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): May 11, 2023

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 May 11, 2023, AVITA Medical, Inc. (the "Company"), reported financial results for its fiscal quarter ended March 31, 2023, and certain other business updates. In conjunction with the report, the Company released a press release attached hereto as Exhibit 99.1. A transcript of the conference call discussing the Company's financial results is furnished hereto as Exhibit 99.2.

The information in Item 2.02 of this Current Report on Form 8-K and Exhibits 99.1 and 99.2 attached hereto is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (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 or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 5.02. Departure of Directors or Certain Officers.

Effective May 11, 2023, Ms. Erin Liberto, the Company's Chief Commercial Officer, resigned from her position and accepted a role with a privately held, non-competitive business. The Company will discontinue the role of Chief Commercial Officer.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description of Exhibit
99.1	Press release issued by the Company dated May 11, 2023
99.2	Transcript of conference call of the Company, dated May 11, 2023
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: May 12, 2023

AVITA MEDICAL, INC.

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

AVITA Medical Reports First Quarter Financial Results and Affirms Full Year Guidance

VALENCIA, California, May 11, 2023 and MELBOURNE, Australia, May 12, 2023 — AVITA Medical, Inc. (NASDAQ: RCEL, ASX: AVH) (the "**Company**"), a regenerative medicine company leading the development and commercialization of first-in-class devices and autologous cellular therapies for skin restoration, today reported financial results for the first quarter March 31, 2023.

Financial Highlights and Recent Updates

- Commercial revenue, which excludes BARDA revenue, of $10.5 million, a 40% increase compared to $7.4 million for the same period in 2022
- Total revenue, which includes BARDA revenue, of $10.6 million, a 40% increase compared to $7.5 million for the same period in 2022
- Gross profit margin was 84% compared to 76% in the same period in 2022
- Expanded field sales organization from 30 to 69, towards our goal of 70
- Automated disaggregation device, RECELL GO™, maintains the Food and Drug Administration (FDA) Breakthrough Device designation
- Appointed two independent members to the Board of Directors, Cary Vance and Robert McNamara
- As of March 31, 2023, $77.6 million in cash, cash equivalents, and marketable securities, with no debt

"With a solid first quarter, we are on track to deliver a year of significant growth revenue," said Jim Corbett, AVITA Medical Chief Executive Officer. "The onboarding and training of our expanded U.S. field sales organization is underway, and we believe we will be fully prepared for the commercial launch of the soft tissue repair indication following expected FDA approval in June. Further, we are on track to submit our PMA supplement to the FDA for RECELL GO by the end of the second quarter. We believe RECELL GO is a critical component of our platform and has the potential to significantly accelerate our growth trajectory."

Future Milestones

- Expect FDA approval for soft tissue repair indication in June 2023 followed by the commercial launch on July 1, 2023
- Anticipate FDA submission of RECELL GO by June 30, 2023
- Expect FDA approval for vitiligo indication in June 2023; pursuing site of service reimbursement for the use of RECELL in the physician office setting, which is expected by 2025

Financial Guidance

- Commercial revenue, which excludes BARDA revenue, for the second quarter 2023 is expected to be in the range of $10.7 to $11.7 million
- Commercial revenue, which excludes BARDA revenue, for the full year 2023, remains unchanged, and is expected to be in the range of $49 to $51 million

Organizational Update

Mr. Terry Bromley has been promoted to Senior Vice President of Global Sales and Ms. Debbie Garner has been promoted to Senior Vice President of Global Marketing and Strategy. Mr. Bromley and Ms. Garner will report directly to Jim Corbett, Chief Executive Officer of AVITA Medical.

On May 11, 2023, Ms. Erin Liberto resigned from her position as Chief Commercial Officer to accept a role with a privately held, non-competing business.

First Quarter 2023 Financial Results

Our commercial revenue, which excludes BARDA revenue, increased by 40% to $10.5 million in the three-months ended March 31, 2023, compared to $7.4 million in the same period in 2022. Total revenue, which includes BARDA revenue, increased by 40% to $10.6 million compared to $7.5 million in the same period in 2022.

The gross profit margin was increased by 8% to 84% compared to 76% for the first quarter of 2022.

Total operating expenses for the quarter increased by 22% to $19.4 million, compared to $16.0 million in the same period in 2022, primarily due to increased field expansion and continued development of the RECELL GO device for the planned submission in June 2023.

Net loss decreased by 3% to $9.2 million, or $0.37 per share, compared to a net loss of $9.5 million, or $0.38 per share, in the same period in 2022.

Adjusted EBITDA* loss remained flat at $6.4 million.

Webcast and Conference Call Information

The Company will host a conference call to discuss the first quarter financial results and, recent business highlights on Thursday, May 11, 2023, at 1:30 p.m. Pacific Time (being Friday, May 12, 2023, at 6:30 a.m. Australian Eastern Daylight Standard Time). 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. A simultaneous webcast of the call will be available via the Company's website at https://ir.avitamedical.com.

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

# # #

ABOUT AVITA MEDICAL, INC.

AVITA Medical® is a regenerative medicine company leading the development and commercialization of devices and autologous cellular therapies for skin restoration. The RECELL® System technology platform, approved by the FDA for the treatment of acute thermal burns in both adults and children, harnesses the regenerative properties of a patient's own skin to create Spray-On Skin™ cells. Delivered at the point-of-care, RECELL enables improved clinical outcomes and validated cost savings. RECELL is the catalyst of a new treatment paradigm and AVITA Medical is leveraging its proven and differentiated capabilities to develop first-in-class cellular therapies for multiple indications, including soft tissue repair and repigmentation of stable vitiligo lesions.

AVITA Medical's 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, soft tissue repair, vitiligo, and aesthetics. The RECELL System is TGA-registered in Australia, received CE-mark approval in Europe and has PMDA approval 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 statements. 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:

Investors & Media
AVITA Medical, Inc.
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AVITA MEDICAL, INC.
Consolidated Balance Sheets
(In thousands, except share and per share data)
(Unaudited)

	As of March 31, 2023	As of December 31, 2022
ASSETS		
Cash and cash equivalents	$ 28,050	$ 18,164
Marketable securities	45,401	61,178
Accounts receivable, net	4,502	3,515
BARDA receivables	516	898
Prepaids and other current assets	1,481	1,578
Inventory	2,811	2,125
Total current assets	82,761	87,458
Marketable securities long-term	4,189	6,930
Plant and equipment, net	1,333	1,200
Operating lease right-of-use assets	1,815	851
Corporate-owned life insurance asset	1,833	1,238
Intangible assets, net	461	465
Other long-term assets	230	122
Total assets	$ 92,622	$ 98,264
LIABILITIES, NON-QUALIFIED DEFERRED COMPENSATION PLAN SHARE AWARDS AND STOCKHOLDERS' EQUITY		
Accounts payable and accrued liabilities	3,752	3,002
Accrued wages and fringe benefits	3,665	6,623
Current non-qualified deferred compensation liability	2,140	78
Other current liabilities	1,929	990
Total current liabilities	11,486	10,693
Non-qualified deferred compensation liability	1,165	1,270
Contract liabilities	382	698
Operating lease liabilities, long term	1,235	306
Total liabilities	14,268	12,967
Non-qualified deferred compensation plan share awards	793	557
Contingencies (Note 12)		
Stockholders' equity:		
Common stock, $0.0001 par value per share, 200,000,000 shares authorized, 25,327,761 and 25,208,436 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	3	3
Preferred stock, $0.0001 par value per share, 10,000,000 shares authorized, no shares issued or outstanding at March 31, 2023 and December 31, 2022.	—	—
Company common stock held by the non-qualified deferred compensation plan	(892)	(127)
Additional paid-in capital	342,400	339,825
Accumulated other comprehensive income	7,858	7,627
Accumulated deficit	(271,808)	(262,588)
Total stockholders' equity	77,561	84,740
Total liabilities, non-qualified deferred compensation plan share awards and stockholders' equity	$ 92,622	$ 98,264

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

	Three- Months Ended	
	March 31, 2023	March 31, 2022
Revenues	$ 10,550	$ 7,539
Cost of sales	(1,667)	(1,778)
Gross profit	8,883	5,761
BARDA income	627	734
Operating expenses:		
Sales and marketing expenses	(6,540)	(4,828)
General and administrative expenses	(8,295)	(7,534)
Research and development expenses	(4,586)	(3,620)
Total operating expenses	(19,421)	(15,982)
Operating loss	(9,911)	(9,487)
Interest expense	(4)	—
Other income	725	28
Loss before income taxes	(9,190)	(9,459)
Provision for income tax	(30)	(4)
Net loss	$ (9,220)	$ (9,463)
Net loss per common share:	$ (0.37)	$ (0.38)
Basic	$ (0.37)	$ (0.38)
Diluted		
Weighted-average common shares:	25,202,088	24,937,999
Basic	25,202,088	24,937,999
Diluted		

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

	Three-Months Ended	
(In thousands)	March 31, 2023	March 31, 2022
Sales and marketing expenses	$ 325	$ 329
General and administrative expenses	2,090	2,327
Research and development expenses	225	276
Total	$ 2,640	$ 2,932

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

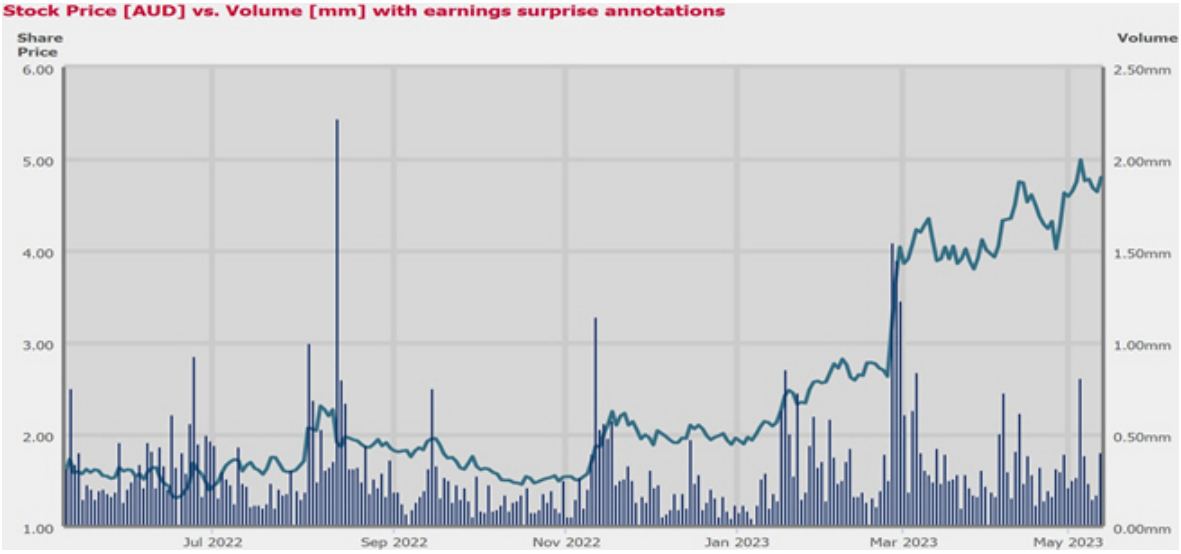
(In thousands)	Three-Months Ended March 31, 2023	March 31, 2022
Net Loss	$ (9,220)	$ (9,463)
Depreciation expense	126	129
Patent Amortization	9	34
Share-based expense	2,640	2,932
Interest Expense	4	—
Income Tax Expense	30	4
Adjusted EBITDA (Non-GAAP)	$ (6,411)	$ (6,364)

S&P Global
Market Intelligence

AVITA Medical, Inc. ASX:AVH
FQ1 2023 Earnings Call Transcripts
Thursday, May 11, 2023 8:30 PM GMT
S&P Global Market Intelligence Estimates

	-FQ1 2023-			-FQ2 2023-	-FY 2023-	-FY 2024-
	CONSENSUS	ACTUAL	SURPRISE	CONSENSUS	CONSENSUS	CONSENSUS
EPS Normalized	(0.37)	(0.55)	NM	(0.52)	(0.63)	(0.31)
Revenue (mm)	15.37	15.76	2.54	17.35	71.39	100.56

Currency: AUD
Consensus as of Apr-17-2023 11:04 AM GMT



	- EPS NORMALIZED -		
	CONSENSUS	ACTUAL	SURPRISE
FQ2 2022	(0.40)	(0.35)	NM
FQ3 2022	(0.33)	(0.33)	NM
FQ4 2022	(0.38)	(0.31)	NM
FQ1 2023	(0.37)	(0.55)	NM

Contents

Table of Contents

Call Participants

EXECUTIVES

James M. Corbett
CEO, President & Executive Director

Jessica Ekeberg

Sean Ekins
Interim CFO & Senior VP of Finance

ANALYSTS

Joshua Thomas Jennings
TD Cowen, Research Division

Ryan Benjamin Zimmerman
BTIG, LLC, Research Division

Unknown Analyst

Presentation

Operator

Good day and thank you for standing by. Welcome to the AVITA Medical, Inc., First Quarter 2023 Earnings Conference Call. At this time, our participants are in a listen-only mode. After the speaker's presentation, there will be a question-and-answer session. [Operator Instructions.] Please be advised that today's conference is being recorded. I would now like to turn the call over to Jessica Ekeberg, Investor Relations. Please go ahead.

Jessica Ekeberg

Thank you, operator. Welcome to AVITA Medical's First Quarter 2023 Earnings Call. Before we begin, let me remind you that this call will include forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements are neither promises nor guarantees and involve known and unknown risks and uncertainties that could cause actual results to differ materially from any expectations expressed or implied by the forward-looking statements. Please review AVITA Medical's most recent filings with the SEC, specifically the risk factors described within the Form 10-Q for the quarter ended March 31, 2023, for additional information. Any forward-looking statements provided during this call are based on management's expectations as of today.

AVITA Medical's press release with the first quarter 2023 results is available on our website, www.avitamedical.com under the Investors section. A recording of today's call will be available on our website by 5:00 p.m. Pacific Time today. Joining me on today's call are Jim Corbett, Chief Executive Officer and Sean Ekins, acting Chief Financial Officer. I will now turn the call over to Jim for his comments.

James M. Corbett
CEO, President & Executive Director

Thank you, Jessica. Good afternoon, everyone, and thank you for joining us today. I will begin today's call by discussing highlights of the first quarter, followed by an update on 2023 priorities. Sean will then provide more detailed commentary on our financial performance before opening the call to Q&A. We started the year with a solid first quarter with commercial revenue of $10.5 million, which is a 40% increase over the same period in 2022. More importantly, we hit the midpoint of our first quarter guidance, which was expected to be between $10 million and $11 million. This keeps us on track to deliver a year of significant revenue growth, which I will discuss later in the call. As a reminder, commercial revenue includes all global revenue and excludes the $100,000 of BARDA revenue recognized in the quarter.

Our commercial revenue is comprised of two components: U.S. revenue and foreign revenue. As mentioned on prior calls, Japan revenue represents a majority of the foreign revenue line item. Sean will detail the drivers of revenue later in this call. We continue to expand RECELL utilization and to develop scientific data to position RECELL as a standard of care. This is evidenced by our significant presence at the upcoming American Burn Association Annual Meeting next week. This forum mobilizes more than 2,000 burn care professionals and providers of burn products, care and related services to share, discover and advance the field. We're pleased to have five podium presentations and three unique poster presentations this year at the meeting and hope to see some of you there.

Additionally, I'm thrilled to announce the appointment of Terry Bromley as Senior Vice President of Global Sales and Debbie Garner as Senior Vice President of Global Marketing and Strategy. Terry and Debbie are veterans of AVITA Medical, having led our U.S. commercial average the last five years. Both Terry and Debbie will directly report to me. As you may have read in today's earnings release, Erin Liberto has accepted a role with a privately held company. We appreciate her contributions to our business, specifically in her efforts to build an experienced and best-in-class commercial team. On behalf of AVITA Medical, I would like to thank Erin for her work and dedication to our organization.

Moving on to 2023 priorities, which we believe will transform our business and expand our growth trajectory. With respect to our two pending applications with the FDA, our PMA supplement for soft

tissue repair and our PMA application for vitiligo, we remain on track and affirm our expectations of June approvals. With the pending PMA supplement for soft tissue repair, we will leverage our existing infrastructure and meaningfully broaden our acute wounds business. As a reminder, the soft tissue indication uses the same reimbursement codes as burns, thus, we will have access to both in-hospital reimbursement through a DRG and outpatient reimbursement through a transitional pass-through code immediately upon FDA approval for soft tissue indications.

Additionally, of our nearly 150 U.S. burn center partners, approximately half are either Level 1 or Level 2 trauma centers which treat 110,000 or more soft tissue injuries. Since we are already VAC approved in those centers, these facilities will have immediate access to the expanded label upon FDA approval of soft tissue repair. To maximize the soft tissue opportunity, last quarter, we announced the expansion of our U.S. field sales organization. In the first quarter, we initiated our expansion plan and began the recruiting and hiring process. We are extremely pleased with our recruitment efforts. As of today, we are ahead of schedule and only have three positions left to fill of the over 40 that we were seeking to add. Additionally, we are underway with the onboarding and training process Further, we reorganized our sales regions, which expanded the regions from two to eight. This has been done in front of the expected June PMA supplement for soft tissue repair, so that the team is in place and trained at launch.

As noted last quarter, this will result in a peak operating expense as a percent of revenue in Q3 2023. However, I emphasize that our contribution margin on a new field sales professional is breakeven with approximately five RECELL kits sold per month per individual. Currently, the average productivity of a direct sales rep exceeds 20 kits per month. This is what I call weaponizing our gross profit to enhance market adoption and penetration where the sales force pays for itself quickly. Given this update, we maintain our expectation of a full commercial launch of soft tissue on July 1, 2023, assuming June approval. For the Vitiligo indication, we are in the process of pursuing reimbursement to allow for in-office use of RECELL. As mentioned on our last call, is in our goal to secure reimbursement by 2025. During the interim period, we will be implementing cash paid for vitiligo patients and physician sponsored studies to build our podium presence.

Now an update on our automation device. Last month, we confirmed that this device now branded as RECELL [GO], maintains the FDA breakthrough device designation for the treatment of acute wounds. RECE GO represents an evolution of the existing RECELL technology and is designed to automate the process of cell disaggregation. Automating the cell disaggregation process will substantially reduce training requirements, allowing us to leverage selling time more effectively. Additionally, it will ease the burden of additional training required by physicians and operating room staff to manually perform disaggregation, leading to increased adoption. RECELL GO is a critical component of our platform, and we believe it will greatly accelerate our growth. We plan to submit our PMA supplement application to the FDA by June 30 of this year. Under the breakthrough device program, the submission will receive prioritized interactive review with an expected January 24 approval. Our dedication to RECELL GO further reflects our continued commitment to innovation and patient care.

With respect to 2023 guidance, for the second quarter of 2023, we expect commercial revenues to be between $10.7 million and $11.7 million. At the midpoint of this guidance, we would be up over 40% over the prior year. We maintain our 2023 annual revenue guidance of $49 million to $51 million, which would be at midpoint of guidance, 47% growth over 2022. In closing, we continue to execute on our 2023 priorities and remain committed to delivering strong results.

With that, I’d like to turn the call over to Sean Ekins, Acting Chief Financial Officer.

Sean Ekins
Interim CFO & Senior VP of Finance

Thank you, Jim. In the three months ended March 31, 2023, our commercial revenue, which excludes part of revenue increased by 40% to $10.5 million compared to $7.4 million in the same period in 2022. The increase in commercial revenue is largely driven by broader surgeon usage as well as deeper penetration, particularly within smaller burn procedures, along with the commencement of commercial sales with our partner, COSMOTEC in Japan. Total revenue, which includes border revenue increased by 40% to $10.6 million compared to $7.5 million in the same period of 2022. [Body] income decreased as reimbursed clinical trial expenditures decreased in the current period as soft tissue and pediatric trial patients largely completed follow-up visits in 2022.

Gross profit margin increased by 8% to 84% compared to 76% in the same period in 2022. Increase in gross profit margin is largely driven by increased production and lower shipping costs. Total operating expenses for the quarter increased by 22% to $19.4 million compared to $16 million in the same period in 2022. The increase in operating expenses is attributable to increased research and development, salaries and benefits, severance costs and selling expenses. Higher research and development expenses were a result of ongoing development of the RECELL GO device with a planned FDA submission in June 2023.

Additionally, we had higher costs associated with the deployment of a team of medical science liaisons in anticipation of our soft tissue launch in July 2023. Salaries and benefits increased concurrently with our strategic plan to expand our commercial sales force ahead of the soft tissue launch. As Jim noted, the expansion of our sales force team will result in additional operating expenses that will peak as a percentage of revenue in Q3 2023.

In the quarter, we incurred severance costs related to two former executive officers. Lastly, higher selling costs are attributable to commissions driven by the increase in our revenues. Net loss decreased by 3% to $9.2 million or $0.37 per share compared to a net loss of $[9.5] million or $0.38 per share in the same period in 2022. Adjusted EBITDA loss stayed flat at $6.4 million. A table reconciling non-GAAP measures is included in today’s press release for reference.

Lastly, I wanted to provide you with an update in regard to our former Commercial Bank, Silicon Valley Bank. We did not encounter any loss of cash or assets as a result of the bank failure. Subsequently, we established a new commercial banking relationship with Bank of America.

With that, we thank you for your time. And now I’ll turn the call back to the operator for your questions.

Question and Answer

Operator

And thank you. [Operator Instructions.] We do ask that you limit yourself to one question and one follow- up. Again, that's one question and one follow-up. One moment for our first question. Our first question comes from Joshua Jennings from TD Cowen.

Joshua Thomas Jennings
TD Cowen, Research Division

Thanks, Jim and Sean. Congrats on the strong start to the year. I was notably impressed by the rapid hiring process and filling all those positions. Those reps typically have their finger on the pulse of opportunities as a validating signal. Can you just talk about — I think we talked about this a little bit on the last earnings call, but the quality of the reps where they're coming from, for one. Do you think it's validating signal to fill good positions so quickly? And then three, in terms of guidance and the potential opening up of the 30% of the burn market that you don't have access to like where your reps are currently situated, does this pull anything forward in terms of that effort in 2023 or should we think about that more impact on 2024. And I have one follow-up.

James M. Corbett
CEO, President & Executive Director

Thanks, Josh. First of all, to your first question, in terms of the quality of the reps, we actually had a very enthusiastic response from the market. And the typical profile came from some other wound and surgical technology companies. And we had multiple candidates for every single role. So, we had a lot of work to do in a very compact time. So, it was really exciting to see the quality of the reps because like you point out, the good reps want to go where the growths going to be. And I think that's what they see with us. So that's was very validating.

With respect to the burns market and getting access to that 30%, I think it's a little bit early for us to project in terms of a tangible way, although we will. We have organized our team such that they've started to make those calls now as we have put them — since we hired them a bit ahead of schedule, we've been able to train them, and then they have been able to start making those calls at those Level 1 trauma centers in order to start the [VAC] process. And it's a little bit early. So therefore, projections aren't quite ready, but I think it's a reasonable assumption that we will start to capture some of those cases as soon as in the third quarter. And as we get momentum, we'll add that to our projections.

Joshua Thomas Jennings
TD Cowen, Research Division

And then just on RECELL GO, I mean, are there — it seems like that program has been almost fully derisked, nothings ever fully derisked with the FDA. But can you just talk about your confidence in terms of the upcoming filing and the time lines for one? And two, just remind us of the gross margin benefit or pricing premium associated with the RECELL GO.

James M. Corbett
CEO, President & Executive Director

Yes. It's a really good set of questions. So, we're inside six weeks from filing approximately. So, we are really in the final validation testing phase. There is a room somewhere that I will not disclose filled with RECELL GO instruments running cycles so that we can validate the cycle time in terms of how many uses per instrument we'll be able to expect. With respect to the financial way to think about this, I'll give you some different elements here because when I give them to you, you will understand what I think the financial outcome really should be, how it really should be framed. We think it's going to cost us about $3,500 to make a RECELL GO instrument. The cassette will be replacing the current RECELL device. So that will be the disposable. But the instrument itself, that $3,500 we project will last approximately 300 uses. And if you just do a little quick math, you would come to the conclusion that, that's about $15 per

use on a $6,500 product with an 83% gross profit. So, the next thing you would come to the conclusion is that each time we place one, its lifetime revenue is approximately $2 million. So, the name of the game here is to make RECELL easy to use for customers to focus on adoption for more and more patients. And I think that is the way the revenue model will benefit.

In terms of the margin model, think about it this way. Last year's gross profit was approximately 83%, half of that gross profit, so half of our cost is fixed overhead. So, over the next year or more, we will double volume. And when we do that, our costs will fall 25%. So, 83% will go to something materially higher. So, we see RECELL GO as the enabler of adoption, the enabler of greater profitability and the enabler of helping more patients get treated with RECELL and live their lives in a more productive way.

Operator

And one moment for our next question. And our next question comes from Matthew O'Brien from Piper Sandler.

Unknown Analyst

This is Phil on for Matt. Congrats on the quarter. Just for starters, can you touch a bit on how Japan — on how much contribution from Japan is baked into guidance here? And I understand this might be a bit further off, but any update on getting the process started for label expansion into soft tissue and vitiligo there?

James M. Corbett
CEO, President & Executive Director

Great set of questions. So, we haven't carved out specific guidance with Japan yet. That said, you can see that we're selling to them in consecutive quarters now. We are going through a process with them where we're negotiating the fiscal year for most Japanese businesses is April 1 to April 1. And the original contract, which was negotiated years ago, was rather loosely framed in terms of a lot of the performance parameters. And we're in the process of working with them to create our dependable forward business model where expressing guidance will be more transparent to us and, therefore, allow us to provide that to you. We do only have burns now. We have dates when we will be delivering to them the clinical modules from soft tissue repair and from vitiligo. And the only thing that — and you can almost predict the timing because we wanted to have the FDA scrub first and the BIMO audits that we experienced for vitiligo already completed so that when we sent them the data, it would be basically adjudicated data by FDA. So, there is a schedule underway to do that within the next 30 to 60 days. Following that will be their projected filing date. So, when we have that, which will certainly be sometime in third quarter, we'll be providing that guidance.

Unknown Analyst

Super helpful. And just a two-parter here to end things on vitiligo. First, what are your expectations for the cash pay market post June approval and then the cash pay market post RECELL GO approval in January 2024? And then the second part of that is, can you go into more detail on the path to coverage and when you can initiate the conversation with CMS?

James M. Corbett
CEO, President & Executive Director

Yes. So, in both cases, I think the cash expectations post approval and post RECELL GO are actually going to be quite modest until we have reimbursement, modest enough that we won't provide guidance to them. The reason is that what we're preparing for is reimbursement. And reimbursement has two phases associated with it. One is through the AMA and through CMS and the other is through private payers. So just to highlight for you about that process. I'll give you a little expectation why we're projecting 2025 as when we will have coverage and payment for Vitiligo treatment in office is we're faced with a couple of different things. So, with respect to AMA, CPT process, we're bound by confidentiality to speak about how that process is going because that is part of their requirement, not ours, actually, but it's theirs. And of course, it's in our interest to respect that. That said, getting CMS payment, although important, the

beneficiary who will be treated on average with vitiligo will be about a 40-year-old person. So, it is the coverage policy of private payers that will matter the most. And we are commencing a post-market study that we have planned that we think we can complete and have ready for that time frame that will help private payers understand the health benefits of these patients who are suffering from the disfigurement, particularly the perceived disfigurement they experienced with vitiligo and the associated health impact from that because that quality of life is really where the benefits align medically and from a cost point of view.

So, vitiligo has got some steps to go through. But we're on the track because our FDA approval is the — it works and it's safe. That said, we did use the patient as their same — as they control. And so that's why we're implementing the post-market study with vitiligo where it will not be the patient being treated partially on part of their body with RECELL and another part with the control. Is that helpful?

Operator

[Operator Instructions. Our next question comes from Ryan Zimmerman from BTIG.

Ryan Benjamin Zimmerman
BTIG, LLC, Research Division

I hope you guys are doing well as well. I just want to follow up on a couple of questions here. So just thinking about kind of the near term and the burn market and soft tissue. My first question is just as we think about you moving into soft tissue trauma of the burn surgeons trained today that are using RECELL, do you think it's the same physician population? Or will it require more training to separate trauma surgeons, separate ER physicians, etc., within those existing facilities that you're in today? And I asked that in the context of kind of the ramp in soft tissue revenue as we think about the back half of the year.

James M. Corbett
CEO, President & Executive Director

Okay. Let me give that a shot because I'm going to try to break up your question in pieces, so I get it more clearly in terms of giving you the right answer. In the accounts that we're in now, there are burn surgeons who also function a good part of their time handling other trauma cases, and they will not need to be trained. There are in those same centers at our Level 1 trauma, trauma surgeons who do not treat burns. We will need to train them, but it will be easier to train staff because there'll be some staff in the ER and places where these patients come who are accustomed to using RECELL and will be very helpful in that case. I think that's one of your questions. Is that right?

Ryan Benjamin Zimmerman
BTIG, LLC, Research Division

That's exactly right, Jim. That's very helpful.

James M. Corbett
CEO, President & Executive Director

Yes. Okay. And of course, when we go to Level 1 trauma, we'll be going to hospitals where the trauma surgeon is not usually an exclusive burn surgeon, but treats them often, but generally smaller TBSA injuries. And those physicians will need to be trained, and we are very ramped up to provide that training. That's one of the certification processes of our new more than double field sales organizations that they're able to support and train a physician and support a case in real time. So, they're actually doing that. We have a buddy program as part of our training where the new reps will travel parts of the week with one of our more veteran team and get the opportunity to both be taught, trained, coached and actually support a case in one of the accounts where we already are presently performing RECELL cases. So, we value the support that our field team provides. So, the standard is quite high. And I recently did a survey for another purpose. And it was only 10, but they were blinded interviews they didn't know it was us. And by far and away, our field sales team, we've got such high markets from any other company that these burn surgeons interact with. So that standard is one we intend to keep.

Ryan Benjamin Zimmerman
BTIG, LLC, Research Division

That's great to hear. And it kind of dovetails into my next question, but of the burns treated today, what's your sense of the composition between inpatient versus outpatient burn if you're comfortable sharing? And just how do you think about the guidance either for second quarter or for the year, given the variability of the burn market, and it kind of is a result of just trying to understand the stability and what the state of the burn market is in your view today just because it can change so rapidly.

James M. Corbett
CEO, President & Executive Director

Well, let me see. First of all, it's a couple of different questions. Let me break them apart again. I want to make sure I answer them. In fact, we monitor the admits of burns nationally. We get — we buy the claims data and we, of course, have our own actual experience. And we do not see volatility in the admits. It's quite steady, quite consistent, notwithstanding our increasing sales line, and we're not adding accounts at this moment, right? We have always been targeted just at the burn centers and only just now are pointing our new team and our new redesigned sales territories towards Level 1 trauma. But the burns that are in the burning centers, which is about 70% of them, they seem to be quite consistent. There's no evidence of seasonality, and there's no significant increase nor a significant decrease. It's quite a steady market. So, I think looking forward, and it will be a little bit harder for us to capture precisely as we start selling in a Level 1 trauma center where we're getting RECELL used in many applications, one of which will be burns, that we will get an increasing amount of burns opportunity than we have access to today. And I'm trying to think about whether I got your answer fully or not. So, feel free to ask.

Ryan Benjamin Zimmerman
BTIG, LLC, Research Division

Yes. No, no, that's great. I apologize for the multipart questions this evening. But the other question was just kind of the composition of the business today between inpatient and outpatient. And maybe just how that's kind of ebbing and flowing as you open up the market.

James M. Corbett
CEO, President & Executive Director

Yes. Actually, it's a very interesting question. We, of course, have the transitional pass-through code for use in outpatient. But in fact, the more severe burns that go to the burn centers do not get much of the outpatient activity. There isn't a big — I wouldn't call it a material part of our business today. That said, those smaller burns that are in the Level 1 trauma centers, we fully expect that outpatient activity to increase significantly because that is, in essence, you get a really bad burn, you go to a burn center and if you get a less — a second degree burn perhaps you end up at a Level 1 trauma center. So, I think we'll see that the outpatient for burns increase. But of course, that's also where a lot of the soft tissue cases will go too.

Ryan Benjamin Zimmerman
BTIG, LLC, Research Division

Yes. That's very helpful, Jim.

James M. Corbett
CEO, President & Executive Director

It will be a little bit difficult to count for that reason. Yes.

Operator

Thank you, and I am showing no further questions. This concludes today's conference call. Thank you for participating, and you may now disconnect.