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 11, 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 August 11, 2022, AVITA Medical, Inc. (the "Company") issued a press release announcing financial results for its second quarter ended June 30, 2022, as well as certain additional business information. A copy of the press release is attached hereto as Exhibit 99.1.

Item 8.01. Other Events.

Also on August 11, 2022, the Company issued a press release announcing topline results from its pivotal randomized, controlled trial evaluating the safety and effectiveness of the RECELL System combined with meshed autograft for reduction of donor skin harvesting in soft tissue reconstruction. A copy of the press release is attached hereto as Exhibit 99.2.

The information under Item 2.02, Item 8.01 and in Item 9.01 below is being furnished and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 and shall not be deemed incorporated by reference into any filing made under the Securities Act of 1933 except as expressly set forth by a specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	AVITA Medical Reports Second Quarter 2022 Financial Results
99.2	AVITA Medical Announces Topline Results from Pivotal Trial in Patients with Soft-Tissue Injuries using the RECELL® System
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: August 12, 2022

AVITA MEDICAL, INC.

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

AVITA Medical Reports Second Quarter 2022 Financial Results

VALENCIA, California, August 11, 2022 and MELBOURNE, Australia, August 12, 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 financial results for its second quarter ended June 30, 2022.

Second Quarter Highlights and Recent Updates:

- Reported commercial revenue, which excludes BARDA revenue, of $8.2 million a 23% increase compared to $6.7 million in the corresponding period in the prior year
- Reported total revenue, which includes BARDA revenue, of $8.3 million compared to $10.3 million in the corresponding period in the prior year, which included $3.6 million in BARDA revenue
- Gross profit margin improved by 3% to 83% compared corresponding period in the prior year
- Topline results from its pivotal randomized controlled trial evaluating the safety and effectiveness of the RECELL® System for healing of soft tissue reconstruction with reduced donor skin
- As of June 30, 2022, the Company had $91.1 million in cash, cash equivalents, and marketable securities, with no debt

Year to date Highlights:

- Reported commercial revenue, which excludes BARDA revenue, of $15.7 million, a 39% increase compared to $11.3 million in the corresponding period in the prior year
- Reported total revenue, which includes BARDA revenue, of $15.9 million compared to $19.1 million in the corresponding period in the prior year, which included $7.8 million in BARDA revenue
- Gross profit margin improved by 2% to 80% compared to the corresponding period in the prior year

"Our commercial team continued to drive further RECELL utilization and penetration within burn centers, and our clinical team advanced our soft tissue reconstruction and vitiligo trials," said Dr. Mike Perry, AVITA Medical Chief Executive Officer. "We look forward to topline data from our vitiligo clinical trial in the second half of this year."

Three Months Ended June 30, 2022 Financial Results

Our commercial revenue, which excludes BARDA revenue, was $8.2 million in the three months ended June 30, 2022, an increase of $1.5 million or 23%, compared to $6.7 million the corresponding period in the prior year. Total revenue, which includes BARDA revenue, was $8.3 million in the second quarter compared to $10.3 million in the corresponding period in the prior year which included $3.6 million in BARDA related revenue that resulted from our delivery of units to managed inventory for BARDA for emergency response preparedness. The growth in commercial revenues was largely driven by an increase in the number of customers ordering as well as the average order size for those customers.

Gross profit margin improved by 3% to 83% compared to the corresponding period in the prior year.

Total operating expenses increased by 3% to $13.9 million compared to $13.4 million in the corresponding period in the prior year. The increase in operating expenses is primarily attributable to higher compensation costs, sales commissions, and professional fees, partially offset by lower clinical trial related expenses. Higher compensation costs resulted from an expansion of our commercial team, while higher commissions were driven by an increase in revenues. Higher professional fees are driven by an increase in pre-commercialization activities for RECELL launches in soft tissue reconstruction and vitiligo. Clinical trial expenses incurred in our soft tissue and vitiligo trials were lower during the period, as the trial participants were in the follow-up phase which is less costly than the earlier recruitment and treatment phase.

Net loss increased by 33% or $1.5 million to $6.3 million, or $0.25 per share, compared to a net loss of $4.7 million, or $0.19 per share, in the corresponding period of the prior year.

Adjusted EBITDA* loss increased by 51%, or $1.6 million to $4.7 million, over the $3.1 million recognized in the corresponding period in the prior year. A table reconciling non-GAAP measures is included in this press release for reference.

Six Months Ended June 30, 2022, Financial Results

Our commercial revenue, which excludes BARDA revenue, was $15.7 million in the six months ended June 30, 2022, an increase of $4.4 million or 39%, compared to $11.3 million in the corresponding period in the prior year. Total revenue, which includes BARDA revenue, was $15.9 million in the current year compared to $19.1 million in the corresponding period in the prior year which included $7.7 million in BARDA related revenue that resulted from our delivery of units to managed inventory for BARDA for emergency response preparedness. The growth in commercial revenues was largely driven by an increase in the number of customers ordering as well as the average order size for those customers.

Gross profit margin improved by 2% to 80% compared to the corresponding period in the prior year.

Total operating expenses increased by 12% to $29.9 million compared to $26.6 million in the corresponding period in the prior year. The increase in operating expenses is primarily attributable to higher compensation costs and professional fees, partially offset by lower clinical trial related expenses. Higher compensation costs were primarily a result of increased share-based compensation expenses due to certain performance milestones being met, higher commissions driven by an increase in revenues, and an expansion of our commercial team. Increased professional fees were driven by an increase in pre-commercialization costs for RECELL launches in soft tissue reconstruction and vitiligo. Research and development expenses were lower relative to the prior year during which higher costs were incurred relating to recruitment and treatment for the soft tissue and vitiligo clinical trials.

Net loss increased by 47% or $5.0 million to $15.7 million, or $0.63 per share, compared to a net loss of $10.7 million, or $0.45 per share, in the corresponding period of the prior year.

Adjusted EBITDA* loss increased by 46%, or $3.5 million to $11.1 million, over the $7.6 million recognized in 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

Commercial 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.

*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.

Webcast and Conference Call Information

The Company will host a conference call to discuss the second quarter financial results after market close on Thursday August 11, 2022, at 2:00 p.m. Pacific Time / 5:00 p.m. Eastern Time (being 7.00 a.m. Australian Eastern Standard Time on Friday August 12, 2022). To access the live call via telephone, please register in advance using the link here. Upon registering, each participant will receive an email confirmation with dial-in numbers and a unique personal PIN that can be used to join the call. The live webinar can be accessed at https://ir.avitamedical.com.

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.'s patented, and proprietary collection and application technology provides innovative treatment solutions derived from the regenerative properties of a patient's own skin. The Company's lead product is the RECELL® System, a device that enables healthcare professionals to Spray-On Skin™ Cells using a small sample of the patient's own skin to create an autologous suspension. The RES® Regenerative Epidermal Suspension™ is then sprayed onto the areas of the patient requiring treatment to regenerate natural healthy epidermis.

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. In February 2022, the FDA reviewed and approved the PMA supplement for RECELL Autologous Cell Harvesting Device, an enhanced RECELL System aimed at providing clinicians a more efficient user experience and simplified workflow.

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 15,000 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 approved 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, received CE-mark approval in Europe, and received Japan's Pharmaceuticals and Medical Devices Act (PMDA) approval for burns in Japan.

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 goal. 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 and realization 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 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.
Consolidated Balance Sheets
(In thousands, except share and per share data)
(Unaudited)

	As of	
	June 30, 2022	December 31, 2021
ASSETS		
Cash and cash equivalents	$ 34,737	$ 55,511
Marketable securities	49,618	29,649
Accounts receivable, net	3,884	3,118
BARDA receivables	338	308
Prepaids and other current assets	1,005	1,213
Restricted cash	202	201
Inventory	2,022	2,132
Total current assets	91,806	92,132
Marketable securities, long-term	6,743	19,692
Plant and equipment, net	1,249	1,262
Operating lease right-of-use assets	1,203	1,544
Intangible assets, net	428	443
Other long-term assets	1,240	942
Total assets	$ 102,669	$ 116,015
LIABILITIES AND SHAREHOLDERS' EQUITY		
Accounts payable and accrued liabilities	2,495	2,708
Accrued wages and fringe benefits	4,174	5,363
Other current liabilities	1,217	1,075
Total current liabilities	7,886	9,146
Contract liabilities	813	952
Operating lease liabilities, long-term	532	918
Other long-term liabilities	715	375
Total liabilities	9,946	11,391
Non-qualified deferred compensation share awards	163	—
Contingencies (Note 12)		
Shareholders' Equity:		
Common stock, $0.0001 par value per share, 200,000,000 shares authorized, 25,003,088 and 24,925,743 shares issued and outstanding at June 30, 2022 and December 31, 2021, respectively	3	3
Preferred stock, $0.0001 par value per share, 10,000,000 shares authorized, no shares issued or outstanding at June 30, 2022 and December 31, 2021	—	—
Additional paid-in capital	336,668	332,484
Accumulated other comprehensive income	7,536	8,060
Accumulated deficit	(251,647)	(235,923)
Total shareholders' equity	92,560	104,624
Total liabilities and shareholders' equity	$ 102,669	$ 116,015

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Revenues	$ 8,335	$ 10,304	$ 15,874	$ 19,069
Cost of sales	(1,386)	(2,053)	(3,164)	(4,199)
Gross profit	6,949	8,251	12,710	14,870
BARDA income	551	440	1,285	1,010
Operating expenses:				
Sales and marketing expenses*	(5,332)	(4,146)	(10,160)	(7,795)
General and administrative expenses*	(5,471)	(5,275)	(13,005)	(10,697)
Research and development expenses*	(3,059)	(3,974)	(6,679)	(8,083)
Total operating expenses	(13,862)	(13,395)	(29,844)	(26,575)
Operating loss	(6,362)	(4,704)	(15,849)	(10,695)
Interest expense	(4)	(9)	(4)	(12)
Other income	109	2	137	9
Loss before income taxes	(6,257)	(4,711)	(15,716)	(10,698)
Income tax expense	(4)	(7)	(8)	(17)
Net loss	$ (6,261)	$ (4,718)	$ (15,724)	$ (10,715)
Net loss per common share:				
Basic	$ (0.25)	$ (0.19)	$ (0.63)	$ (0.45)
Diluted	$ (0.25)	$ (0.19)	$ (0.63)	$ (0.45)
Weighted-average common shares:				
Basic	24,971,243	24,860,738	24,954,712	23,803,460
Diluted	24,971,243	24,860,738	24,954,712	23,803,460

* Total operating expenses include impact of share-based compensation as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Sales and marketing expenses	$ 285	$ 63	$ 614	$ 301
General and administrative expenses	983	1,172	3,310	2,102
Research and development expenses	146	175	422	340
Total	1,414	1,410	4,346	2,743

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Net Loss	$ (6,261)	$ (4,718)	$ (15,724)	$ (10,715)
Depreciation expense	129	145	258	282
Patent Amortization	8	31	42	61
Share-based expense	1,414	1,410	4,346	2,743
Interest Expense	4	9	4	12
Income Tax Expense	4	7	8	17
Adjusted EBITDA (Non-GAAP)	$ (4,702)	$ (3,116)	$ (11,066)	$ (7,600)

PR 08112022

AVITA Medical Announces Topline Results from Pivotal Trial in Patients with Soft-Tissue Injuries using the RECELL® System

- *AVITA Medical plans to submit PMA supplement for this new indication to FDA by the end of 2022*

VALENCIA, Calif. and MELBOURNE, Australia, 11 AUGUST 2022 — AVITA Medical, Inc. (NASDAQ: RCEL, ASX: AVH) (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 announced topline results from its pivotal randomized, controlled trial evaluating the safety and effectiveness of the RECELL System combined with meshed autograft for reduction of donor skin harvesting in soft tissue reconstruction. Injuries considered for the clinical trial included any full-thickness acute skin defect, such as degloving or peeled back skin injuries, road rash, surgical wounds, and flesh-eating disease.

“Soft-tissue injuries can be challenging to treat and I am very pleased with the outcomes using RECELL – especially the use of less donor skin when treating a variety of injuries,” said Dr. Steven E. Mapula, Assistant Professor of Surgery TCU and Division Chief of Plastic Surgery at John Peter Smith Hospital. “Following FDA approval, I look forward to utilizing RECELL broadly to help patients with a wide variety of soft-tissue injuries.”

The study design included co-primary endpoints, based on pairwise comparisons where each subject received both RECELL used in combination with widely-meshed skin grafting and the Control treatment of conventional skin grafting; one endpoint had a hypothesis of superiority for donor skin sparing and the other co-primary endpoint had a hypothesis of non-inferiority for healing. Preliminary review of adverse events shows consistency with our years of prior RECELL experience, reinforcing the product’s compelling safety profile. The primary study outcomes are as follows:

- The donor sparing endpoint was met, showing a superior ratio of treated injury area to donor site area ($p<0.001$) with RECELL versus Control
- The healing endpoint did not reach pre-specified statistical non-inferiority, however, observed values for healing with RECELL were the same or slightly better than Control

“Our study has shown statistically superior donor sparing and comparable healing rates for RECELL treatment of soft tissue injuries and we are confident in moving forward with our plan for a PMA submission later this year,” said Dr. Mike Perry, Chief Executive Officer of AVITA Medical. “The RECELL System has been used to effectively treat serious burn injuries and we anticipate that the RECELL System will be well-positioned to treat patients with soft-tissue injuries, pending FDA review and approval.”

The Company also plans to submit detailed results from the trial for peer-reviewed publication.

Skin grafting is the standard of care for soft tissue reconstruction, including post-trauma and post-surgical skin reconstruction. Skin grafting requires the harvesting of donor skin, resulting in an additional wound to the patient. Significant pain, delayed healing, risk of infection, the need for multiple procedures, discoloration and scarring are associated with donor site wounds.[i] The total addressable market (“TAM”) for soft tissue repair is approximately $1 billion and more than twice as large as the TAM for burns. Further, if FDA approved, the existing reimbursement codes utilized for burn treatment with the RECELL System will apply to this indication.

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This press release was authorized by the review committee of AVITA Medical, Inc.

FOR FURTHER INFORMATION:

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PR 08082022

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[i] Ter Horst B, Chouhan G, Moiemen NS, Grover LM. Advances in keratinocyte delivery in burn wound care. Advanced drug delivery reviews. 2018 Jan 1; 123:18-32.