL system and the emergency preparedness, represents a transaction with a customer and as such are in the scope of ASC 606. Amounts received from BARDA for the research and development of the Company's product are classified as BARDA income in the consolidated statements of operations and are accounted for under IAS 20. For further details refer to BARDA Income and Receivables below.

Revenues for commercial customers (hospitals and treatment centers) are recognized as control of the product is transferred to customers, at an amount that reflects the consideration expected to be received in exchange for the product. Revenues are recognized net of volume discounts. As such, revenue is recognized only to the extent a significant reversal of revenues is not expected to occur in subsequent periods. For the Company's contracts that have an original duration of one year or less, the Company elected the practical expedient applicable to such contracts and does not consider the time value of money. Further, because of the short duration of these contracts, the Company has not disclosed the transaction price for the remaining performance obligations as of each reporting period or when the Company expects to recognize this revenue. The Company has further applied the practical expedient to exclude sales tax in the transaction price and expense contract fulfillment costs such as commissions and shipping and handling expenses as incurred.

For revenues related to the BARDA contract within the scope of ASC 606, the Company identified two performance obligations: (i) the procurement of 5,614 RECELL units; and (ii) emergency preparedness services. Through this contract the Company promises to procure the product through a vendor management inventory arrangement and to stand ready to provide emergency deployment services related to the product. Emergency preparedness services include procuring necessary storage containers, housing, and maintaining the containers (and product), and providing shipping and handling services in the event of an emergency situation. This stand ready obligation is a series of distinct services that are substantially the same and have the same pattern of transfer to the customer, overtime as services are consumed.

The total transaction price for the portion of the BARDA contract that is within the scope of ASC 606, was determined to be \$9.2 million. The transaction price was allocated on a stand-alone selling price basis as follows: \$7.6 million to the procurement of the RECELL product, which is classified as revenues when recognized in the consolidated statements of operations and \$1.6 million to the emergency deployment services which is classified as revenues when recognized in the consolidated statements of operations. The \$1.6 million for emergency deployment includes variable consideration which is deemed immaterial to the contract as a whole. The Company estimated the stand-alone selling price of the procurement of the RECELL product based on historical pricing of the Company's product at the initial execution of the contract. The Company estimated the stand-alone selling price of the emergency deployment services performed based on the Company's projected cost of providing the services plus an applicable profit margin as denoted in the contract.

The Company's performance obligations are either satisfied at a point in time or over time as services are provided. The product procurement performance obligation is satisfied at a point in time, upon transfer of control of the product. As such, the related revenue for these performance obligations is recognized at a point in time as revenue within the Company's consolidated statement of operations. In addition to guidance under ASC 606, the Company recognizes revenue from the sales of RECELL product to BARDA for placement into vaccine stockpiles in accordance with Securities and Exchange Commission (SEC) Interpretation, *Commission Guidance regarding Accounting for Sale of Vaccines and BioTerror Countermeasures to the Federal Government for Placement into the Pediatric Vaccine Stockpile or the Strategic National Stockpile (SNS)*. Under this guidance, revenue is recognized when product is placed in the BARDA vendor-managed inventory as control of the product has been transferred to the customer at the time of delivery to the VMI. RECELL units that have been delivered to BARDA have a product replacement obligation at no cost to BARDA due to the product's limited shelf-life. The estimated cost of the expired inventory over the term of the contract is recognized on a per unit basis at the time of delivery. The liability is released upon replacement of the product along with a corresponding reduction to inventory. The emergency preparedness services performance obligation is satisfied over time. Revenue for the emergency deployment will be recognized on a straight-line basis during the term of the contract as services are consumed over time. Services recognized are included in sales within the consolidated statements of operations. Contract costs to fulfil the performance obligations are incremental and expected to be recovered are capitalized and amortized on a straight-line basis over the term of the contract. Contract costs are included in other long-term assets.

Contract Liabilities

The Company receives payments from customers based on contractual terms. Trade receivables are recorded when the right to consideration becomes unconditional. The Company satisfies its performance obligation on product sales when the products are shipped or delivered, depending on the terms of the sale. Payment terms on invoiced amounts are typically 30-90 days, and do not include a financing component. Contract liabilities are recorded when the Company receives payment prior to satisfying its obligation to transfer goods to a customer.

Cost of Sales

Cost of sales related to products includes costs to manufacture or purchase, package, and ship the Company's products. Costs also include relevant production overhead and depreciation and amortization. These costs are recognized when control of the product is transferred to the customer and revenue is recognized.

Income Taxes

Income taxes are accounted for using the liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of assets and liabilities and their respective tax basis. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income or loss in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment date. Deferred tax assets are reduced by a valuation allowance if it is more likely than not that a portion of the deferred tax asset will not be realized. We recognize interest and penalties related to unrecognized tax benefits on the income tax expense line in the accompanying consolidated statement of operations. Accrued interest and penalties are included on the related tax liability line in the consolidated balance sheet.

The Company reviews its uncertain tax positions regularly. An uncertain tax position represents the Company's expected treatment of a tax position taken in a filed return or planned to be taken in a future tax return or claim that has not been reflected in measuring income tax expense for financial reporting purposes. The Company recognizes the tax benefit from an uncertain tax position when it is more-likely-than-not that the position will be sustained upon examination on the basis of the technical merits or the statute of limitations for the relevant taxing authority to examine and challenge the tax position has expired.

Cash and Cash Equivalents

Consists of cash held at deposit institutions and cash equivalents. Cash equivalents consist of short-term highly liquid investments with original maturities of three months or less from the date of purchase and consist primarily of money market funds. The Company holds cash at deposit institutions in the amount of \$5.0 million and \$4.4 million of which \$492,000 and \$203,000 is denominated in foreign currencies in foreign institutions as of June 30, 2022 and December 31, 2021, respectively. As of June 30, 2022 and December 31, 2021, the Company held cash equivalents in the amount of \$29.7 million and \$51.1 million, respectively.

Restricted Cash

Pursuant to a contractual agreement to maintain the business credit card, the Company must maintain restricted cash deposits which amounted to approximately \$202,000 and \$201,000 as of June 30, 2022 and December 31, 2021, respectively.

Concentrations

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents, marketable securities, trade receivables, BARDA receivables and other receivables. As of June 30, 2022 and December 31, 2021, substantially all of the Company's cash was deposited in accounts at financial institutions, and amounts may exceed federally insured limits. Management believes that the Company is not exposed to significant credit risk due to the financial strength of the depository institutions in which its cash is held.

As of June 30, 2022, no single commercial customer accounted for more than 10% of total net accounts receivable. As of December 31, 2021, one commercial customer accounted for approximately 10% of net accounts receivable. For the three months ended June 30, 2022 and 2021, no single customer accounted for more than 10% of revenues. For the six months ended June 30, 2022 and 2021, no single customer accounted for more than 10% of revenues. BARDA revenue for emergency deployment accounted for approximately 1% and 35% of total revenues for the three months ended June 30, 2022 and 2021, respectively. For the six months ended June 30, 2022 and 2021, BARDA revenue for emergency deployment accounted for approximately 1% and 41% of total revenues, respectively. BARDA receivables for emergency preparedness services accounted for 4% and 3% of total BARDA

receivables as of June 30, 2022 and December 31, 2021, respectively. See table below for breakdown of BARDA receivables (in thousands).

	As of June 30, 2022	As of December 31, 2021
BARDA procurement and emergency preparedness services	\$ 15	\$ 9
BARDA expense reimbursements	323	299
Total BARDA receivables	<u>\$ 338</u>	<u>\$ 308</u>

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Marketable Securities

We classify all highly liquid investments with original maturities of three months or less from the date of purchase as cash equivalents and all highly liquid investments with stated maturities of greater than three months as marketable securities. The Company classifies marketable securities as short-term when they have remaining contractual maturities of one year or less from the balance sheet date, and as long-term when the investments have remaining contractual maturities of more than one year from the balance sheet date. Classification is determined at the time of purchase and re-evaluated each balance sheet date. Short-term marketable securities represent investment of cash available for current operations. We account for our marketable securities as available-for-sale securities.

All marketable securities, which consist of corporate debt securities, U.S government agency obligations, U.S treasury and commercial paper are denominated in the U.S. dollars, have been classified as “available for sale”, and are carried at fair value. Unrealized gains and losses, net of any related tax effects, are excluded from earnings and are included in other comprehensive income (loss) and reported as a separate component of shareholders equity until realized. Realized gains and losses on marketable securities are included in other income in the accompanying consolidated statements of operations. The cost of any marketable securities sold is based on the specific identification method. The amortized cost of marketable securities is adjusted for amortization of premiums and accretion of discounts to maturity. Interest on marketable securities is included in other income. In accordance with the Company’s investment policy, management invests to diversify credit risk and only invests in securities with high credit quality, including U.S. government securities, and the maximum final maturity from the date of purchase is thirty-seven months.

If necessary, the Company will recognize an allowance for credit losses on available-for-sale debt securities on an individual basis, and will no longer consider other than-temporary impairment or immediately reduce the cost basis of the investment provided that it is more likely than not that the security will be held to recovery or maturity. Further, the Company will recognize any improvements in estimated credit losses on available-for-sale debt securities immediately in earnings and reduce the existing allowance for credit losses. The Company will disaggregate its available-for-sale debt securities into the following categories: commercial paper, corporate debt, government and agency securities and money market funds. The Company’s corporate bonds are comprised of predominantly high-grade corporate bonds while its government and agency securities are U.S. treasury bonds, and U.S. agency bonds. The Company has analyzed both corporate bonds and government and agency securities and identified that both types of securities have similar risk characteristics in that they are traded infrequently and have contractual interest rates and maturity dates.

To evaluate for impairment, management reviews credit rating changes, securities trends, interest rate movements and unrealized loss at the security level of the Company’s available for sale debt securities. If any of these give rise to a potential credit concern, the Company performs a discounted cash flow analysis to determine the credit portion of the impairment. The discounted cash flow analysis will be performed either internally or through the assistance of a qualified third party. Once the credit component of the impairment is determined, the Company will record the impaired amount as an allowance to the available-for-sale debt securities balance and as a charge to other income in the accompanying consolidated statements of operations, not to exceed the amount of the unrealized loss. The Company assesses expected credit losses at the end of each reporting period and adjusts the allowance through other income.

BARDA Income and Receivables

The AVITA Group was awarded a Biomedical Advance Research and Development Authority (“**BARDA**”) contract in September 2015. The contract with BARDA expires December 31, 2023. Under this arrangement BARDA supported the Company’s research and development for the Company’s product, including the U.S. clinical regulatory program targeted towards PMA, the Company’s compassionate use program, clinical and health economics research. Currently, the BARDA contract is supporting the Company’s clinical trial in soft-tissue reconstruction.

Consideration received under the BARDA arrangement is earned and recognized under a cost-plus-fixed-fee arrangement in which the Company is reimbursed for direct costs incurred plus allowable indirect costs and a fixed-fee earned. Billings under the contracts are based on approved provisional indirect billing rates, which permit recovery of fringe benefits, general and administrative expenses and a fixed fee.

The Company has concluded that grants under the BARDA arrangement are not within the scope of ASC 606, as it does not meet the definition of a contract with a “customer.” The Company has further concluded that Subtopic 958-605, *Not-for-Profit-Entities-Revenue Recognition* also does not apply, as the Company is a business entity and the payments are with governmental agencies or units. With respect to the BARDA arrangement, we considered the guidance in IAS 20, *Accounting for Government Grants and Disclosure of Government Assistance*, by analogy. BARDA income and related receivables are recognized when there is reasonable assurance that the amount will be received, and all attaching conditions have been complied with. When the payment relates to an expense item, the amount received is recognized as income over the period when the expense was incurred.

Leases

The Company has operating leases for corporate office space, manufacturing and warehouse facility. The Company's operating leases have remaining lease terms of one year to two years, some of which include options to renew the lease. At contract inception, the Company determines whether the contract is a lease or contains a lease. A contract contains a lease if the Company is both able to identify an asset and can conclude it has the right to control the identified asset for a period of time. Leases with an initial term of twelve months or less are not recorded on the consolidated balance sheet.

Right of use ("ROU") assets represent the Company's right to control an underlying asset for the lease term, and lease liabilities represent the Company's obligation to make lease payments arising from the lease. ROU assets and lease liabilities are recognized at commencement date based on the present value of lease payments over the lease term. As the Company's leases do not provide an explicit rate, the Company used its incremental borrowing rate ("IBR") based on the information available at commencement date in determining the discount rate used to present value lease payments. In determining the IBR, the Company considered its credit rating and current market interest rates. The IBR used approximates the interest that the Company would be required to pay for a collateralized loan over a similar term. The Company's leases typically do not include any residual value guarantees or asset retirement obligations.

The Company's lease terms are only for periods in which it has enforceable rights. A lease is no longer enforceable when both the lessee and the lessor each have the right to terminate the lease without permission from the other party with no more than an insignificant penalty. The Company has options to renew some of these leases for three years after their expiration. The Company considers these options, which may be elected at the Company's sole discretion, in determining the lease term on a lease-by-lease basis. Lease expense is recognized on a straight-line basis over the lease term and is primarily included in general and administrative expenses in the accompanying consolidated statements of operations.

The Company has lease agreements with lease and non-lease components, which are accounted for as a single lease component for all underlying asset classes. Some leases require variable payments for common area maintenance, property taxes, parking, insurance and other variable costs. The variable portion of lease payments is not included in operating lease assets or liabilities. Variable lease costs are expensed when incurred.

Share-based compensation

The Company records compensation expense for stock options based on the fair market value of the awards on the date of grant. The fair value of share-based compensation awards is amortized over the vesting period of the award. Compensation expense for performance-based awards is evaluated based on the number of shares ultimately expected to vest, estimated at each grant date based on management's expectations regarding the relevant performance criteria, if any. The Black-Scholes option pricing model and Monte Carlo Simulation were used to estimate the fair value of the time-based and performance-based options, respectively. To estimate the grant date fair value of the performance vesting employee stock options, we utilized a Monte Carlo simulation-based approach to capture the holder's expected post-vesting exercise behavior. Specifically, we simulated the Company's stock price from the valuation date to the maturity of the options on daily basis using Geometric Brownian Motion, whereby the options are assumed to be early exercised if the simulated stock price exceeded a certain exercise threshold estimated based on empirical research. Under ASU 2016-09, *Compensation – Stock Compensation ("ASC 718") Improvements to Employee Share-Based Payment Accounting*, the Company elected to account for forfeitures as they occur.

The following assumptions were used in the valuation of stock options.

- Expected volatility – determined using the average of the historical volatility using daily intervals over the expected term and the derived volatility using the longest term available of 12 months.
- Expected dividends - based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future
- Expected term – the expected term of the Company’s stock options for tenure only vesting has been determined utilizing the “simplified” method as described in the SEC’s Staff Accounting Bulletin No. 107 relating to share-based compensation. The simplified method was chosen because the Company has limited historical option exercise experience due to its short operating history of awards granted, with the first plan being established in 2016 which was primarily used for executive awards. Further, the Company does not have sufficient history of exercises in the U.S. market given the AVITA Group’s recent redomiciliation from Australia to the United States in 2020. The initial term input of options with a performance condition was set to the contractual term of 10 years for the modeling process, while the expected term within each simulation path was determined by the early exercise mechanism discussed above within the Monte Carlo simulation model.
- Risk-free interest rate – the risk-free interest rate is based on the U.S. Treasury yield in effect at the time of grant for a period approximately equal to the expected term of the award.

Segment Reporting

Operating segments are defined as components of an enterprise for which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. The Company’s chief operating decision maker is its Chief Executive Officer. To date, the Company has viewed its operations and manages its business as one segment.

Deferred Compensation Plan and Investments in Corporate-Owned Life Insurance

The Company’s Deferred Compensation Plan (the “**DCP**”), which became effective in October 2021, allows highly compensated key employees to elect to defer a portion of their salary, bonus, commissions and RSU awards to later years. Management determined that the DCP shall be accounted for similarly to a defined benefit plan under ASC 715, *Compensation – Retirement Benefits*, and should follow accounting treatment that is similar to a cash balance plan. Management determined that the employee portion and employer portion of the deferred compensation should be recognized as compensation expense with a corresponding credit to deferred compensation liability. The matching contribution will be accrued over the vesting period of two-years with 25% vesting in the first year and 75% vesting in the second year. Employees aged 55 or older immediately vest in employer matching contributions. The change in the liability between each reporting period is accounted for as compensation expense with a corresponding adjustment to deferred compensation liability. Upon distribution, the Company will record the distribution as a decrease to compensation liability with corresponding credit to cash. The Company funds the DCP through a Corporate-Owned Life Insurance (“**COLI**”). Per the ASC 325-30-25-1A, *Investments – Other*, COLI is recorded as an asset in other long-term assets as it does not meet the definition of a plan asset under ASC 715. The Company invests in COLI policies relating to its deferred compensation plan. Investments in COLI policies are recorded at their cash surrender values as of each balance sheet date. Changes in the cash surrender value during the period are recorded as a gain or loss in the statements of operations in other income.

Rabbi Trust

During April 2022, we established a rabbi trust for a select group of participants in which share awards granted under the 2020 Omnibus Incentive Plan (“**2020 Plan**”) may be deposited. The plan permits diversification of fully vested shares awarded into other equity securities subject to a six-month and one day holding period subsequent to vesting. The rabbi trust is an irrevocable trust and no portion of the trust fund may be used for any purpose other than the delivery of those assets to the participants. The assets held in the rabbi trust are subject to the claims of our general creditors in the event of bankruptcy or insolvency. The value of the assets of the rabbi trust is consolidated into our financial statements. In accordance with ASR 268, *Redeemable Preferred Stock*, and ASC 718, *Compensation – Stock Compensation*, the deferred share awards are classified as an equity instrument and changes in fair value of the amount owed to the participant are not recognized. Further, the redemption amounts are based on the vested percentage and is recorded outside of equity as non-qualified deferred compensation share awards on the Consolidated Balance Sheet. As of June 30, 2022, a total of 71,749 shares awards have been deferred, none of which have vested. These unvested share awards are recorded at the redemption value of the share awards outside of equity as non-qualified deferred compensation share awards.

3. Accounting Standards Update

Recently Adopted Accounting Pronouncements

In November 2021, the FASB issued ASU 2021-10, “*Government Assistance (Topic 832): Disclosures by Business Entities about Government Assistance*.” ASC 832 requires business entities to provide certain disclosures when they (1) have received government assistance and (2) use a grant or contribution accounting model by analogy to other accounting guidance. The guidance will require business entities to disclose the nature of the transactions, accounting policies used to account for the transactions, and state which line items on the balance sheet and income statement are affected by these transactions and the amount applicable to each financial statement line. Business entities will also have to disclose significant terms and conditions of transactions with a government such as the duration of the agreement, any commitments made by either side, provisions, and contingencies. The guidance in ASU 2021-10 is effective for all entities for fiscal years beginning after December 15, 2021. Entities may apply the provision either (1) prospectively to all transactions within the scope of ASC 832 that are reflected in the financial statements as of the adoption date and all new transactions entered into after the date of adoption or (2) retrospectively. The Company adopted this standard as of January 1, 2022. The adoption did not have a material impact on the consolidated financial statements or disclosures.

In December 2019, the FASB issued ASU 2019-12, *Simplifying the Accounting for Income Taxes*, or ASU 2019-12, which includes amendments to simplify the accounting for income taxes by removing certain exceptions to the general principles in ASC 740, *Income Taxes*, or ASC 740. The amendments also improve consistent application of and simplify U.S. GAAP for other areas of ASC 740 by clarifying and amending existing guidance. The new guidance is effective for the Company for annual periods beginning after December 15, 2021 and interim periods within fiscal years beginning after December 15, 2022. Early adoption of the amendments is permitted. The Company adopted this standard as of January 1, 2022. The adoption did not have a material impact on the consolidated financial statements.

Recent Accounting Pronouncements Not Yet Adopted

All other newly issued but not yet effective accounting pronouncements have been deemed to be not applicable or immaterial to the Company.

4. Marketable Securities

The following table summarizes the amortized cost and estimated fair values of debt securities available for sale:

	June 30, 2022			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Carrying Value
(in thousands)				
Cash Equivalents:				
Money market funds	\$ 29,747	\$ -	\$ -	\$ 29,747
Current marketable securities:				
U.S Treasury securities	\$ 30,843	\$ 1	\$ (292)	\$ 30,552
Commercial paper	12,236	-	-	12,236
Corporate debt securities	4,988	-	(42)	4,946
U.S Government Agency Obligations	1,904	-	(20)	1,884
Total current marketable securities	<u>\$ 49,971</u>	<u>\$ 1</u>	<u>\$ (354)</u>	<u>\$ 49,618</u>
Long-term marketable securities:				
U.S Treasury securities	\$ 5,995	\$ -	\$ (171)	\$ 5,824
Corporate debt securities	930	-	(11)	919
Total Long-term marketable securities	<u>\$ 6,925</u>	<u>\$ -</u>	<u>\$ (182)</u>	<u>\$ 6,743</u>

	As of December 31, 2021			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Carrying Value
(in thousands)				
Cash Equivalents:				
Money market funds	\$ 51,112	\$ -	\$ -	\$ 51,112
Current marketable securities:				
Commercial paper	\$ 19,586	\$ -	\$ -	\$ 19,586
Corporate debt securities	7,068	-	(7)	7,061
Asset-backed securities	3,002	-	-	3,002
Total current marketable securities	\$ 29,656	\$ -	\$ (7)	\$ 29,649
Long-term marketable securities:				
U.S Treasury securities	\$ 18,043	\$ -	\$ (89)	\$ 17,954
Corporate debt securities	1,746	-	(8)	1,738
Total Long-term marketable securities	\$ 19,789	\$ -	\$ (97)	\$ 19,692

The maturities of debt securities available for sale are summarized in the following table using contractual maturities. Actual maturities may differ from contractual maturities due to obligations that are called or prepaid.

	As of June 30, 2022		As of December 31, 2021	
	Amortized Cost	Carrying Value	Amortized Cost	Carrying Value
Due in one year or less	49,971	49,618	\$ 29,656	\$ 29,649
Due after one year through three years	6,925	6,743	\$ 19,789	\$ 19,692

Gross unrealized gains and losses on the Company's marketable securities were an unrealized gain of \$1,000 and an unrealized loss of \$536,000 as of June 30, 2022, which resulted in a net unrealized loss of \$535,000. Gross unrealized gains and losses on the Company's marketable securities were an unrealized gain of \$0 and an unrealized loss of \$104,000 as of December 31, 2021 which resulted in a net unrealized loss of \$104,000. As of June 30, 2022, and December 31, 2021, the Company did not recognize credit losses. The Company has accrued interest income of \$136,000 and \$72,000 as of June 30, 2022, and December 31, 2021, respectively, recorded in prepaids and other current assets.

5. Fair Value Measurements

The authoritative guidance on fair value measurements establishes a framework with respect to measuring assets and liabilities at fair value on a recurring basis and non-recurring basis. Under the framework, fair value is defined as the exit price, or the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants, as of the measurement date. The framework also establishes a three-tier hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. Observable inputs are inputs market participants would use in valuing the asset or liability and are developed based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the factors market participants would use in valuing the asset or liability and are developed based on the best information available in the circumstances. The hierarchy consists of the following three levels:

Level 1: Inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities that the reporting entity can access at the measurement date.

Level 2: Inputs are inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly.

Level 3: Inputs are unobservable inputs for the asset or liability

The following tables present information about the Company's financial assets measured at fair value on a recurring basis, based on the three-tier fair value hierarchy:

(in thousands)	As of June 30, 2022			
	Level 1	Level 2	Level 3	Total
Cash Equivalents				
Money market funds	\$ 29,747	\$ -	\$ -	\$ 29,747
Total cash equivalents	29,747	-	-	29,747
Short-term marketable securities				
U.S Treasury securities	-	30,552	-	30,552
Commercial paper	-	12,236	-	12,236
Corporate debt securities	-	4,946	-	4,946
U.S Government Agency Obligations	-	1,884	-	1,884
Total short-term marketable securities	-	49,618	-	49,618
Long-term investments				
U.S Treasury securities	-	5,824	-	5,824
Corporate debt securities	-	919	-	919
Total long-term marketable securities	-	6,743	-	6,743
Total marketable securities and cash equivalents	\$ 29,747	\$ 56,361	\$ -	\$ 86,108

(in thousands)	As of December 31, 2021			
	Level 1	Level 2	Level 3	Total
Cash Equivalents				
Money market funds	\$ 51,112	\$ -	\$ -	\$ 51,112
Total cash equivalents	51,112	-	-	51,112
Short-term marketable securities				
Commercial paper	-	19,586	-	19,586
Asset-backed securities	-	3,002	-	3,002
Corporate debt securities	-	7,061	-	7,061
Total short-term marketable securities	-	29,649	-	29,649
Long-term investments				
U.S Treasury securities	-	17,954	-	17,954
Corporate debt securities	-	1,738	-	1,738
Total long-term marketable securities	-	19,692	-	19,692
Total marketable securities and cash equivalents	\$ 51,112	\$ 49,341	\$ -	\$ 100,453

The Company's Level 1 assets include money market instruments and are valued based upon observable market prices. Level 2 assets consist of commercial paper, U.S Government agency obligations, corporate debt securities and U.S Treasury securities. Level 2 securities are valued based upon observable inputs that include reported trades, broker/dealer quotes, bids and offers. As of June 30, 2022 and December 31, 2021, the Company had no investments that were measured using unobservable (Level 3) inputs. There were no transfers between fair value measurement levels as of June 30, 2022 or December 31, 2021.

6. Leases

During August 2021, the Company remeasured the lease liability for an office lease due to a change in the lease term. As a result of the remeasurement of the lease liability, there was an increase of approximately \$392,000 to the operating lease ROU assets and operating lease liabilities. There was no impact on earnings as a result of the modification.

The following table sets forth the Company's operating lease expenses which are included in general and administrative expenses in the consolidated statements of operations (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2022	2021	2022	2021
Operating lease cost	\$ 194	\$ 186	\$ 388	\$ 372
Variable lease cost	13	12	25	25
Total lease cost	<u>\$ 207</u>	<u>\$ 198</u>	<u>\$ 413</u>	<u>\$ 397</u>

Supplemental cash flow information related to operating leases for the three and six months ended June 30, 2022 and 2021 was as follows (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2022	2021	2022	2021
Cash paid for amounts included in the measurement of lease liabilities:				
Operating cash outflows from operating leases	\$ 199	\$ 192	\$ 397	\$ 383

Supplemental balance sheet information, as of June 30, 2022 and December 31, 2021 related to operating leases was as follows (in thousands):

	As of June 30, 2022	As of December 31, 2021
Reported as:		
Operating lease right-of-use assets	\$ 1,203	\$ 1,544
Total right-of-use assets	<u>\$ 1,203</u>	<u>\$ 1,544</u>
Other current liabilities:		
Operating lease liabilities, short-term	\$ 756	\$ 720
Operating lease liabilities, long term	532	918
Total operating lease liabilities	<u>\$ 1,288</u>	<u>\$ 1,638</u>
Operating lease weighted average remaining lease term (years)	1.85	2.30
Operating lease weighted average discount rate	6.58%	6.51%

As of June 30, 2022, maturities of the Company's operating lease liabilities are as follows (in thousands):

	Operating Leases
Remainder of 2022	\$ 406
2023	649
2024	313
2025	-
Total lease payments	1,368
Less imputed interest	(80)
Total operating lease liabilities	<u>\$ 1,288</u>

As of June 30, 2022, there were no leases entered into that had not yet commenced.

7. Inventory

The composition of inventory is as follows (in thousands):

	As of June 30, 2022	As of December 31, 2021
Raw materials	\$ 1,576	\$ 1,222
Work in process	383	176
Finished goods	63	734
Total inventory	<u>\$ 2,022</u>	<u>\$ 2,132</u>

The Company has reduced the carrying value of its inventories to reflect the lower of cost or net realizable value. Charges for estimated excess and obsolescence are recorded in cost of sales in the consolidated statements of operations and were \$61,000 and \$12,000, for the three months ended June 30, 2022 and 2021, respectively. Charges for estimated excess and obsolescence were \$158,000 and \$255,000 for the six-months ended June 30, 2022 and 2021, respectively.

8. Intangible Assets

The composition of intangible assets, net is as follows (in thousands):

	Weighted Average Life	As of June 30, 2022			As of December 31, 2021		
		Gross Amount	Accumulated Amortization	Net Carry Amount	Gross Amount	Accumulated Amortization	Net Carry Amount
Patent 1	2	\$ 211	\$ (210)	\$ 1	\$ 209	\$ (182)	\$ 27
Patent 2	13	135	(23)	112	123	(18)	105
Patent 3	14	192	(31)	161	192	(25)	167
Patent 5	20	46	(4)	42	46	(3)	43
Patent 6	20	42	(4)	38	39	(2)	37
Patent 7	13	2	-	2	2	-	2
Patent 8	20	13	-	13	3	-	3
Patent 10	19	3	-	3	3	-	3
Patent 11	19	6	-	6	6	-	6
Trademarks	Indefinite	50	-	50	50	-	50
Total intangible assets		<u>\$ 700</u>	<u>\$ (272)</u>	<u>\$ 428</u>	<u>\$ 673</u>	<u>\$ (230)</u>	<u>\$ 443</u>

During the three and six months ended June 30, 2022 and 2021, the Company did not identify any events or changes in circumstances that indicated that the carrying value of its intangibles may not be recoverable. As such, there was no impairment of intangibles assets recognized for the three and six months ended June 30, 2022 and 2021. Amortization expense of intangibles included in the consolidated statements of operations was \$8,000 and \$31,000 for the three months ended June 30, 2022 and 2021, respectively. Amortization expense of intangibles included in the consolidated statements of operations was \$42,000 and \$61,000 for the six months ended June 30, 2022 and 2021, respectively.

The Company expects the future amortization of amortizable intangible assets held at June 30, 2022 to be (in thousands)

	Estimated Amortization Expense
2023	31
2024	31
2025	30
2026	30
2027	30
Thereafter	226
Total	\$ 378

9. Plant and Equipment

The composition of property, plant and equipment, net is as follows (in thousands):

	<u>Useful Lives</u>	<u>As of June 30, 2022</u>	<u>As of December 31, 2021</u>
Computer equipment	3 years	\$ 728	\$ 740
Computer software	3 years	801	811
Construction in progress		187	29
Furniture and fixtures	7 years	440	440
Laboratory equipment	5 years	625	566
Leasehold improvements	Lesser of life or lease term	242	242
RECELL Moulds	5 years	129	129
Less: accumulated amortization and depreciation		(1,903)	(1,695)
Total plant and equipment, net		\$ 1,249	\$ 1,262

Depreciation expense related to plant and equipment for the three months ended June 30, 2022 and 2021 was \$129,000 and \$145,000, respectively. Depreciation expense related to plant and equipment for the six months ended June 30, 2022 and 2021 was \$258,000 and \$282,000, respectively.

10. Prepaids and Other Current Assets and Other Long-Term Assets

Prepaids and other current assets consisted of the following (in thousands):

	<u>As of June 30, 2022</u>	<u>As of December 31, 2021</u>
Prepaid expenses	\$ 838	\$ 1,124
Lease deposits	2	2
Accrued investment income	136	72
Other receivables	29	15
Total prepaids and other current assets	\$ 1,005	\$ 1,213

Prepaid expenses primarily consist of prepaid benefits and insurance.

Other long-term assets consisted of the following (in thousands):

	As of June 30, 2022	As of December 31, 2021
BARDA contract costs	378	504
Corporate-owned life insurance policies	737	304
Long-term lease deposits	124	124
Long-term prepaids	1	10
Total other long-term assets	<u>1,240</u>	<u>\$ 942</u>

11. Reporting Segment and Geographic Information

The Company views its operations and manages its business in one reporting segment. Long-lived assets are primarily located in the United States as of June 30, 2022, and December 31, 2021 with an insignificant amount located in Australia and the United Kingdom.

Revenue by region for the three and six months ended June 30, 2022, and 2021 were as follows (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2022	2021	2022	2021
Revenue:				
United States	\$ 8,278	\$ 10,240	\$ 15,676	\$ 18,965
Foreign:				
Australia	29	49	116	74
United Kingdom	28	15	82	30
Total	<u>\$ 8,335</u>	<u>\$ 10,304</u>	<u>\$ 15,874</u>	<u>\$ 19,069</u>

Revenue and cost of sales by customer type for the three and six months ended June 30, 2022, and 2021 were as follows (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2022	2021	2022	2021
Revenue:				
Commercial sales	\$ 8,242	\$ 6,699	\$ 15,688	\$ 11,321
BARDA:				
Product sales	-	3,509	-	7,594
Services for emergency preparedness	93	96	186	154
Total	<u>\$ 8,335</u>	<u>\$ 10,304</u>	<u>\$ 15,874</u>	<u>\$ 19,069</u>
	Three months ended June 30,		Six months ended June 30,	
	2022	2021	2022	2021
Cost of sales				
Commercial cost	\$ 1,302	\$ 1,214	\$ 3,007	\$ 2,180
BARDA:				
Product cost	-	759	(12)	1,889
Emergency preparedness service cost	84	80	169	130
Total	<u>\$ 1,386</u>	<u>\$ 2,053</u>	<u>\$ 3,164</u>	<u>\$ 4,199</u>

12. Contingencies

The Company is subject to certain contingencies arising in the ordinary course of business. The Company records accruals for these contingencies to the extent that a loss is both probable and reasonably estimable. If some amount within a range of loss appears to be a better estimate than any other amount within the range, that amount is accrued. Alternatively, when no amount within a range of loss appears to be a better estimate than any other amount, the lowest amount in the range is accrued. The Company expenses legal costs associated with loss contingencies as incurred. As of June 30, 2022 and December 31, 2021, the Company did not have any outstanding or threatened litigation that would have a material impact to the financial statements.

13. Common and Preferred Stock

The Company's CHESSE Depository Interests ("CDIs") are quoted on the ASX under the ticker code, "AVH". The Company's shares of common stock are quoted on NASDAQ under the ticker code, "RCEL". One share of common stock on NASDAQ is equivalent to five CDIs on the ASX.

As a result of the 'implicit consolidation' that occurred under the AVITA group's redomiciliation from Australia to the United States of America (the "Redomiciliation"), the number of shares of common stock on issue in the Company (as set out in the consolidated financial statements) is less than the number of ordinary shares in AVITA Medical (the prior parent company of the AVITA group) that was previously set out in the consolidated financial statements of AVITA Medical. All common share amounts included in the consolidated financial statements have been retroactively reduced by a factor of one hundred and all per share amounts have been increased by a factor of one hundred, with the exception of the Company's common stock par value.

The Company is authorized to issue 200,000,000 shares of common stock, par value \$0.0001 per share, and 10,000,000 shares of preferred stock, par value \$0.0001 per share, issuable in one or more series as designated by the Company's board of directors. No other class of capital stock is authorized. As of June 30, 2022, and December 31, 2021, 25,003,088 and 24,925,743 shares of common stock, respectively, were issued and outstanding and no shares of preferred stock were outstanding.

On March 1, 2021, the Company issued 3,214,250 shares of common stock at the offering price of \$21.50 per share. The gross proceeds from the offering were approximately \$69.1 million while the Company incurred \$5.1 million in capital issuance expenses. The offering was made pursuant to a shelf registration statement on Form S-3 (File No. 333-249419) that was previously filed with the Securities and Exchange Commission (the "SEC") on October 9, 2020 and declared effective on October 16, 2020. It was also publicly released on the ASX. The final prospectus supplement relating to and describing the terms of the offering was filed with the SEC on February 25, 2021 (in the United States) and released on the ASX on March 1, 2021 (in Australia).

14. Revenues

Revenues

The Company's revenue consists of sale of the RECELL System to hospitals or other treatment centers ("commercial customers") and to BARDA (collectively "**customers**"), predominately in the United States. In addition, the Company records service revenue for the emergency preparedness services provided to BARDA.

Performance Obligations

For commercial contracts, we identified the hospital or treatment center as the customer in Step 1 of the 5-step model of ASC 606 and have determined a contract exists with those customers. As these contracts typically have a single performance obligation (i.e. product delivery), no allocation of the transaction price is required in Step 4 of the model. Control of the product is transferred to the customer at a point in time, at the point in time at which the goods are either shipped or delivered to our customers' facilities, depending on the terms of the contract. The transaction price is stated within the contract and is therefore fixed consideration. The transaction price does not include the sales tax that are imposed by governmental authorities.

For the contract with BARDA, the Company identified two performance obligations (i) the procurement of 5,614 RECELL units; and (ii) emergency preparedness services. The Company's performance obligations are either satisfied at a point in time or over time as services are provided. The product procurement performance obligation is satisfied at a point in time, upon transfer of control of the product. RECELL units that have been delivered to BARDA have a product replacement obligation at no cost to BARDA due to product's limited shelf-life. The estimated cost of the expired inventory over the term of the contract is recognized on a per unit basis at the time of delivery. The liability is released upon replacement of the product along with a corresponding reduction to inventory. The Company has estimated deferred cost of approximately \$52,000 and \$64,000 as of June 30, 2022 and December 31, 2021, respectively, for the rotation cost of the product. Such amounts are recorded in other current liabilities and other long-term liabilities as of June 30, 2022, and December 31, 2021, respectively. The emergency preparedness services performance obligation is

satisfied over time. Revenue for the emergency deployment will be recognized on a straight-line basis during the term of the contract as services are consumed over time. Services recognized for the three months ended June 30, 2022 and 2021 were \$93,000 and \$96,000, respectively, and are included in sales within the consolidated statements of operations. Services recognized for the six months ended June 30, 2022 and 2021 were \$186,000 and \$154,000, respectively. Contract costs to fulfil the performance obligation are incremental and expected to be recovered are capitalized and amortized on a straight-line basis over the term of the contract. As of June 30, 2022 and December 31, 2021 contract costs of \$378,000 and \$504,000 are included in other long-term assets, respectively.

Remaining Performance Obligations

Revenues from remaining performance obligations are calculated as the dollar value of the remaining performance obligations on executed contracts. The estimated revenue expected to be recognized in the future related to performance obligations that are unsatisfied (or partially unsatisfied) pursuant to the Company's existing customer agreements is \$813,000 and \$952,000 as of June 30, 2022 and December 31, 2021, respectively. Approximately \$378,000 for June 30, 2022 and \$517,000 for December 31, 2021 of the total balance relates to our July 2020 contract with BARDA for the purchase, delivery and storage of RECELL Systems for emergency response preparedness for a period of three years. The Company expects to recognize this amount as services are provided to BARDA. For the remaining balance of \$435,000 as of June 30, 2022 and December 31, 2021, the Company expects to recognize revenue on a straight-line basis over the term of the contract commencing with the generation of commercial sales to COSMOTEC. We are contracted to manage this inventory of product until the federal government requests shipment or at contract termination on December 31, 2023.

Variable Consideration

The Company evaluates its contracts with customers for forms of variable consideration, which may require an adjustment to the transaction price based on their estimated impact. For commercial customers, revenue from the sale of goods is recognized net of volume discounts. The Company uses the expected value method when estimating variable consideration. Revenue is only recognized to the extent that it is probable that a significant reversal will not occur. Variable consideration under the BARDA contract is not material to the consolidated financial statements.

Contract Assets and Contract Liabilities

Contract assets include amounts related to the Company's contractual right to consideration for both completed and partially completed performance for which the Company does not have the right to payment. As of the period ended June 30, 2022 and December 31, 2021, the Company does not have any contract assets.

Contract liabilities are recorded when the Company receives payment prior to satisfying its obligation to transfer goods to a customer. The Company had \$813,000 and \$952,000 of contract liabilities as of June 30, 2022 and December 31, 2021, respectively. The balance relates to the unsatisfied performance obligation for emergency preparedness under the BARDA contract and COSMOTEC. Performance obligation will be satisfied, and revenue will be recognized over time over the term of the contract. For the three months ended June 30, 2022 and 2021, the Company recognized \$93,000 and \$96,000 of revenue from amounts included in the beginning balance of contract liabilities. For the six months ended June 30, 2022, and 2021, the Company recognized \$186,000 and \$154,000 of revenue from amounts included in the beginning balance of contract liabilities.

Cost to Obtain and Fulfill a Contract

Commercial contract fulfillment costs include commissions and shipping expenses. The Company has opted to immediately expense the incremental cost of obtaining a contract when the underlying related asset would have been amortized over one year or less. The Company generally does not incur costs to obtain new contracts.

BARDA Contract Costs

Cost to fulfill the BARDA emergency preparedness performance obligation, which primarily consist of billed costs to BARDA incurred in connection with the emergency deployment services, are incremental and expected to be recovered. Costs are capitalized and amortized on a straight-line basis over the term of the contract. As of June 30, 2022, and December 31, 2021, the Company had \$378,000 and \$504,000 of contracts costs included in other long-term assets. Amortization expense related to deferred contract costs were \$84,000 and \$80,000, during the three months ended June 30, 2022, and 2021, respectively, and are classified as cost of sales on the accompanying consolidated statements of operations. Amortization expense related to deferred contract costs were \$169,000 and \$129,000, during the six months ended June 30, 2022, and 2021, respectively. There was no impairment loss in relation to deferred contract costs during the three months ended June 30, 2022, and 2021, or the six months ended June 30, 2022 and 2021.

Disaggregated Revenue

The Company disaggregates revenue from contracts with customers into geographical regions and by customer type. As noted in the segment footnote, the Company's business consists of one reporting segment. A reconciliation of disaggregated revenue by geographical region and customer type is provided in Segment Note 11.

15. Share-Based Payment Plans

Overview of Employee Share-Based Compensation Plans

Our former parent company, AVITA Medical, adopted the Employee Share Plan and the Incentive Option Plan (collectively, the "2016 Plans"). Upon completion of the Redomiciliation, the 2016 Plans were terminated with respect to future grants and accordingly, there are no more shares available to be issued under the 2016 Plans. In addition, upon completion of the Redomiciliation, the Company had an implicit consolidation or reverse stock split of 100:1 and all share information presented below in relation to the 2016 Plans has been presented on a reverse stock split basis. During November 2020, the Company, pursuant to Rule 416 under the Securities Act of 1933, filed a registration statement on Form S-8 to register a total of 1,750,000 shares of common stock which may be issued pursuant to the terms of the Company's 2020 Omnibus Incentive Plan ("2020 Plan"). On December 22, 2021, the Company's stockholders approved the issuance of options and awards to the Board of Directors and the CEO. These awards are subject to the vesting and performance conditions as denoted in the individual agreements.

The 2020 Plan provides for the grant of the following Grants: (a) Incentive Stock Options, (b) Nonstatutory Stock Options, (c) Stock Appreciation Rights, (d) Restricted Stock Grants, (e) Restricted Stock Unit Grants, (f) Performance Grants, and (g) Other Grants. The 2020 Plan will be administered by the Compensation Committee or by the Board acting as the Compensation Committee. Subject to the general purposes, terms and conditions of the 2020 Plan, applicable law and any charter adopted by the Board governing the actions of the Compensation Committee, the Compensation Committee will have full power to implement and carry out the 2020 Plan. Without limitation, the Compensation Committee will have the authority to interpret the plan, approve persons to receive grants, determine the terms and number of shares of the grants, determine vesting and exercisability of grants, and make all other determinations necessary or advisable in connection with the administration of this Plan.

The contractual term of awards granted under the 2020 Plan is ten years from the date of its grant. Unless otherwise specified, the vesting period of awards granted under the 2020 Plan was: (i) vest over a four year period in four equal installments, 25% at the end of each year from the date of grant, and /or (ii) subject to other performance criteria and hurdles, as determined by the Compensation Committee.

Share-Based Payment Expenses

Share-based payment transactions are recognized as compensation expense based on the fair value of the instrument on the date of grant. The Company uses the graded-vesting method to recognize compensation expense. Compensation cost is reduced for forfeitures as they occur in accordance with ASU 2016-09, simplifying the Accounting for Share-Based Payments ("ASU 2016-09"). During the three months ended June 30, 2022, and 2021, the Company recorded share-based compensation expense of \$1.4 million, and \$1.4 million, respectively. During the six months ended June 30, 2022, and 2021, the Company recorded share-based compensation expense of \$4.3 million, and \$2.7 million, respectively. No income tax benefit was recognized in the consolidated statements of operations for share-based payment arrangements for the three months ended June 30, 2022, and 2021, or the six months ended June 30, 2022, and 2021.

The Company has included share-based compensation expense as part of operating expenses in the accompanying consolidated statements of operations as follows (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2022	2021	2022	2021
Sales and marketing expenses	\$ 285	\$ 63	\$ 614	\$ 301
General and administrative expenses	983	1,172	3,310	2,102
Research and development expenses	146	175	422	340
Total	<u>\$ 1,414</u>	<u>\$ 1,410</u>	<u>\$ 4,346</u>	<u>\$ 2,743</u>

A summary of share option activity as of June 30, 2022, and changes during the period ended is presented below:

	Service Only Share Options	Performance Based Share Options	Market Awards	Total Share Options
Outstanding shares at December 31, 2021	1,129,126	599,994	27,600	1,756,720
Granted	42,700	-	-	42,700
Exercised	(125)	-	-	(125)
Expired	(3,025)	-	-	(3,025)
Forfeited	(22,200)	-	-	(22,200)
Outstanding shares at June 30, 2022	1,146,476	599,994	27,600	1,774,070
Exercisable at June 30, 2022	648,117	349,469	-	997,586

Restricted Stock Units

Restricted stock units (“RSUs”) are granted to executives as part of their long-term incentive compensation. RSUs granted prior to the 2020 Plan arise out of contracts between the Company's former parent company, AVITA Medical and the holders of such securities. RSUs granted as a result of stockholder approval at the December 22, 2021 Annual General Meeting (“AGM”) arise out of contracts between the Company and the holders of such securities. These RSU awards were approved by the Compensation Committee as determined necessary. All RSU awards have a contractual term of 10 years and vest in accordance with the tenure or performance conditions as determined by the Compensation Committee and set out in the contracts between the Company and the holders of such securities. The grant date fair value is determined based on the price of the Company stock price on the date of grant (stock price determined on NASDAQ post Redomiciliation and ASX prior to the Redomiciliation). RSUs primarily consist of awards to the CEO and other executives as well as Non-Executive Directors (as occurred following the 2021 AGM). The CEO RSU awards are described below.

A summary of the status of the Company's unvested RSUs as of June 30, 2022, and changes that occurred during the year is presented below:

	Service Condition RSU	Performance Condition RSU	Market Condition	Total RSU's
Unvested RSUs outstanding at December 31, 2021	114,757	135,093	47,640	297,490
Granted	5,000	-	-	5,000
Vested	(47,507)	(29,713)	-	(77,220)
Forfeited	(4,350)	-	-	(4,350)
Unvested RSUs outstanding at June 30, 2022	67,900	105,380	47,640	220,920

2019 CEO RSUs

On November 2019, the equivalent of 395,542 RSUs were issued to the CEO with the following vesting terms:

- Tenure – the equivalent of 142,521 RSUs with a vesting period of three-years commencing on June 1, 2020. As of June 30, 2022, the last tranche of 47,507 RSUs vested and were appropriately released and no RSUs are outstanding from this award.
- Milestone performance – 253,021 of the RSUs would vest upon satisfaction of various performance conditions. As of June 30, 2022, all milestones have been achieved and all of the RSUs vested and were appropriately released and no RSUs are outstanding from this award.

2021 AGM Awards

On December 22, 2021, as part of the Company's 2021 AGM, the Company's stockholders approved the grant of stock option awards and RSUs to the CEO and the Board of Directors. These awards are referred to as the 2021 AGM Awards.

Awards to the CEO under the 2021 AGM Awards

On December 22, 2021, the CEO was issued an aggregate 150,480 options and RSUs comprising:

- 37,600 tenure-based options and RSUs (23,800 RSUs and 13,800 options) with 25% of those options and RSUs vesting annually commencing on December 14, 2022.
- 37,640 performance-based options and RSUs (23,840 RSUs and 13,800 options) that vest upon satisfaction of the below conditions:
 - 9,410 awards (5,960 RSUs and 3,450 options) - Achieve Centers for Medicare and Medicaid Services reimbursement for out-patient transitional pass-through payment code (TPT) by June 30, 2022. This performance condition was met during the quarter ended March 31, 2022 resulting in RSUs vesting and the 5,960 shares of common stock being issued in respect of those vested RSUs and the 3,450 options vesting (although those vested options have not been exercised by the CEO as at the date of this Form 10-Q).
 - 9,410 awards (5,960 RSUs and 3,450 options) - Achieve Japanese approval from Pharmaceuticals and Medical Device Agency (PMDA) and reimbursement code by September 30, 2022
 - 9,410 awards (5,960 RSUs and 3,450 options) - Achieve profitability of the Company's Burns business for two consecutive quarters by March 31, 2023
 - 9,410 awards (5,960 RSUs and 3,450 options) - Achieve US FDA approval of vitiligo indication by December 31, 2023
- 75,240 stretch-performance based options and RSUs (47,640 RSUs and 27,600 options) that vest upon satisfaction of the below conditions:
 - 37,620 (23,820 RSUs and 13,800 options) - Achieve a doubling based on a 10-day volume-weighted average price ("VWAP") of the Company's share price as of the date of the 2021 Annual Meeting (being December 14, 2021) by June 30, 2023. The target share price is \$25.74.
 - 37,620 (23,820 RSUs and 13,800 options) - Achieve a market capitalization of the Company of greater than or equal to US\$1.25 billion (as compared to market capitalization of ~US\$435M as of October 14, 2021) and maintain that market capitalization for at least 30 consecutive calendar days on or before December 31, 2024.

In order for any options or RSUs issued to the CEO to vest, both the service condition and the relevant performance or market condition (as set out in the relevant agreement between the Company and the CEO) must be satisfied. The market awards will partially vest upon satisfaction of the market condition, and the other portions will vest on the anniversary of the vesting condition or December 14 of the relevant year. The VWAP condition has a minimum of three potential tranches and the market capitalization award has a minimum of two potential tranches. For market-based awards, share-based compensation expense will be recognized over the longer of the expected achievement period for the relevant market condition and the service condition. The market condition period and the valuation of each tranche were determined using a Monte Carlo simulation. In the event the market condition is met prior to the expected achievement period, any then-unrecognized compensation expense associated with the options or RSUs that have vested with respect to both the market condition and the service condition will be recognized immediately in the Company's consolidated statements of operations.

Awards to the Board of Directors under the 2021 AGM Awards

The Board of Director awards consist of an aggregate 68,600 options and RSUs as follows:

- 41,400 tenure-based options and RSUs (15,300 options and 26,100 RSUs) vesting 12-months from the grant date.
 - 6,900 tenure-based options and RSUs (4,350 RSUs and 2,550 options) granted to each of the six non-executive board members based on the vesting terms detailed above.
- 27,200 tenure-based options and RSUs (9,850 options and 17,350 RSUs) vesting on the first, second and third anniversary of the grant date in equal amounts (i.e. 1/3 of the RSUs and options will vest on each anniversary of the grant date, being on December 22 of each relevant year).
 - 13,600 tenure-based options and RSUs (8,675 RSUs and 4,925 options) granted to Jan Stern Reed and James Corbett as an initial grant in connection with their appointment to the Board of Directors.

16. Income Taxes

At December 31, 2021, the Company and its subsidiaries had net operating loss carryforwards for federal, state, United Kingdom, and Australian income tax purposes of \$122.0 million, \$79.7 million, \$31.9 million and \$38.2 million respectively. The net

operating loss carryforwards may be subject to limitation regarding their utilization against taxable income in future periods due to “change of ownership” provisions of the Internal Revenue Code and similar state and foreign provisions. Of these carryforwards, \$21.7 million will expire, if not utilized, between 2026 through 2038. The state carryforwards begin to expire between 2026 through 2041. The remaining carryforwards have no expiration. The Company is forecasting current year losses and has full valuation allowances against its deferred tax assets. Tax expense for the three months ended June 30, 2022 and 2021 of \$4,000 and \$7,000, respectively, is related to state minimum taxes. Tax expense for the six months ended June 30, 2022 and 2021, is \$8,000 and \$17,000, respectively.

In assessing the recoverability of its deferred tax assets, the Company considers whether it is more likely than not that its deferred assets will be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income in those periods in which temporary differences become deductible and/or net operating losses can be utilized. The Company considers all positive and negative evidence when determining the amount of the net deferred tax assets that are more likely than not to be realized. This evidence includes, but is not limited to, historical earnings, scheduled reversal of taxable temporary differences, tax planning strategies and projected future taxable income. Based upon the weight of available evidence including the uncertainty regarding the Company’s ability to utilize certain net operating losses and tax credits in the future, the Company has established a valuation allowance against its net deferred tax assets of \$51.3 million and \$46.9 million as of December 31, 2021 and 2020, respectively. The deferred tax assets are primarily net operating loss carryforwards for which management has determined it is more likely than not that the deferred tax assets will not be realized.

The Company recognizes the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities based on the technical merits of the position. The tax benefits recognized in the consolidated financial statements related to a particular tax position are measured based on the largest benefit that has a greater than a 50% likelihood of being realized upon settlement. The amount of unrecognized tax benefits is adjusted as appropriate for changes in facts and circumstances, such as significant amendments to existing tax law, new regulations or interpretations by the taxing authorities, new information obtained during a tax examination, or resolution of an examination.

The Company has not identified any uncertain tax positions as of June 30, 2022 or December 31, 2021.

The Company files income tax returns in the U.S. federal, California and certain other state and foreign jurisdictions. The Company remains subject to income tax examinations for its U.S. federal and state income taxes generally for fiscal years ended June 30, 2006 and forward. The Company also remains subject to income tax examinations for international income taxes for fiscal years ended June 30, 2018 through June 30, 2021, and for certain other U.S. state and local income taxes generally for the fiscal years ended June 30, 2018 through June 30, 2021.

17. Net Loss per Share

The following is a reconciliation of the basic and diluted loss per share computations:

	Three months ended June 30,		Six months ended June 30,	
	(in thousands, except per share data)			
	2022	2021	2022	2021
Net Loss	\$ (6,261)	\$ (4,718)	\$ (15,724)	\$ (10,715)
Weighted-average common shares – outstanding, basic	24,971	24,861	24,955	23,803
Weighted-average common shares – outstanding, diluted	24,971	24,861	24,955	23,803
Net loss per common share, basic	\$ (0.25)	\$ (0.19)	\$ (0.63)	\$ (0.45)
Net loss per common share, diluted	\$ (0.25)	\$ (0.19)	\$ (0.63)	\$ (0.45)

The Company’s basic net loss per share is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding for the relevant period. For the purposes of the calculation of diluted net loss per share, options to purchase common stock, restricted stock units and unvested shares of common stock issued upon the early exercise of stock options have been excluded from the calculation of diluted net loss per share as their effect is anti-dilutive. Because the Company has reported a net loss for the three and six months ended June 30, 2022, and 2021, diluted net loss per common share is the same as the basic net loss per share for those periods.

18. Retirement Plans

The Company offers a 401(k)-retirement savings plan (the “**401(k) Plan**”) for its employees, including its executive officers, who satisfy certain eligibility requirements. The Internal Revenue Code of 1986, as amended, allows eligible employees to defer a portion of their compensation, within prescribed limits, on a pre-tax basis through contributions to the 401(k) Plan. The Company matches contributions to the 401(k) Plan based on the amount of salary deferral contributions the participant makes to the 401(k) Plan. The Company will match up to 6% of an employee’s compensation that the employee contributes to his or her 401(k) Plan account. Total Company matching contributions to the 401(k) Plan were \$239,000 and \$202,000 in the three months ended June 30, 2022 and 2021, respectively, and \$471,000 and \$423,000 in the six months ended June 30, 2022 and 2021.

Deferred compensation plans

The Company’s Deferred Compensation Plan (the “**DCP**”), which became effective on October 2021 allows for eligible management and highly compensated key employees to elect to defer a portion of their salary, bonus, commissions and RSU awards to later years. Cash deferrals are immediately vested and are subject to investment risk and a risk of forfeiture under certain circumstances. RSU deferrals are subject to the vesting conditions of the award. For cash deferrals, the Company matches 4% to 6% (depending on level) of employee contributions. These matching employer contributions are vested over a two-year period with 25% vesting on year one and 75% vesting on year two for employees under 55 years of age. Employer contributions for employees over 55 years of age are immediately vested. Employer contributions to the DCP were \$38,000 and \$0 for the three months ended June 30, 2022 and 2021, and \$122,000 and \$0 for the six months ended June 30, 2022 and 2021. The Company’s deferred compensation plan liability was \$715,000 and \$262,000 as of June 30, 2022 and December 31, 2021, respectively, and is included in other long-term liabilities.

The Company established a COLI to fund the DCP. The COLI is subject to creditor claims in the event of insolvency, but the assets held in the COLI are not available for general corporate purposes. Amounts in the COLI are invested in a number of funds. The securities are carried at the cash surrender value and are included in other long-term assets on the Consolidated Balance Sheets. We record investment gains and losses in operating expenses on the consolidated statements of operations, along with the offsetting amount related to the increase or decrease in deferred compensation liability.

The fair values of the Company’s deferred compensation plan assets and liability are included in the table below. For additional information on the fair value hierarchy and the inputs used to measure fair value, see Note 5, Fair Value Measurements.

	Fair Value as of June 30, 2022				Fair Value as of December 31, 2021			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Corporate-owned life insurance policies (1)	-	737	-	737	-	304	-	304

(1) The corporate-owned life insurance contracts are recorded at cash surrender value, which is provided by a third party and reflects the net asset value of the underlying publicly traded mutual funds and are categorized as Level 2.

Rabbi Trust

During April 2022, we established a rabbi trust for a select group of participants in which share awards granted under the 2020 Omnibus Incentive Plan (“**2020 Plan**”) may be deposited. The plan permits diversification of fully vested shares awarded into other equity securities subject to a six-month holding period subsequent to vesting. The rabbi trust is an irrevocable trust and no portion of the trust fund may be used for any purpose other than the delivery of those assets to the participants. The assets held in the rabbi trust are subject to the claims of our general creditors in the event of bankruptcy or insolvency. The value of the assets of the rabbi trust is consolidated into our financial statements. In accordance with ASR 268, *Redeemable Preferred Stock*, and ASC 718, *Compensation — Stock Compensation*, the deferred share awards are classified as an equity instrument and changes in fair value of the amount owed to the participant are not recognized. Further, the redemption amounts of based on the vested percentage is recorded as temporary equity on the Consolidated Balance Sheet. As of June 30, 2022, a total of 71,749 shares awards have been deferred, none of which have vested. These unvested share awards are recorded at the redemption value of the share awards as non-qualified deferred compensation in the consolidated balance sheets.

The following table summarizes the eligible share award activity for the as of June 30, 2022, and December 31, 2021:

	As of	
	June 30, 2022	December 31, 2021
Non-qualified deferred compensation share awards:		
Balance at inception/beginning of period	-	-
Change in classification	192	-
Change in redemption value	(29)	-
Diversification of share awards	-	-
Ending Balance	<u>163</u>	<u>-</u>

19. Subsequent Events

The Company has evaluated subsequent events through the filing of this Quarterly Report on Form 10-Q and determined that there have been no events that have occurred that would require adjustments to our disclosures in the consolidated financial statements.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q.

Our actual results and timing of certain events may differ materially from the results discussed, projected, anticipated, or indicated in any forward-looking statements. We caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this Quarterly Report on Form 10-Q. In addition, even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained in this Quarterly Report on Form 10-Q, they may not be predictive of results or developments in future periods.

The following information and any forward-looking statements should be considered in light of factors discussed elsewhere in this Quarterly Report on Form 10-Q, including those risks identified under Part II, Item 1A. Risk Factors.

We caution readers not to place undue reliance on any forward-looking statements made by us, which speak only as of the date they are made. We disclaim any obligation, except as specifically required by law and the rules of the SEC and the ASX, to publicly update or revise any such statements to reflect any change in our expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

Overview

The AVITA group of companies (comprising AVITA Medical, Inc. (“AVITA” or the “Company”) and its subsidiaries, including AVITA Medical Pty Limited, previously known as AVITA Medical Limited, (“AVITA Medical”)) (collectively, “AVITA Group” or “we”, “us”, or “our”) is a commercial-stage regenerative medicine company focused on the treatment of burns, trauma and other acute injuries, together with skin defects like vitiligo. The Company's lead product is the RECELL® System, 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. In September 2018, the United States Food & Drug Administration (“FDA”) granted premarket approval (“PMA”) to the RECELL System for use in the treatment of acute thermal burns in patients eighteen years and older. Following receipt of our original PMA, we commenced commercializing the RECELL System in January 2019 in the United States. In 2021 FDA expanded the approval to include pediatric acute full-thickness thermal burns. In February 2022, the FDA approved a PMA supplement for the RECELL® Autologous Cell Harvesting Device with enhanced ease-of-use, aimed at providing clinicians a more efficient user experience and simplified workflow. In addition, the FDA has granted the Company Investigational Device Exemptions (“IDES”) which have enabled the Company to initiate pivotal clinical trials to further expand the approval of the RECELL System for soft tissue reconstruction and vitiligo. Enrollment of those clinical trials is complete, with topline results recently announced for the soft tissue reconstruction trial. Results from those studies are intended to support the Company's pursuit of FDA approval to market the RECELL System in the United States for those indications.

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, and simultaneously significantly reducing the amount of donor skin required. The RECELL System is designed to be used at the point of care as a standalone product, or in combination with “skin grafts”, known as split-thickness skin autografts, depending on the depth of the burn injury. The pivotal studies leading to the RECELL System's FDA PMA for the treatment of acute thermal burns, demonstrated that the RECELL System treated burns using 97.5 percent less donor skin when used alone in second-degree burns, and 32 percent less donor skin when used with autograft for third-degree burns compared to standard of care autografting. In these studies, a statistically significant reduction in donor skin required to treat burn patients with the RECELL System was realized without any associated compromise to healing or safety outcomes. Donor site outcomes from the clinical trial for second-degree burns also revealed a statistically significant reduction in patient-reported pain, increased patient satisfaction and improved scar outcomes.

Our compelling data from prospective, randomized, controlled clinical trials conducted at major United States burn centers, health economics modeling, and real-world use globally demonstrate 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.

The RECELL System is Therapeutic Goods Administration (“TGA”) registered in Australia cleared for use in the treatment of burns, acute wounds, scars and vitiligo. In Europe, the RECELL System received CE-mark approval for the treatment of burns, acute wounds, chronic wounds, scars and vitiligo. In February 2019, our marketing partner COSMOTEC filed a Japan's

Pharmaceuticals and Medical Devices Act (“PMDA”) application for approval to market the RECELL System in Japan for the treatment of burns and other wounds. In February 2022, COSMOTEC’s application for regulatory approval was approved by the PMDA with labelling for treatment of burns. Presently, we are not actively marketing the RECELL System internationally and therefore do not derive meaningful revenue from the RECELL System in these markets.

Our website address is www.avitamedical.com. Information contained on our website is not part of or incorporated into this report. We make our periodic reports, together with any amendments, available on our website, free of charge, as soon as reasonably practicable after we electronically file or furnish the reports with the Securities and Exchange Commission (“SEC”) or with the Australian Securities Exchange (“ASX”). The SEC maintains an internet site, www.sec.gov, which contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. Copies of announcements made by the Company to the ASX are available on ASX’s website (www.asx.com.au).

Corporate History

AVITA Medical, the former parent company of the AVITA Group, began as a laboratory spin-off in the Australian State of Western Australia. Clinical Cell Culture (C3) (being the prior name of AVITA Medical) was formed under the laws of the Commonwealth of Australia in December 1992 and has operated as AVITA Medical since 2008. AVITA Medical’s ordinary shares originally began trading in Australia on the Australian Securities Exchange (“ASX”) on August 9, 1993. AVITA Medical’s American Depository Shares (“ADSs”) traded over the counter on the OTCQX under the ticker symbol “AVMXY” from May 14, 2012 through September 30, 2019 and its ADSs began trading on the NASDAQ on October 1, 2019, under the ticker symbol “RCEL”.

The Company’s CDI’s are quoted on the ASX under AVITA Medical’s former ASX ticker code, “AVH”. The Company’s shares of common stock are quoted on NASDAQ under AVITA Medical’s former NASDAQ ticker code, “RCEL”. One share of common stock on NASDAQ is equivalent to five CDIs on the ASX.

COVID-19 Business Update and Risks Associated with COVID-19

Beginning in the first quarter of 2020, the ongoing coronavirus (“COVID-19”) pandemic has created significant disruptions to the global economies and financial markets. In the United States, State and Local Governmental authorities have responded by issuing orders, of varying degrees, requiring quarantines, restrictions on travel, mandatory closures of certain non-essential businesses, as well as providing recommendations to minimize social gatherings or interactions. Due to such orders, the COVID-19 pandemic began impacting our operations and financial results. For example, on March 19, 2020, the Executive Department of the State of California issued Executive Order N-33-20, ordering all individuals in the State of California to stay at home or at their place of residence except as needed to maintain continuity of operations of federal critical infrastructure sectors. Our primary operations are located in Valencia and Ventura, California. In response to this order, we took certain business measures which included institution of various workplace protections to ensure the safety of our employees (e.g., wearing of masks, wiping down high touch areas, etc.), and the limiting of vendors and visitors to our facilities. Essential staff in manufacturing and limited support functions have continued to work from our locations following appropriate hygiene and social distancing protocols. To reduce the risk to our employees and their families from potential exposure to COVID-19, we limited activities at our corporate headquarters, encouraged our employees to work from home, encouraged virtual meetings, restricted non-essential business travel, made physical modifications and enhancements to our facilities to effect social distancing, and provided personal protective equipment to our employees. We also increased safety stocks of our product, established temporary satellite product storage locations, and accelerated initiatives to increase sourcing options. Once most restrictions were lifted, we resumed in-office work at our corporate headquarters during March 2022, on a hybrid work schedule for some of our employees. We also lifted the restriction on non-essential business travel as more states and countries began to lift travel restrictions. However, during July 2022, due to the resurgence in COVID-19 cases and hospitalizations in Los Angeles County due primarily to the Omicron BA.5 variant, we have resumed work from home for our employees at the corporate headquarters with essential staff and manufacturing and limited support functions continuing to work from our locations as we continue to monitor the fluid situation. Throughout the pandemic, we have remained focused on managing the business for the long-term, including maintaining our employee workforce as well as continuing to invest in critical research and development, clinical, and corporate infrastructure-related programs.

The ongoing global COVID-19 pandemic presents significant risks to us and may have far reaching impacts on our business, operations, and financial results and condition, directly and indirectly, including, without limitation, impacts on: the health of our management and employees; manufacturing, distribution, marketing and sales operations; research and development activities, including clinical activities; and customer and patient behaviors. Moreover, beginning in March 2020, access to hospitals and other customer sites was restricted to essential personnel, which negatively impacted our ability to promote the use of the RECELL System with physicians, and to enroll our clinical studies. In addition, some hospitals and other burn centers suspended the treatment of burn patients or re-distributed those patients to other treatment facilities and, together with a general reduction in broader economic activity (e.g., reduced travel, reduced mobility, suspension of certain business operations, etc.), this resulted in a reduction in the volume of

burn procedures using the RECELL System in the immediate period following the implementation of those protective measures. In addition, we experienced periodic enrollment cessation in our clinical trials due to COVID-19 as well as having individuals excluded because they had contracted COVID-19.

We are continuing to monitor the impact of the COVID-19 pandemic on our employees, customers, and on the markets in which we operate. We will take further actions that we consider prudent to address the COVID-19 pandemic, including reducing spending, while ensuring that we can support our customers and continue to develop our products. The ultimate extent of the impact of the COVID-19 pandemic on us, including the discovery and spread of existing and future contagious variants to COVID-19 such as Omicron BA.5, remains highly uncertain and will depend on future developments and factors that continue to evolve. These factors, among others include the widespread vaccination of populations including recently approved booster regimens, especially in the U.S. and improvements in treatments and therapeutics for those with COVID-19, which are outside of our control, and could exist for an extended period of time even after the pandemic might end. Further imposition of quarantines, shelter-in-place and similar government orders which are outside of our control have also impacted and could continue to impact our third-party manufacturers and suppliers which could in turn adversely impact the availability or cost of materials, which could disrupt our supply chain.

Results of Operations for the three months ended June 30, 2022 compared to the three months ended June 30, 2021.

The table below summarizes the results of our continuing operations for each of the periods presented (in thousands).

	Three Months Ended June 30,			% Change Favorable/(Unfavorable)
	2022	2021	Change (\$)	
Revenues	\$ 8,335	\$ 10,304	\$ (1,969)	(19%)
Cost of sales	(1,386)	(2,053)	667	32%
Gross profit	6,949	8,251	(1,302)	(16%)
BARDA income	551	440	111	25%
Operating expenses:				
Sales and marketing expenses	(5,332)	(4,146)	(1,186)	(29%)
General and administrative expenses	(5,471)	(5,275)	(196)	(4%)
Research and development expenses	(3,059)	(3,974)	915	23%
Total operating expenses	(13,862)	(13,395)	(467)	(3%)
Operating loss	(6,362)	(4,704)	(1,658)	(35%)
Interest expense	(4)	(9)	5	56%
Other income	109	2	107	5350%
Loss before income taxes	(6,257)	(4,711)	(1,546)	(33%)
Income tax expense	(4)	(7)	3	43%
Net loss	\$ (6,261)	\$ (4,718)	\$ (1,543)	(33%)

Total net revenues decreased by 19% to \$8.3 million, compared to \$10.3 million in the corresponding period in the prior year. The decrease in the current period revenue was driven by our recognition of \$3.6 million in Biomedical Advanced Research and Development Authority (“BARDA”) related revenue in the prior year resulting from our delivery of units to managed inventory for BARDA for emergency response preparedness. Our commercial revenue in the current period increased by \$1.5 million or 23%, compared to the corresponding period in the prior year. The growth in commercial revenues was largely driven by an increase in the number of customers ordering as well as the average order size for those customers.

Gross profit margin increased by 3% to 83% compared to the corresponding period in the prior year. In the prior year our gross margins were lower compared to historical periods due to the lower price point associated with units that were delivered to managed inventory for BARDA as the BARDA contract was negotiated prior to establishing a higher price point through commercialization in the United States.

BARDA income increased by 25% to \$551,000, compared to \$440,000 for the corresponding period in the prior year. 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. BARDA income increased as a result of funding by BARDA for the pivotal trial for use of the RECELL System for soft tissue reconstruction.

Total operating expenses increased by 3% or \$0.5 million to \$13.9 million, compared with \$13.4 million in the corresponding period in the prior year.

Sales and marketing expenses increased by 29% or \$1.2 million to \$5.3 million, compared to \$4.1 million incurred in the corresponding period in the prior year. Higher costs in the current year were primarily attributed to an increase in pre-commercialization costs, an increase in field personnel and higher share-based compensation expenses. Increased pre-commercialization costs were incurred for planning for RECELL launches in soft tissue reconstruction and vitiligo. Higher costs for field personnel were due to additional headcount added to deepen penetration within individual customer accounts. Higher share-based compensation expenses were due to our granting of a long-term incentive plan to drive value to the business.

General and administrative expenses increased by 4% or \$0.2 million to \$5.5 million, compared to \$5.3 million incurred in the same period in the prior year. The increase was primarily due to higher compensation costs associated with expanding our workforce to support the overall operations along with higher professional fees, partially offset by lower stock-based compensation expenses. Increased professional fees were associated with costs to further expand the capabilities in our Ventura facility. Lower share-based compensation expenses in the current quarter were driven by certain milestones being met in the prior year.

Research and development expenses decreased by 23% or \$0.9 million to \$3.1 million, compared to \$4.0 million incurred in the same period in the prior year. Higher costs in the prior year were primarily driven by research and development costs associated with furthering the Company's pipeline along with ramping up clinical trial costs related activities for treatment of soft tissue and vitiligo. The favorable variance is not a purposeful reduction in spending but reflects that certain programs were in lower cost phases during this quarter.

Results of Operations for the six months ended June 30, 2022 compared to the six months ended June 30, 2021.

The table below summarizes the results of our continuing operations for each of the periods presented (in thousands).

	Six-Months Ended June 30,			% Change Favorable/(Unfavorable)
	2022	2021	Change (\$)	
Revenues	\$ 15,874	\$ 19,069	\$ (3,195)	(17%)
Cost of sales	(3,164)	(4,199)	1,035	25%
Gross profit	12,710	14,870	(2,160)	(15%)
BARDA income	1,285	1,010	275	27%
Operating expenses:				
Sales and marketing expenses	(10,160)	(7,795)	(2,365)	(30%)
General and administrative expenses	(13,005)	(10,697)	(2,308)	(22%)
Research and development expenses	(6,679)	(8,083)	1,404	17%
Total operating expenses	(29,844)	(26,575)	(3,269)	(12%)
Operating loss	(15,849)	(10,695)	(5,154)	(48%)
Interest expense	(4)	(12)	8	67%
Other income	137	9	128	1422%
Loss before income taxes	(15,716)	(10,698)	(5,018)	(47%)
Income tax expense	(8)	(17)	9	53%
Net loss	\$ (15,724)	\$ (10,715)	\$ (5,009)	(47%)

Total net revenues decreased by 17% to \$15.9 million, compared to \$19.1 million in the corresponding period in the prior year. The decrease in the current year revenue was driven by our recognition of \$7.8 million in BARDA related revenue in the prior year resulting from our delivery of units to managed inventory for BARDA for emergency response preparedness. Our commercial revenue in the current year increased by \$4.4 million or 39%, compared to the corresponding period in the prior year. The growth in commercial revenues was largely driven by an increase in the number of customers ordering as well as the average order size for those customers.

Gross profit margin increased by 2% to 80% compared to the corresponding period in the prior year. In the prior year our gross margins were lower compared to historical periods due to the lower price point associated with units that were delivered to managed inventory for BARDA as the BARDA contract was negotiated prior to establishing a higher price point through commercialization in the United States.

BARDA income increased by 27% to \$1.3 million, compared to \$1.0 million for the corresponding period in the prior year. 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. BARDA income increased as a result of funding by BARDA for the pivotal trial for use of the RECELL System for soft tissue reconstruction.

Total operating expenses increased by 12% or \$3.3 million to \$29.9 million, compared with \$26.6 million in the corresponding period in the prior year.

Sales and marketing expenses increased by 30% or \$2.4 million to \$10.2 million, compared to \$7.8 million incurred in the corresponding period in the prior year. Higher costs in the current year were driven by an increase in salaries and benefits, increase in pre-commercialization costs, higher share-based compensation expenses and higher travel costs. Increased salaries and benefits are attributable to an increase in field personnel to further deepen the penetration within individual customer accounts, along with higher commissions due to the increase in revenues. Higher pre-commercialization costs were incurred for planning for RECELL launches in soft tissue reconstruction and vitiligo. Increased share-based compensation expenses were driven by our granting of a long-term incentive plan to drive value to the business. Higher travel costs were due to fewer COVID-19 travel restrictions in the current year.

General and administrative expenses increased by 22% or \$2.3 million to \$13.0 million, compared to \$10.7 million incurred in the same period in the prior year. The increase was primarily driven by higher share-based compensation expenses associated with the acceleration for certain performance milestones being met in the period, along with higher compensation costs. Higher compensation costs were associated with expanding our workforce to support the overall operations along with hiring of an executive at the end of March 2021.

Research and development expenses decreased by 17% or \$1.4 million to \$6.7 million, compared to \$8.1 million incurred in the same period in the prior year. Higher costs in the prior year were primarily driven by research and development costs associated with furthering the Company's pipeline along with ramping up clinical trial costs related activities for treatment of vitiligo. The favorable variance is not a purposeful reduction in spending but reflects that certain programs were in lower cost phases during this period.

Liquidity and Capital Resources

We expect to utilize cash reserves until U.S. sales of our products reach a level sufficient to fund ongoing operations. The AVITA Group has historically funded its research and development activities, and more recently its substantial investment in sales and marketing activities, through raising capital by issuing securities, and it is expected that similar funding will be obtained to provide working capital if and when required. As of June 30, 2022, the Company has sufficient cash reserves to fund operations for the next 12-months. If the Company is unable to raise capital in the future, the Company may need to curtail expenditures by scaling back certain research and development or other programs.

The following table summarizes our cash flows for the periods presented (in thousands):

(In Thousands)	Six Months ended	
	June 30, 2022	June 30, 2021
Net cash used in operations	\$ (12,877)	\$ (12,536)
Net cash used in investing activities	(7,845)	(526)
Net cash provided by financing activities	1	64,058
Effect of foreign exchange rate on cash and cash equivalents and restricted cash	(52)	(15)
Net increase/(decrease) in cash and cash equivalents and restricted cash	(20,773)	50,981
Cash and cash equivalents and restricted cash at beginning of year	55,712	59,966
Cash and cash equivalents and restricted cash at end of year	34,939	110,947

Six months ended June 30, 2022, and 2021.

Net cash used in operating activities was \$12.9 million and \$12.5 million during the six months ended June 30, 2022, and 2021, respectively. The increase was primarily driven by higher operating costs partially offset by the collection of BARDA and trade receivables outstanding in the current period.

Net cash used in investing activities was \$7.9 million and \$0.5 million during the six months ended June 30, 2022, and 2021, respectively. Cash flows used for investing activities was primarily attributable to our investments into marketable securities.

Net cash provided by financing activities was \$1 thousand and \$64.0 million during the six months ended June 30, 2022, and 2021, respectively. The decrease in cash provided by financing activities is related to proceeds from the capital raise in March 2021.

Capital management.

We aim to manage capital so that the Company continues as a going concern while also maintaining optimal returns to stockholders and benefits for other stakeholders. We also aim to maintain a capital structure that ensures the lowest cost of capital available to the Company. We regularly review the Company's capital structure and seek to take advantage of available opportunities to improve outcomes for the Company and its stockholders.

For the period ended June 30, 2022, there were no dividends paid and we have no plans to commence the payment of dividends. We have no purchase commitments or long-term contractual obligations as of June 30, 2022. We have no committed plans to issue further shares on the market but will continue to assess market conditions and the Company's cash flow requirements to ensure the Company is appropriately funded in order to pursue its various opportunities.

There is no significant external borrowing at the reporting date. Neither the Company nor any of the subsidiaries are subject to externally imposed capital requirement.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements (as defined in the rules and regulations of the SEC) that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to investors.

Commitments and Contractual Obligations

The Company does not have any contractual obligations or purchase commitments, except for lease obligations for the period ended June 30, 2022. For details of lease obligations refer to Note 6 in the consolidated financial statements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

As a smaller reporting company, we are not required to provide the information required by this Item.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our Chief Executive Officer and our Chief Financial Officer evaluated, with the participation of our management, the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. As of June 30, 2022, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures, as defined in Securities Exchange Act Rule 13a-15(e) and 15d-15(e), were effective.

Our disclosure controls and procedures have been formulated to ensure (i) that information that we are required to disclose in reports that we file or submit under the Securities Exchange Act of 1934 was recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms and (ii) that the information required to be disclosed by us is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures.

Changes in Internal Controls over Financial Reporting

There was no change in our internal controls over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the second quarter of fiscal year 2022 covered by this Quarterly Report on Form 10-Q that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

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Part II - Other Information

Item 1. LEGAL PROCEEDINGS

None.

Item 1A. Risk Factors

Refer to “COVID-19 Business Update and Risks Associated with COVID-19” in Part 1 above.

Item 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

Item 3. DEFAULTS UPON SENIOR SECURITIES

None.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

Item 5. OTHER INFORMATION

None

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Item 6. EXHIBITS

(a) The following exhibits are filed as part of the Quarterly Report on Form 10-Q:

Exhibit No.	Description
31.1	Rule 13a-14(a) Certification of Chief Executive Officer
31.2	Rule 13a-14(a) Certification of Chief Financial Officer
32	18 U.S.C. Section 1350 Certifications
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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Signatures

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: August 11, 2022

AVITA MEDICAL, INC.

By: /s/ Dr. Michael Perry

Dr. Michael Perry
President and Chief Executive Officer
(Principal Executive Officer)

By: /s/ Michael Holder

Michael Holder
Chief Financial Officer

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CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Dr. Michael Perry, certify that:

1. I have reviewed this quarterly report on Form 10-Q of AVITA Medical, Inc.
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report.
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 11, 2022

/s/ Dr. Michael Perry

Name: Dr. Michael Perry

Title: President and Chief Executive Officer
(Principal Executive Officer)

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CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michael Holder, certify that:

1. I have reviewed this quarterly report on Form 10-Q of AVITA Medical, Inc.
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report.
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) designed such disclosure controls and procedures or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, is made known to us by others within those entities, particularly during the period in which this report is being prepared.
 - b) designed such internal control over financial reporting or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.
 - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 11, 2022

/s/ Michael Holder

Name: Michael Holder

Title: Chief Financial Offer

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**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code), each of the undersigned officers of AVITA Medical, Inc. (the "Company"), does hereby certify, to such officer's knowledge, that:

The Quarterly Report on Form 10-Q for the period ended June 30, 2022 of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: August 11, 2022

/s/ Dr. Michael Perry

Name: Dr. Michael Perry
Title: President and Chief Executive Officer
(Principal Executive Officer)

Dated: August 11, 2022

/s/ Michael Holder

Name: Michael Holder
Title: Chief Financial Officer

These certifications are furnished pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by such Act, be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Such certifications will not be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent that the Company specifically incorporates them by reference.

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