

**AVITA Medical, Inc.
Financial Report for Fiscal First Quarter 2021**

VALENCIA, Calif, November 8, 2021 and MELBOURNE, Australia, November 9, 2021 (GLOBE NEWSWIRE) — AVITA Medical, Inc. (NASDAQ: RCEL, ASX: AVH) (Company), filed the attached Form 10-Q for the three month period ended 30 September 2021. A copy of the filing is attached and 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.

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ABOUT AVITA Medical, Inc.

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

AVITA Medical's first U.S. product, the RECELL® System, was approved by the U.S. Food and Drug Administration (FDA) in September 2018. The RECELL® System is approved for acute partial-thickness thermal burn wounds in patients 18 years of age and older or application in combination with meshed autografting for acute full-thickness thermal burn wounds in pediatric and adult patients. The RECELL® System is used to prepare Spray-On Skin™ Cells using a small amount of a patient's own skin, providing a new way to treat severe burns, while significantly reducing the amount of donor skin required. The RECELL® System is designed to be used at the point of care alone or in combination with autografts depending on the depth of the burn injury. Compelling data from randomized, controlled clinical trials conducted at major U.S. burn centers and real-world use in more than 8,000 patients globally, reinforce that the RECELL® System is a significant advancement over the current standard of care for burn patients and offers benefits in clinical outcomes and cost savings. Healthcare professionals should read the INSTRUCTIONS FOR USE - RECELL® Autologous Cell Harvesting Device (<https://recellsystem.com/>) for a full description of indications for use and important safety information including contraindications, warnings, and precautions.

In international markets, our products are marketed under the RECELL® System brand to promote skin healing in a wide range of applications including burns, chronic wounds, and aesthetics. The RECELL® System is TGA-registered in Australia and received CE-mark approval in Europe. To learn more, visit www.avitamedical.com.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This press release includes forward-looking statements. These forward-looking statements generally can be identified by the use of words such as "anticipate," "expect," "intend," "could," "may," "will," "believe," "estimate," "look forward," "forecast," "goal," "target," "project," "continue," "outlook," "guidance," "future," other words of similar meaning and the use of future dates. Forward-looking statements in this press release include, but are not limited to, statements concerning, among other things, our ongoing clinical trials and product development activities, regulatory approval of our products, the potential for future growth in our business, and our ability to achieve our key strategic, operational, and financial goals. Forward-looking statements by their nature address matters that are, to different degrees, uncertain. Each forward-looking statement contained in this press release is subject to risks and uncertainties that could cause actual results to differ materially from those

expressed or implied by such statement. Applicable risks and uncertainties include, among others, the timing of regulatory approvals of our products; physician acceptance, endorsement, and use of our products; failure to achieve the anticipated benefits from approval of our products; the effect of regulatory actions; product liability claims; risks associated with international operations and expansion; and other business effects, including the effects of industry, economic or political conditions including, but not limited to the ongoing COVID-19 pandemic which are outside of the company's control. Investors should not place considerable reliance on the forward-looking statements contained in this press release. Investors are encouraged to read our publicly available filings for a discussion of these and other risks and uncertainties. The forward-looking statements in this press release speak only as of the date of this release, and we undertake no obligation to update or revise any of these statements.

FOR FURTHER INFORMATION:

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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 September 30, 2021

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 November 5, 2021 was 24,925,118

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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 results of operations and financial position, the anticipated impact of the novel coronavirus, or COVID-19, pandemic on our business, business strategy, prospective products, product approvals, research and development costs, anticipated timing and likelihood of success of clinical trials, expected timing of the release of clinical trial data, the plans and objectives of management for future operations and future results of anticipated products, are forward-looking statements. 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 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.

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	
	September 30, 2021	June 30, 2021
ASSETS		
Cash and cash equivalents	\$ 60,484	\$ 110,746
Marketable securities	29,703	-
Accounts receivable, net	3,118	3,467
BARDA receivables	603	3,936
Prepays and other current assets	1,129	1,333
Restricted cash	201	201
Inventory	1,892	1,647
Total current assets	97,130	121,330
Marketable securities, long-term	19,801	-
Plant and equipment, net	1,357	1,458
Operating lease right-of-use assets	1,710	1,480
Intangible assets, net	472	472
Other long-term assets	703	761
Total assets	\$ 121,173	\$ 125,501
LIABILITIES AND SHAREHOLDERS' EQUITY		
Accounts payable and accrued liabilities	2,439	3,120
Accrued wages and fringe benefits	3,663	3,321
Other current liabilities	951	949
Total current liabilities	7,053	7,390
Contract liabilities	1,018	1,075
Operating lease liabilities, long-term	1,107	878
Other long-term liabilities	503	503
Total liabilities	9,681	9,846
Contingencies (Note 12)		
Shareholders' Equity:		
Common stock, \$0.0001 par value per share, 200,000,000 shares authorized, 24,925,118 and 24,895,864 shares issued and outstanding at September 30, 2021 and June 30, 2021, respectively	3	3
Preferred stock, \$0.0001 par value per share, 10,000,000 shares authorized, no shares issued or outstanding at September 30, 2021 and June 30, 2021	-	-
Additional paid-in capital	330,734	328,889
Accumulated other comprehensive income	8,199	8,259
Accumulated deficit	(227,444)	(221,496)
Total shareholders' equity	111,492	115,655
Total liabilities and shareholders' equity	\$ 121,173	\$ 125,501

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 September 30,	
	2021	2020
Revenues	\$ 7,020	\$ 5,060
Cost of sales	(1,088)	(929)
Gross profit	5,932	4,131
BARDA income	374	596
Operating expenses:		
Sales and marketing expenses ⁽¹⁾	(3,518)	(3,265)
General and administrative expenses ⁽¹⁾	(5,349)	(8,302)
Research and development expenses ⁽¹⁾	(3,388)	(3,374)
Total operating expenses	(12,255)	(14,941)
Operating loss	(5,949)	(10,214)
Interest expense	(9)	(7)
Other income	16	4
Loss before income taxes	(5,942)	(10,217)
Income tax expense	(6)	(10)
Net loss	<u>\$ (5,948)</u>	<u>\$ (10,227)</u>
Net loss per common share:		
Basic	\$ (0.24)	\$ (0.48)
Diluted	\$ (0.24)	\$ (0.48)
Weighted-average common shares:		
Basic	24,905,403	21,503,643
Diluted	24,905,403	21,503,643

(1) Refer to Note 2 for information about a reclassification of share-based compensation expense

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

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

	Three Months Ended September 30,	
	2021	2020
Net loss	\$ (5,948)	\$ (10,227)
Foreign currency translation gain/(loss)	(50)	48
Net unrealized loss on marketable securities, net of tax	(10)	-
Comprehensive loss	<u>\$ (6,008)</u>	<u>\$ (10,179)</u>

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

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

Three Months Ended September 30, 2021

	Common Stock			Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount	Additional Paid-in Capital			
Balance at June 30, 2021	24,895,864	\$ 3	\$ 328,889	\$ 8,259	\$ (221,496)	\$ 115,655
Net loss	-	-	-	-	(5,948)	(5,948)
Share-based compensation	-	-	1,842	-	-	1,842
Exercise of stock options	500	-	3	-	-	3
Vesting of restricted stock units	28,754	-	-	-	-	-
Other comprehensive loss	-	-	-	(60)	-	(60)
Balance at September 30, 2021	24,925,118	\$ 3	\$ 330,734	\$ 8,199	\$ (227,444)	\$ 111,492

Three Months Ended September 30, 2020

	Common Stock			Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount	Additional Paid-in Capital			
Balance at June 30, 2020	21,467,912	\$ 3	\$ 259,165	\$ 8,146	\$ (194,913)	\$ 72,401
Net loss	-	-	-	-	(10,227)	(10,227)
Share-based compensation	-	-	3,266	-	-	3,266
Exercise of stock options	3,538	-	-	-	-	-
Vesting of restricted stock units	151,837	-	-	-	-	-
Translation gain	-	-	-	48	-	48
Balance at September 30, 2020	21,623,287	\$ 3	\$ 262,431	\$ 8,194	\$ (205,140)	\$ 65,488

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

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

	Three Months Ended September 30,	
	2021	2020
Cash flow from operating activities:		
Net loss	\$ (5,948)	\$ (10,227)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	174	211
Share-based compensation	1,842	3,266
Non-cash lease expense	162	131
Patent impairment loss	19	-
Remeasurement and foreign currency transaction loss	(27)	80
Excess and obsolete inventory related charges	46	(77)
Contract cost amortization	82	-
Provision for doubtful accounts	3	-
Amortization of premium of marketable securities	36	-
Changes in operating assets and liabilities:		
Trade and other receivables	345	(283)
BARDA receivables	3,333	(15)
Prepays and other current assets	203	(65)
Inventory	(293)	(453)
Operating lease liability	(166)	(127)
Other long-term assets	(24)	(54)
Accounts payable and accrued expenses	(655)	(860)
Accrued wages and fringe benefits	347	765
Other current liabilities	6	(5)
Contract liabilities	(57)	-
Net cash used in operations	(572)	(7,713)
Cash flows from investing activities:		
Purchase of marketable securities	(49,550)	-
Cash paid for property and equipment	(67)	(209)
Cash paid for patent filing fees	(21)	(87)
Net cash used in investing activities	(49,638)	(296)
Cash flow from financing activities:		
Principal repayment of finance lease	-	(4)
Proceeds from exercise of stock options	3	-
Net cash provided/(used) by financing activities	3	(4)
Effect of foreign exchange rate on cash and restricted cash	(55)	127
Net decrease in cash and cash equivalents and restricted cash	(50,262)	(7,886)
Cash and cash equivalents and restricted cash beginning of the period	110,947	73,840
Cash and cash equivalents and restricted cash end of the period	\$ 60,685	\$ 65,954
Supplemental Disclosure of Cash Flow Information		
Cash paid for income taxes	\$ 28	\$ 42
Cash paid for interest	\$ 9	\$ 1
Plant and equipment purchases not yet paid	\$ 27	\$ 50

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 tissue 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 and pediatric acute full thermal burns in 2021. Following receipt of the Company’s PMA, AVITA commenced commercializing the RECELL System in January 2019 in the United States. In addition, the FDA has granted the Company three Investigational Device Exemptions (“**IDEs**”) studies which have enabled the Company to initiate pivotal clinical investigational studies to seek expanded FDA (supplementary) PMA of the RECELL System for each of soft tissue reconstruction and vitiligo. Enrollment of those clinical studies is ongoing and, if successful, those studies would enable the Company to commence commercializing the RECELL System in the United States in each of those indications.

In March 2020, the World Health Organization declared the outbreak of a novel strain of the coronavirus (“**COVID-19**”) a pandemic. COVID-19 is having, and will likely continue to have, an effect on the Company’s business, results of operations, financial condition, and cash flows, and its future impacts remain highly uncertain and unpredictable. The Company has considered the disruptions caused by COVID-19, including lower than forecasted sales, delays to the speed of enrollment in the Company’s clinical trials that may, if successful, support commercial approval and new revenues in additional markets, and macroeconomic factors, that may impact its estimates. 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 September 30, 2021 and through the date of this report. The Company’s business and operations have been impacted by COVID-19 as the effects of COVID-19 related travel restrictions have reduced accidents and the incidence of burns and burns admissions. 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.

Redomiciliation

On June 29, 2020, a statutory scheme of arrangement under Australian law to effect a redomiciliation of the AVITA Group from Australia to the United States of America was implemented (the “**Redomiciliation**”). The Redomiciliation was approved by shareholders on June 15, 2020 and approved by the Federal Court of Australia on June 22, 2020.

Pursuant to the Redomiciliation, all ordinary shares in AVITA Medical, the former parent company of the AVITA Group, were exchanged for shares of common stock in the Company. As a result, the Company became the sole shareholder of AVITA Medical and the new parent company of the AVITA Group. In conjunction with the Redomiciliation, an implicit consolidation or reverse split on a 1 for 100 basis was implemented whereby shareholders of AVITA Medical received one share of common stock in the Company for every 100 shares held in AVITA Medical.

Under the Redomiciliation, eligible shareholders in AVITA Medical received consideration in the form of:

- five CDIs in the Company for every 100 ordinary shares in AVITA Medical that were held by them; or
- one share of common stock in the Company for every 5 ADSs in AVITA Medical that were held by them.

The Company’s CDIs are quoted on the ASX under AVITA Medical’s previous ASX ticker code, “AVH”. The Company’s shares of common stock are quoted on NASDAQ under AVITA Medical’s previous NASDAQ 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 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 issued and

outstanding in AVITA Medical that was previously set out in the consolidated financial statements of AVITA Medical. All common stock amounts included in these 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.

As a result of the Redomiciliation, the reporting currency of the AVITA Group has changed from the Australian dollar to the U.S. dollar. In accordance with SEC regulation, SX Rule 320 (e), the impact of the change in the reporting currency was included in a component of other comprehensive income (loss).

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 annual report on Form 10-K for the fiscal year ended June 30, 2021 filed with the SEC on August 26, 2021 (United States) and the ASX on August 27, 2021 (Australia) (the "Annual Report").

There have been no changes to the Company's significant accounting policies as described in the annual report on Form 10-K that have had a material impact on the Company's consolidated financial statements, except for the investment in marketable securities as described below. See the summary of the Company's significant accounting policies set forth in the notes to its consolidated financial statements included in the Annual Report.

Reclassification

Certain amounts in the prior period Consolidated Statement of Operations have been reclassified to conform to the presentation of the current period financial statements. These reclassifications had no effect on the previously reported operating expense, loss before taxes, net loss and earnings per share.

After the issuance of the consolidated financial statements for the year ended June 30, 2020, and the quarter ended September 30, 2020, the Company concluded that the presentation of share-based compensation should be reclassified to the functional expense line items consistent with cash compensation in accordance with SAB Topic 14. The Company has determined that such change in presentation of prior period amounts in the Statement of Operations is not material to the consolidated financial statements.

The Company reclassified share-based compensation expense of \$3.3 million for the three months ended September 30, 2020 to sales and marketing expense of \$330,000, general and administrative expense of \$2.8 million and research and development expenses of \$170,000.

	Quarter-ended September 30, 2020		
(in thousands)	As previously reported	Amount reclassified	As Reported
Sales and marketing expense	\$ (2,935)	\$ (330)	\$ (3,265)
General and administrative expense	(5,536)	(2,766)	(8,302)
Research and development expense	(3,204)	(170)	(3,374)
Share-based compensation	(3,266)	3,266	-
Total operating expenses	(14,941)	-	(14,941)
Operating loss	(10,214)	-	(10,214)
Loss before income taxes	(10,217)	-	(10,217)
Net Loss	(10,227)	-	(10,227)

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 on 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 asset, the useful lives of long-lived assets, inventory obsolescence, accounting for 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 \$41,000 and loss of \$37,000 for the three months ended September 30, 2021 and 2020, 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 September 30, 2021 and 2020, the Company recorded losses of \$14,000 and \$43,000, respectively.

Comprehensive Income (Loss)

The components of comprehensive income (loss) consist of net income (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 income (loss) to net loss during the quarter ended September 30, 2021.

Revenue Recognition

Under Topic 606 – *Revenue from Contracts with Customers*, 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 Topic 606, 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

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 statement 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.

Volume Discounts — The Company generally provides contracted customers with volume discounts that are explicitly stated in the Company's customer contracts. The RECELL system is sold with respective volume discounts based on aggregated sales over a 12-month period on a customer-by-customer basis. Revenue from these sales is recognized based on the price specified in the contract, net of estimated volume discounts, and net of any sales tax charged. Goods sold are not eligible for return. The Company has determined such discounts are not distinct from the Company's sale of products to the customer and, therefore, these payments have been recorded as a reduction of revenue and as a reduction to accounts receivable, net.

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, (ii) emergency preparedness services. Through this contract the Company promises to sell 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, over time 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 statement of operations and \$1.6 million to the emergency deployment services which is classified as revenues when recognized in the consolidated statement 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 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 statement 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.

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 \$2.5 million and \$54.2 million of which \$318,000 and \$273,000 is denominated in foreign currencies in foreign institutions as of September 30, 2021 and June 30, 2021, respectively. As of September 30, 2020 and June 30, 2021, the Company held cash equivalents in the amount of \$58 million and \$56.5 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 \$201,000 and \$201,000 as of September 30, 2021 and June 30, 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 September 30, 2021 and June 30, 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 September 30, 2021 no single commercial customer accounted for more than 10% of total revenues or net accounts receivable. BARDA service revenue for emergency deployment accounted for approximately 1.3% and 0% of total revenues for the three months ended September 30, 2021 and 2020, respectively. BARDA receivables for emergency preparedness services accounted for 14% and 91% of total BARDA receivables as of September 30, 2021 and June 30, 2021, respectively. As of June 30, 2021, no single commercial customer accounted for more than 10% of total revenues or net accounts receivable. See table below for breakdown of BARDA receivables (in thousands).

	As of September 30, 2021	As of June 30, 2021
BARDA procurement and emergency preparedness services	\$ 86	\$ 3,583
BARDA expense reimbursements	517	353
Total BARDA receivables	<u>\$ 603</u>	<u>\$ 3,936</u>

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. We account for our marketable securities as available-for-sale securities.

All marketable securities, which consist of corporate debt securities, asset backed securities, 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 stockholders equity until realized. Realized gains and losses on marketable securities are included in interest and other income, net, 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: 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. Under this arrangement BARDA supported the Company's research and development for the Company's product, including the ongoing U.S. clinical regulatory program targeted towards PMA, our compassionate use program, clinical and health economics research. The BARDA contract supported the Company's ongoing Pediatric Scalds clinical trial.

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 relationship is 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. During the current year the Company does not have any finance leases as they were repaid in the prior year. The Company's operating leases have remaining lease terms of two year to three 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 condensed 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 stock-based compensation awards is amortized over the vesting period of the award. Compensation expense for performance-based awards is measured based on the number of shares ultimately expected to vest, estimated at each reporting 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. 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 stock-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, the first plan was established in 2016 and was primarily used for Executives awards. Further, the Company does not have sufficient history of exercises in the U.S. market given the recent redomiciliation to the United States during 2020. The expected term of options with a performance condition was set to the contractual term of 10 years. The contractual term was used options with performance condition were awarded to C-Suite executives and the Company assumes that they will hold them longer than rank and file employees.
- 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.

3. Accounting Standards Update

Recent Accounting Pronouncements Not Yet Adopted

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 is currently evaluating the potential impact that the adoption of ASU 2019-12 will have on its consolidated financial statements.

4. Marketable Securities

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

	September 30, 2021			
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Carrying Value
(in thousands)				
Cash Equivalents:				
Money market funds	\$ 58,038	-	-	\$ 58,038
Current marketable securities:				
Commercial paper	\$ 19,577	-	-	\$ 19,577
Corporate debt securities	7,107	1	(2)	7,106
Asset-backed securities	3,019	1	-	3,020
Total current marketable securities	\$ 29,703	2	(2)	\$ 29,703
Long-term marketable securities:				
Corporate debt securities	1,758	-	(2)	1,756
U.S Treasury securities	18,053	-	(8)	18,045
Total Long-term marketable securities	\$ 19,811	-	(10)	\$ 19,801

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 September 30, 2021	
	Amortized Cost	Carrying Value
Due in one year or less	29,703	29,703
Due after one year through five years	19,811	19,801

Gross unrealized gains and losses on the Company's marketable securities were an unrealized gain of \$2,000 and an unrealized loss of \$12,000 as of September 30, 2021 which resulted in a net unrealized loss of \$10,000. During the three months ended September 30, 2021, the Company did not recognize credit losses. For the year ended June 30, 2021, the Company did not have any marketable securities. The Company has accrued interest income of \$59,000 as of September 30, 2021, recorded in Prepaids and Other Current Assets. Money market funds were included in the cash and cash equivalents line item.

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 September 30, 2021			
	Level 1	Level 2	Level 3	Total
Cash Equivalents				
Money market funds	\$ 58,038	\$ -	\$ -	\$ 58,038
Total cash equivalents	58,038	-	-	58,038
Short-term marketable securities				
Commercial paper	-	19,577	-	19,577
Asset-backed securities	-	3,020	-	3,020
Corporate debt securities	-	7,106	-	7,106
Total short-term marketable securities	-	29,703	-	29,703
Long-term investments				
Corporate debt securities	-	1,756	-	1,756
U.S Treasury securities	-	18,045	-	18,045
Total long-term marketable securities	-	19,801	-	19,801
Total marketable securities and cash equivalents	\$ 58,038	\$ 49,504	\$ -	\$ 107,542

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, asset back securities, 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 September 30, 2021, the Company had no investments that were measured using unobservable (Level 3) inputs. There were no transfers between fair value measurement levels during the first quarter of 2022. For the year ended June 30, 2021, the Company did not have any marketable securities, cash equivalents consisted of money market funds and were classified as a level 1.

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 September 30,	
	2021	2020
Operating lease cost	\$ 188	\$ 175
Variable lease cost	12	12
Total lease cost	\$ 200	\$ 187

Supplemental cash flow information related to operating leases for the three months ended September 30, 2021 and 2020 was as follows (in thousands):

	Three months ended September 30,	
	2021	2020
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash outflows from operating leases	\$ 192	\$ 171

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

	As of September 30, 2021	As of June 30, 2021
Reported as:		
Operating lease right-of-use assets	\$ 1,710	\$ 1,480
Total right-of-use assets	<u>\$ 1,710</u>	<u>\$ 1,480</u>
Other current liabilities:		
Operating lease liabilities, short-term	\$ 699	\$ 702
Operating lease liabilities, long term	1,107	878
Total operating lease liabilities	<u>\$ 1,806</u>	<u>\$ 1,580</u>
Operating lease weighted average remaining lease term (years)	2.53	2.67
Operating lease weighted average discount rate	6.49%	6.70%

As of September 30, 2021, maturities of the Company's operating lease liabilities are as follows (in thousands):

	Operating Leases
Remaining 2022	\$ 592
2023	816
2024	448
2025	104
Total lease payments	1,960
Less imputed interest	(154)
Total operating lease liabilities	<u>\$ 1,806</u>

As of September 30, 2021, there were no leases entered into that had not yet commenced.

7. Inventory

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

	As of September 30, 2021	As of June 30, 2021
Raw materials	\$ 1,062	\$ 982
Work in process	262	241
Finished goods	568	424
Total inventory	<u>\$ 1,892</u>	<u>\$ 1,647</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 statement of operations and were \$46,000 and a reversal of \$77,000, three months ended September 30, 2021 and September 30, 2020, respectively.

8. Intangible Assets

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

	As of September 30, 2021				As of June 30, 2021			
	Weighted Average Life	Gross Amount	Accumulated Amortization	Net Carry Amount	Gross Amount	Accumulated Amortization	Net Carry Amount	
Patent 1	3	\$ 201	\$ (157)	\$ 44	\$ 264	\$ (190)	\$ 74	
Patent 2	14	150	(19)	131	138	(16)	122	
Patent 3	15	186	(21)	165	163	(19)	144	
Patent 5	20	46	(3)	43	46	(2)	44	
Patent 6	20	39	(1)	38	39	(1)	38	
Patent 8	20	3	-	3	3	-	3	
Trademarks	Indefinite	48	-	48	47	-	47	
Total intangible assets		\$ 673	\$ (201)	\$ 472	\$ 700	\$ (228)	\$ 472	

During the three months ended September 30, 2021, the Company recorded an impairment charge of \$19,000 for an abandoned patent. During the three months ended September 30, 2020, 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 ended September 30, 2020. Amortization expense of intangibles included in the consolidated statements of operations was \$27,000 and \$23,000 for the three months ended September 30, 2021 and 2020, respectively.

The Company expects the future amortization of amortizable intangible assets held at September 30, 2021 to be (in thousands):

	Estimated Amortization Expense
Remaining 2022	\$ 55
2023	31
2024	31
2025	31
2026	31
2027	31
Thereafter	214
Total	<u><u>\$ 424</u></u>

9. Plant and Equipment

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

	Useful Lives	As of September 30, 2021	As of June 30, 2021
Computer equipment	3 years	\$ 725	\$ 722
Computer software	3 years	776	775
Construction in progress		85	48
Furniture and fixtures	7 years	439	440
Laboratory equipment	5 years	529	523
Leasehold improvements	Lesser of life or lease term	242	242
RECELL Moulds	5 years	129	129
Less: accumulated amortization and depreciation		(1,568)	(1,421)
Total plant and equipment, net		<u>\$ 1,357</u>	<u>\$ 1,458</u>

Depreciation expense related to plant and equipment for the three months ended September 30, 2021 and 2020 was \$147,000 and \$188,000, respectively.

10. Prepaids and Other Current Assets and Other long-term assets

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

	As of September 30, 2021	As of June 30, 2021
Prepaid expenses	\$ 1,032	\$ 853
Accrued investment income	59	-
Other receivables	38	480
Total prepaids and other current assets	<u>\$ 1,129</u>	<u>\$ 1,333</u>

Prepaid expenses primarily consist of prepaid benefits and insurance.

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

	As of September 30, 2021	As of June 30, 2021
BARDA contract costs	\$ 564	\$ 613
Long-term lease deposits	124	126
Long-term prepaids	15	22
Total other long-term assets	<u>\$ 703</u>	<u>\$ 761</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 September 30, 2021 and 2020 with an insignificant amount located in Australia and the United Kingdom.

Revenue by region for the three ended September 30, 2021 and 2020 were as follows (in thousands):

	Three months ended September 30,	
	2021	2020
Revenue:		
United States	\$ 6,924	\$ 4,970
Foreign:		
Australia	66	80
United Kingdom	30	10
Total	<u>\$ 7,020</u>	<u>\$ 5,060</u>

Revenue and Cost of sales by Customer type for the three September 30, 2021 and 2020 were as follows (in thousands):

	September 30,	
	2021	2020
Revenue:		
Commercial sales	\$ 6,928	\$ 5,060
BARDA:		
Product sales	-	-
Services for emergency preparedness	92	-
Total	<u>\$ 7,020</u>	<u>\$ 5,060</u>

	September 30,	
	2021	2020
Cost of sales		
Commercial cost	\$ 1,006	\$ 929
BARDA:		
Product cost	-	-
Emergency preparedness service cost	82	-
Total	<u>\$ 1,088</u>	<u>\$ 929</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 September 30, 2021 and June 30, 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

On June 29, 2020, a statutory scheme of arrangement under Australian law to effect a redomiciliation of the AVITA Group from Australia to the United States of America was implemented (the “**Scheme**”). The Scheme was approved by shareholders on June 15, 2020 and approved by the Federal Court of Australia on June 22, 2020.

Pursuant to the Scheme, all ordinary shares in AVITA Medical, the former parent company of the AVITA Group, were exchanged for shares of common stock in AVITA Medical, Inc., which at the time was named AVITA Therapeutics, Inc. As a result, AVITA Medical, Inc. became the sole shareholder of AVITA Medical and the new parent company of the AVITA Group. In

conjunction with the Scheme, an implicit reverse split on a 1 for 100 basis was implemented whereby shareholders of AVITA Medical received one share of common stock in AVITA Medical, Inc. for every 100 ordinary shares held in AVITA Medical. AVITA Therapeutics, Inc. changed its name to AVITA Medical, Inc. in December 2020.

Under the Scheme, eligible shareholders in AVITA Medical received consideration in the form of:

- five CDIs in AVITA Medical, Inc. for every 100 ordinary shares in AVITA Medical that were held by them; or
- one share of common stock in AVITA Medical, Inc. for every 5 ADSs in AVITA Medical that were held by them.

The Company's CDIs are quoted on the ASX under AVITA Medical's existing ASX ticker code, "AVH". The Company's shares of common stock are quoted on NASDAQ under AVITA Medical's existing NASDAQ 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 Scheme, 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 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 September 30, 2021, and June 30, 2021, 24,925,118 and 24,895,864 shares of common stock, respectively, were issued and outstanding and no shares of preferred stock were outstanding.

14. Revenues

Revenues

The Company's revenue consists of sale of the RECELL System to hospitals or other treatment centers 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 \$343,000 and \$343,000 as of September 30, 2021 and June 30, 2021, respectively, for the rotation cost of the product. Such amounts are recorded in other current liabilities and other long-term liabilities in the amounts of \$77,000 and \$266,000 as of September 30, 2021 and \$77,000 and \$266,000 as of June 30, 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 September 30, 2021 and 2020 were \$92,000 and \$0, respectively, and are included in sales within the consolidated statement of operations. 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 September 30, 2021 and June 30, 2021 contract costs of \$564,000 and \$613,000 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 \$1.0 million and \$1.1 million as of September 30, 2021 and June 30, 2021, respectively. Approximately \$583,000 for September 30, 2021 and \$665,000 for June 30, 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 September 30, 2021 and June 30, 2021, the Company expects to recognize revenue upon receiving Japanese Pharmaceuticals and Medical Device Act approval of the RECELL System in Japan. For the contract with BARDA, we recognized \$92,000 and \$0 of service revenue related to the emergency readiness performance obligation during the three months ended September 30, 2021, and 2020. 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 September 30, 2021 and June 30, 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 \$1.0 million and \$1.1 million of contract liabilities as of September 30, 2021 and June 30, 2021, respectively. Balance primarily relates to the unsatisfied performance obligation for emergency preparedness under the BARDA contract. Performance obligation will be recognized over time over the term of the contract. For the three months ended September 30, 2021 and 2020, the Company recognized \$92,000 of revenue recognized from amounts included in the beginning balance of contract liabilities. For the three months ended September 30, 2020, the amounts were not significant.

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 fulfil 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 September 30, 2021 and June 30, 2021, the Company had \$564,000 and \$613,000 of contracts costs included in other long-term assets. Amortization expense related to deferred contract costs were \$82,000 and \$0, during the three months ended September 30, 2021 and 2020, respectively, and are classified as cost of sales on the accompanying consolidated Statements of Operations. There was no impairment loss in relation to deferred contract costs during the three months ended September 30, 2021 and 2020.

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. 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**”).

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 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 September 30, 2021 and 2020, the Company recorded share-based compensation expense of \$1.8 million, and \$3.3 million, respectively. No income tax benefit was recognized in the consolidated statement of operations for share-based payment arrangements for the three months ended September 30, 2021 and 2020.

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 September 30,	
	2021	2020
Sales and marketing expenses	\$ 291	\$ 330
General and administrative expenses	1,251	2,766
Research and development expenses	300	170
Total	<u>\$ 1,842</u>	<u>\$ 3,266</u>

A summary of share option activity as of September 30, 2021 and changes during the period ended is presented below:

	Service Only Share Options	Performance Based Share Options	Total Share Options
Outstanding shares at June 30, 2021	997,826	495,669	1,493,495
Granted	94,100	92,875	186,975
Exercised	(500)	-	(500)
Expired	(4,400)	-	(4,400)
Forfeited	(15,225)	(2,350)	(17,575)
Outstanding shares at September 30, 2021	<u>1,071,801</u>	<u>586,194</u>	<u>1,657,995</u>
Exercisable at September 30, 2021	447,699	307,332	755,031

Restricted Stock Units

Restricted stock units (“RSUs”) are granted to executives as part of their long-term incentive compensation. RSUs granted prior to the current year and under the 2020 Plan, 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. They have a contractual term of 10 years and vest in accordance with the tenure or performance conditions as determined by the Compensation Committee. 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.

A summary of the status of the Company’s unvested RSUs as of September 30, 2021, and changes during the period is presented below:

	Service Condition RSU	Performance Condition RSU	Total RSU's
Unvested RSUs outstanding at June 30, 2021	47,507	52,507	100,014
Granted	-	87,500	87,500
Vested	-	(28,754)	(28,754)
Forfeited	-	-	-
Unvested RSUs outstanding at September 30, 2021	47,507	111,253	158,760

16. Income Taxes

At June 30, 2021, the Company and its subsidiaries had net operating loss carryforwards for federal, state, United Kingdom, and Australia income tax purposes of \$111.8 million, \$66.5 million, \$32.8 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 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 September 30, 2021 and 2020 of \$6,000 and \$10,000, respectively, is related to state minimum taxes.

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 \$49.1 million and \$41.9 million as of June 30, 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 positions 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 September 30, 2021 or June 30, 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.

The Tax Cuts and Jobs Act (“the Tax Act”) was enacted on December 22, 2017 and reduced U.S. corporate income tax rates to 21% as of January 1, 2018. The rate change became effective during tax year June 30, 2018, resulting in a blended statutory tax rate of 28% and a decrease in the Company’s deferred tax assets and the associated valuation allowance in tax year June 30, 2018.

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act (“**CARES Act**”) was enacted in the United States. The CARES Act provides numerous tax provisions and other stimulus measures, including temporary changes regarding the prior and future utilization of net operating losses and technical corrections from prior tax legislation for tax depreciation of certain qualified improvement property. The Company evaluated the provisions of the CARES Act and does not anticipate the associated impacts, if any, will have a material effect on our financial position.

On December 27, 2020, the Consolidated Appropriations Act, 2021 (CAA 2021) was signed into law which included a number of provisions including, but not limited to the extension of numerous CARES Act provisions such as employment tax credits and enhanced business meals deductions. Accordingly, the effects of the CCA have been incorporated into the income tax provision computation for the year ended June 30, 2021. These provisions did not have a material impact on the income tax provision.

17. Net Loss per Share

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

	Three months ended September 30, (in thousands, except per share data)	
	2021	2020
Net Loss	\$ (5,948)	\$ (10,227)
Weighted-average common shares – outstanding, basic	24,905	21,504
Weighted-average common shares – outstanding, diluted	24,905	21,504
Net loss per common share, basic	\$ (0.24)	\$ (0.48)
Net loss per common share, diluted	\$ (0.24)	\$ (0.48)

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 months ended September 30, 2021 and 2020, 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 \$183,000 and \$165,000 in the three months ended September 30, 2021 and 2020, respectively.

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 tissue 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 and pediatric acute full thermal burns in 2021. Following receipt of the Company's PMA, AVITA commenced commercializing the RECELL System in January 2019 in the United States. In addition, the FDA has granted the Company three Investigational Device Exemptions ("IDEs") studies which have enabled the Company to initiate pivotal clinical investigational studies to seek expanded FDA (supplementary) PMA of the RECELL System for each of soft tissue reconstruction, and vitiligo. Enrollment of those clinical studies is ongoing and, if successful, those studies would enable the Company to commence commercializing the RECELL System in the United States in each of those indications.

The Company's first United States ("U.S.") product, the RECELL® System, was approved by the U.S. Food and Drug Administration ("FDA") in September 2018 for the treatment of acute thermal burn injuries in patients 18 years and older. The RECELL System is used to prepare Spray-On Skin Cells using a small amount of a patient's own skin, providing a new way to treat severe burns, 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 transplants", known as split-thickness skin autografts, depending on the depth of the burn injury. The pivotal studies leading to the RECELL System's FDA premarket approval ("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.

Following receipt of our PMA, we commenced commercializing the RECELL System in January 2019 in the U.S., and we expect the dominant focus of our commercial efforts to be directed towards the U.S. market going forward.

The RECELL System is Therapeutic Goods Administration (“TGA”) registered in Australia cleared for use in the treatment of burns, acute wounds, scars and repigmentation (vitiligo). In Europe, the RECELL System received CE-mark approval for the treatment of burns, chronic wounds, scars and vitiligo. 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. 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 Depositary 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”.

On June 29, 2020, a statutory scheme of arrangement under Australian law to effect a redomiciliation of the AVITA Group from Australia to the United States of America was implemented (the “Redomiciliation”). The Redomiciliation was approved by shareholders on June 15, 2020 and approved by the Federal Court of Australia on June 22, 2020.

Pursuant to the Redomiciliation, all ordinary shares in AVITA Medical, the former parent company of the AVITA Group, were exchanged for shares of common stock in the Company. As a result, the Company became the sole shareholder of AVITA Medical and the new parent company of the AVITA Group. In conjunction with the Redomiciliation, an implicit consolidation or reverse split on a 1 for 100 basis was implemented whereby shareholders of AVITA Medical received one share of common stock in the Company for every 100 shares held in AVITA Medical.

Under the Redomiciliation, eligible shareholders in AVITA Medical received consideration in the form of :

- five CHES Depositary Interests (“CDIs”) in the Company for every 100 ordinary shares in AVITA Medical that were held by them; or
- one share of common stock in the Company for every 5 ADSs in AVITA Medical that were held by them.

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.

As a result of the ‘implicit consolidation’ that occurred under the Redomiciliation, the number of shares of common stock issued and outstanding in the Company (as set out in the consolidated financial statements) is less than the number of ordinary shares in AVITA Medical that was set out in the consolidated financial statements of AVITA Medical prior to August 28, 2020.

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

The 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. The Company’s business and operations have been impacted by COVID-19 as the effects of COVID-19 related travel restrictions have reduced accidents and the incidence of burns and burns admissions. In addition, during the pandemic, our commercial team’s access to hospitals was limited to case attendance and training. As COVID-19 abates and the restrictions are lifted, we anticipate that burn related accidents will resume to pre-COVID levels. In response to the pandemic, we have taken certain business measures which include 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. We have 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 have increased safety stocks of our product, established temporary satellite product storage locations, and accelerated initiatives to increase sourcing options. 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 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.

Beginning in March 2020, 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 Santa Clarita and Ventura, California. We have taken a variety of steps to address the impact of the COVID-19 pandemic, while attempting to minimize business disruption. 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, all other staff have been required to work from home (excluding our field force). We continue to restrict non-essential travel to protect the health and safety of our employees and customers.

Moreover, beginning in March 2020, access to hospitals and other customer sites was restricted to essential personnel, which has 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, more recently we have experienced periodic enrollment cessation due to COVID-19 as well as having individuals excluded because they have contracted COVID-19.

Approximately 50% of the Company's revenues (excluding BARDA) come from twenty accounts with physicians and hospitals. These accounts as well are susceptible to the effects of COVID-19 and COVID-19 restrictions. To the extent that COVID-19 or other factors cause such physicians or hospitals to be unable to treat patients or delay the treatment of patients using the RECELL System in a particular quarter, or make patients unavailable because of COVID-19, our revenues could be negatively affected.

We are continuing to monitor the impact of the COVID-19 pandemic on our employees and customers and on the markets in which we operate and 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 highly contagious variants to COVID-19, including the Delta variant, 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 September 30, 2021 compared to the three months ended September 30, 2020.

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

	Three Months Ended September 30,		\$ Change	% Change
	2021	2020		
Revenues	\$ 7,020	\$ 5,060	\$ 1,960	39%
Cost of sales	(1,088)	(929)	(159)	17%
Gross profit	5,932	4,131	1,801	44%
BARDA income	374	596	(222)	(37)%
Operating expenses:				
Sales and marketing expenses	(3,518)	(3,265)	(253)	8%
General and administrative expenses	(5,349)	(8,302)	2,953	(36)%
Research and development expenses	(3,388)	(3,374)	(14)	0%
Total operating expenses	(12,255)	(14,941)	2,686	(18)%
Operating loss	(5,949)	(10,214)	4,265	(42)%
Interest expense	(9)	(7)	(2)	29%
Other income	16	4	12	300%
Loss before income taxes	(5,942)	(10,217)	4,275	(42)%
Income tax expense	(6)	(10)	4	(40)%
Net loss	\$ (5,948)	\$ (10,227)	\$ 4,279	(42)%

Total revenues for the three months ended September 30, 2021 was \$7.0 million, an increase of \$2.0 million or 39% over the \$5.1 million reported for the three months ended September 30, 2020. The increase was largely driven by broader utilization among our customer base as well as deeper penetration within individual customer accounts.

Gross profit margin for the three months ended September 30, 2021, was 85% compared to 82% for the same period in 2020 driven largely by the lower shipping costs and increased production at our Ventura facility.

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. Under the BARDA grant, income of \$374,000 was recognized during the three months ended September 30, 2021, compared to income of \$596,000 for the three months ended September 30, 2020. BARDA arrangement declined as a result of wind-down of certain activities associated with supporting the pivotal trials for the treatment of pediatric scald injuries.

Total operating expenses decreased 18% or \$2.7 million to \$12.3 million, compared with \$14.9 million reported for the same period in the prior year.

Sales and marketing expenses increased \$0.3 million or 8% to \$3.5 million compared to \$3.3 million recognized in the same period in the prior year. Higher costs in the current year are driven by increased travel costs due to fewer COVID-19 related travel restrictions.

General and administrative expenses decreased \$3.0 million or 36% to \$5.3 million compared to \$8.3 million recognized in the same period in the prior year. The decrease was driven by higher share-based compensation expenses in the prior year associated with certain performance milestones being met along one-time professional services costs associated with establishing the Company as a domestic filer with the SEC following completion of the Redomiciliation, and severance costs associated with a former executive employee in the prior year.

Research and development expenses were \$3.4 million in the current year and flat to the same period in the prior year. Although research and development expenses were flat in the current year, we had higher costs in the prior year driven by research costs to further characterize and optimize our regenerative epidermal suspension, in addition to research and development costs for the new Ease of Use RECELL device which was submitted to the FDA for approval in July 2021. These higher costs in the prior year were offset with higher costs in the current year driven by the enrollment in our soft tissue reconstruction clinical trial, our preclinical research with Houston Methodist Research Institute to explore molecular reversal of cellular aging, along with further development of a next generation device for more automated implementation of the core Spray-On Skin technology for vitiligo.

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. 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)	Three Months Ended September 30,	
	2021	2020
Net cash used in operations	\$ (572)	\$ (7,713)
Net cash used in investing activities	(49,638)	(296)
Net cash provided by financing activities	3	(4)
Effect of foreign exchange rate on cash and restricted cash	(55)	127
Net increase in cash and restricted cash	(50,262)	(7,886)
Cash and restricted cash at beginning of year	110,947	73,840
Cash and restricted cash at end of year	60,685	65,954

Three months ended September 30, 2021 and 2020.

Net cash used in operating activities was \$572,000 and \$7.7 million during the three months ended September 30, 2021 and 2020, respectively. The decrease was primarily driven by lower operating costs along with collection of the BARDA receivables.

Net cash used in investing activities was \$49.7 million and \$296,000 during the three months ended September 30, 2021 and 2020, respectively. Cash flows used for investing activities was primarily attributable to our investments into marketable securities.

Net cash provided by financing activities was relatively flat year in the comparative quarters

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 September 30, 2021, there were no dividends paid and we have no plans to commence the payment of dividends. 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 investors.

Commitments and Contractual Obligations

Our contractual obligations consist of operating leases as described in Footnote 8. During the three months ended September 30, 2021, the Company remeasured the lease liability for an office lease due to a change in the lease term.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to various market risks that may arise from adverse changes in market rates and prices, such as interest rates and foreign exchange fluctuations. We do not enter into derivatives or other financial instruments for trading or speculative purposes.

Interest Rate Risk

Our exposure to market risk for changes in interest rates relates to the increase or decrease in the amount of interest income we can earn on our cash and cash equivalents and marketable securities. The carrying value of our cash equivalents approximated fair value. Marketable securities are recorded at fair value, therefore, declines in interest rates over time will reduce our interest income while increases in interest rates will increase our interest income. A hypothetical 100 basis point change in interest rates along the entire interest rate yield curve would increase or decrease our interest rate yields on our investments and interest income by approximately \$100,000 for each \$10.0 million in interest-bearing investments.

Foreign Currency Exchange Rate Risk

A majority of our assets and liabilities are maintained in the United States in U.S. Dollars and a majority of our sales and expenditures are transacted in U.S. Dollars. However, we also transact with foreign customers in currencies other than the U.S. Dollar. These foreign currency revenues, when converted into U.S. Dollars, can vary depending on average exchange rates during a respective period. In addition, certain of our foreign subsidiaries transact in their respective country's local currency, which is also their functional currency. As a result, expenses of these foreign subsidiaries, when converted into U.S. Dollars can also vary depending on average monthly exchange rates during a respective period.

We are exposed to foreign currency gains or losses on outstanding foreign currency denominated receivables and payables, as well as our foreign currency denominated cash balances and certain intercompany transactions. In addition, other transactions between us or our subsidiaries and a third-party, denominated in a currency different from the functional currency, are foreign currency transactions. Realized and unrealized foreign currency gains or losses on these transactions are also included in our statements of operations as incurred.

The balance sheets of each of our foreign subsidiaries whose functional currency is not the U.S. Dollar are translated into U.S. Dollars at the rate of exchange at the balance sheet date and the statements of comprehensive income and cash flows are translated into U.S. Dollars using an approximation of the average quarterly exchange rates applicable during the period. Any foreign exchange gain or loss as a result of translating the balance sheets of our foreign subsidiaries whose functional currency is not the U.S. Dollar is included in equity as a component of accumulated other comprehensive income.

Our foreign currency exchange rate exposures are primarily with the Australian Dollar and the British pound. Foreign currency exchange rates may experience significant volatility from one period to the next. During the three months ended September 30, 2021, we estimate fluctuations in the exchange rates between the U.S. Dollar and other foreign currencies, to be insignificant.

We currently do not enter into forward exchange contracts to hedge exposures denominated in foreign currencies and do not use derivative financial instruments for trading or speculative purposes. The effect of additional changes in foreign currency exchange rates could have a material effect on our future operating results or cash flows, depending on which foreign currency exchange rates change and depending on the directional change (either a strengthening or weakening against the U.S. Dollar). We estimate that the potential impact of a hypothetical 10% adverse change in all applicable foreign currency exchange rates from the rates in effect as of September 30, 2021 would have resulted in an estimated reduction of \$92,000 in reported pre-tax income for the three months ended September 30, 2021. As our foreign operations continue to grow, our exposure to foreign currency exchange rate risk may become more significant.

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 September 30, 2021, 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 first 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. We have not experienced any material impact to our internal controls over financial reporting despite the fact that many of our employees are working remotely due to the COVID-19 pandemic. We are continually monitoring and assessing the impact of the COVID-19 situation on our internal controls to minimize any undesirable effect on control design and operating effectiveness.

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

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
101.SCH	Inline XBRL Taxonomy Extension Schema
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: November 8, 2021

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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