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): February 28, 2022

AVITA Medical, 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 February 28, 2022, AVITA Medical, Inc. (the "Company") issued a press release announcing its financial results for the quarter ending December 31, 2021, and its transition period fiscal year ("Transition Period") from July 1, 2021, to December 31, 2021. A copy of the Company's press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

The information under Item 2.02 in this current report on Form 8-K and the related information in the exhibit attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description of Exhibit
99.1	Press release, titled "AVITA Medical Reports Quarter Ending December 31, 2021, and Transition Period July 1, 2021, to December 31, 2021, Financial Results"
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: March 1, 2022

AVITA MEDICAL, INC.

By: /s/ *Donna Shiroma*
Name: Donna Shiroma
Title: General Counsel

AVITA Medical Reports Quarter Ending December 31, 2021, and Transition Period July 1, 2021, to December 31, 2021, Financial Results

VALENCIA, Calif, February 28, 2022 and MELBOURNE, Australia, March 1, 2022 — AVITA Medical, Inc. (NASDAQ: RCEL, ASX:AVH) (the "**Company**"), a regenerative medicine company that is developing and commercializing a technology platform that enables point-of-care autologous skin restoration for multiple unmet needs, today reported its financial results for the quarter ending December 31, 2021, and its transition period fiscal year ("**Transition Period**") from July 1, 2021, to December 31, 2021.

As announced in December 2021, the Company determined to change the Company's fiscal year from June 30 to December 31. As a result of this change, the Company is reporting a six-month Transition Period.

Financial Highlights and Recent Updates:

- Revenue increased 37% to $14.0 million in the Transition Period ended December 31, 2021, compared to $10.2 million over the six-month corresponding period in the prior year
- Revenue increased 35% to $6.9 million in the fourth quarter of 2021, compared to $5.1 million in the corresponding period in the prior year
- Completed enrollment in two clinical trials with the goal of submitting premarket approval (PMA) supplements in 2022
  - In December 2021, completed enrollment of pivotal clinical trial evaluating the safety and effectiveness of the RECELL® System for the repigmentation of stable vitiligo lesions
  - In January 2022, completed enrollment of pivotal study of the RECELL System for soft tissue reconstruction (trauma)
- In January 2022, successfully established proof of concept with preclinical data in two key areas of cell-based gene therapy – skin rejuvenation and epidermolysis bullosa
- In February 2022, received FDA approval of the premarket approval application (PMA) supplement for RECELL® Autologous Cell Harvesting Device, an enhanced RECELL system aimed at providing clinicians a more efficient user experience and simplified workflow
- In February 2022, Japan's Pharmaceuticals and Medical Devices Agency (PMDA) approved our application for commercialization of the RECELL system with an initial burns indication in Japan to be commercialized in a marketing and distribution partnership with COSMOTEC (an M3 company)
- As of December 31, 2021, the Company had approximately $55.5 million in cash and cash equivalents and $49.3 million in short-term and long-term marketable securities, and no debt

"We are pleased with the terrific results that we are achieving with RECELL in US burn centers, as well as with our recent achievement of many key corporate milestones." said Dr. Mike Perry, AVITA Medical Chief Executive Officer. "Our success in burns will help us prepare for and is expected to increase our future adoption with respect to commercialization in much larger markets for soft tissue reconstruction and vitiligo in the second half of 2023."

Financial Results for the Three-Months Ended December 31, 2021, compared to the Three-Months Ended December 31, 2020

Revenue increased 35% to $6.9 million, compared to $5.1 million in the corresponding period in the prior year. The increase was largely driven by broader utilization among our customer base as well as deeper penetration within individual customer accounts.

Gross profit margin was 88% compared with 84% in the corresponding period in the prior year. Higher gross margin was driven by increased production at our Ventura facility and the extension of our shelf-life.

Total operating expenses increased 42% to $14.8 million, compared to $10.4 million in the corresponding period in the prior year. The increase in operating expenses was primarily driven by higher share-based compensation costs, higher costs with ongoing development of a next generation automated skin preparation device, pre-commercialization planning for RECELL launches in soft tissue reconstruction and vitiligo, as well as increased hands-on professional education and training events. Higher share-based compensation costs in the current year were due to the reversal of a previously recognized expense for unvested awards related to the resignation of an executive officer in the prior year. A decrease in COVID-19 related travel restrictions in the current year enabled more in-person professional education and training events.

Net loss increased 52% or $2.9 million to $8.5 million, over the $5.6 million recognized in the corresponding period in the prior year. The increase in net loss was driven by higher operating expenses as described above, partially offset by higher revenue during the year.

Adjusted EBITDA* loss increased by 13%, or $0.7 million to $6.5 million, over the $5.8 million recognized in the corresponding period in the prior year. A table reconciling non-GAAP measures is included in this press release for reference.

Financial Results for the Transition Period Ended December 31, 2021, compared to the Six Months Ended December 31, 2020

Revenue increased 37% to $14.0 million, compared to $10.2 million in the corresponding period in the prior year. RECELL® commercial revenues were $13.8 million, while RECELL revenues associated with U.S. Department of Health and Human Services' Biomedical Advanced Research and Development Authority within the Office of the Assistant Secretary for Preparedness and Response ("**BARDA**") were $0.2 million. Revenues associated with BARDA were attributable to our services over the vendor managed inventory for RECELL units purchased in the prior year.

Gross profit margin was 86% compared with 83% in the corresponding period in the prior year, driven largely by the extension of our shelf-life.

Total operating expenses increased 7% to $27.1 million, compared to $25.3 million in the corresponding period in the prior year. The increase in operating expenses was primarily driven by ongoing development of a next generation automated skin preparation device, pre-commercialization planning for RECELL launches in soft tissue reconstruction and vitiligo, as well as increased hands-on professional education and training events. These higher costs were partially offset by certain one-time professional services to establish the Company as a domestic filer with the SEC following completion of the AVITA corporate group's redomiciliation to the United States, and severance costs associated with a former executive employee incurred in the prior year.

Net loss decreased 9%, or $1.5 million to $14.4 million compared to the $15.9 million recognized in the corresponding period in the prior year. The decrease in net loss was driven by higher revenue during the year, partially offset by higher operating expenses as described above.

Adjusted EBITDA* loss decreased by 17%, or $2.1 million to $10.4 million compared to $12.5 million recognized over the corresponding period in the prior year. A table reconciling non-GAAP measures is included in this press release for reference.

Calendar Year 2022 Revenue Guidance

Total revenues in calendar year 2022 are projected to be approximately $30 million, excluding BARDA revenues, which represents a 20% increase year-over year. We project BARDA revenues of approximately $0.3 million in calendar year 2022, as compared to $7.9 million in calendar year 2021, since we completed delivery of RECELL units into the national stockpile in 2021. As we emerge from COVID-19, we expect further RECELL adoption in US burn centers where we are focusing our commercial efforts. The adoption of RECELL, and its positive patient outcomes and safety profile, positions us very well for broader commercial expansion planned for soft tissue reconstruction and vitiligo indications in the second half of 2023 following anticipated FDA approval.

* Adjusted EBITDA is a non-GAAP financial measure. See the appendix to this release for a discussion of Non-GAAP financial measures, including a reconciliation to the most closely correlated GAAP measure.

Authorized for release by the Chief Financial Officer of AVITA Medical, Inc.

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ABOUT AVITA Medical, Inc.

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

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

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

To learn more, visit www.avitamedical.com.

Use of Non-GAAP Measure

AVITA Medical's reported earnings are prepared in accordance with generally accepted accounting principles in the United States, or GAAP, and represent earnings as reported to the Securities and Exchange Commission. AVITA Medical has provided in this release certain financial information that has not been prepared in accordance with

GAAP. AVITA Medical's management believes that the non-GAAP adjusted EBITDA described in the release, which includes adjustments for specific items that are generally not indicative of our core operations, provides additional information that is useful to investors in understanding AVITA Medical's underlying performance, business and performance trends, and helps facilitate period-to-period comparisons and comparisons of its financial measures with other companies in AVITA Medical's industry. However, the non-GAAP financial measures that AVITA Medical uses may differ from measures that other companies may use. Non-GAAP financial measures are not required to be uniformly applied, are not audited and should not be considered in isolation or as substitutes for results prepared in accordance with GAAP.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This press release includes forward-looking statements. These forward-looking statements generally can be identified by the use of words such as "anticipate," "expect," "intend," "could," "may," "will," "believe," "estimate," "look forward," "forecast," "goal," "target," "project," "continue," "outlook," "guidance," "future," other words of similar meaning and the use of future dates. Forward-looking statements in this press release include, but are not limited to, statements concerning, among other things, our ongoing clinical trials and product development activities, regulatory approval of our products, the potential for future growth in our business, and our ability to achieve our key strategic, operational, and financial goals. Forward-looking statements by their nature address matters that are, to different degrees, uncertain. Each forward- looking statement contained in this press release is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statement. Applicable risks and uncertainties include, among others, the timing of regulatory approvals of our products; physician acceptance, endorsement, and use of our products; failure to achieve the anticipated benefits from approval of our products; the effect of regulatory actions; product liability claims; risks associated with international operations and expansion; and other business effects, including the effects of industry, economic or political conditions including, but not limited to the ongoing COVID-19 pandemic which are outside of the company's control. Investors should not place considerable reliance on the forward-looking statements contained in this press release. Investors are encouraged to read our publicly available filings for a discussion of these and other risks and uncertainties. The forward-looking statements in this press release speak only as of the date of this release, and we undertake no obligation to update or revise any of these statements.

FOR FURTHER INFORMATION:

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

	As of		
	December 31, 2021	**June 30, 2021**	**June 30, 2020**
ASSETS			
Cash and cash equivalents	$ 55,511	$ 110,746	$ 73,639
Marketable securities	29,649	—	—
Accounts receivable, net	3,118	3,467	2,076
BARDA receivables	308	3,936	356
Prepaids and other current assets	1,213	1,333	990
Restricted cash	201	201	201
Inventory	2,132	1,647	1,125
Total current assets	92,132	121,330	78,387
Marketable securities long-term	19,692	—	—
Plant and equipment, net	1,262	1,458	1,363
Operating lease right-of-use assets	1,544	1,480	2,347
Intangible assets, net	443	472	364
Other long-term assets	942	761	1
Total assets	$ 116,015	$ 125,501	$ 82,462
LIABILITIES AND SHAREHOLDERS' EQUITY			
Accounts payable and accrued liabilities	2,708	3,120	4,333
Accrued wages and fringe benefits	5,363	3,321	2,816
Other current liabilities	1,075	949	560
Total current liabilities	9,146	7,390	7,709
Contract liabilities	952	1,075	435
Operating lease liabilities, long term	918	878	1,917
Other long-term liabilities	375	503	—
Total liabilities	11,391	9,846	10,061
Contingencies (Note 10)			
Shareholders' Equity:			
Common stock, $0.0001 par value per share, 200,000,000 shares authorized, 24,925,743 and 24,895,864 shares issued and outstanding at December 31, 2021 and June 30, 2021, respectively	3	3	3
Preferred stock, $0.0001 par value per share, 10,000,000 shares authorized, no shares issued or outstanding at June 30, 2021 and June 30, 2020	—	—	—
Additional paid-in capital	332,484	328,889	259,165
Accumulated other comprehensive income	8,060	8,259	8,146
Accumulated deficit	(235,923)	(221,496)	(194,913)
Total shareholders' equity	104,624	115,655	72,401
Total liabilities and shareholders' equity	$ 116,015	$ 125,501	$ 82,462

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

	Three-months ended December 31, 2021	Three-months ended December 31, 2020	Transition Period July 1 – December 31, 2021	Six-Month Period July 1 – December 31, 2020
Revenues	$ 6,936	$ 5,103	$ 13,956	$ 10,163
Cost of sales	(817)	(821)	(1,905)	(1,750)
Gross profit	6,119	4,282	12,051	8,413
BARDA income	206	449	580	1,045
Operating expenses:				
Sales and marketing expenses (1)	(4,954)	(3,600)	(8,472)	(6,865)
General and administrative expenses (1)	(5,647)	(3,401)	(10,996)	(11,703)
Research and development expenses (1)	(4,198)	(3,361)	(7,586)	(6,735)
Total operating expenses	(14,799)	(10,362)	(27,054)	(25,303_
Operating loss	(8,474)	(5,631)	(14,423)	(15,845)
Interest expense	(8)	(3)	(17)	(10)
Other income	22	4	38	8
Loss before income taxes	(8,460)	(5,630)	(14,402)	(15,847)
Income tax benefit/(expense)	(19)	(11)	(25)	(21)
Net loss	$ (8,479)	$ (5,641)	$ (14,427)	$ (15,868)
Net loss per common share:				
Basic	$ (0.34)	$ (0.26)	$ (0.58)	$ (0.74)
Diluted	$ (0.34)	$ (0.26)	$ (0.58)	$ (0.74)
Weighted-average common shares:				
Basic	24,925,424	21,623,509	24,915,414	21,563,576
Diluted	24,925,424	21,623,509	24,915,414	21,563,576

(1) Includes share-based compensation expense as noted in table below.

	Three-months ended December 31, 2021	Three-months ended December 31, 2020	Transition Period July 1 – December 31, 2021	Six-Month Period July 1 – December 31, 2020
Sales and marketing expenses	372	294	663	624
General and administrative expenses	1,067	(774)	2,318	1,992
Research and development expenses	307	134	607	304
Total operating expenses	1,746	(346)	3,588	2,920

Reconciliation of reported Net Loss (GAAP) to Adjusted EBIDTA (NON-GAAP) Measure – Unaudited

	Three-months ended December 31, 2021	Three-months ended December 31, 2020	Transition Period Ended July 1 - December 31, 2021	Six-Month Period July 1 - December 31, 2020
Net loss	$ (8,479)	$ (5,641)	$ (14,427)	$ (15,868)
Depreciation Expense	127	135	274	324
Patent Amortization	32	27	56	49
Share Based Payment Expense	1,746	(346)	3,588	2,920
Interest Expense	9	3	17	10
Income Tax Expense	19	11	25	21
Adjusted EBITDA (Non-GAAP)	$ (6,546)	$ (5,811)	$ (10,467)	$ (12,544)