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

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): August 27, 2020

Avita Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-39059
(Commission
File Number)

85-1021707
(IRS Employer
Identification No.)

28159 Avenue Stanford, Suite 220, Valencia, CA 91355
(Address of principal executive offices, including Zip Code)

661.367.9170
(Registrant's telephone number, including area code)

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

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

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2 of the Securities Exchange Act of 1934. Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected 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.

Item 2.02. Results of Operations and Financial Condition.

On August 27, 2020, Avita Therapeutics, Inc. (the “Company”), filed its Appendix 4E (“Preliminary Final Report”) for the fiscal year ended June 30, 2020 with the Australian Securities Exchange (“ASX”), in accordance with ASX rules and regulations. The Preliminary Final Report was prepared in U.S. dollars pursuant to Generally Accepted Accounting Principles.

A copy of the front portion of the Company’s Preliminary Final Report for the fiscal year ended June 30, 2020 is included as Exhibit 99.1 to this report. The other portion of the Company’s Preliminary Final Report is the Form 10-K of the Company, which was filed with the U.S. Securities and Exchange Commission on August 27, 2020.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description of Exhibit</u>
99.1	<u>Front portion of the Company’s Preliminary Final Report for the fiscal year ended June 30, 2020</u>

SIGNATURE

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 hereunto duly authorized.

Date: August 27, 2020

AVITA THERAPEUTICS, INC.

By: /s/ David McIntyre

Name: David McIntyre

Title: Chief Financial Officer



Appendix 4E
Preliminary Final Report
30 June 2020

AVITA THERAPEUTICS, INC.
ARBN 641 288 155

Results for announcement to the market

(In thousands, except net tangible asset backing per ordinary security)

<u>Financial Results</u>	<u>Movement</u>	<u>June 2020</u> USD	<u>June 2019</u> USD
Sale of goods	Up 161%	14,263	5,474
Other income	Down 26%	4,612	6,253
Loss for the period attributable to owners of the parent	Up 67%	42,030	25,102
Total comprehensive loss attributable to owners of the parent	Up 68%	42,068	25,001

<u>Dividends</u>	<u>Amount per Ordinary</u> <u>Security</u>	<u>Franked amount per</u> <u>security</u>
2018 interim dividend	Nil	Nil
2017 interim dividend	Nil	Nil
Record date for determining entitlements to interim dividends	N/A	

<u>Net Tangible Asset Backing</u>	<u>June 2020</u>	<u>June 2019</u>
Net tangible asset backing per ordinary security	\$ 3.3556	\$ 1.1012

• **Annual financial results:**

This report is based on the accompanying consolidated 2020 Financial Statements which have been audited by Grant Thornton LLP with the Report of Independent Registered Public Accounting Firm included in the 2020 Financial Statements.

• **Changes in control over entities:**

AVITA Therapeutics, Inc. (“**Avita Therapeutics**” or the “**Company**”) was incorporated on April 17, 2020 in the State of Delaware in the United States of America and is the parent company of the Avita group of companies, including AVITA Medical Limited (“**AVITA Medical**”) and its subsidiaries (“**AVITA Group**”). The former parent company of the AVITA Group, AVITA Medical, was formed under the laws of the Commonwealth of Australia on December 21, 1992 and has operated as AVITA Medical Limited since 2008. AVITA Medical’s ordinary shares began trading in Australia on the Australian Securities Exchange (“**ASX**”) on August 9, 1993 (under the ticker symbol “**GRC**”, and subsequently under the ticker symbol “**AVH**”). 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 became the new parent company of the AVITA Group, and all ordinary shares in AVITA Medical (including those represented by ADSs) held by securityholders were exchanged for shares of common stock or CHESS Depositary Interests (“**CDIs**”) (with five CDIs representing one share of common stock) in AVITA Therapeutics. 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 tickersymbol, “**AVH**”. AVITA Therapeutics’ shares of common stock trade on NASDAQ and its CDIs trade on ASX (with five CDIs representing one share of common stock).

Other than the change in parent company of the AVITA Group as a result of the scheme of arrangement (mentioned above), there were no other entities within the AVITA Group over which control has been gained or lost during fiscal year 2020.

- **Details of dividends and dividend reinvestment plans:**

No dividends have been declared or proposed.

- **Details of associates or joint ventures:**

N/A

- **Set of accounting standards used in compiling the report:**

The audited consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the U.S. (US GAAP) and are denominated in U.S. dollars.

- **Details of audit disputes or audit qualification:**

None.

Results of Operations:

Revenue of the RECELL System totaled \$14.3 million for the year ended June 30, 2020, an increase of \$8.8 million or 161% over the

\$5.5 million for the year ended June 30, 2019. Similar to prior years, most of the current year 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. U.S. sales during the year ended June 30, 2020 totaled \$13.8 million compared to \$4.4 million in the prior year. Gross margin for the year ended June 30, 2020 was 79% compared to 77% 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 contract, income of \$3.9 million was recognized during the year ended June 30, 2020 compared to income of \$5.9 million for the year ended June 30, 2019. BARDA invoices declined as a result of the wind-down of certain activities associated with supporting the U.S. FDA approval of the RECEL System as well as the compassionate use and continued access programs.

Operating costs for the year ended June 30, 2020 totaled \$57.9 million, a \$22.2 million or 62% increase over the \$35.7 million incurred during the year ended June 30, 2019. Sales and marketing expenses for the year ended June 30, 2020 totaled \$14.8 million, an increase of \$2.6 million or 21% over the \$12.3 million recognized during the year ended June 30, 2019. This increase was primarily attributed to commercialization activities being provided for the entire fiscal year ended June 30, 2020 versus the prior fiscal year where those activities were rendered for less than twelve months. General and administrative expenses totaled \$18.1 million for the year ended June 30, 2020, an increase of \$4.6 million or 34% over the \$13.6 million recognized during the year ended June 30, 2019. The increase was primarily a result of the costs related to the Redomicile Transaction, together with additional headcount associated with the growth of the Company and the Company’s status as a cross listed entity on NASDAQ and the ASX. Research and development expenses for the year ended June 30, 2020 totaled \$8.5 million, an increase of \$0.6 million or 7% over the \$7.9 million recognized during the year ended June 30, 2019. Share-based compensation also increased to \$16.5 million for the year ended June 30, 2020, an increase of \$14.6 million or 747% over the \$1.9 million recognized during the year ended June 30, 2019 primarily due to the increase in the grant date fair value of awards granted during the year. The increase in the grant date fair value of the awards is due to the increase in the Company’s stock price.

Net loss after tax for the year ended June 30, 2020 was \$42 million, an increase of \$16.9 million or 67% over the \$25.1 million recognized during the year ended June 30, 2019. The increase in net loss was driven by the higher operating costs described above, partially offset by the higher revenue during the year. 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 as well as income under the BARDA contract.

Update on the Company’s Cash Position:

The Company had cash and restricted cash of \$73.8 million at June 30, 2020 compared to \$20.4 million at June 30, 2019

Net cash used in operating activities was \$22.7 million and \$19.3 million during the years ended June 30, 2020 and 2019, respectively. The increase was primarily due to higher operating costs associated with a full year of commercialization of the RECELL System in the United States, and the expansion of research and development.

Net cash used in investing activities was \$0.8 million and \$1.2 million during the years ended June 30, 2020 and 2019, respectively. Cash flows used for investing activities was primarily attributable to payments for the purchase of property and equipment.

Net cash provided by financing activities was \$77.1 million and \$29.7 million for the years ended June 30, 2020 and 2019, respectively. The Avita Group completed a series of financing transactions and received proceeds from the issuance of shares and exercise of options.

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.

During the year ended June 30, 2020, we raised additional capital via a private placement in the amount of \$81.7 million (through our former parent company, AVITA Medical). We sold the equivalent of 2,033,898 shares of common stock at an equivalent issue price of \$40.17 per share for total net proceeds of \$76.6 million, after deducting commission and offering expenses.

Please refer to our audited consolidated financial statements with accompanying notes, which are attached hereto.

Additional information

Additional Appendix 4E disclosure requirements and commentary on these results is contained in the attached Form 10-K Annual Report for the period ended June 30, 2020.