
**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, 2020

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 THERAPEUTICS, 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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
Emerging growth company	<input checked="" type="checkbox"/>		

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 6, 2020 was 21,623,287

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

	As of	
	September 30, 2020	June 30, 2020
ASSETS		
Cash	\$ 65,753	\$ 73,639
Accounts receivable, net	2,360	2,076
BARDA receivables	371	356
Prepays and other current assets	1,054	990
Restricted cash	201	201
Inventory	1,657	1,125
Total current assets	71,396	78,387
Plant and equipment, net	1,349	1,363
Operating lease right-of-use assets	2,216	2,347
Intangible assets	403	364
Other long term assets	55	1
Total assets	<u>\$ 75,419</u>	<u>\$ 82,462</u>
LIABILITIES AND SHAREHOLDERS' EQUITY		
Accounts payable and accrued liabilities	\$ 3,570	\$ 4,333
Accrued wages and fringe benefits	3,589	2,816
Other current liabilities	561	560
Total current liabilities	7,720	7,709
Contract liabilities	435	435
Operating lease liabilities, long term	1,776	1,917
Total liabilities	<u>9,931</u>	<u>10,061</u>
Contingencies (Note 10)		
Shareholders' Equity:		
Common stock, \$0.0001 par value per share, 200,000,000 shares authorized, 21,623,287 and 21,467,912 shares issued and outstanding at September 30, 2020 and June 30, 2020, respectively	3	3
Preferred stock, \$0.0001 par value per share, 10,000,000 shares authorized, no shares issued or outstanding at September 30, 2020 and June 30, 2020	—	—
Additional paid-in capital	262,431	259,165
Accumulated other comprehensive income	8,194	8,146
Accumulated deficit	(205,140)	(194,913)
Total shareholders' equity	<u>65,488</u>	<u>72,401</u>
Total liabilities and shareholders' equity	<u>\$ 75,419</u>	<u>\$ 82,462</u>

The accompanying notes form part of the consolidated financial statements

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

	Three months ended September 30,	
	2020	2019
Revenues	\$ 5,060	\$ 3,250
Cost of sales	929	619
Gross profit	<u>4,131</u>	<u>2,631</u>
BARDA income	596	2,051
Operating expenses:		
Sales and marketing expenses	2,935	2,962
General and administrative expenses	5,536	3,071
Research and development expenses	3,204	1,635
Share-based compensation	<u>3,266</u>	<u>672</u>
Total operating expenses	<u>14,941</u>	<u>8,340</u>
Operating loss	(10,214)	(3,658)
Interest expense	7	11
Other income	4	103
Loss before income taxes	(10,217)	(3,566)
Income tax expense	10	—
Net loss	<u>\$ (10,227)</u>	<u>\$ (3,566)</u>
Net loss per common share:		
Basic	\$ 0.48	\$ 0.19
Diluted	\$ 0.48	\$ 0.19
Weighted-average common shares:		
Basic	21,503,643	18,719,857
Diluted	21,503,643	18,719,857

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

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

	<u>Three months ended September 30,</u>	
	<u>2020</u>	<u>2019</u>
Net loss	\$ (10,227)	\$ (3,566)
Foreign currency translation gain/(loss)	48	(34)
Comprehensive loss	<u>\$ (10,179)</u>	<u>\$ (3,600)</u>

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

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

	Three Months Ended September 30, 2020					
	Common Stock		Additional Paid-in- Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount				
Balance at June 30, 2020	<u>21,467,912</u>	<u>\$ 3</u>	<u>\$259,165</u>	<u>\$ 8,146</u>	<u>\$ (194,913)</u>	<u>\$ 72,401</u>
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	<u>21,623,287</u>	<u>\$ 3</u>	<u>\$262,431</u>	<u>\$ 8,194</u>	<u>\$ (205,140)</u>	<u>\$ 65,488</u>
	Three Months Ended September 30, 2019					
	Common Stock		Additional Paid-in- Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount				
Balance at June 30, 2019	<u>18,712,996</u>	<u>\$ 3</u>	<u>\$165,473</u>	<u>\$ 8,184</u>	<u>\$ (152,828)</u>	<u>\$ 20,832</u>
Net loss	—	—	—	—	(3,566)	(3,566)
Share-based compensation	—	—	672	—	—	672
Issuance of common stock to director in lieu of directors fees	15,853	—	107	—	—	107
Beginning balance adjustment related to the adoption of ASC 842	—	—	—	—	(55)	(55)
Translation loss	—	—	—	(34)	—	(34)
Balance at September 30, 2019	<u>18,728,849</u>	<u>\$ 3</u>	<u>\$166,252</u>	<u>\$ 8,150</u>	<u>\$ (156,449)</u>	<u>\$ 17,956</u>

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

AVITA Therapeutics, Inc.
Condensed Consolidated Statement of Cash Flows
(In thousands)
(Unaudited)

	Three Months ended	
	September 30,	
	2020	2019
Cash flow from operating activities:		
Net loss	\$(10,227)	\$(3,566)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	211	66
Non-cash lease expense	131	122
Loss (gain) on foreign currency transactions	80	(5)
Provision for write-down of inventories	(77)	8
Share-based compensation	3,266	672
Issuance of common stock to directors in lieu of directors fees	—	107
Changes in operating assets and liabilities:		
Trade and other receivables	(283)	(1,915)
BARDA receivables	(15)	309
Prepays and other current assets	(65)	268
Inventory	(453)	(135)
Operating lease liability	(127)	(132)
Other long term assets	(54)	3
Accounts payable and accrued expenses	(860)	(810)
Accrued wages and fringe benefits	765	286
Other current liabilities	(5)	(155)
Other long term liabilities	—	(4)
Net cash used in operations	<u>(7,713)</u>	<u>(4,881)</u>
Cash flows from investing activities:		
Cash paid for property and equipment	(209)	(86)
Cash paid for patent filing fees	(87)	(66)
Net cash used in investing activities	<u>(296)</u>	<u>(152)</u>
Cash flow from financing activities:		
Principal repayment of finance lease	(4)	(17)
Net cash used in financing activities	<u>(4)</u>	<u>(17)</u>
Effect of foreign exchange rate on cash and restricted cash	127	(22)
Net decrease in cash and restricted cash	<u>(7,886)</u>	<u>(5,072)</u>
Cash and restricted cash at beginning of the period	<u>73,840</u>	<u>20,374</u>
Cash and restricted cash end of the period	<u>\$ 65,954</u>	<u>\$ 15,302</u>
Supplemental Disclosure of Cash Flow Information		
Cash paid for income taxes	\$ 42	\$ —
Cash paid for Interest	\$ 1	\$ 5
Fixed assets in accounts payable	\$ 50	\$ —

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

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

1. The Company

Nature of the Business

The AVITA group of companies (comprising AVITA Therapeutics, Inc. (“**AVITA Therapeutics**” or the “**Company**”) and its subsidiaries, including 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. Following receipt of our PMA, we 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, pediatric scalds, 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 adverse effect on our 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, as of September 30, 2020 and through the date of this report. During the three months ended September 30, 2020, COVID-19 had minor effects on the Company’s operations and financial position and cash flows. 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, the Company, a newly formed Delaware corporation, acquired all of the issued share capital of AVITA Medical, a then public company incorporated under the laws of the Commonwealth of Australia and former parent company of the AVITA Group. The acquisition was completed pursuant to a scheme of arrangement under Australian law, and was approved by the Federal Court of Australia on June 22, 2020, and by shareholders of AVITA Medical on June 15, 2020 (the “**Redomiciliation**”). Under the Redomiciliation, all of the issued and outstanding ordinary shares of AVITA Medical, including those ordinary shares held in the form of American Depositary Shares (“**ADSs**”), were exchanged for newly issued shares of common stock of the AVITA Therapeutics or CHESS Depositary Interests (“**CDIs**”). This exchange was conducted on the basis of one share of common stock of AVITA Therapeutics for every 100 ordinary shares of AVITA Medical, effecting an ‘implicit consolidation’ or ‘reverse split’. The holders of ordinary shares of AVITA Medical received one CDI for every 20 ordinary shares held in AVITA Medical, and the holders of AVITA Medical **ADSs** (each of which previously represented 20 ordinary shares in AVITA Medical) received one share of common stock in AVITA Therapeutics for every five **ADSs** held. The common stock of AVITA Therapeutics began trading on The NASDAQ Stock Exchange LLC (“**NASDAQ**”) upon market open on July 1, 2020 under the same ticker code, “**RCEL**” as AVITA Medical’s **ADSs** were traded under prior to the Redomiciliation.

As part of the exchange of shares under the Redomiciliation, a reverse split was also simultaneously implemented such that the number of shares of common stock on issue in AVITA Therapeutics (as set out in the condensed 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.

The Redomiciliation resulted in the domicile of the AVITA Group moving from Australia to the United States of America, with AVITA Therapeutics becoming the ultimate parent company of the AVITA Group. In addition, the existing listing of AVITA Medical ordinary shares on the Australian Securities Exchange (“**ASX**”) (as its primary listing) and AVITA Medical **ADSs** on NASDAQ (as its secondary listing) was inverted and replaced with a new listing of AVITA Therapeutics common stock on NASDAQ (as its primary listing) under the existing ticker symbol, “**RCEL**” and AVITA Therapeutics **CDIs** on the ASX (as its secondary listing) under the existing ticker symbol, **AVH**. Five **CDIs** traded on ASX are equivalent to one share of common stock traded on NASDAQ.

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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, S-X 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 condensed 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, 2020 filed with the SEC on August 27, 2020 (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 condensed consolidated financial statements. See the summary of the Company’s significant accounting policies set forth in the notes to its consolidated financial statements included in the Annual Report.

Principles of Consolidation

The accompanying condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. As a result of the Redomiciliation, the parent company of the AVITA Group changed from AVITA Medical to AVITA Therapeutics. All intercompany transactions and balances have been eliminated on consolidation.

Use of Estimates

The preparation of the accompanying condensed 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, accounting for income taxes and share-based compensation 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

The financial position and results of operations of the Company’s 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, which are not material, are included in general and administrative expenses in the condensed consolidated statements of operations.

Revenue Recognition

Revenues 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. Effective July 1, 2018, the Company adopted ASC 606, *Revenue from Contracts with Customers*, using the modified retrospective method applicable to all contracts that were not completed at the date of initial application. This update outlined a comprehensive new revenue recognition model designed to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The new standard also required additional qualitative disclosures. Refer to Note 12 – Revenues for further information.

For the Company’s contracts that have an original duration of one year or less, the Company used 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.

Concentrations

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash, and trade and other receivables. As of September 30, 2020, and June 30, 2020, substantially all of the Company's cash was deposited in accounts at financial institutions, and amounts 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, 2020 and June 30, 2020, no single customer accounted for more than 10% of net accounts receivable. For the three months ended September 30, 2020, no single customer accounted for more than 10% of total revenues. For the three months ended September 30, 2019, one customer accounted for 13% of total revenues.

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 supports 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, and U.S. pediatric burn programs.

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.

3. Accounting Standards Update

Recently Adopted Accounting Pronouncements

In August 2018, the FASB issued ASU No. 2018-15, *Intangibles-Goodwill and Other-Internal-Use Software* (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract, which provides new guidance on the accounting for implementation, set-up, and other upfront costs incurred in a hosted cloud computing arrangement. Under the new guidance, entities will apply the same criteria for capitalizing implementation costs as they would for an internal-use software license arrangement. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. This ASU can be adopted prospectively to eligible costs incurred on or after the date of adoption or retrospectively. Effective July 1, 2020, the Company adopted this standard using the prospective transition method. The adoption of this update did not have a material impact on the Company's condensed consolidated financial statements.

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 condensed consolidated financial statements.

4. Leases

On July 1, 2019, the Company adopted Accounting Standards Codification No. 842, *Leases*, (“ASC 842”), which requires lessees to recognize operating leases on the balance sheet as a right-of-use asset (“ROU”) and lease liability.

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.

The Company has operating leases for corporate office space, manufacturing and warehouse facility. The Company has finance leases for equipment and furniture. The Company’s leases have remaining lease terms of less than one year to five years, some of which include options to renew the lease. Approximately \$7,000 and \$11,000 in finance leases was included in Other current liabilities as of September 30, 2020 and June 30, 2020, respectively.

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 implicit 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. The Company used the IBR on July 1, 2019 for its operating leases that commenced on or prior to that date. 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. Additionally, the Company used the portfolio approach when applying the discount rate selected based on the dollar amount and term of the obligation. Certain leases for equipment and furniture contain bargain purchase options and are classified as finance leases. 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.

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 ROU assets or operating lease liabilities. Variable lease costs are expensed when incurred.

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

	<u>Three Months ended</u> <u>September 30, 2020</u>	<u>Three Months ended</u> <u>September 30, 2019</u>
Operating lease cost	\$ 175	\$ 175
Variable lease cost	12	12
Total lease cost	<u>\$ 187</u>	<u>\$ 187</u>

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Supplemental cash flow information related to operating leases for the three months ended September 30, 2020 and 2019 was as follows (in thousands):

	<u>Three Months ended September 30, 2020</u>	<u>Three Months ended September 30, 2019</u>
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash outflows from operating leases	\$ 171	\$ 166

Supplemental balance sheet information, as of September 30, 2020 and June 30, 2020 related to operating leases was as follows (in thousands):

	<u>As of September 30, 2020</u>	<u>As of June 30, 2020</u>
Reported as:		
Operating lease right-of-use assets	\$ 2,216	\$ 2,347
Total right-of-use assets	<u>\$ 2,216</u>	<u>\$ 2,347</u>
Other current liabilities:		
Operating lease liabilities, short-term	\$ 548	\$ 533
Operating lease liabilities, long term	1,776	1,917
Total operating lease liabilities	<u>\$ 2,324</u>	<u>\$ 2,450</u>
Operating lease weighted average remaining lease term (years)	3.66	3.91
Operating lease weighted average discount rate	7.50%	7.50%

As of September 30, 2020, maturities of the Company's operating lease liabilities are as follows (in thousands):

	<u>Operating Leases</u>
Remaining 2021	\$ 524
2022	717
2023	740
2024	588
2025 and thereafter	87
Total lease payments	\$ 2,656
Less imputed interest	(332)
Total operating lease liabilities	<u>\$ 2,324</u>

As of September 30, 2020, there were no leases entered into that had not yet commenced.

5. Inventory

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

	<u>September 30, 2020</u>	<u>June 30, 2020</u>
Raw materials	\$ 1,035	\$ 947
Work in process inventory	271	—
Finished goods	351	\$ 178
Total inventory	<u>\$ 1,657</u>	<u>\$ 1,125</u>

The Company has reduced the carrying value of its inventories to reflect the net realizable value. Charges for estimated excess and obsolescence are recorded in cost of sales in the condensed consolidated statement of operations. Inventory impairments recognized in cost of sales are a result of expired product and were \$43,000 and \$53,000 for the three months ended September 30, 2020 and 2019, respectively.

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6. Intangible Assets

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

	Weighted Average Life	As of September 30, 2020			As of June 30, 2020		
		Gross Amount	Accumulated Amortization	Net Carry Amount	Gross Amount	Accumulated Amortization	Net Carry Amount
Patent 1	3	\$ 237	\$ (121)	\$ 116	\$ 235	\$ (101)	\$ 134
Patent 2	14	105	(9)	96	74	(9)	65
Patent 3	15	127	(11)	116	125	(9)	116
Patent 5	20	46	(1)	45	26	—	26
Trademarks	Indefinite	30	—	30	23	—	23
Total intangible assets		<u>\$ 545</u>	<u>\$ (142)</u>	<u>\$ 403</u>	<u>\$ 483</u>	<u>\$ (119)</u>	<u>\$ 364</u>

During the three months ended September 30, 2020 and 2019, the Company did not identify any events or changes in circumstances that indicated the carrying value of its intangibles may not be recoverable. As such, there was no impairment of intangibles assets recognized for the three months ended September 30, 2020 and 2019. Amortization expense of intangibles included in the condensed consolidated statements of operations was \$23,000 and \$0 for the three months ended September 30, 2020 and 2019, respectively.

The Company expects the future amortization of amortizable intangible assets held at September 30, 2020 to be (in thousands):

	Estimated Amortization Expense
Remainder of 2021	\$ 70
2022	67
2023	21
2024	21
2025	21
2026 and thereafter	173
Total	<u>\$ 373</u>

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7. Property, Plant and Equipment

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

	Useful Lives	As of September 30, 2020	As of June 30, 2020
Computer equipment	3 years	\$ 825	\$ 802
Computer software	3 years	496	369
Construction in progress		91	138
Furniture and fixtures	7 years	427	425
Laboratory equipment	5 years	233	194
Leasehold improvements	Lesser of life or lease term	216	216
RECELL Moulds	5 years	130	100
Less: accumulated amortization and depreciation		(1,069)	(881)
Total property, plant and equipment, net		\$ 1,349	\$ 1,363

Depreciation expense related to plant and equipment was \$188,000 and \$66,000 for the three months ended September 30, 2020 and 2019, respectively.

8. Prepaids and Other Current Assets

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

	As of September 30, 2020	As of June 30, 2020
Prepaid expenses	\$ 850	\$ 792
Lease deposits	98	123
Other receivables	106	75
Total prepaids and other current assets	\$ 1,054	\$ 990

Prepaid expenses primarily consist of prepaid benefits and insurance.

9. Reporting Segment and Geographic Information

The Company views its operations and manages its business in one reporting segment. Long-lived assets were primarily located in the United States as of September 30, 2020 and June 30, 2020 with an insignificant amount located in Australia and the United Kingdom. Revenue by region for the three months ended September 30, 2020 and 2019 were as follows (in thousands):

	Three Months ended September 30, 2020	Three Months ended September 30, 2019
Revenue:		
United States	\$ 4,970	\$ 3,130
Foreign:		
Australia	80	46
United Kingdom	10	74
Total	\$ 5,060	\$ 3,250

10. 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, 2020 and June 30, 2020, the Company did not have any outstanding or threatened litigation that would have a material impact to the financial statements.

11. 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 Therapeutics. As a result, AVITA Therapeutics 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 Therapeutics for every 100 ordinary shares held in AVITA Medical.

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

- five CDIs in AVITA Therapeutics for every 100 ordinary shares in AVITA Medical that were held by them; or
- one share of common stock in AVITA Therapeutics 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 condensed 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 condensed 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, 2020, and June 30, 2020, 21,623,287 and 21,467,912 shares of common stock, respectively, were issued and outstanding and no shares of preferred stock were outstanding.

12. Revenues

Revenues

The Company’s revenue consists of sale of the RECELL System to hospitals or other treatment centers (“customers”), predominately in the United States.

Contract Assets and 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 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 September 30, 2020, and June 30, 2020, the Company did 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 \$435,000 and \$435,000 of contract liabilities as of September 30, 2020 and June 30, 2020, respectively. For the three months ended September 30, 2020 and 2019, revenue recognized from amounts included in the beginning balance of contract liabilities was not significant.

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 \$9.6 million as of September 30, 2020. The majority of which relates to our July 13, 2020 contract with BARDA for the purchase, delivery and storage of RECELL Systems under the Strategic National Stockpile ("SNS") for a period of three years for use in a mass casualty or other emergency situation.

13. Share-Based Payment Plans**Overview of Employee Share-Based Compensation Plans**

In November 2014, our former parent company, AVITA Medical, adopted the Employee Share Plan and the Incentive Option Plan (collectively, the "2016 Plans"). The 2016 Plans previously authorized the issuance of stock options or other share-based instruments representing up to 7.5% of outstanding capital of AVITA Medical. Any increase in the maximum number of shares issuable under the 2016 Plans was subject to shareholder approval or to an increase in the total number of ordinary shares outstanding. Upon Redomiciliation, the 2016 Plans were terminated with respect to future grants and accordingly, there are no more shares available to be issued under the 2016 Plans. In addition, upon Redomiciliation, the Company had an implicit 100-1 reverse stock split and all share information presented below has been presented on a reverse split stock basis. At the 2020 Annual Meeting of Stockholders that will be held on November 9, 2020, the Company intends to seek shareholder approval for a new employee stock option plan.

Share-Based Payment Expenses

Share-based payment transactions are recognized as compensation cost based on the fair value of the instrument on the date of grant. The Company uses the binomial option valuation model to estimate the grant date fair value of employee stock options.

During the three months ended September 30, 2020 and 2019, the Company recorded stock-based compensation expense of \$3.2 million and \$672,000, respectively. No income tax benefit was recognized in the condensed consolidated statement of comprehensive loss for share-based payment arrangements for the three months ended September 30, 2020 and 2019.

A summary of stock option activity under the employees share option plan arrangement as of September 30, 2020 and changes during the period then ended is presented below:

	Service Only Stock Options	Performance Based Stock Options	Total Stock Options
Outstanding at June 30, 2020	904,353	356,171	1,260,524
Exercised	(3,538)	—	(3,538)
Expired	(1,636)	(2)	(1,638)
Forfeited	(21,778)	—	(21,778)
Outstanding at September 30, 2020	<u>877,401</u>	<u>356,169</u>	<u>1,233,570</u>
Exercisable at September 30, 2020	296,803	298,897	595,700

Restricted Stock Units

Restricted stock units ("RSUs") are granted to executives as part of their long-term incentive compensation. RSU awards are approved by the Compensation Committee as determined necessary. The RSU awards have a contractual term of 10 years and vest in accordance with the tenure or performance conditions as determined by the Compensation Committee. The grant date fair value is determined based on the price of the Company stock on the ASX on the date of grant. RSUs primarily consist of awards to the Chief Executive Officer and other executives.

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A summary of the status of the Company's unvested shares as of September 30, 2020, and changes during the three months ended September 30, 2020, is presented below:

	Service Condition RSU	Performance Condition RSUs	Total RSU
Unvested RSUs outstanding at June 30, 2020	95,013	244,346	339,359
Vested	—	(151,837)	(151,837)
Forfeited	—	(2)	(2)
Unvested RSUs outstanding at September 30, 2020	<u>95,013</u>	<u>92,507</u>	<u>187,520</u>

14. Income Taxes

At June 30, 2020, the Company and its subsidiaries had net operating loss carryforwards for U.S. federal, state, United Kingdom, and Australian income tax purposes of \$88.5 million, \$57.5 million, \$29.8 million, and \$34.1 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, in various years through 2038. The remaining loss carryforwards have no expiration.

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 full valuation allowance against all its net deferred tax assets. 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 condensed 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, 2020 or June 30, 2020.

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 its financial position.

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15. Net Loss per Share

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

	Three Months Ended September 30,	
	2020	2019
	(in thousands, except per share data)	
Net Loss	\$ 10,227	\$ 3,566
Weighted-average common shares - outstanding, basic	21,504	18,720
Weighted-average common shares - outstanding, diluted	21,504	18,720
Net loss per common share, basic	\$ 0.48	\$ 0.19
Net loss per common share, diluted	\$ 0.48	\$ 0.19

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, 2020 and 2019, diluted net loss per common share is the same as the basic net loss per share for those periods.

The loss per share incorporates the impact of the reverse stock split that was effectuated in conjunction with the Redomiciliation. In accordance with ASC 260, the impact of the reverse stock split was retrospectively applied for all periods presented.

16. 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 \$165,000 and \$154,000 in the three months ended September 30, 2020 and 2019, respectively.

17. Subsequent Events

The Company has considered all events occurring subsequent to September 30, 2020 and has concluded that all significant events have been disclosed in the condensed consolidated financial statements and accompanying notes.

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 condensed 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, 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 Therapeutics, Inc. (“**AVITA Therapeutics**” or the “**Company**”) and its subsidiaries, including AVITA Medical Limited (“**AVITA Medical**”)) (collectively, “**AVITA Group**” or “**we**”, “**us**”, or “**our**”) is a regenerative medicine group with a technology platform positioned to address unmet medical needs in burn injuries, trauma and other acute injuries, together with skin defects like vitiligo. Our patented and proprietary platform technology provides innovative treatment solutions derived from the regenerative properties of a patient’s own skin. Our medical device works by preparing Spray-On Skin™ Cells, an autologous cellular suspension comprised of the patient’s skin cells, which is then sprayed on the patient in order to regenerate natural healthy epidermis.

Our 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

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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 Therapeutics, a Delaware corporation, was originally formed in April 2020. The former parent company of the AVITA Group, AVITA Medical, was formed under the laws of the Commonwealth of Australia in December of 1992 and has operated as AVITA Medical since 2008. AVITA Medical’s ordinary shares originally began trading in Australia on the ASX on August 9, 1993. AVITA Medical’s ordinary shares, in the form of American Depositary Shares (“ADSs”), began trading on the NASDAQ Stock Market LLC (“NASDAQ”) on October 1, 2019 under the ticker symbol “RCEL”.

With effect from June 29, 2020, a statutory scheme of arrangement was implemented under Australian law to change the domicile of the AVITA Group from Australia to the U.S. Under the scheme of arrangement, AVITA Therapeutics, being a company incorporated in the State of Delaware in the U.S., became the new parent company of the AVITA Group, and all ordinary shares in AVITA Medical (including ordinary shares represented by ADSs) held by securityholders were exchanged for shares of common stock or CHESSE Depositary Interests (“CDIs”). As a result, the existing listing of AVITA Medical on the ASX (as its primary listing) and on NASDAQ (as its secondary listing) was inverted and replaced with a new listing of AVITA Therapeutics on NASDAQ (as its primary listing) under the existing ticker symbol, “RCEL”, and on the ASX (as its secondary listing) under the existing ticker symbol, “AVH”. AVITA Therapeutics’ shares of common stock trade on NASDAQ and its CDIs trade on ASX (with five CDIs trading on ASX representing one share of common stock on NASDAQ).

COVID-19 Business Update

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 have restricted 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 significant reduction in the volume of burn procedures using the RECELL System in the immediate period following the implementation of those protective measures. 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 remains highly uncertain and will depend on future developments and factors that continue to evolve, most of which are outside of our control, and could exist for an extended period of time even after the pandemic might end. Quarantines, shelter-in-place and similar government orders have also impacted and may continue to impact, our third-party manufacturers and suppliers, and could in turn adversely impact the availability or cost of materials, which could disrupt our supply chain.

Results of Operations

The table below summarizes the results of our continuing operations for each of the periods presented.

	Three months ended September 30,		\$ Change	% Change
	2020	2019		
Revenues	\$ 5,060	\$ 3,250	\$ 1,810	56%
Cost of sales	929	619	310	50%
Gross profit	4,131	2,631	1,500	57%
BARDA income	596	2,051	(1,455)	-71%
Operating expenses:				
Sales and marketing expenses	2,935	2,962	(27)	-1%
General and administrative expenses	5,536	3,071	2,465	80%
Research and development expenses	3,204	1,635	1,569	96%
Share-based compensation	3,266	672	2,594	386%
Total operating expenses	14,941	8,340	6,601	79%
Operating loss	(10,214)	(3,658)	(6,556)	179%
Interest expense	7	11	(4)	-36%
Other income	4	103	(99)	-96%
Loss before income taxes	(10,217)	(3,566)	(6,651)	187%
Income tax expense	10	—	10	100%
Net loss	<u>\$(10,227)</u>	<u>\$(3,566)</u>	<u>\$(6,661)</u>	<u>187%</u>

Three months ended September 30, 2020 compared to three months ended September 30, 2019

Revenue of the RECELL System totaled \$5.1 million for the three months ended September 30, 2020, an increase of \$1.8 million or 56% over the \$3.3 million reported for the three months ended September 30, 2019. Consistent with the prior year, the current quarter increase in sales occurred in the United States as a result of the September 2018 FDA approval and commencement of the U.S. national market launch of the RECELL System in January 2019. Gross margin for the three months ended September 30, 2020 was 82% compared to 81% for the same period in 2019.

BARDA income consisted of funding from the Biomedical Advanced Research and Development Authority (“BARDA”), 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 \$596,000 was recognized during the three months ended September 30, 2020 compared to income of \$2.1 million for the three months ended September 30, 2019. BARDA arrangement declined as a result of wind-down of certain activities associated with supporting the U.S. FDA approval of the RECELL System as well as the compassionate use and continued access programs.

Operating costs for the year ended September 30, 2020 totaled \$14.9 million, a \$6.6 million or 79% increase over the \$8.3 million incurred during the three months ended September 30, 2019. Sales and marketing expenses for the three months ended September 30, 2020 totaled \$2.9 million and were flat compared to the three months ended September 30, 2019. General and administrative expenses totaled \$5.5 million for the three months ended September 30, 2020, an increase of \$2.5 million or 80% over the \$3.1 million recognized during the three months ended September 30, 2019. The increase was driven by the Company’s status as a cross listed entity on NASDAQ and the ASX, 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. Research and development expenses for the three months ended September 30, 2020 totaled \$3.2 million, an increase of \$1.6 million or 96% over the \$1.6 million recognized during the three months ended September 30, 2019. The increase was primarily attributed to the commencement of pivotal trials for treatment of pediatric scald injuries, soft tissue reconstruction, treatment of vitiligo and other research and development activities to further promote the RECELL device. Share based compensation also increased to \$3.2 million for the three months ended September 30, 2020, an increase of \$2.5 million or 386% over the \$672,000 recognized during the three months ended September 30, 2019. The increase was primarily driven by an increase in awards granted along with the increase in grant fair value. The increase in the grant date fair value of the awards is due to the increase in the Company’s stock price compared to the prior year.

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Net loss for the three months ended September 30, 2020 was \$10.2 million, an increase of \$6.6 million or 187% over the \$3.6 million recognized during the three months ended September 30, 2019. The increase in net loss was driven by the higher operating costs described above, partially offset by the higher revenue during the three months ended September 30, 2020. As a result of the U.S. national launch of the RECELL System in January 2019, and the expansion of research and development including multiple pivotal clinical studies seeking premarket approval from the FDA, operating expenses are expected to increase in future periods. These expenses are expected to be partially offset by increased commercial sales of the RECELL System.

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:

<u>(In Thousands)</u>	<u>Three Months Ended</u> <u>September 30,</u>	
	<u>2020</u>	<u>2019</u>
Net cash used in operations	\$ (7,713)	\$ (4,881)
Net cash used in investing activities	(296)	(152)
Net cash used in financing activities	(4)	(17)
Effect of foreign exchange rate on cash and restricted cash	127	(22)
Net decrease in cash and restricted cash	(7,886)	(5,072)
Cash and restricted cash at beginning of the period	73,840	20,374
Cash and restricted cash at end the period	65,954	15,302

Three Months Ended September 30, 2020, and 2019

Net cash used in operating activities was \$7.7 million and \$4.9 million during the three months ended September 30, 2020 and 2019, respectively. The increase was primarily due to higher operating costs associated with the Company's status as a cross listed entity on NASDAQ and the ASX, the commercialization of the RECELL System in the United States, and the expansion of research and development activities.

Net cash used in investing activities was \$296,000 and \$152,000 during the three months ended September 30, 2020 and 2019, respectively. Cash flows used for investing activities was primarily attributable to payments for the purchase of a property and equipment.

Net cash used by financing activities was \$4,000 and \$17,000 for the three months ended September 30, 2020 and 2019, respectively, and related to principal repayment of finance lease.

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 three months ended September 30, 2020, 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.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Financial instruments, which subject us to concentrations of credit risk, consist primarily of cash. We maintain cash in three financial institutions. We perform periodic evaluations of the relative credit standing of these institutions.

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, 2020, 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 were 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 fiscal year 2021 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 COVID-19 situation on our internal controls to minimize the impact on their design and operating effectiveness.

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Part II - Other Information

Item 1. LEGAL PROCEEDINGS

None.

Item 1A. Risk Factors

None.

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:

<u>Exhibit No.</u>	<u>Description</u>
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	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Linkbase
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase

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 10, 2020

AVITA THERAPEUTICS, INC.

By: /s/ Dr. Michael Perry
Dr. Michael Perry
President and Chief Executive Officer
(Principal Executive Officer)

By: /s/ Sean Ekins
Sean Ekins
VP of Finance
(Interim Principal Financial and Accounting Officer)

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

I, Dr. Michael Perry, certify that:

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

Date: November 10, 2020

/s/ Dr. Michael Perry

Name: Dr. Michael Perry

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

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

I, Sean Ekins, certify that:

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

Date: November 10, 2020

/s/ Sean Ekins

Name: Sean Ekins

Title: VP of Finance

(Interim Principal Financial and Accounting Officer)

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

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

The Quarterly Report on Form 10-Q for the period ended September 30, 2020 of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 10, 2020

/s/ Dr. Michael Perry

Name: Dr. Michael Perry

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

Dated: November 10, 2020

/s/ Sean Ekins

Name: Sean Ekins

Title: VP of Finance
(Interim Principal Financial and Accounting Officer)

The foregoing certification is being furnished solely pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code) and is not being filed as part of the Form 10-Q or as a separate disclosure document.