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): July 9, 2020

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

Delaware	**001-39059**	**85-1021707**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

28159 Avenue Stanford, Suite 220, Valencia, CA 91355	**661.367.9170**
(Address of principal executive offices, including Zip Code)	**(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 July 9, 2020, Avita Therapeutics, Inc. (the "Company"), issued a press release announcing preliminary unaudited results for the fourth quarter and full year ended June 30, 2020 and certain other business updates (the "Business Update Press Release"). A copy of the press release is included as Exhibit 99.1 to this report.

The information under this Item 2.02 and in Exhibit 99.1 is preliminary, has not been audited and is subject to change upon completion of the Company's closing procedures.

Item 8.01. Other Events.

On July 9, 2020, the Company issued the Business Update Press Release referenced in Item 2.02 above, which contained a Company update regarding various activities including the U.S. Biomedical Advanced Research and Development Authority procurement, future market opportunities of the vitiligo pivotal trial, outpatient market, status on two pivotal studies, publication releases, Japanese marketing partner, and other Company updates. A copy of the Business Update Press Release is included as Exhibit 99.1 to this report.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description of Exhibit
99.1	Preliminary Unaudited Results for the Fourth Quarter and Full Year Ended June 30, 2020, Together with a Company Update

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: July 9, 2020

AVITA THERAPEUTICS, INC.

By: /s/ David McIntyre
Name: David McIntyre
Title: Chief Financial Officer

AVITA Therapeutics Provides Company Update and Preliminary Unaudited Results for the Fourth Quarter and Fiscal Year 2020

Valencia, Calif., USA, and Melbourne, Australia, July 9, 2020 — AVITA Therapeutics, Inc. (NASDAQ: RCEL, ASX:AVH), a regenerative medicine company that is developing and commercializing a technology platform that enables point-of-care autologous skin restoration for multiple unmet needs, announced today preliminary unaudited results for the fourth quarter and full year ended June 30, 2020, together with a company update.

Preliminary Unaudited Results for Three Month Period Ended June 30, 2020

With effect from July 1, 2020, the Company is reporting financial results in United States dollars (US$), and prepared in accordance with U.S. Generally Accepted Accounting Principles (U.S. GAAP).

- U.S. RECELL® System Sales:
  - US$3.79M in the fourth quarter versus $3.78M in the third quarter, or an increase of 0.2%.
  - To compare with the Company's previously reported results (as reported under International Financial Reporting Standards (IFRS)):
    - U.S. RECELL System sales were US$3.88M (A$5.95M) in the fourth quarter versus US$3.86M (A$5.81M) in the third quarter, or an increase of 0.6% (2.4%).
- Total global net revenue for the fourth quarter (unaudited):
  - US$3.88M in the fourth quarter, a decrease of US$0.06M or 1.6% over the US$3.94M recognized during the previous quarter.
  - To compare with the Company's previously reported results (as reported under IFRS) fourth quarter net revenue was approximately A$6.08M, versus A$5.96M in the third quarter, or an increase of 2.0%.
- Cash and Cash Equivalents:
  - At the end of the fourth quarter, the Company had cash of approximately US$73.84M, a decrease of US$5.92M or 7.4% over the US$79.76M held at the end of previous quarter (inclusive of more than US$1M expended during the quarter on redomiciliation and preparation for U.S. GAAP compliance).
  - To compare with the Company's previously reported results (as reported under IFRS) cash at the end of the fourth quarter was A$107.02M, a decrease of A$22.92M from the A$129.94M reported in the previous quarter, driven by A$14.28M attributable to the effect of movement in the exchange rates on cash, and A$8.64M in operating expenses.

- Commercial metrics:
    - Estimated procedural volumes decreased by approximately 4% from the prior quarter.
    - New accounts added – 8.
    - Cumulative accounts with Value Analysis Committee (VAC) approval – 77.

“We are pleased with our fourth quarter results given the challenges and limited patient and facility access that we have experienced with the onset of the COVID-19 pandemic,” said Dr. Mike Perry, AVITA Therapeutics’ Chief Executive Officer. “Like many others, this quarter we witnessed the most challenging commercial conditions since the RECELL System was launched in the U.S. in early 2019. While burns are not considered elective procedures, the incidence of burns was not immune to the impact of COVID-19 as nationwide protective (executive) orders drove a reduction in accidents resulting in burn injuries. Despite the tough macro environment, the clear benefits of the RECELL System including shortened length of hospital stays, together with less invasive and fewer surgeries, continues to resonate with hospitals, physicians, and patients, which is reflected in our results this quarter.”

Preliminary Unaudited Results for the Full Year Ended June 30, 2020

- Total consolidated sales:
    - Fiscal year 2020 sales were approximately US$14.32M, an increase of US$8.78M or 160% over the US$5.45M recognized during the previous full year.
    - To compare with the Company’s previously reported results (as reported under IFRS) fiscal 2020 sales were approximately A$21.72M, an increase of A$14.02M or 182% over the A$7.71M recognized during the previous full year.
- U.S. RECELL System Sales:
    - Fiscal year 2020 sales were approximately US$13.79M, an increase of US$9.39M or 213% over the US$4.40M recognized during the previous full year.
    - To compare with the Company’s previously reported results (as reported under IFRS) fiscal 2020 sales were approximately A$21.03M, an increase of A$14.82M or 238% over the A$6.21M recognized during the previous full year.

Company Update

Quarter Ended June 30, 2020

During the fourth quarter we witnessed a wide degree of variability with both revenue and procedural volumes, together with an environment where our customers mandated highly restrictive access practices for our field force given the COVID-19 pandemic. Face-to-face interaction with our burn caregivers continues to be exclusively at “physician request” for case support within the operating theater only, and does not permit participation in the aftercare setting or otherwise enable clinical and business development, for example, to expand utilization of the RECELL System across different burns and users. Given the current state of affairs, we have no reason to believe that these measures, and our limited access, will change in the short term.

As previously stated, burn procedures are neither elective nor deferrable, however the rate of occurrence of these events is very dependent on broader economic activity and “people movement”. As such, we saw many of our customers initially experience reduced burn volumes due to the social distancing and shelter-in-place restrictions that have been implemented across the nation.

The reprioritization of hospital resources to support COVID-19 readiness meant that our April results were the lowest monthly revenue and procedural volumes seen this calendar year. Fortunately, as the quarter developed, the benefits of the RECELL System providing reduced hospital stays, and fewer and smaller surgeries, together with both a gradual uptick in burn incidence and hospitals (partially) reverting back from a COVID-19 centric focus, enabled a recovery of both revenue and procedural volume growth through May and June. As with many companies in the current pandemic environment, it is difficult to predict revenue and procedural volume over the coming months, but we are pleased with current utilization rates and our physician commitment.

BARDA

The Company continues to work with the U.S. Biomedical Advanced Research and Development Authority (BARDA) on the procurement of the RECELL System for the U.S. strategic national stockpile for public health medical emergencies (with an estimated contract value of US$7.6 million). The Company is hopeful of providing further updates on this topic during this quarter.

Future Market Opportunities

Set out below is an update on our various future market opportunities:

- Vitiligo
    - On June 2, 2020 the Company announced that it had submitted an Investigational Device Exemption (IDE) supplement with the U.S. Food and Drug Administration (FDA) for the initiation of a pivotal clinical trial to investigate the RECELL System for the treatment of vitiligo.
    - On July 1, 2020, the FDA approved the IDE application for the pivotal study which is titled “A Prospective Multi-Arm Blinded-Evaluator Within-Subject Randomized Controlled Clinical Study to Investigate the Safety and Effectiveness of RECELL for Repigmentation of Stable Vitiligo.”
        - The Company is continuing to work with FDA to finalize two (2) outstanding study design considerations and will provide further updates, including details regarding the study and initiation plan, over the next several weeks.
        - The Company expects to commence enrollment in the vitiligo pivotal study in the second half of this calendar year.
    - The Company continues to have a high degree of confidence that the RECELL System can be an effective therapeutic offering for patients with stable vitiligo. More than 1,000 patients have been treated with the RECELL System for vitiligo outside of the United States, and to date there are eight (8) publications demonstrating the benefits of the RECELL System in vitiligo.
- Outpatient (Burn Market)
    - As previously disclosed, the Company is seeking incremental reimbursement, and FDA approval of our next generation “RECELL 2.0” (expected in the middle of 2021), to assist with market access in the outpatient hospital setting.
        - Once we navigate through the above, our initial focus in the outpatient hospital setting will target our existing burn center customer base which has the highest outpatient volumes.
    - By comparison, since October 1, 2019 the Company has benefited from various reimbursement codes for patients admitted for burn treatment in the inpatient hospital setting (under the Hospital Inpatient Prospective Payment System (IPPS)), including the following:
        - Medicare reimburses hospitals for inpatient services using MS-DRGs (Medicare Severity Diagnosis-Related Groups) (see MS-DRG 927, 928 and 929 for various types of burns (which are non-specific to the RECELL System)).

- Specific ICD-10-PCS code series describing our “cell suspension technique” for the use of the RECELL System (see the “OHR” codes within ICD-10-PCS). These procedure codes are assigned to the same DRGs for payment as other skin grafts.
- Current Procedural Terminology (CPT) for physicians to support reimbursement for physician rendered healthcare services.
    - There is no procedure-specific CPT code for the RECELL System’s cell suspension autografting and so, per recommendations from the American Burn Association, providers using the RECELL System are guided to the existing long-standing epidermal autografting codes (e.g. CPT code 15110[1] and 15115)[2].

- In the outpatient setting, the Company has been seeking a New Technology Ambulatory Payment Classification (APC) under the Outpatient Prospective Payment System (OPPS) since late 2019. However, based on feedback from The Centers for Medicare & Medicaid Services (CMS) and given recent changes to the OPPS payments system discussed below, the Company will now instead pursue a Transitional Pass-through Payment Application (TPT) to support separate additional Medicare payment for the RECELL System.
    - CMS has advised the Company that the availability of the long-standing CPT code 15110 and CPT code 15115 (which providers may presently utilize in both the inpatient and outpatient hospital setting) excludes our ability to apply for a New Technology APC for use in the outpatient setting.
    - On January 1, 2020, CMS implemented changes to the OPPS and ambulatory surgical centers (ASC) payment systems to permit medical devices, including the RECELL System, “that have received FDA marketing authorization and are part of the Breakthrough Devices Program [to] be approved [by CMS for TPT] through the quarterly [review] process” (as opposed to the typical annual review process).
- TPT was established by CMS to provide an alternative payment pathway for “transformative medical devices”. Similar to the New Technology APC, if approved CMS would create a new C code and would allow the RECELL System to be billed and paid separately in hospital outpatient facilities and ASCs.
- As a recipient of Breakthrough Device status, AVITA Therapeutics will work with CMS through the next CMS scheduled quarterly review cycle and is hopeful of having a C code in place for the RECELL System on January 1, 2021 (which should not change our current commercialization timeline for the outpatient hospital setting).

- Existing Registration / Pivotal Clinical Studies
    - As previously reported, prior to the onset of COVID-19, in late March the Company initiated two pivotal studies for (1) the treatment of pediatric scalds, and (2) soft tissue reconstruction.
    - Enrollment of clinical studies across the United States are largely paused at present and the Company’s enrollment of the aforementioned studies are accordingly largely on hold.
    - The Company has enrolled three (3) patients in the pediatric scald study and one (1) patient in the soft tissue reconstruction study.
    - The Company anticipates that enrollment will resume in the ensuing quarter.

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1 CPT code 15110: Epidermal autograft, trunks, arms, legs; CPT code 15115: Epidermal autograft, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and / or multiple digits.

2 It should be noted that the CPT code may be used in both the inpatient and the outpatient hospital setting.

Publications

Notable publications released during the quarter were as follows:

- "A Pilot Multi-Centre Prospective Randomised Controlled Trial of RECELL for the Treatment of Venous Leg Ulcers." Hayes et al. *International Wound Journal*.
- "Impact of graft cell density and viability on repigmentation upon noncultured autologous cell suspension transplantation in vitiligo and piebaldism." Uitentuis et al. *Clinical and Experimental Dermatology*.

Japan

AVITA Therapeutics continues to work with our Japanese marketing partner, COSMOTEC, to advance our application for approval to market the RECELL System in Japan pursuant to Japan's Pharmaceuticals and Medical Devices Act. The application has been constructed broadly to seek approval for the treatment of patients with burns, chronic wounds and vitiligo in three (3) size configurations of the RECELL System.

Progress on the application has been delayed due to the COVID-19 pandemic and the associated State of Emergency declaration in Japan. In addition, Japan's regulatory agency, the Pharmaceuticals and Medical Devices Agency (PMDA), has now requested various non-clinical "raw data" (e.g., original hand written copies of data entry forms or records) of a small subset of our historic studies, some of which were conducted more than ten (10) years ago. To facilitate PDMA's request, AVITA Therapeutics is repeating three (3) non-clinical or "benchtop" tests. These tests are expected to be completed and submitted in August, and the Company hopes to then advance our application for approval of the RECELL System in Japan.

Other Updates

- Redomiciliation
  - Redomiciliation of the Company from Australia to the United States was implemented on June 29, 2020 with trading resuming on both the ASX (ticker: AVH) and NASDAQ (ticker: RCEL).
- Financial Reporting
  - With the completion of redomiciliation to the United States, the Company has transitioned to U.S. dollar denominated financial reporting prepared in accordance with U.S. GAAP. The Company expects to publish on the ASX and NASDAQ the Company's results for the twelve (12) months ended June 30, 2020 (i.e., annual report) in the last week of August (and submitted on Form 10-K as prescribed by the U.S. Securities and Exchange Commission).
- Investor Conferences
  - The Company will participate in the Morgan Stanley Virtual 18th Annual Global Healthcare Conference which is scheduled to take place in September. Further details will be provided closer to the date.
  - The Company will participate in the Cantor Global Healthcare Conference which is scheduled to take place in September. Further details will be provided closer to the date.
- The Company launched a new corporate website which can be found at www.avitamedical.com.

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

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ABOUT AVITA THERAPEUTICS, INC.

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

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

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

To learn more, visit www.avitamedical.com.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This letter includes forward-looking statements. These forward-looking statements generally can be identified by the use of words such as "anticipate," "expect," "intend," "could," "may," "will," "believe," "estimate," "look forward," "forecast," "goal," "target," "project," "continue," "outlook," "guidance," "future," other words of similar meaning and the use of future dates. Forward-looking statements in this letter include, but are not limited to, statements concerning, among other things, our ongoing clinical trials and product development activities, regulatory approval of our products, the potential for future growth in our business, and our ability to achieve our key strategic, operational and financial goal. Forward-looking statements by their nature address matters that are, to different degrees, uncertain. Each forward- looking statement contained in this letter is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statement. Applicable risks and uncertainties include, among others, the timing of regulatory approvals of our products; physician acceptance, endorsement, and use of our products; failure to achieve the anticipated benefits from approval of our products; the effect of regulatory actions; product liability claims; risks associated with international operations and expansion; and other business effects, including the effects of industry, economic or political conditions outside of the company's control. Investors should not place considerable reliance on the forward-looking statements contained in this letter. Investors are encouraged to read our publicly available filings for a discussion of these and other risks and uncertainties. The forward-looking statements in this letter speak only as of the date of this release, and we undertake no obligation to update or revise any of these statements.

FOR FURTHER INFORMATION:

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