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

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2024

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number: 001-39059

AVITA MEDICAL, INC.

(Exact name of registrant as specified in its charter)

Delaware	**85-1021707**
(State or other jurisdiction of incorporation or organization)	**(IRS Employer Identification No.)**

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

Registrant's telephone number, including area code: (661) 367-9170

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

Title of each class	**Trading Symbol**	**Name of each exchange on which registered**
Common Stock, par value $0.0001 per share	**RCEL**	**Nasdaq Capital Market**

Securities registered pursuant to section 12(g) of the Act:
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer", "accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☒		

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the voting and nonvoting common equity held by non-affiliates of the registrant was approximately $203,434,831 on June 30, 2024, using the closing price on June 28, 2024 of $7.92.

The number of shares of the registrant's $0.0001 par value common stock outstanding as of February 7, 2025 was 26,357,542.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Company's Proxy Statement for the Annual Meeting of Stockholders to be held on June 4, 2025, are incorporated by reference into Part III of this Form 10-K.

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (this "Annual Report") and our other public filings contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements give expectations or forecasts of future events. Forward-looking statements can sometimes, but not always, be identified by words such as "believe," "expect," "anticipate," "contemplate," "continue," "estimate," "goal," "guidance," "forecast," "look forward," "outlook," "predict," "project," "plan," "should," "target," "intend," "may," "will," "would," "potential" and similar expressions to future periods. Forward-looking statements are not based on historical facts but rather represent current expectations and assumptions. Factors that may influence or contribute to the inaccuracy of the forward-looking statements or cause actual results to differ materially from expected or desired results may include, without limitation: uncertainties associated with our expectations regarding future revenue, or future growth in revenue, profit, or gross and/or operating margins; the ability to achieve or sustain profitability; contributions to adjusted EBITDA; industry market conditions; increased competition; changes in our production capacity; failure to obtain, maintain and enforce our intellectual property rights, including our expectations regarding the future scope of such rights; failure to obtain and/or maintain regulatory approvals and comply with applicable regulations; the conduct or outcome of pre-clinical or clinical (human) studies; operational and management restructuring activities; our ability to find and maintain partnerships relating to collaborations, strategic arrangements, and licensing arrangements; mergers and acquisitions (and related integration activities); if third parties fail to uphold their contractual duties or meet expected deadlines; our ability to obtain and maintain favorable coverage and reimbursement determinations from third party payors; market reaction to growth or product initiatives; our ability to expand our sales and marketing organizations to address existing and new markets that we intend to target; market penetration of our products; the ability to continue to scale our manufacturing operations to meet the demand for our products; our ability to attract and retain qualified personnel, including management; solvency; non-compliance with debt covenants, which may result in the acceleration of our debt obligations or the need for renegotiations with our lenders, tax and interest rates; inflationary pressures on the U.S. and global economies, respectively; changes in the legal or regulatory environments; the impact of a cybersecurity breach, terrorist attack or other geopolitical instability, pandemic or epidemic, or natural disaster; and future working capital, costs, productivity, business process, rationalization, investment (including rates), consulting, operational, financial, and capital projects and/or initiatives.

Forward-looking statements relate to the future and are subject to many risks, assumptions and uncertainties, including those risks set forth in this Annual Report in Part I, Item IA Risk Factors and elsewhere. Although we believe the expectations reflected in the forward-looking statements are reasonable, actual results, developments and business decisions could differ materially from those contemplated by such forward-looking statements. The environment in which we operate is highly competitive, regulated and rapidly changing and it is not possible for our management to predict all risks, as new risks emerge from time to time.

All subsequent written and oral forward-looking statements by or attributable to us or persons acting on our behalf are expressly qualified in their entirety by these factors. We undertake no obligation to publicly update or revise any forward-looking statements whether as a result of new information, future developments or otherwise, except as may be required by law.

As used herein, unless the context otherwise requires, references to "we," "our," "us," "the Company," and "AVITA Medical" refer to AVITA Medical, Inc., a Delaware corporation, and its subsidiaries.

Currency

In this Annual Report, all references to "dollars" or "$" are to the currency of the United States.

PART I

Item 1. BUSINESS

OVERVIEW

AVITA Medical is a leading therapeutic acute wound care company delivering transformative solutions. Our technologies are designed to optimize skin restoration procedures, effectively accelerating patient healing and recovery. Our solutions improve the healing outcomes for patients with traumatic injuries and surgical repairs, addressing critical healing needs that arise from unpredictable and life-changing events. Our offerings currently include our core technology platform, RECELL® ("RECELL"), as well as PermeaDerm® and Cohealyx™, each designed to target acute wound care needs.

At the forefront of our portfolio is our patented and proprietary RECELL, approved by the United States Food & Drug Administration ("the "FDA") for the treatment of thermal burn wounds and full-thickness skin defects, and for repigmentation of stable depigmented vitiligo lesions. In 2024, we expanded our product offerings to address additional acute wound care needs. In January, we signed an exclusive multi-year distribution agreement with Stedical Scientific, Inc. ("Stedical") to market, sell, and distribute PermeaDerm, a biosynthetic wound matrix in the U.S. In July, we entered into an exclusive multi-year development and distribution agreement with Regenity Biosciences ("Regenity"), granting us exclusive rights to market, sell, and distribute Cohealyx, an AVITA-medical branded collagen-based dermal matrix in the U.S., with potential expansion into the European Union, Australia, and Japan. These agreements strengthen our commitment to offering a comprehensive suite of solutions for acute wounds.

CORPORATE HISTORY

AVITA Australia, the former parent company of AVITA Medical, was founded in December 1992. On October 1, 2019, AVITA Australia began trading its American Depositary Shares on the Nasdaq Capital Market ("Nasdaq") under the symbol "RCEL". Today, our common stock continues to trade on Nasdaq under "RCEL" and our CHESS Depositary Interests ("CDIs") trade on the Australian Securities Exchange ("ASX") under the symbol "AVH."

STRATEGY

Prior to 2024, our business was centered around our breakthrough RECELL technology. While RECELL remains the cornerstone of our portfolio, we strategically expanded our product offerings in 2024 by adding products complementary to RECELL. These new products address a wider range of clinical needs in acute wound care, enhancing our ability to reach more patients globally, ultimately improving their healing outcomes.

To further our mission of improving clinical outcomes and establishing new standards of acute wound care, we have outlined the following strategic objectives:

- Increase market penetration in U.S. burn centers, positioning RECELL GO® as the standard of care in burn management
- Expand adoption of RECELL GO for the treatment of full-thickness skin defects throughout the U.S
- Begin a targeted RECELL GO mini rollout to trauma and burn centers treating smaller wounds in the first quarter of 2025
- Commence a post-market study of Cohealyx in early 2025 to develop clinical data for commercialization in the second quarter of 2025
- Seek additional business development opportunities complementary to our core RECELL technology and target markets
- Obtain CE mark approval in the first quarter of 2025, allowing us to market RECELL GO in the European Union and Australia under existing distribution agreements
- Continue developing opportunities and strengthening global partnerships to transform patient outcomes worldwide
- Drive commercial revenue growth, generate positive cash flow, and achieve operating profitability

PRODUCT PORTFOLIO

RECELL Technology Platform

At the forefront of our portfolio is our patented and proprietary RECELL technology. RECELL harnesses the regenerative properties of a patient's own skin to create an autologous skin cell suspension, Spray-On Skin™ Cells, delivering a transformative solution at the point of care. This breakthrough technology serves as the catalyst for a new treatment paradigm enabling improved clinical outcomes.

How RECELL Works

The core platform technology of RECELL enables clinicians to harvest a thin split-thickness skin sample from the patient and process it into an autologous cellular suspension, Spray-On Skin Cells. This suspension is prepared at the point of care in as little as 30 minutes and includes the patient's own skin cells, keratinocytes, fibroblasts, and melanocytes, all critical to acute wound healing and repigmentation through the wound bed.

The patented and proprietary platform technology underlying the Spray-On Skin Cells originated in Australia, based on the seminal work of Professor Fiona Wood and fellow scientist Marie Stoner.

Device Evolution

Since its initial introduction, we have continued to refine and expand the RECELL technology to meet a range of clinical and workflow needs, culminating in multiple device configurations for different wound sizes. We expect the RECELL GO platform to serve as a growth driver, further advancing our strategy to expand our impact on patient care.

- RECELL Autologous Cell Harvesting Device ("RECELL 1920"): The first RECELL device offered in the U.S. is a single-use, stand-alone, battery operated, autologous cell harvesting device containing enzymatic and buffer solutions, sterile surgical instruments, and actuators. Each RECELL 1920 device can be used to treat areas of up to 1,920 cm^2.

- RECELL Autologous Cell Harvesting Device with Ease-of-Use ("RECELL Ease-of-Use" or "RECELL EOU"): RECELL EOU is an enhanced ease-of-use device aimed at providing clinicians a more efficient user experience and streamlined workflow. Each RECELL EOU can be used to treat areas of up to 1,920 cm^2.

- RECELL GO® Autologous Cell Harvesting Device ("RECELL GO"): RECELL GO is our next-generation device featuring enhanced features that streamline the preparation of Spray-On Skin Cells. RECELL GO significantly reduces the training burden on medical staff, improves workflow efficiency in the operating room, and precisely regulates the incubation times of the RECELL Enzyme™to optimize cell yield and promote cell viability. It consists of two components:

    - A multi-use, AC-powered RECELL GO Processing Device (the "RPD"), which controls and manages the pressure applied to disaggregate the donor skin cells and precisely controls the incubation time of the RECELL Enzyme™ to optimize cell yield and promote cell viability.

    - A RECELL GO Preparation Kit (the "RPK"), which contains a single-use RECELL GO Cartridge, disaggregation head, RECELL Enzyme, and other components. A single RPK can treat areas up to 1,920 cm^2.

- RECELL GO mini Autologous Cell Harvesting Device ("RECELL GO mini"): RECELL GO mini is a line extension of the RECELL GO system, designed specifically to treat smaller wounds up to 480 cm^2. It utilizes the same RECELL GO Processing Device (RPD) but features a RECELL GO mini Preparation Kit (the "mini RPK"), which includes a single-use RECELL GO mini Cartridge optimized for smaller skin samples. These modifications reduce resource use and minimize waste, making RECELL GO mini an accessible option for clinicians treating smaller wounds. This design aims to broaden adoption of the RECELL GO platform in trauma and burn centers. Rollout to trauma and burn centers that currently treat smaller wounds will begin during the first quarter of 2025.

Key U.S. FDA Regulatory Approvals

Date	Device / Indication	Description
September 2018	RECELL 1920	Indicated for treating second- and third-degree acute thermal burns in patients 18 years and older. Commercialization commenced in January 2019 in the U.S.
June 2021	Expanded use of RECELL 1920	Approved for use in combination with meshed autografting for acute full-thickness thermal wounds in both pediatric and adult patients, and for full-thickness thermal burns over 50% total body surface area ("TBSA").
February 2022	RECELL EOU	Approved a single-use device providing a more efficient user experience and streamlined workflow.
June 2023	Full-thickness skin defects	Granted based on pivotal trial results for soft tissue repair and reconstruction. Commenced commercial launch in June 2023.
June 2023	Repigmentation of stable depigmented vitiligo	Expanded RECELL EOU indication for stable depigmented vitiligo lesions.
May 29, 2024	RECELL GO	Next-generation autologous cell harvesting device to treat thermal burn wounds and full-thickness skin defects; designed for wounds up to 1,920 cm^2. Following this approval, we shipped the first RECELL GO order on May 30, 2024, to accommodate the first case for its use on May 31, 2024.
December 23, 2024	RECELL GO mini	Next-generation autologous cell harvesting device to treat thermal burn wounds and full-thickness skin defects; designed for smaller wounds (up to 480 cm^2). Targeted rollout expected in Q1 2025.

Market Opportunity

Burn Injuries

In the U.S., approximately 40,000 people have burn injuries severe enough to require hospital admission annually, with an inpatient mortality rate of 2.7%. Severe burns (typically defined as second- and third-degree) often require autologous split-thickness skin grafts ("STSGs") to achieve definitive closure of the burn wound. However, donor-site creation in a STSG, or autograft, procedure is associated with significant pain, risk of infection, scarring, delayed healing, and increased healthcare costs.

The clinical benefits of closing wounds quickly are well recognized and include increased survival, shorter hospital stays, decreased pain duration, and reduced infection-related complications. However, for large burn injuries, the patient may not have enough healthy donor skin available right away to complete treatment of the entire burn injury area when using traditional grafting techniques. In extensively burned patients, donor sites must heal so they can re-harvest from the same sites, resulting in delays in treatment and closure, multiple procedures, and lengthened hospital stays. While waiting for donor skin, these burn wounds may be temporarily covered with allograft (cadaver skin) or xenograft (typically pig skin). As such, treatment with STSGs is expensive, costing around $579,000 and 59.4 days in hospital for a patient with a 40% TBSA burn injury to recover and return to normal day to day activities.

RECELL has demonstrated the ability to reduce donor-site harvesting requirements while maintaining or improving clinical outcomes. Pivotal clinical studies indicated that using RECELL significantly reduced donor-skin requirements by up to 97.5% for second-degree burns and 32% for third-degree burns when used with autografts, compared to standard of care autografting, without comprising healing. Additionally, the clinical trial for second-degree burns revealed a statistically significant reduction in patient-reported pain, increased patient satisfaction, and improved scar outcomes.

Retrospective studies demonstrated that fewer autografting procedures are required for definitive closure of full-thickness burns when using the RECELL versus conventional autografts alone. In pediatric cases (N = 284), treatment with RECELL resulted in a 56% reduction in the mean number of autograft procedures required compared to National Burn Repository (**"**NBR**"**) data. Additionally, in adult patients with greater than 50% TBSA (N=318), RECELL resulted in a 60% reduction in the mean number of autograft procedures versus NBR data.

In addition to these clinical benefits, RECELL has proven health economic benefits and a compelling cost-effectiveness model. For deep partial-thickness burns, RECELL reduces total treatment costs by an average of 26%, or approximately $37,000, for patients with 10% TBSA and approximately $150,000, for patients with 40% TBSA. For full-thickness burns, RECELL reduces total treatment cost by 3%, or approximately $6,000 for patients with 10% TBSA and by 42% or approximately $243,000, for patients with 40% TBSA. These savings are achieved through shorter hospital stays, fewer procedures, and minimized donor site sizes. All of these cost savings estimates are net of the cost of the RECELL device.

We developed a budget impact model showing that, in a burn center with 200 patients, treatment using RECELL reduces annual total treatment costs from approximately $39.4 million to $32.6 million, saving 17% or approximately $6.8 million per year compared to conventional autografting alone. Additionally, real world evidence published by IQVIA and funded by our company and the Biomedical Advanced Research and Development Authority ("BARDA") demonstrates that these economic savings apply to a wide range of burn sizes.

The U.S. burn treatment market is highly concentrated, with around 140 burn centers and 300 burn surgeons treating approximately 75% of severe burn patients. Historically, our target market was burn centers, which represented about 25,000 RECELL-eligible burn injuries. However, with FDA approval for full-thickness skin defects, we are now expanding into trauma centers to address the additional 10,000 RECELL-eligible burn injuries treated outside dedicated burn centers.

As we continue to innovate and expand the capabilities of RECELL, our commitment to redefining the standard of burn care remains unwavering. RECELL is an invaluable asset for treating burn injuries that require grafting by reducing the need for autografting procedures, shortening hospital stays, and providing significant cost savings. Our vision is clear: to redefine healing, improve outcomes, and transform lives for patients worldwide.

AVITA Medical has a policy of providing the RECELL System to a provider only after they have been certified, which includes extensive training in the use of the product and in the aftercare of the patient. In general, we have found that most U.S. burn centers follow the industry-standard process of evaluating RECELL and then it is reviewed by their hospital's Value Analysis Committee ("VAC") prior to purchasing. In general, most surgeons follow a typical adoption curve, starting from where they see the greatest economic and clinical value, which is the use of RECELL for treatment of larger burns. With time and continued use, surgeons typically progress to adoption of RECELL for smaller, less severe burns and facial burns.

In the U.S., the RECELL System is reimbursed through established mechanisms for both inpatient and outpatient care. For inpatient treatments, hospitals receive payments based on the Medicare Severity Diagnosis-Related Group ("MS-DRG") system, which classifies hospital stays by diagnosis and procedures performed. For physicians, as well as in outpatient and ambulatory surgical center ("ASC") settings, new Category I Current Procedural Terminology ("CPT") codes (15011–15018), effective January 1, 2025, have been introduced to describe Skin Cell Suspension Autograft ("SCSA") procedures performed with the RECELL System. These codes replace previously utilized codes and facilitate standardized billing for healthcare providers. The Company continues to collaborate with both Medicare and commercial payers to expand coverage and ensure appropriate reimbursement for the RECELL System and its associated procedures, aiming to enhance patient access and support broader adoption in clinical practice.

Full-Thickness Skin Defects

A wound is a breach in the integrity of the skin, with full-thickness wounds extending through the dermal layer into deeper tissues. These acute wounds can arise from traumatic avulsions, surgical excisions, or resections. The cause or origin of the wound directly impacts healing potential, response to treatment options, and likely complications. In the U.S., we estimate that roughly 272,000 procedures annually could be eligible for RECELL Treatment.

Traumatic Wounds. Traumatic wounds are subdivided by the mechanism of injury into lacerations, abrasions, avulsions, degloving, crush, penetrating, or bites. Traumatic wounds often arise in high-energy circumstances and result in extensive zones of injury with damage to multiple tissue types. Missing cutaneous tissue, macerated edges, and contamination are common and can complicate wound healing. In the U.S., we estimate there are approximately 122,000 annual procedures that are eligible for treatment with RECELL.

Surgical Wounds. Surgical wounds are precise incisions intentionally created to access underlying organs, relieve compartmental pressure, excise diseased cutaneous tissue (infected or severely inflamed or necrotic), or to harvest tissue for autografting (flaps and grafts). In the U.S., we estimate there are approximately 12,500 annual procedures that are eligible for treatment with RECELL.

Surgical Resections and Excisions for Cancer. Surgical resections and excisions for cancer are procedures used to remove and treat various skin cancers. In the U.S., we estimate there are approximately 136,000 annual procedures that are eligible for treatment with RECELL.

Similar to burns, full-thickness skin defects are associated with large areas of skin loss and as such, some of the top unmet needs identified by surgeons are closely aligned:

- Reduced donor skin harvesting
- Reduced scarring
- Reduced pain
- Uniform pigmentation with surrounding skin

Given the benefits of reducing donor skin harvesting, just as with the burns indication, we designed a clinical trial to demonstrate the use of less donor skin without compromising healing outcomes relative to conventional autografting. The trial was essentially a repeat of the successful previous trial in full-thickness burns, but with a population of patients with full-thickness, non-burn injuries. The study design included two co-primary endpoints based on pairwise comparisons where each subject received both RECELL treatment and standard of care treatment: 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. Both co-primary endpoints were met, demonstrating statistically significant donor-sparing and non-inferior healing outcomes with RECELL versus standard of care, meaning less skin from the patient is required to repair and close the wound without compromising the healing outcomes relative to convention autografting. In addition to these results, RECELL has been successfully used to treat full-thickness skin injuries outside the U.S. for many years and there exist several case reports on the treatment of traumatic injuries that have been the subject of peer-reviewed scientific publications and presentations at medical conferences.

The approval for the treatment of full-thickness skin defects represents a significant opportunity. Given approximately 50% of the U.S. burn centers are classified as trauma centers, this indication opens doors in trauma centers already using RECELL for burn care. Further, we are expanding our burn market opportunity by virtue of our approval for full-thickness skin defects as we are extending our reach to include trauma centers. This market expansion allows us to reach more trauma centers, leveraging our existing resources and creating synergies with the burns market.

From a reimbursement perspective, the same DRG code that is currently being used to treat inpatient burns is now being applied for the treatment of full-thickness skin defects. Additionally, the outpatient TPT “C” code we have been granted for RECELL can also be utilized for the treatment of full-thickness skin defects in the outpatient setting.

Vitiligo

Vitiligo is a disease that causes the loss of skin pigmentation, or color, in patches. The extent of color loss from vitiligo is unpredictable, can affect the skin on any part of the body, and may also affect hair and the inside of the mouth. Vitiligo occurs when melanocytes, the pigment-producing skin cells, die or stop producing melanin, the pigment that gives skin, hair, and eyes color. Vitiligo is believed to be an autoimmune disorder in which a patient’s immune system attacks and destroys the melanocytes in the skin. It may also be caused by heredity factors or a triggering event, such as sunburn, stress, or exposure to industrial chemicals. Vitiligo affects people of all skin types, but it may be more noticeable in people with darker skin. It is estimated that worldwide vitiligo prevalence is between 0.5 to 2% of the population.

Following FDA approval, we conducted a post-market study and initiated a health economics study to capture the longitudinal healthcare costs for a vitiligo patient. Both studies were submitted for publication in 2024. In early 2025, we expect these studies to be published, which will support the possible reimbursement necessary for the commercialization of the vitiligo indication.

PermeaDerm

We hold an exclusive multi-year distribution agreement with Stedical to market, sell, and distribute PermeaDerm, a biosynthetic wound matrix. PermeaDerm is FDA-cleared for the treatment of a variety of wound types and sizes until healing is achieved. Its transparent structure helps clinicians monitor the wound without frequent dressing changes. Additionally, PermeaDerm's flexibility and ease of use make it an ideal choice for a wide range of clinical settings, from acute care hospitals to burn centers, which complements RECELL by providing a versatile solution for wound care management.

Cohealyx

Through our multi-year exclusive development and distribution agreement with Regenity, we hold the rights to market, sell, and distribute Cohealyx, an AVITA-Medical branded collagen-based dermal matrix in the U.S., with the potential to commercialize the product in the European Union, Japan, and Australia. Cohealyx features an advanced bovine collagen-based design engineered to facilitate tissue integration and revascularization resulting in reduced treatment timelines and improved patient outcomes in full-thickness wounds.

Preclinical studies in porcine models demonstrated that Cohealyx generated robust tissue capable of consistently supporting a split-thickness skin graft in a two-stage procedure earlier than leading dermal matrices in the study. While animal model results do not necessarily translate to clinical results, this expedited timeline is anticipated to lead to quicker wound closure and streamlined clinician workflows, resulting in shorter hospital stays, reduced treatment costs, and better patient outcomes.

The FDA granted 510(k) clearance for Cohealyx on December 19, 2024. Early evaluations to provide comprehensive feedback are underway, with the first three patients being treated in January 2025. To build on preclinical success and develop clinical data in support of the commercial launch, we plan to conduct a post-market clinical study in early 2025 to demonstrate Cohealyx's performance in real-world settings, focusing on clinical efficacy, time-to-graft reduction, and the associated cost savings in the treatment of full-thickness wounds and burns. The full commercialization launch is expected to begin in the second quarter of 2025.

INTERNATIONAL STRATEGY

In international markets, the RECELL System has received various approvals and registrations to promote skin healing in a wide range of applications including burns and full-thickness skin defects. These endorsements include Therapeutic Goods Administration ("TGA") registration in Australia, Conformité Européene ("CE") mark approval in Europe, and Pharmaceuticals and Medical Devices Act ("PMDA") approval in Japan under the Pharmaceuticals and Medical Devices Act for burns. Our global commercialization strategy is focused on Australia, the European Union ("European Union or "EU"), Japan, and the United Kingdom ("United Kingdom" or "UK").

In alignment with our strategic growth objectives, we initiated a global commercialization strategy in 2023. This initiative targets key markets including Australia, the European Union, Japan, and the United Kingdom. Leveraging the exclusive use of third-party distributors, we have successfully secured distribution agreements in 16 countries, including, Australia, Austria, Belgium, Denmark, Finland, Germany, Ireland, Japan, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the UK. Our efforts remain robust as we continuously seek and establish new distribution partnerships within these primary markets.

RESEARCH & DEVELOPMENT

Our research and development activities are focused on advancing our innovative products and building a comprehensive portfolio of solutions, as well as developing clinical applications to advance the management of wound care. Additionally, we continue to conduct clinical studies to provide further efficacy and health economic evidence.

We continue to commit resources to product development to ensure the RECELL platform continues to evolve and that we maintain robust patent protection. On May 29, 2024, the FDA approved our PMA supplement for RECELL GO, our next generation autologous cell harvesting device for the treatment of thermal burn wounds and full-thickness skin defects. RECELL GO maintains the FDA Breakthrough Device designation from predecessor devices. RECELL GO is comprised of a reusable durable base unit and a single-use sterile cartridge. The RECELL GO system aims to control the current manual process of cell disaggregation and filtration, as well as soak time, reducing variability across medical providers compared to the current device. This revolutionary design will also reduce training requirements, allowing us to leverage our sales team more effectively. In turn, we believe the reduction in training medical professionals will lead to increased adoption across our indications and the broader market. RECELL GO offers us an opportunity to expand our intellectual property portfolio. With each iteration of our RECELL device, we anticipate preservation of the therapeutic power of Spray-on Skin Cells, deployed in devices that become appropriate for use in an increasing range of clinical settings.

On June 28, 2024, we submitted a PMA supplement for RECELL GO mini, which is designed to address small wounds up to 480 cm^2. This version retains the same multi-use processing units as RECELL GO but features a modified cartridge designed for the smaller donor skin samples needed for smaller wounds. On December 23, 2024, the FDA approved our PMA supplement for RECELL GO mini.

In 2024, we completed a post-market study to evaluate repigmentation using RECELL and seek to measure the improvement in the quality-of life following treatment of stable vitiligo with RECELL. Additionally, we initiated a healthcare economic study to capture the longitudinal healthcare costs for a vitiligo patient. In early 2025, we expect these studies to be published, which will support the possible reimbursement necessary for the commercialization of the vitiligo indication.

SALES AND MARKETING

Our commercial organization is focused on clinical case support, staff training, and building awareness to further expand interest in the clinical and economic benefits of RECELL. It is not uncommon in the treatment of wounds to have rotating staff and it is our commitment for all those working with RECELL to be comfortable with the technology both during the procedure as well as during aftercare.

Our commercial organization is composed of highly experienced medical sales representatives as well as former burn and trauma nurses. This organization covers both burns and full-thickness skin defects.

HUMAN CAPITAL

AVITA Medical's investment in the U.S. commercial success of RECELL has led to the development of best-in-class teams supporting sales, clinical education and training, reimbursement, medical affairs, as well as corporate management and infrastructure. As of December 31, 2024, we had 260 full-time and part-time employees. As of December 31, 2024, 99% of our workforce was based in the United States ("United States or "U.S."), with a significant number of our management and professional employees having prior experience with leading medical device, biotech, or pharmaceutical companies. None of our employees are covered by collective bargaining agreements.

We embrace differences, diversity and varying perspectives amongst our employee base and are proud to be an equal opportunity employer. We do not discriminate based on race, religious creed, color, national origin, ancestry, physical disability, mental disability, medical condition, genetic information, marital status, sex, gender, gender identity, gender expression, age, military or veteran status, sexual orientation or any other protected characteristic established by federal, state, or local laws. A diverse workforce as well as an inclusive culture and work environment are fundamentally important and strategic to us, beginning with our Board of Directors and CEO and extending to all levels of the Company. As of December 31, 2024, the Directors of the Company were 33% female, our senior executive team was 40% female and our total employee base was 52.5% female. In addition to promoting gender diversity, we encourage ethnically diverse talent through our recruiting and retention efforts.

INTELLECTUAL PROPERTY

We protect our intellectual property, core technologies, and other know-how through a combination of patents, trademarks, trade secrets, and IP protection clauses in our agreements. Additionally, we rely on our research and development program, clinical trials, know-how and marketing programs to advance our products and product candidates, and to expand our intellectual property rights. We expect that our research and development pipeline, strategic partnerships, and improvements to RECELL GO have the potential to result in additional patent applications in the next calendar year.

In 2024, AVITA Medical initiated a global patent strategy to cover its flagship RECELL GO product and secured patent protection for RECELL GO in all commercial markets prior to its June 2024 product launch. AVITA Medical added to its RECELL GO patent coverage throughout 2024, ending the year with 18 enforceable patent assets and 13 pending patent applications globally having expiration dates ranging from March 2034 to December 2043. Additionally, AVITA Medical expects (i) an additional three U.S. patent grants that cover RECELL GO to be issued in 2025, and (ii) multiple corresponding patent allowances to be issued at the European Patent Office ("EPO") in 2025 and 2026. The Company believes that this layered and extensive patent coverage, in conjunction with built-in advantages from global regulatory approval processes and our first-to-market position, give RECELL GO strong protection in the marketplace.

More broadly, as of December 31, 2024, AVITA Medical's patent portfolio comprised 29 patent grants and 33 pending patent applications worldwide, with patent coverage either secured or in progress in the U.S., China, Japan, Australia, Brazil, Canada, France, Germany, Hong Kong, Italy, Spain, the UK, and at the EPO, the European Union Intellectual Property Office, and the World Intellectual Property Organization. These assets cover the all-in-one RECELL product, RECELL GO, methods of using the RECELL System, methods of evaluating the therapeutic potential of Regenerative Epidermal Suspension ("RES"), a cell-free and allogeneic RES supernate, and methods of preparing a cell suspension with exogenous agents to promote wound healing.

Additionally, AVITA Medical owns and defends a global trademark portfolio comprising 148 registered trademarks, common or state law trademarks, and pending trademark applications, including “AVITA Medical,” the AVITA Medical logo, “RECELL,” “RECELL GO”, the RECELL GO logo, “Spray-On Skin,” the RECELL System logo, “Cohealyx,” the Cohealyx logo, and others in the U.S. and international markets.

FACILITIES

AVITA Medical leases approximately 17,500 square feet of administrative and office space in Valencia, California that is currently leased through October 31, 2026. The Company operates an FDA-registered production plant in Ventura, California, in a 27,480 square foot facility that is currently leased through September 30, 2027. The Ventura facility has one 3-year option to extend the lease, at our sole option, which allows for a total lease extension period through September 30, 2030. The Company also has an administrative office lease in Irvine, California of approximately 10,700 square feet that is currently leased through the end of July 2028. We also lease a limited amount of incubator space in Irvine, California for scientific research and product development activities.

MANUFACTURING, SUPPLY AND PRODUCTION

We produce the RECELL System in the Ventura facility under current Good Manufacturing Practices (“cGMP”) and per ISO 13485, which also meets the regulatory requirements of other jurisdictions in which we sell the RECELL System. We maintain a state of regulatory compliance and inspection readiness at all times, and any future material changes to our production processes for the RECELL System will be submitted for approval to the FDA and regulatory authorities in other jurisdictions as required.

Within the Ventura facility we perform the final manufacturing, assembly, packaging, and warehousing of the RECELL System.

AVITA Medical sources multiple components, sub-assemblies, and materials from third-party suppliers, who are required to meet our cGMP quality specifications and associated regulatory requirements. To ensure continuity of supply, we maintain multiple sources of supply for key components, subassemblies and materials, and the majority of critical raw materials and services have multiple qualified suppliers. While a small number of materials remain single sourced, we are actively working to qualify and validate additional suppliers for these materials as we continue to evaluate methods of removing risk from the supply chain for the RECELL System. We believe that our current manufacturing capacity at the Ventura facility is sufficient to meet the expected commercial demand for the RECELL System for burns, full-thickness skin injuries, and other indications under development, for the foreseeable future. Additionally, in the second half of 2024, we implemented lean manufacturing methods to increase efficiencies in the production of the RECELL System.

AVITA Medical serves the U.S. burn market by shipping the RECELL System directly from our Ventura facility to customers. From time-to-time we may also store small quantities of the RECELL System at satellite distribution sites within the U.S. to better support access of the RECELL System to our U.S. customers.

BARDA CONTRACT

BARDA, under the Assistant Secretary for Preparedness and Response, within the U.S. Department of Health and Human Services (“HHS”) has supported our company since 2015. A contract with BARDA provided funding for the development of the RECELL System. The BARDA contract also supported the Company’s clinical trial in soft-tissue reconstruction, which led to the full-thickness skin defect indication. In addition to the clinical support provided by BARDA, we managed an inventory system of RECELL Devices for BARDA to bolster emergency preparedness and support the logistics of emergency deployment of RECELL Systems for use in mass casualty or other emergency situations. Between 2015 and December 31, 2024, we have received an aggregate total of $40.5 million in payments under the contract with BARDA.

As of December 31, 2023, we no longer have a contractual obligation to manage an inventory system for BARDA. However, from that date through September 28, 2025, we will provide access to RECELL inventory in the event of a national emergency. BARDA will pay for any devices requisitioned from this inventory along with a nominal annual maintenance fee to ensure first right of access.

COMPETITION

We currently believe that there is no direct competition for RECELL. Additionally, our innovative technology is supported by robust intellectual property rights and we believe that regulatory approval processes around the world will continue to provide additional and significant barriers to entry against meaningful competition. Despite these meaningful competitive advantages, the medical device, biotechnology, and pharmaceutical industries are highly competitive and subject to rapid advancements in technology, as well as changes in practice. In the future, we may face competition from various sources, including medical device, pharmaceutical, and wound care companies, academic and medical institutions, governmental agencies, medical practitioners, and public and private research institutions, among others. Consequently, any product that we successfully develop and/or commercialize will compete with both existing therapies and any new therapies that may emerge in the future.

In the burns and non-burn wound markets, our indirect competitor is primarily split-thickness autografts. While RECELL complements autografts for the treatment of various wound injuries, split-thickness autografts represent the traditional surgical procedure and the current standard of care. However, based on our clinical trials, we believe that RECELL offers sustainable competitive, clinical, and economic advantages over the traditional surgical procedure. We also believe that our current portfolio products (PermeaDerm and Cohealyx), as well as future portfolio products, will enhance these advantages.

GOVERNMENT REGULATIONS

The production and marketing of the RECELL System and any additional product candidates developed in future ongoing research and development activities are subject to regulation by numerous governmental authorities including the FDA in the U.S. and similar agencies in other countries throughout the world. Pursuant to its authority under the Federal Food, Drug, and Cosmetic Act (the "FD&C Act"), the FDA has jurisdiction over medical devices in the U.S. The FDA regulates the design, development, manufacturing, and distribution of medical devices to ensure that medical products distributed domestically are safe and effective for their intended uses. The FD&C Act classifies medical devices into one of three categories based on the risks associated with the device and the level of control necessary to provide reasonable assurance of safety and effectiveness. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously 510(k) cleared device are categorized as Class III. These devices typically require submission and approval of a PMA. The RECELL System is categorized as a Class III medical device, and in September 2018 the FDA granted our PMA for use in the treatment of acute thermal burns in patients 18 years and older. In June 2021, the FDA approved a supplement to our PMA to expand the use of RECELL in pediatric patients with full-thickness burns. In June 2023, the FDA approved a supplement to our PMA to expand the use of RECELL for full-thickness skin defects and an original PMA to expand the use of RECELL for the repigmentation of stable depigmented vitiligo lesions. On May 29, 2024, the FDA approved our PMA supplement for RECELL GO, our next generation autologous cell harvesting device, to treat thermal burn wounds and full-thickness skin defects. On December 23, 2024, the FDA approved RECELL GO mini.

To support additional PMAs or PMA supplements in the U.S. or applications for approval in other regions, the completion of additional clinical and non-clinical studies and supporting development activities will likely be required. Clinical trials can take many years to complete and require the expenditure of substantial resources. The length of time varies substantially according to the type, complexity, novelty, and intended use of the product candidate. We cannot make any assurances that once clinical trials are completed by us or a collaborative partner, we will be able to submit as scheduled a marketing approval request to the applicable governmental regulatory authority, or that such request and application will be reviewed and cleared by such governmental authority in a timely manner, or at all. Although we intend to make use of fast-track and abbreviated regulatory approval programs when possible and commercially appropriate, we cannot be certain that we will be able to obtain the clearances and approvals necessary for clinical testing or for manufacturing and marketing our product candidates. Delays in obtaining regulatory approvals could adversely affect the development and commercialization of our product candidates and could adversely impact our business, financial condition, and results of operations. During the course of clinical trials and non-clinical studies, product candidates may exhibit unforeseen and unacceptable safety considerations. If any unacceptable side effects were to occur, we may, or regulatory authorities may require us to, interrupt, limit, delay or abort the development of our potential products.

Any products manufactured or distributed by us pursuant to regulatory approvals are subject to continuing regulation by the FDA and similar agencies in other countries, including maintaining records supporting manufacturing and distribution under cGMP, periodic reporting, advertising, promotion, compliance with any post-approval requirements imposed as a conditional of approval, recordkeeping and reporting requirements, including adverse events experiences. After approval, material changes to the approved product, such as adding new indications or other labeling claims, or changes to the manufacturing process, are subject to prior approval by the FDA and other regulatory agencies. Medical device manufacturers and their subcontractors are required to register their establishments with the FDA, certain state agencies and international agencies. Subcontractors are subject to periodic announced and unannounced inspections by the FDA and other agencies for compliance with cGMP. We have established processes in place for categorization of vendor criticality and the associated activities for qualification and monitoring of vendors. These activities include, but are not limited to, requiring certification of supplier in conformance to relevant cGMP requirements and other FDA and international agency regulatory requirements, approved supplier lists, and regularly Company-conducted audits. In addition, all goods and services purchased from suppliers by us must be purchased from only those suppliers on the approved supplier list. Furthermore, the Company itself will continue to comply with all relevant FDA requirements and regulations and any applicable international agency regulatory requirements in its continued manufacturing and promotion of its FDA approved commercial products.

In addition to FDA approval in the U.S., the RECELL System has received various approvals and registrations in international markets. The RECELL System is TGA-registered in Australia, received CE-mark approval in Europe, and received Japan's PMDA approval for burns in Japan.

HEALTHCARE LAWS AND REGULATIONS

AVITA Medical is a manufacturer of medical devices, and therefore we are subject to regulations by the FDA and various federal and state healthcare laws and regulations. These regulations govern our advertising and promotional practices, our interactions with healthcare providers ("HCPs"), and our reporting of any payments made to HCPs. AVITA Medical is committed to the highest standards of business conduct in accordance with the AdvaMed Code of Ethics.

Interactions with Healthcare Providers

Providing any benefits or advantages to HCPs in order to induce or encourage the use or referral of AVITA products is strictly prohibited by both U.S. and international laws and regulations. Restrictions under applicable federal and state healthcare laws and regulations include but are not limited to the following:

- The federal healthcare Anti-Kickback Statute ("AKS"). AKS prohibits any person from soliciting, offering, receiving, or providing any remuneration in cash or in kind, whether directly or indirectly, to induce or reward the referral, purchase, lease, order, or recommendation of any item or service for which payment may be made in whole or in part under a federal healthcare program such as Medicare and Medicaid.
- The federal False Claims Act ("FCA"). FCA may be enforced by either the U.S. Department of Justice or private whistleblowers should they choose to bring civil (qui tam) actions on behalf of the federal government. The FCA imposes civil penalties, as well as liability for treble damages and for attorneys' fees and costs, on individuals or entities who knowingly present, or cause to be presented, claims for payment that are false or fraudulent to the federal government. FCA also imposes similar penalties on those who make a false statement material to a fraudulent claim, or who improperly avoid, decrease, or conceal an obligation to pay money to the federal government.
- State and foreign laws and regulations may apply to sales or marketing arrangements and claims involving healthcare devices or services reimbursed by non-governmental third-party payors.

Additionally, certain state laws require medical device companies to comply with voluntary guidelines in our interactions with healthcare providers promulgated by global trade associations and relevant compliance guidance issued by the HHS, Office of Inspector General. Such guidelines prohibit medical device manufacturers from offering or providing certain types of payments or gifts to health care providers; and/or require the disclosure of gifts or payments to healthcare providers.

Interactions with Foreign Officials and Entities

The U.S. Foreign Corrupt Practices Act ("FCPA") prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party, or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the U.S. to comply with accounting provisions requiring companies to maintain books and records that accurately and fairly reflect all transactions of companies, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. We are also subject to similar regulations under the Australian bribery laws and other anti-corruption laws that apply in countries where we do business.

Federal and State Reporting

Pursuant to the federal National Physician Payment Transparence Program (Open Payments) Act, AVITA Medical is required to report any payments or transfers of value to HCPs annually to the Centers for Medicare and Medicaid Services within the HHS. In addition to adhering to these federal reporting requirements, we are required to make similar annual reports to relevant state agencies.

Privacy

Various federal, state, and foreign laws govern the privacy and security of consumer and patient information. We comply with all such applicable laws.

ENVIRONMENTAL, HEALTH AND SAFETY MATTERS

We are subject to extensive environmental, health and safety laws and regulations in a number of jurisdictions, primarily in California and the U.S., governing, among other things: the use, storage, registration, handling, emission and disposal of chemicals, waste materials and sewage; chemicals, air, water and ground contamination; and air emissions and the cleanup of contaminated sites, including any contamination that could result from spills due to our failure to properly dispose of production waste materials. Our operations at our Ventura manufacturing facility produce a small amount of waste materials that are considered minimally hazardous, and we use a third-party waste disposal company to remove any waste generated during operations from the facility. Our activities require permits from various governmental authorities including local municipal authorities. Local and state authorities may conduct periodic inspections in order to review and ensure our compliance with the various regulations. We are not presently aware of any material violations or deficiencies. These laws, regulations and permits could potentially impose additional costs related to compliance or remediation.

AVAILABLE INFORMATION

The Company files annual, quarterly and current reports, proxy statements and other documents with the Securities and Exchange Commission ("SEC") under the Exchange Act. The SEC maintains a website that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The public can obtain any documents that we file with the SEC at www.sec.gov. In addition, copies of announcements made by the Company to ASX are available on the ASX website (www.asx.com.au) and also, under the heading "Investors: Press Releases" at the following link on our website https://ir.avitamedical.com/press-releases/news-releases. Our filings with the SEC, including without limitation, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, are available free of charge on our website under the heading "Investors: Financials _SEC Filings" at the following link on our website (https://ir.avitamedical.com/financials/sec-filings), as soon as reasonably practicable after we file or furnish them electronically with the SEC. We maintain a website at www.avitamedical.com. Information contained on our website is not part of or incorporated into this Annual Report.

ORGANIZATIONAL STRUCTURE

As of December 31, 2023, the business activities of AVITA Medical Pty Limited, AVITA Medical Europe Limited, Visiomed Group Pty Ltd, C3 Operations Pty Ltd and Infamed Pty Ltd were liquidated. AVITA Medical Americas LLC was transferred from C3 Operations Pty Ltd to be directly held by the Company. As of January 28, 2025, AVITA Medical Pty Limited, AVITA Medical Europe Limited, Visiomed Group Pty Ltd, C3 Operations Pty Ltd and Infamed Pty Ltd were deregistered, leaving AVITA Medical Americas, LLC as the sole subsidiary of the Company.

Item 1A. RISK FACTORS

Our business faces significant risks. You should carefully consider all of the information set forth in this annual report, including the following risk factors. Our business, results of operations, and financial condition could be materially and adversely affected by any of these risks, and in such event, the trading price of our common stock would likely decline, and you might lose all or part of your investment. This Annual Report also contains forward-looking statements that involve risks and uncertainties, and our results could materially differ from those anticipated in these forward-looking statements. See "*Forward-Looking Statements*" included elsewhere within this Annual Report for a discussion of certain risks, uncertainties and assumptions associated with these statements.

Risks Related to Our Business Operations

We have experienced significant losses, expect losses to continue for the foreseeable future and may never achieve or maintain profitability.

Although we have begun full scale marketing and sales of our RECELL® System in the United States and other jurisdictions, we have not yet achieved profitability. We had a total net loss of $61.8 million and $35.4 million for the year ended December 31, 2024 and December 31, 2023, respectively. We have incurred a cumulative deficit of $359.8 million through December 31, 2024. We anticipate that we may continue to incur losses at least until sales of the RECELL System are adequate to fund operating expenses. We may not be able to successfully achieve or sustain profitability. Successful transition to profitable operations is dependent upon achieving a level of revenues adequate to support our cost structure, including in new markets where regulatory approval is in process or pending.

Servicing our debt requires a significant amount of cash and we are subject to a number of restrictive covenants relating to our indebtedness, which may restrict our business and financing activities.

Pursuant to the Credit Agreement that we entered with OrbiMed Advisors, LLC (as amended, the "Credit Agreement") on October 18, 2023, most recently amended in the Credit Agreement's Third Amendment, on November 7, 2024 (the "Third Amendment"), we incurred $40.0 million of indebtedness secured by substantially all of our assets. This level of debt could have significant consequences on future operations, including increasing our vulnerability to adverse economic and industry conditions and limiting our flexibility in planning for, or reacting to, changes in our business and the markets in which we compete.

Our ability to make scheduled payments of interest depends on our future performance, which is subject to interest rate risk, as well as economic, financial, competitive, and other factors beyond our control. We are exposed to risks related to a potential rising interest rate environment for the debt, which could cause our borrowing costs to rise and impact our liquidity. Our business may not generate cash flow from operations in the future sufficient to service our debt in cash while simultaneously making necessary capital expenditures. In addition, if the Company's net revenue does not equal or exceed a certain amount for upcoming fiscal periods as set forth in the Credit Agreement, then the Company will be required to repay 5% of the outstanding principal amount of its indebtedness (along with interest accrued on that principal amount if not already paid) in equal quarterly installments, in addition to paying both a repayment fee and a prepayment fee with each quarterly installment.

If we are unable to generate sufficient cash flow to satisfy payment obligations under the Credit Agreement, we may be required to adopt one or more alternatives, such as obtaining additional equity capital on terms that may be onerous or highly dilutive. We may not be able to engage in any of these activities, or such activities may only be available to the Company on undesirable terms, which could result in a default on our debt obligations.

The restrictions and covenants in the Credit Agreement may also prevent us from taking actions that we believe would be in the best interests of our business, and may make it difficult for us to successfully execute our business strategy or effectively compete with companies that are not similarly restricted. Our ability to comply with these covenants in future periods will largely depend on the success of our products, and our ability to successfully implement our overall business strategy. We may be unsuccessful in obtaining waivers or amendments to restrictions and covenants in certain agreements with our customers or counterparties. And any breach by the Company of covenants and restrictions in such agreements could result in a default under the Credit Agreement, which could result in an acceleration of the repayment of our indebtedness.

We may require additional financing in the future to continue the development and commercialization of our RECELL System or any future products, which may cause dilution to our existing stockholders. If additional financing is not available, we may have to postpone, reduce or cease operations.

If we are unable to achieve profitability sufficient to permit us to fund our operations, repay indebtedness in accordance with the Credit Agreement, and take other planned actions, we may be required to raise additional capital. There can be no assurance that such capital would be available on favorable terms, or available at all. If we raise additional capital through the issuance of equity, the percentage ownership held by existing stockholders may be reduced, and the market price of our common stock or CDIs could fall due to an increased number of shares or CDIs available for sale in the market. If we are unable to secure additional capital as circumstances require, we may not be able to fund our planned activities or continue our operations.

The markets in which we operate are highly competitive and innovative. Our competitors may develop products that render our products less attractive or obsolete and our business may deteriorate.

The markets for our products are highly competitive and our competitors may develop products that may more effectively compete with our products. Our competitors may have significantly more financial and other resources to invest in product development. We must, therefore, continue to develop and market new products, or we risk our products becoming obsolete, in which case, our revenues may decline, adversely impacting our financial condition or our business prospects.

Our success depends, in part, on our relationships with, and the efforts of, third-party distributors.

We rely on third-party distributors for a portion of our sales in countries outside of the U.S. Our distributors may not commit the necessary resources to market and sell our products to the level of our expectations, and, regardless of the resources they commit, they may not be successful. If we are not able to maintain our distribution network, if our distribution network is not successful in marketing and selling our products, or if we experience a significant reduction, cancellation, or change in the size and timing of orders from our distributors, our revenues could decline significantly and lead to an inability to meet operating cash flow requirements, which would have a material adverse effect on our business, financial condition, or results of operations.

We may be unsuccessful in commercializing our RECELL System or other future products due to unfavorable pricing regulations or third-party coverage or reimbursement policies.

We cannot guarantee that we will receive favorable pricing or reimbursement for use of our products. The rules and regulations that govern pricing and reimbursement for medical products vary widely from country to country or from indication to indication, and within the United States, can also vary widely from one health system or hospital to the next. In some foreign jurisdictions, including the EU and the individual jurisdictions within it, the government largely controls pricing of medical products. In other countries, coverage negotiations must occur at the regional or hospital level. And pricing negotiations can take considerable time after the receipt of marketing approval for a medical product.

As a result, even after obtaining regulatory approval for a product in a particular country, we may be subject to price regulations or limited reimbursement, which may delay or limit our commercial launch of the product and negatively impact the revenue we are able to generate from the sale of the product in that country. Further, such pricing limitations may hinder our ability to recoup our total investment in our RECELL System or other future products. If we are unable to promptly obtain coverage and profitable payment rates from hospital budgets, as well as from either government-funded or private purchasers, for the RECELL System or any future products, this could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products, and our overall financial condition.

For example, we presently benefit from various reimbursement codes, including the following:

- Medicare Severity Diagnosis-Related Groups (“MS-DRGs”), for hospitals with inpatient services.
- Specific International Classification of Disease, 10th revision, Procedure Classification System (“ICD-10-PCS”) code series describing our “cell suspension technique” for the use of the RECELL System.
- CPT codes that describe “skin cell suspension autograft to support physician reimbursement by professional healthcare services and for facility services at ambulatory surgical centers (“ASCs”), and Ambulatory Payment Classifications (“APCs”) for hospital reimbursement for outpatient department services.

There can be no guarantee that the above reimbursement codes will not be withdrawn, reduced, consolidated or otherwise altered in a manner which is not supportive of ongoing commercial use of the RECELL System.

Certain of our products are dependent on specialized sources of supply potentially subject to disruption which could have a material, adverse impact on our business.

Due to the cost and regulatory requirements associated with qualifying multiple suppliers, in 2023, we single-sourced some of our material components. To the extent that any of these single-sourced suppliers experience disruptions in deliveries due to production, quality, or other issues, we are potentially subject to similar production delays or unfavorable cost increases. In 2024, we started investing resources to secure additional suppliers for some of our key raw materials, but these efforts only mitigate, but do not eliminate, our supply chain risk.

We rely on third parties to conduct, supervise, and monitor our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain or maintain regulatory approval for or commercialize our products and our business could be substantially harmed.

We rely on clinical research organizations ("CROs") and clinical trial sites to ensure our clinical trials are conducted properly and on time. While we have agreements governing their activities, we have limited influence over their actual performance. CROs manage and monitor the duties and functions pertaining to clinical trials and we control only certain aspects of our CROs' activities. Nevertheless, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with applicable protocol, legal, regulatory, and scientific standards, and our reliance on CROs does not relieve us of our such responsibilities.

We and our CROs are required to comply with the FDA's GCPs for conducting, recording, and reporting the results of clinical trials to assure that the data and reported results are credible and accurate and that the rights, integrity, and confidentiality of clinical trial participants are protected. The FDA, and comparable foreign regulatory authorities, enforce these GCPs through periodic inspections of trial sponsors, principal investigators, and clinical trial sites. If we or our CROs fail to comply with applicable GCPs, the clinical data generated in our future clinical trials may be deemed unreliable and the FDA or other foreign regulatory authorities may require us to perform additional clinical trials before approving any marketing applications.

If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements, or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain or maintain regulatory approval for, or successfully commercialize, our products. If any such event were to occur, our financial results and the commercial prospects for our products would be harmed, our costs could increase, and our ability to generate revenues could be delayed. If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. Further, switching or adding additional CROs involves additional costs and requires management resources. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which could materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these challenges or delays will not have a material adverse impact on our business, financial condition, or results of operations.

We may encounter substantial delays in further clinical studies necessary to support regulatory applications for additional commercial applications of our technology.

We cannot guarantee that any pre-clinical testing or clinical trials will be conducted as planned or on schedule, or completed at all. As a result, we may not achieve the expected clinical milestones necessary for approval by the FDA, or other regulators, for the use of our RECELL System for additional applications in the United States or other countries.

A failure in a clinical study or regulatory application can occur at any stage. Events that may prevent successful or timely commencement, enrollment or completion of a clinical study or a regulatory application include:

- delays in raising, or inability to raise, sufficient capital to fund the planned trials;
- delays in reaching a consensus with regulatory agencies on trial design;
- changes in trial design;
- inability to identify, recruit, and train suitable clinical investigators;
- inability to add new clinical trial sites;

- delays in reaching agreement on acceptable terms for the performance of the trials with prospective clinical research organizations and clinical trial sites;
- delays in recruiting suitable clinical sites and patients (i.e., subjects) to participate in clinical trials;
- imposition of a clinical hold by regulatory agencies for any reason, including negative clinical results, safety concerns or as a result of an inspection of manufacturing or clinical operations or trial sites;
- failure by any relevant parties to adhere to clinical trial requirements;
- failure to perform in accordance with the FDA's Good Clinical Practice ("GCPs"), or applicable regulatory guidelines in other countries;
- delays in the testing, validation, manufacturing, and delivery to the clinical sites of the product candidates;
- delays caused by clinical trial sites not completing a trial;
- failure to demonstrate adequate effectiveness;
- occurrence of serious adverse events in clinical trials associated with the product candidates that are viewed to outweigh its potential benefits;
- changes in regulatory requirements or guidance that require amending or submitting new clinical protocols;
- adverse events, safety issues, product recalls, manufacturing or supply chain interruptions, or poor clinical outcomes where the RECELL System is being used commercially; and
- disagreements with regulatory agencies in the interpretation of the data from our clinical trials.

Delays, including delays caused by the above factors, can be costly and could negatively affect our ability to complete clinical trials for our product candidates. If we are not able to successfully complete clinical trials or are not able to do so in a timely and cost-effective manner, we will not be able to obtain regulatory approval for the use of our RECELL System for additional applications, all of which could have a material adverse effect on our business, financial condition, or results of operations.

Product development is an expensive, uncertain and lengthy process.

We have significant product development projects ongoing that, if successful, are intended to continue to improve the consistency and ease for the use of RECELL across indications and wound sizes, as well as expand our portfolio of complementary products. The costs, timeline, and ultimate success of these product development programs are subject to risk and uncertainty. If we are not able to develop and obtain regulatory approval for our new products in a timely fashion and within budget, our business prospects and financial condition may suffer.

Development and commercialization of our products require successful completion of the regulatory approval process and may suffer delays or fail.

In the United States, as well as other jurisdictions, we have been and will be required to apply for and receive regulatory authorization before we can market our products. For instance, the first generation of RECELL has been approved by regulatory authorities in Australia and the EU for use in the treatment of burns and acute wounds, and by regulatory authorities in Japan for use in certain treatments of burns. However, we will require additional clinical data or approvals from regulatory authorities within these jurisdictions to market improved versions of RECELL for the same or additional indications, and from any other jurisdictions in which we seek to market the product. This process can be time-consuming and complicated, and may result in unanticipated delays or fail altogether.

To secure marketing authorization, an applicant generally is required to submit an application that includes the data supporting pre-clinical and clinical safety and effectiveness as well as detailed information on the manufacturing and control of the product, proposed labeling, and other additional information. Before marketing authorization is granted, regulatory authorities may require the inspection of the manufacturing facility and quality systems (including those of third parties) at which the product candidate is manufactured and tested, as well as potential audits of the non-clinical and clinical trial sites that generated the data cited in the marketing authorization application.

We cannot predict whether any additional marketing authorizations will ultimately be granted or how long the applicable regulatory authority or agency approval processes will take. Regulatory agencies, including the FDA, have substantial discretion in the approval process. In addition, the approval process and the requirements governing clinical trials vary from country to country. The policies of the FDA or other regulatory authorities may change, and additional government regulations may be enacted that could prevent, limit or delay the necessary approval of any products we may develop and commercialize. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or elsewhere. If we are slow or unable to adapt to new or changed requirements, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which may impact our ability to achieve or sustain profitability.

Additionally, any future regulatory approvals that we receive may also contain requirements for costly post-marketing testing and surveillance to monitor the safety and effectiveness of the product. Once a product is approved, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export, distribution, and record-keeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submission of safety and other post-marketing reports, registration, and continued compliance with good manufacturing practices (including for any clinical trials that we conduct post-approval).

Finally, per FDA regulations, changes made to products, specifications, or test data evaluation methodology would generally require communication with the FDA. There are several pathways for communicating with the FDA of such changes. As part of such review, the FDA may request additional information, at which time the product may become temporarily unavailable.

We are highly dependent on our regulatory approval in the United States and failure to maintain that approval would materially impact our business and prospects.

Our business is highly dependent on the PMA we received in September 2018 from the FDA, including subsequent PMA supplement approvals for acute wound indications. This PMA allows us to sell our RECELL and RECELL GO in the United States, our current primary market. While we intend to take every action and precaution to ensure that our PMA remains effective, it is possible that the FDA could take a position in the future that requires a modification, temporary suspension or revocation of our PMA. Any such action by the FDA would have a material adverse effect on our business.

Obtaining and maintaining regulatory approval for a product in one jurisdiction does not mean that we will be successful in obtaining regulatory approval for that product in other jurisdictions.

Obtaining and maintaining regulatory approval for a product in one jurisdiction does not guarantee that we will be able to obtain or maintain similar approval in other jurisdictions; further, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even though the FDA has granted marketing approval for use of our RECELL System for the treatment of full-thickness skin defects and vitiligo, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing, and promotion of the product in those jurisdictions if not currently approved. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including the requirement in such jurisdictions of additional clinical studies due to clinical trials conducted in one jurisdiction not being accepted by regulatory authorities in other jurisdictions. In addition, in certain jurisdictions outside the United States, the reimbursement and/or intended price of a medical device must be approved before it can be approved for sale in that jurisdiction.

Product recalls or inventory losses caused by unforeseen events may adversely affect our operating results and financial condition.

Our products are manufactured, stored, and distributed using technically complex processes requiring specialized facilities, highly specific raw materials and other production constraints. The complexity of these processes, as well as strict company and government standards for the manufacture, storage, and distribution of our product candidates, subject us to risks. In addition, process deviations or unanticipated effects of approved process changes may result in production runs of our RECELL System not complying with stability requirements or specifications. The occurrence or suspected occurrence of production and distribution difficulties can lead to lost inventories and in some cases product recalls, with consequential reputational damage and the risk of product liability. The investigation and remediation of any identified problems can consume management resources and cause production delays, substantial expense, lost sales, and delays of new product launches. In the event our production efforts require a recall or result in an inventory loss, our operating results and financial condition may be adversely affected.

We face manufacturing risks that may adversely affect our ability to manufacture products and could reduce our gross margins and negatively affect our business and operating results.

Our success depends, in part, on our ability to manufacture our current and future products in sufficient quantities and on a timely basis to meet demand, while managing manufacturing costs, while continuing to adhere to product quality standards and comply with regulatory quality system requirements. We have a manufacturing facility located in Ventura, California where we produce, package, and warehouse the RECELL System. We also rely on global third-party manufacturers for production of some of the components used in the RECELL System. If our facility or the facilities of our third-party contract manufacturers suffer damage or experience a force majeure event, this could materially impact our ability to operate.

We are also subject to other risks relating to our manufacturing capabilities, including:

- quality levels and reliability of components, sub-assemblies, and materials that we source from third-party suppliers, who are required to meet our quality specifications, some of whom are our single-source suppliers for the products they supply;
- failure to secure raw materials, components, and materials in a timely manner, in sufficient quantities or on commercially reasonable terms;
- inability to secure raw materials, components, and materials of sufficient quality to meet the exacting needs of medical device manufacturing;
- inability to increase production capacity or volumes to meet demand.

As demand for our products increases, we will have to invest additional resources to purchase raw materials and components, sub-assemblies, and materials, hire and train employees, and enhance our manufacturing processes. If we fail to increase our production capacity efficiently to meet demand for our products, we may not be able to fill customer orders on a timely basis, our sales may not increase in line with our expectations, and our operating margins could fluctuate or decline. It may not be possible for us to manufacture our products at a cost or in quantities sufficient to make these products commercially viable or to maintain current operating margins, all of which could have a material adverse effect on our business, financial condition, or results of operations. Accordingly, we are continually identifying additional third-party suppliers who could serve as replacement suppliers should the need arise.

Compliance with environmental, health and safety requirements is costly and, if not achieved, could result in material financial fines, costly litigation, and a material adverse impact on the business.

Our manufacturing and other processes may involve the use of hazardous materials subject to federal, state, local, and foreign environmental requirements. Under some environmental laws and regulations, we could be held responsible for costs at third-party sites that we have used for waste disposal, or for contamination at our past or present facilities. Failure to comply with current or future environmental laws or regulations could result in significant fines and expenses which could have an adverse impact on our financial condition or business prospects.

We may be subject to civil fines and/or criminal penalties if the FDA determines that we have marketed or promoted our products for off-label usage.

If the FDA determines that our marketing activities constitute off-label promotion, the FDA could impose civil fines or even criminal penalties on the Company and our executives, withdraw or recall our approved product from the market, as well as limit our products from such off-label usage.

We rely on information technology systems for critical business functions and the operations of our business.

We rely upon complex, integrated information technology ("IT") systems in our business functions including our quality systems to operate our business. If any of our IT systems were to be disrupted or fail, our business could suffer irreparable harm, including financial loss, adverse impact to our operations, and reputational damage.

A cyber security incident could be disruptive to our business, compromise confidential data, cause reputation harm, and subject us to litigation and federal and state governmental inquiries.

We collect and store sensitive business and other information, including intellectual property and trade secrets, on our networks. Our business operations are dependent upon the secure maintenance of this information. Despite the implementation of security measures, our IT systems and those of our vendors and customers are vulnerable to attack and damage from computer viruses, malware, denial of service attacks, unauthorized access, or other harm, including from threat actors seeking to cause disruption to our business. We face risks related to the protection of information that we maintain—or engage a third-party to maintain on our behalf—including unauthorized access, acquisition, use, disclosure, or modification of such information. Cyberattacks are increasing in their frequency, sophistication, and intensity and have become increasingly difficult to detect. Cyberattacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering, and other means to affect service reliability and threaten the confidentiality, integrity, and availability of information. Beyond external criminal activity, systems that access or control access to our services and databases may be compromised as a result of human error, fraud or malice on the part of employees or third parties, or may result from accidental technological failure. A material cyberattack or security incident could cause interruptions in our operations and could also damage our reputation, financial condition, and results of operations.

We receive, collect, process, use, and store a large amount of information from our customers and our own employees, including personal information and other sensitive and confidential information. If threat actors are able to circumvent or breach our security systems, they could steal any information located therein or cause serious and potentially long-lasting disruption to our operations. Security breaches or attempts thereof could also damage our reputation and expose us to a risk of litigation, sanctions, and/or monetary loss. We also face risks associated with security breaches affecting third parties that conduct business with us or our customers and others who interact with our data. While we maintain insurance that covers certain security incidents, we may not carry appropriate insurance or maintain sufficient coverage to compensate for damage from all events and related potential liability.

We are subject to diverse laws and regulations relating to data privacy and security, such as federal and state data protection regulations, including the California Consumer Privacy Act, as amended, and European data privacy laws, including the General Data Protection Regulation. Complying with these numerous and complex regulations is expensive and difficult, and failure to comply with these regulations could result in regulatory scrutiny, civil liability and related fines, or damage to our reputation. In addition, any security breach or attempt thereof could result in liability for stolen assets or information, additional costs associated with repairing any system damage, incentives offered to clients or other business partners to maintain business relationships after a breach, and implementation of measures to prevent future breaches, including organizational changes, deployment of additional personnel and protection technologies, increased employee training, and engagement of third-party experts and consultants. The costs incurred to remediate any security incident could be substantial.

In addition, we cannot assure you that any of our third-party service providers with access to our sensitive or confidential information, or to that of our customers and/or employees, will not experience security breaches or attempts thereof, which could have a corresponding effect on our business.

Risks Relating to our Industry and Technology

We face competition from the existing standard of care and any future potential changes in medical practice and technology and the possibility that our competitors may develop products, treatments or procedures that are similar, more advanced, safer or more effective than ours.

The medical device, biotechnology and pharmaceutical industries, specifically relating to the areas where we currently or intend to market our RECELL System, are intensely competitive and subject to significant changes due to technology and medical practice standards. We may face competition from any number of different sources with respect to any products we develop and commercialize.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products, treatments or procedures that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than our RECELL System or any future products we develop. Many of our current or future competitors may have significantly greater financial resources and experience in research and development, manufacturing, pre-clinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we may have. Mergers and acquisitions in the medical device, pharmaceutical, and biotechnology industries, or specifically in the wound care markets, may result in increased concentration of resources among a smaller number of our competitors. Other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These companies compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies necessary for, or complementary to, our programs.

If we are unable to effectively protect our intellectual property, we may not be able to operate our business and third parties may be able to use and profit from our technology, both of which would impair our ability to be competitive.

Our success will be heavily dependent on our ability to obtain and maintain meaningful patent protection for our technologies and products throughout the world. Patent law relating to the technology fields in which we operate continues to evolve. The amount of protection to maintain over our proprietary rights, therefore, is uncertain. Further, the validity and enforceability of our patent portfolio cannot be predicated with certainty. We will rely on patents to protect a significant part of our intellectual property and to enhance our competitive position. However, our presently pending or future patent applications may be denied, and any patent previously issued to us may be challenged, invalidated, held unenforceable or circumvented. Our patents have expected expiration dates ranging from 2032 to 2033, while our pending patent applications, if granted, would have expiration dates ranging from 2034 to 2043. Furthermore, the patent protections we have been granted may not be broad enough to prevent competitors from producing products similar to ours.

In the ordinary course of business and as appropriate, we intend to apply for additional patents covering both our technologies and products, as we deem appropriate. Our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or developing competing products and technologies.

We may find it difficult to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on all of our technologies and products in every jurisdiction is expensive. Competitors could reverse engineer our technologies in jurisdictions where we have not obtained patent protection to develop their own products. These products may compete with our products and may not be covered by any patent claims or other intellectual property rights.

The laws of some countries do not protect intellectual property rights to the same extent as the laws of the United States and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. This lack of protection could make it difficult for us to stop the infringement of our patents. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert the efforts and attention of key personnel from other aspects of our business. If we fail to obtain adequate patent protection for our proprietary technology, our ability to be commercially competitive internationally will be materially impaired.

If third parties make claims of intellectual property infringement against us, or otherwise seek to establish their intellectual property rights equal or superior to ours, we may have to spend time and money in response and potentially discontinue certain of our operations.

While we currently do not believe it to be the case, third parties may claim that we are employing their proprietary technology without authorization or that we are infringing on their patents. If such claims were made, we could incur substantial costs coupled with diversion of key technical personnel in defending against these claims. Furthermore, parties making claims against us may be able to obtain injunctive or other equitable relief which could effectively halt our ability to further develop, commercialize, and sell products. In the event of a successful claim of infringement, courts may order us to pay damages and obtain one or more licenses from third parties. We may not be able to obtain these licenses at a reasonable cost, if at all. Defense of any lawsuit or failure to obtain any of these licenses could prevent us from commercializing available products and have a material negative effect on our financial condition and business prospects.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights and we may be unable to protect our rights to, or use of, our technology.

If we choose to go to court to stop someone else from using the intellectual property claimed in our patents or our licensed patents, that individual or company has the right to ask the court to rule that these patents are invalid and/or should not be enforced against that third party. These lawsuits are expensive and would distract our key personnel and consume time and other resources, even if we were successful in stopping the infringement of these patents. In addition, there is a risk that a court will decide that our patents are invalid or unenforceable and that we do not have the right to stop the other party from using the inventions or, even if the validity or enforceability of these patents is upheld, the court may refuse to stop the other party because the competitors' activities do not infringe our rights.

We could be subject to product liability lawsuits, which could result in costly and time-consuming litigation and significant liabilities.

The development of medical device products, such as our RECELL System, involves an inherent risk of product liability claims and associated financial liability and adverse publicity. Any products we may develop could be found to be harmful or to contain harmful substances and expose us to substantial liability and risk of litigation or may force us to discontinue production. We may be unable to obtain or maintain insurance on reasonable terms or otherwise protect ourselves against potential product liability claims that could impede or prevent further business development of any products we may create and commercialize. Furthermore, a product liability claim could damage our reputation, regardless of the claim's merit or whether liability for such claims is covered by insurance. A product liability claim against us or the withdrawal of a product from the market could have a material adverse effect on our financial condition or business operations. Furthermore, product liability lawsuits, regardless of their success, would likely be time-consuming and expensive to resolve and would divert management's time and attention, which could seriously harm our business.

The continued successful commercialization of the RECELL System for FDA approved and pending indications, will depend in part on the extent to which government authorities and healthcare insurers establish adequate reimbursement levels and pricing policies.

Continued sales of the RECELL System depend in part on the availability of coverage and reimbursement from third-party payers such as government insurance programs, including Medicare and Medicaid, private health insurers, health maintenance organizations and other healthcare-related organizations, who are increasingly challenging the price of medical device products and services.

Both the federal and state governments in the United States continue to propose and pass new legislation, regulations, and policies affecting coverage and reimbursement rates, which are designed to contain or reduce the cost of health care. Continued federal and state proposals and healthcare reforms are likely, which could limit the prices that can be charged for the RECELL System and may further limit our commercial opportunity. For example, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or the IRA, into law which, among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost through a newly-established manufacturer discount program. It is possible that the Affordable Care Act will be subject to judicial or Congressional challenges in the future. Accordingly, we continue to evaluate the effect that the Affordable Care Act has on our business.

There also may be future changes unrelated to the IRA that result in reductions in potential coverage and reimbursement levels for our products, and we cannot predict the scope of any future changes or the impact that those changes would have on our operations. Cost control initiatives may decrease coverage and payment levels and, in turn, impact the prices that we will be able to charge and/or the volume of our sales. We are unable to predict all changes to the coverage or reimbursement methodologies that will be applied by private or government payers. Any denial of private or government payer coverage, such as the Affordable Care Act or the IRA, as well as other federal, state, and foreign healthcare reform measures that have been and may be adopted in the future, or inadequate reimbursement, could reduce our revenue and business prospects. Additionally, if associated rebate obligations are substantially greater than we expect, our future net revenue and profitability could be materially diminished.

Our current and future relationships with regulators, HCPs, third-party payors, customers, and consultants will be subject to applicable healthcare laws and regulations, as well as to other laws and regulations addressing fraud and abuse, and failure to comply with such laws could expose us to penalties.

Our business operations, as well as our current and future relationships with regulators, healthcare professionals, third-party payors, customers, and consultants may expose us to healthcare laws and regulations, as well as to other laws and regulations addressing fraud and abuse. These laws regulate our business as well as the financial arrangements and relationships through which we conduct our operations, including how we research, market, sell, and distribute our products for which we obtain marketing approval. Such laws include:

- Anti-Kickback Statute: the AKS prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation; in addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil FCA.
- False Claims Act: the federal false claims laws including the civil False Claims Act, which can be enforced through civil whistleblower or *qui tam* actions, and civil monetary penalties laws, which impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or knowingly making, or causing to be made, a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; in addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act.
- Data/Privacy Protection: a number of federal, state and foreign laws, regulations, guidance and standards that impose requirements regarding the protection of consumer information that are applicable to or affect our operations.
- Physician Payment Sunshine Act: the federal transparency requirements regarding payments in the healthcare industry, sometimes referred to as the "Sunshine Act," require certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under federal government healthcare programs, to report annually to CMS information related to payments or other "transfers of value" made to HCPs and nurse practitioners.
- Anti-Corruption Laws: Our operations are subject to anti-corruption laws, including laws combating foreign bribery in Australia and the FCPA in the U.S., and other anti-corruption laws that apply in countries where we do business. Anti-corruption laws generally prohibit us and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. We participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under these anti-corruption laws. In addition, we cannot predict the nature, scope, or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered, interpreted or changed.
- State and Foreign Laws: Analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to our business practices, including but not limited to, research, distribution, sales, and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, or may otherwise restrict payments to healthcare providers and other potential referral sources; as well as state laws that require medical device companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government. State laws that require medical device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or drug pricing, as well as state and local laws that require the registration of sales representatives may also apply to our business and operations.

Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our financial condition and operations, as well as business prospects, may be impaired.

Macroeconomic and Social Risks

Adverse changes in general economic conditions or uncertainty about future economic conditions, could adversely affect us.

We are subject to the risks arising from adverse changes in general economic market conditions. Uncertainty about future economic conditions could negatively affect our current and prospective customers causing them to delay the purchase of our products. Customer and consumer demand for our products may be impacted by weak economic conditions, recession, equity market volatility or other negative economic factors in the U.S. or other nations. The severity and length of time that a downturn in economic and financial market conditions may persist, as well as the timing, strength, and sustainability of any recovery from such downturn, are unknown and beyond our control. Poor economic conditions could harm our business, financial condition, operating results, and cash flows.

Risks Relating to Our Common Stock and CDIs

We have never paid a dividend on our common stock and CDIs and do not intend to do so in the foreseeable future, and consequently, investors' only opportunity to realize a return on their investment in the Company is through the appreciation in the price of our common stock and CDIs.

We do not anticipate paying cash dividends on our common stock and CDIs in the foreseeable future and intend to retain all earnings, if any, to fund our operations. Even if funds are legally available for distribution, we may be unable to pay any dividends to our stockholders because of limitations imposed by a lack of liquidity. Accordingly, our stockholders may have to sell some or all of their common stock or CDIs (as applicable) in order to generate cash flow from their investment. Our stockholders may not receive a gain on their investment when they sell their common stock or CDIs and may lose some or all of their investment. Any determination to pay dividends in the future on our common stock and CDIs will be made at the discretion of our Board of Directors and will depend on our results of operations, financial condition, contractual restrictions, restrictions imposed by applicable law, capital requirements, and other factors that our Board of Directors deems relevant.

As long as we remain subject to the rules of the Australian Securities Exchange ("ASX") and of Nasdaq, we will be unable to access equity capital without stockholder approval if such equity capital sales would result in an equity issuance above regulatory thresholds, and consequently, we may be unable to obtain financing sufficient to sustain our business if we are unsuccessful in soliciting requisite stockholder approvals.

Our ability to access equity capital is currently limited by ASX Listing Rule 7.1, which provides that a company must not, subject to specified exceptions, issue or agree to issue during any consecutive 12-month period any equity securities, or other securities with rights to conversion to equity, if the number of those securities in aggregate would exceed 15% of the number of outstanding common shares at the commencement of that 12-month period unless stockholder approval is obtained.

Our equity issuances will be limited by ASX Listing Rule 7.1 so long as we continue to be listed on the ASX and this constraint may prevent us from raising the full amount of equity capital needed for operations without prior stockholder approval.

In addition to ASX Listing Rule 7.1, we are also subject to Nasdaq Listing Rule 5635(d), commonly referred to as the Nasdaq 20% Rule, which requires stockholder approval of a transaction other than a public offering involving the sale, issuance, or potential issuance by a company of common stock (or securities convertible into or exercisable for common stock) equal to 20% or more of the common stock, or 20% or more of the voting power outstanding before the issuance for less than the greater of book or market value of the shares. While less restrictive than ASX Listing Rule 7.1, the operation of the Nasdaq 20% rule could limit our ability to raise capital through issuance of common stock or convertible securities without jeopardizing our listing status. If we were to violate the Nasdaq 20% rule, the Company would be subject to delisting from Nasdaq and share prices and trading volumes would likely suffer.

There has been relatively limited trading volume in the markets for our common stock and CDIs, and more active, liquid trading markets for such securities may never develop.

Trading in our common stock on Nasdaq and our CDIs on the ASX is often thin and susceptible to wide fluctuations in trading prices due to such limited trading volume and other factors, some of which may have little to do with our operations or business prospects. Limited liquidity in the trading markets for our common stock and CDIs may adversely affect a stockholder's ability to sell its shares of our common stock or CDIs at the time it wishes to sell them or at a price that it considers acceptable. In addition, if a more active, liquid public trading market does not develop we may be limited in our ability to raise capital by selling shares of common stock or CDIs. We cannot assure you that more active, liquid public trading markets for our common stock and CDIs will develop or, if developed, will be sustained.

The market price and trading volume of our common stock and CDIs may be volatile and may be affected by variability in our performance from period to period and economic conditions beyond management's control.

The market price of our common stock (including common stock represented by CDIs) may be highly volatile and could be subject to wide fluctuations. This means that our stockholders could experience a decrease in the value of their common stock or CDIs regardless of our operating performance or prospects. The market prices of securities of companies operating in the medical device sectors have often experienced fluctuations that have been unrelated or disproportionate to their operating results. In addition, the trading volume of our common stock and CDIs may fluctuate and cause significant price variations to occur. If the market price of our common stock or CDIs declines significantly, our stockholders may be unable to resell our common stock or CDIs at or above their purchase price, if at all. There can be no assurance that the market price of our common stock and CDIs will not fluctuate or significantly decline in the future.

Some specific factors that could negatively affect the price of our common stock and CDIs or result in fluctuations in their price and trading volume include:

- actual or expected fluctuations in our operating results;
- actual or expected changes in our growth rates or our competitors' growth rates;
- results of clinical trials of our product candidates;
- results of clinical trials of our competitors' products;
- regulatory actions with respect to our products or our competitors' products;
- reports of one or more patients experiencing adverse events;
- publication of research reports by analysts about us or our competitors in the industry;
- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- fluctuations of exchange rates between the U.S. dollar and the Australian dollar;
- issuance by us of debt or equity securities;
- litigation involving our company, including stockholder litigation;
- investigations or audits by regulators into the operations of our company;
- proceedings initiated by our competitors or clients;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- sales or perceived potential sales of the common stock or CDIs by us, our directors, executive management team or our stockholders in the future;
- short selling or other market manipulation activities;
- announcement or expectation of additional financing efforts;
- terrorist acts, acts of war or periods of widespread civil unrest;
- natural disasters and other calamities;
- changes in market conditions for medical device stocks;
- our inability to raise additional capital, limiting our ability to continue as a going concern;
- changes in market prices for our product or for our raw materials;
- changes in market valuations of similar companies;
- changes in key personnel for us or our competitors;
- speculation in the press or investment community;
- changes or proposed changes in laws and regulations affecting our industry; and
- conditions in the financial markets in general or changes in general economic conditions.

If research analysts publish unfavorable commentary or downgrade our common stock or CDIs, it could adversely affect our share price and trading volume.

The trading market for our common stock and CDIs depends, in part, on the research and reports that analysts publish about us and our business and industry. If one or more analysts downgrade our shares or CDIs, publish unfavorable commentary about the Company or cease publishing reports about us or our business, the price of our common stock and CDIs could decline. If one or more of the analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our common stock and CDIs could decrease, which could cause our share price or trading volume to decline.

The requirements of being a public company in the United States and listed on the ASX may strain our resources and divert management's attention.

As a public company, we are subject to the reporting requirements of the Exchange Act, the U.S. Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), the Dodd-Frank Act, and the listing standards and the rules and regulations of Nasdaq. We are also subject to the reporting requirements under the ASX Listing Rules due to the listing of our CDIs on ASX. The requirements of these rules and regulations will increase our legal, accounting, and financial compliance costs, make some activities more difficult, time-consuming and costly, and can place significant strain on our personnel, systems, and resources. As a result of our disclosure of information in filings required of a public company, our business and financial condition is more visible, which may result in threatened or actual litigation, including by competitors, stockholders or third parties. If such claims are successful, and even if the claims do not result in litigation or are resolved in our favor, these claims, and the time and resources necessary to resolve them, could divert the resources of our management and harm our business and operating results.

We are an emerging growth company, and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

- We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, and as such, have taken advantage of certain exemptions and relief from various U.S. reporting requirements that are applicable to other public companies that are not emerging growth companies, including (i) not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, (ii) having the option of delaying the adoption of certain new or revised financial accounting standards, (iii) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and (iv) exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. Accordingly, the information contained herein and in other reports we file with the SEC may be different than the information our investors receive from other public companies in which they hold stock. Further, we have elected to take advantage of the extended transition period for complying with new or revised accounting standards until those standards would otherwise apply to private companies. As a result, our operating results and financial statements may not be comparable to the operating results and financial statements of other companies who have adopted the new or revised accounting standards. It is possible that some investors will find our common stock and CDIs less attractive as a result, which may result in a less active trading market for our common stock and CDIs, and higher volatility in our stock and CDI price.

We expect to lose emerging growth company status on December 31, 2025, which is the last day of the fiscal year following the fifth anniversary of the first sale of our common stock pursuant to an effective registration statement under the Securities Act. In connection with losing such status, we may expect to incur significant expenses and devote substantial management effort toward ensuring compliance with the requirements of Section 404 of the Sarbanes-Oxley Act. An independent assessment of our internal controls may detect materials weaknesses, which could lead to regulatory scrutiny, a loss of confidence by stockholders, and resulting adverse effect on the market price of our common stock and CDIs.

General Risk Factors

The Company's cash, cash equivalents and marketable securities could be adversely affected by bank failures or other events affecting financial institutions and could adversely affect our liquidity and financial performance.

We regularly maintain domestic cash deposits in Federal Deposit Insurance Corporation ("FDIC") insured banks, which exceed the FDIC insurance limits. We also maintain cash deposits in foreign banks where we operate, some of which are not insured or are only partially insured by the FDIC or other similar agencies. The failure or rumored failure of a bank, or events involving limited liquidity, defaults, non-performance, bankruptcy, receivership or other adverse developments in the financial or credit markets impacting financial institutions, may lead to disruptions in access to our bank deposits. These disruptions may adversely impact our liquidity and financial performance. There can be no assurance that our deposits in excess of the FDIC or other comparable insurance limits will be backstopped by the U.S. or applicable foreign government, or that any bank or financial institution with which we do business will be able to obtain needed liquidity from other banks, government institutions or by acquisition in the event of a failure or liquidity crisis. As such, those funds in bank deposit accounts in excess of the standard FDIC insurance limits are uninsured and subject to the risk of bank failure.

Currently, we have full access to all funds in deposit accounts or other money management arrangements. The failure of any bank in which we deposit our funds could reduce the amount of cash that we have available for our operations or delay our ability to access such funds. In the event of such failure, we may experience delays or other issues in meeting our financial obligations, our ability to access our cash and cash equivalents may be threatened and could have a material adverse effect on our business and financial condition.

Future adverse developments with respect to specific financial institutions or the broader financial services industry may also lead to market-wide liquidity shortages.

If we fail to manage our growth effectively, our business could be disrupted.

Our future financial performance and ability to successfully commercialize our products and to compete in the market will depend, in part, on our ability to manage any future growth effectively. We expect to make significant investments to facilitate our future growth through, among other things:

- new product development;
- commercial development of our RECELL System to include full-thickness skin defects;
- clinical trials for additional indications; and
- funding of our marketing and sales infrastructure.

Any failure to manage future growth effectively could have a material adverse effect on our business and results of operations.

Our growth and success depend on our ability to attract and retain additional highly qualified and skilled sales and marketing, research and development, operational, managerial, legal, and finance personnel.

Competition for skilled personnel is intense and the unexpected loss of an employee with a particular skill could have a material adverse effect on our operations until a replacement can be found and trained. If we cannot attract and retain skilled scientific and operational personnel for our research and development and manufacturing operations on acceptable terms, we may not be able to develop and commercialize our products. Further, any failure to effectively onboard and train new personnel could prevent us from successfully growing our company.

There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws or other laws including trade related laws. If we are not in compliance with these laws, we may be subject to criminal and civil penalties, disgorgement, and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations, and liquidity.

Likewise, any investigation of potential violations of these laws by respective government bodies could also have an adverse impact on our reputation, our business, financial condition, and results of operations.

Item 1B. UNRESOLVED STAFF COMMENTS

None

Item 1C. CYBERSECURITY

Risk Management and Strategy

AVITA Medical has implemented an Information Security Management System (**"**ISMS**"**). The Company's ISMS is a continuous process designed to analyze the potential risks, vulnerabilities, the likeliness of occurrence and the related consequences of cybersecurity threats. The process is based on establishing the context, assessing the risks, and treating the risks. The key concept of the ISMS is to consistently maintain and improve confidentiality, integrity, and availability of information assets that should be protected by the organization on behalf of itself and its clients, and third parties. Once a risk, threat or vulnerability is identified, the Company establishes a risk treatment plan to take corrective action to prevent risks that can be avoided and minimize the ones that cannot. We engage an independent third-party cybersecurity services and consulting firm to continuously review our information security and provide technical oversight. We also conduct internal phishing campaigns and perform an independent penetration test on an annual basis. In addition, we conduct regular security awareness training and testing of our employees. The Company has not had any material cybersecurity incidents.

All related activities ISMC activities have been structured into a framework consisting of:

1. Context establishment - Established in accordance with the requirements of International Organization for Standardization 27001 and 27002 ("ISO 27001" and "ISO 27002"). The ISO 27001, Information security management systems, provides a framework and guidelines for establishing, implementing and managing an ISMS and ISO 27002, Information security controls, provides a reference set of generic information security controls including implementation guidance.
2. Risk Assessment - Relates to an evaluation and identification of risks, threats and vulnerabilities that exist or could exist, identifies the likelihood of occurrence and potential consequences. As part of the risk assessment management prioritizes the assessed risks from low to high based on likelihood and level of impact.
3. Risk Treatment – will detail the remediation process for risks, vulnerabilities and threats identified to reduce the risk to an acceptable level.
4. Risk Acceptance- The Company's risk assessment is evaluated from a Low (1) to a High (3) on the Impact the threat would have on the Company and its operations and the likelihood of occurrence. Threat ratings created from the Impact and probability calculations will result with a value from 1- 9.
    a. Low (1 – 2.99) = Risk level acceptable and no further action deemed necessary
    b. Medium (2 – 5.99) and High (6 - 9) – implement risk management to reduce the risk to an acceptable level
5. Risk Communications- Results of the risk assessment are communicated to appropriate levels of management. Report includes the identified risk and vulnerability summaries. Updates will include treatment plans and status updates.
6. Risk Monitoring and Review - Continuously performed to evaluate any changes or the need for changes. The Company uses the Ontrack software solution ("Ontrack") to monitor and track all aspects of risk assessment. Ontrack also serves as tool to track any cybersecurity incidents and remediation tasks.

Disclosure of Management's Responsibility

The Company's Chief Financial Officer is responsible for overseeing the Cybersecurity Risk Management Program and leading the Company's efforts to mitigate technology risks in partnership with various business leaders in the organization. For qualifications of the CFO refer to Item 10 of the Form 10-K. We have protocols, policies and tools in place to mitigate cybersecurity risk. They also provide the administrative, technical, and physical safeguards to ensure the security, confidentiality, integrity and availability of confidential information and personal information from unauthorized access, use, disclosure, alteration, destruction or theft. In addition, we engage an independent third party annually to assess our IT general controls and IT security. Special focus is given to maintaining and improving our alignment with ISO 27001. Additionally, we have a cybersecurity incident response plan in place that provides a documented framework for handling high and low severity security incidents and facilitates coordination across multiple parts of the business. Finally, cybersecurity is integrated into the Company's training as all employees are required to take security awareness training.

Disclosure of the Board's Responsibility

While management is primarily responsible for assessing and managing cybersecurity risks on a day-to-day basis, the Company's Board of Directors oversees management's efforts to assess and manage risk. The Board of Directors (through the Audit Committee) monitors the cybersecurity risk assessment and response process. The Audit Committee is briefed by our Chief Financial Officer on our cybersecurity ISMS program and the overall cybersecurity risk environment. The briefing may include discussions on topics such as: information security and technology risks, cybersecurity risk assessment process and updates, information risk management strategies, and progress on cybersecurity and data protection training initiatives for employees, among others.

Item 2. PROPERTIES

Our principal corporate office is located at 28159 Avenue Stanford, Suite 220, Valencia, California 91355. We lease the 17,500 square foot facility under a lease agreement that expires on October 31, 2026. Our production plant in Ventura, California is a 27,480 square foot facility that we lease through September 30, 2027 with the right to extend the lease, at our sole option, up to an additional three years. The Company also has an administrative office lease in Irvine, California of approximately 10,700 square feet that is currently leased through the end of July 2028. On January 1, 2024, we also began leasing a 3,400 square foot storage facility adjacent to our existing production plant in Ventura. We extended the lease through December 31, 2025 and have an option to extend the lease for an additional year through December 31, 2026. We do not own any real property. We believe that leased facilities are adequate to meet current needs and that additional facilities will, if required, be available for lease to meet future needs.

Item 3. LEGAL PROCEEDINGS

We are currently not aware of any material pending legal proceedings to which we are a party or of which any of our property is the subject, nor are we aware of any such proceedings that are contemplated by any governmental authority. From time to time, as an operating business, we are involved in routine disputes (both formal and informal) with customers, manufacturing partners and employees.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

The Company's common stock is quoted on the Nasdaq Capital Market under the ticker symbol "RCEL" and the Company's CDIs are quoted on the ASX under the ticker code "AVH". One share of common stock on Nasdaq is equivalent to five CDIs on the ASX.

Holders

As of January 27, 2025, the Company had approximately 4 unique stockholders of record of our common stock (which includes 19,321 holders of record of the Company's CDIs, with each representing 1/5 of a share of common stock, and CHESS Depositary Nominees Pty Ltd, holds the legal title to all of the outstanding common stock underlying the CDIs of the Company).

Dividends

We have never paid cash dividends to our stockholders or to the holders of ordinary shares in the former parent company, AVITA Australia. We intend to retain future earnings for use in our business and do not anticipate paying cash dividends on our common stock and CDIs in the foreseeable future. Any future dividend policy will be determined by our board of directors and will be based upon various factors, including our results of operations, financial condition, current and anticipated cash needs, future prospects, contractual restrictions and other factors as our board of directors may deem relevant.

Item 6. [Reserved]

Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITIONS AND RESULTS OF OPERATIONS

Objective

The purpose of this Management's Discussion and Analysis is to better allow our investors to understand and view our company from management's perspective. We are providing an overview of our business and strategy including a discussion of our financial condition and results of operations. The following discussion and analysis of our financial condition and results of operations for the years-ended December 31, 2024 and 2023, should be read in conjunction with our consolidated financial statements and related notes included in this Annual Report.

Overview

AVITA Medical, Inc. ("we", "our", "us") is a leading therapeutic acute wound care company delivering transformative solutions. Our technologies are designed to optimize skin restoration procedures, effectively accelerating patient healing and recovery. Our solutions improve the healing outcomes for patients with traumatic injuries and surgical repairs, addressing critical healing needs that arise from unpredictable and life-changing events. At the forefront of our portfolio is our patented and proprietary RECELL® System ("RECELL System" or "RECELL"), approved by the U.S. Food & Drug Administration (the "FDA") for the treatment of thermal burn wounds and full-thickness skin defects, and for repigmentation of stable depigmented vitiligo lesions. RECELL harnesses the regenerative properties of a patient's own skin to create an autologous skin cell suspension, Spray-On Skin™Cells, delivering a transformative solution at the point of care. This breakthrough technology serves as the catalyst for a new treatment paradigm enabling improved clinical outcomes. In the United States, we also hold the rights to market, sell, and distribute PermeaDerm®, a biosynthetic wound matrix, under the terms of an exclusive multi-year distribution agreement (the "Stedical Agreement") with Stedical Scientific, Inc. ("Stedical"). We also entered into an exclusive multi-year development and distribution agreement with Collagen Matrix, Inc. dba Regenity Biosciences ("Regenity"). Regenity will manufacture and supply Cohealyx™, an AVITA Medical-branded, FDA-cleared, collagen-based dermal matrix. Under the agreement, we will hold the exclusive rights to market, sell, and distribute Cohealyx in the U.S., with potential expansion into the European Union, Australia, and Japan.

The single-use RECELL Autologous Cell Harvesting Device ("RECELL Ease-of-Use" or "RECELL EOU") is approved by the FDA for the treatment of thermal burn wounds and full-thickness skin defects, and repigmentation of stable depigmented vitiligo lesions. Our next-generation device, RECELL GO™ Autologous Cell Harvesting Device ("RECELL GO"), is FDA-approved to treat thermal burn wounds and full-thickness skin defects. RECELL GO introduces enhanced features that streamline the preparation of Spray-On Skin Cells and improves workflow efficiency in the operating room. It consists of two components: the RECELL GO Processing Device (the "RPD") and the RECELL GO Preparation Kit (the "RPK"). The RPD is a multi-use, AC-powered device that controls the RPK. The RPK is a single-use cartridge that contains the RECELL Enzyme™. The RPD regulates the pressure applied to disaggregate the cells and precisely controls the incubation time of the RECELL Enzyme to optimize cell yield and promote cell viability.

We are focused on becoming the leading provider of therapeutic acute wound care solutions addressing unmet medical needs in burn injuries and full-thickness skin defects. We will continue to drive commercial revenue growth to generate free cash flow and achieve operating profit. To achieve these objectives, we intend to:

- Become the standard of care in the U.S. burn care market by increasing penetration and adoption in burn centers with our recently FDA-approved RECELL GO
- Expand adoption of RECELL technology for the treatment of full-thickness skin defects in the U.S. with RECELL GO
- Launch RECELL GO mini, which is designed to address smaller wounds, following FDA approval in December of 2024
- Launch Cohealyx™ after FDA 510(k) clearance received in December of 2024
- Expand our global presence within Australia, the European Union, Japan, and the U.K.through the exclusive use of third-party distributors
- Continue to grow commercial activities in Japan through our partnership with COSMOTEC Company, Ltd ("COSMOTEC") by leveraging our current Pharmaceuticals and Medical Devices Act approval for RECELL with an indication in burns
- Continue to pursue business development opportunities that are complementary to our core RECELL technology and/or our targeted markets, such as our exclusive distribution agreements with Stedical and Regenity
- Expect post-market study, TONE, and the health care economics study, both related to our vitiligo initiative to be published in early 2025

Business Environment and Current Trends

The macroeconomic environment may have unexpected adverse effects on businesses and healthcare institutions globally that may negatively impact our consolidated operating results. There remains significant uncertainty in the current macroeconomic environment due to factors including supply chain shortages, increased cost of healthcare, changes to inflation rates, a competitive labor market, and other related global economic conditions and geopolitical conditions. If these conditions continue or worsen, they could adversely impact our future operating results.

Changes in reimbursement rates by third party payors may place additional financial pressure on hospitals and the broader healthcare system. Healthcare institutions may take actions to mitigate any persistent pressures on their budgets and such actions could impact the future demand for our products. Geopolitical conditions may also impact our operations. Although we do not have operations in Russia, Ukraine or in the Middle East, the continuation of the military conflicts in these regions and/or an escalation of the conflicts beyond their current scope may further weaken the global economy that could result in additional inflationary pressures or supply chain constraints.

Recent Developments

On January 10, 2024, we entered into an exclusive multi-year distribution agreement with Stedical to commercialize PermeaDerm® Biosynthetic Wound Matrix ("PermeaDerm") in the United States. PermeaDerm is cleared by the FDA as a transparent matrix for use in the treatment of a variety of wound types until healing is achieved. Under the terms of the Stedical Agreement, we hold the exclusive rights to market, sell, and distribute PermeaDerm products, including any future enhancements or modifications, within the United States. The initial term is for five years, with the option to renew for an additional five years, contingent upon meeting certain minimum requirements.

On February 16, 2024, we amended our contract with the Biomedical Advanced Research and Development Authority ("BARDA"), under the Assistant Secretary for Preparedness and Response, within the U.S. Department of Health and Human Services, dated September 29, 2015, to extend the term through September 28, 2025. Under the modified contract, BARDA will have access to our RECELL inventory in the event of a national emergency. In the case of a national emergency, BARDA will pay for RECELL devices at a reduced price for the first 1,000 units and will then pay retail price for any additional units. No additional inventory build will be required as part of this modification as we have sufficient inventory in stock to fulfill this requirement. BARDA will pay us approximately $333,000 in maintenance fees over the term of the contract to ensure its first right of access to our RECELL inventory.

On May 29, 2024, the FDA approved our premarket approval ("PMA") supplement for RECELL GO, our next generation autologous cell harvesting device, to treat thermal burn wounds and full-thickness skin defects. Following this approval, we shipped the first RECELL GO order on May 30, 2024, to accommodate the first case for its use on May 31, 2024.

On June 28, 2024, we submitted a PMA supplement for RECELL GO mini, which is designed to address small wounds up to 480 cm^2. This version retains the same multi-use processing units as RECELL GO but features a smaller cartridge designed for the smaller donor skin samples needed for smaller wounds. This submission maintains the FDA Breakthrough Device designation from predecessor devices, providing a prioritized 180-day review period.

On July 31, 2024, we entered into a multi-year exclusive development and distribution agreement with Regenity to market, sell, and distribute Cohealyx, an AVITA-Medical branded collagen-based dermal matrix in the U.S., with the potential to commercialize the product in the European Union, Japan, and Australia.

On November 12, 2024, we entered into a partnership with Revolution Surgical Pty Ltd, to market and distribute the RECELL System in Australia and New Zealand.

On December 19, 2024, the FDA granted 510(k) clearance for Cohealyx. We plan to develop clinical data for Cohealyx in early 2025 to build on preclinical success and support the product's full commercial launch. The post-market clinical study will assess Cohealyx's performance in real-world settings, focusing on clinical efficacy and cost savings in the treatment of full-thickness wounds and burns. In the U.S., we expect to launch full commercialization efforts in the beginning of the second quarter of 2025.

On December 23, 2024, the FDA approved RECELL GO mini. We expect RECELL GO mini to serve as a growth driver within the broader RECELL GO platform, further advancing our strategy to expand our impact on patient care. Launch will begin with trauma and burn centers that currently treat smaller wounds during the first quarter of 2025.

Results of Operations

Year-Ended December 31, 2024, compared to the Year-Ended December 31, 2023

The table below summarizes the results of our operations for each of the periods presented (in thousands).

	Year Ended			
Statement of Operations Data:	**December 31, 2024**	**December 31, 2023**	**$ Change**	**% Change**
Sales revenue	$ 63,893	$ 50,143	13,750	27.4%
Lease revenue	358	-	358	100.0%
Total revenues	64,251	50,143	14,108	28.1%
Cost of sales	(9,094)	(7,780)	(1,314)	(16.9)%
Gross profit	55,157	42,363	12,794	30.2%
BARDA income	-	1,428	(1,428)	(100.0)%
Operating expenses:				
Sales and marketing	(58,195)	(37,291)	(20,904)	(56.1)%
General and administrative	(33,195)	(28,334)	(4,861)	(17.2)%
Research and development	(20,360)	(20,821)	461	2.2%
Total operating expenses	(111,750)	(86,446)	(25,304)	(29.3)%
Operating loss	(56,593)	(42,655)	(13,938)	(32.7)%
Interest expense	(5,361)	(1,143)	(4,218)	*nm
Other income, net	163	8,483	(8,320)	(98.1)%
Loss before income taxes	(61,791)	(35,315)	(26,476)	(75.0)%
Income tax expense	(54)	(66)	12	(18.2)%
Net loss	$ (61,845)	$ (35,381)	(26,464)	(74.8)%

*nm = not meaningful

Total revenues increased by 28%, or $14.1 million, to $64.3 million, compared to $50.1 million in the year-ended December 31, 2023. Our commercial revenue was $64.0 million for the year-ended December 31, 2024, an increase of $14.2 million, or 29%, compared to $49.8 million in the year-ended December 31, 2023. The growth in commercial revenues was largely driven by deeper penetration within customer accounts and new accounts for full-thickness skin defects.

Gross profit margin was 85.8% compared to 84.5% in the corresponding period in the prior year. This increase was largely driven by increases in both revenues and the volume of production.

BARDA income decreased to zero, compared to $1.4 million in the corresponding period in the prior year due to the ending of reimbursable clinical trials. BARDA income in the prior year consisted of funding received from the Biomedical Advanced Research and Development Authority, under the Assistant Secretary for Preparedness and Response, within the U.S. Department of Health and Human Services, under ongoing USG Contract No. HHSO100201500028C.

Total operating expenses increased by 29% or $25.3 million to $111.8 million, compared with $86.4 million in the year-ended December 31, 2023.

Sales and marketing expenses increased by 56%, or $20.9 million, to $58.2 million, compared to $37.3 million in the year-ended December 31, 2023. Higher costs in the current year were related to increases in salaries and benefits and personnel expenses of approximately $8.7 million, commissions expense of $7.4 million, stock-based compensation expense of $1.8 million, $1.2 million in professional fees, $0.6 million in other selling expenses, $0.6 million in travel expenses, and $0.2 million in rent expense, plus $0.4 million in all other expenses, net. The increase in salaries and benefits, personnel-related expenses, stock-based compensation, travel expenses, and other selling expenses are due to the expansion of the sales force to support our growing commercial capabilities. Higher commissions were directly associated with the increase in revenues. The increase in professional fees are primarily due to consulting expenses related to our foreign distribution network. The increase in rent is due to increased office space to accommodate our growing operations.

General and administrative expenses increased by 17%, or $4.9 million, to $33.1 million, compared to $28.3 million in the year-ended December 31, 2023. The increase was attributable to increases in salaries and benefits and personnel expenses of $2.9 million, stock-based compensation of $2.4 million, and rent expense of $0.5 million, partially offset by lower deferred compensation expenses of $0.4 million, lower insurance expense of $0.3 million plus lower other corporate expenses, net of $0.3 million. The increase in salaries and benefits and stock-based compensation are primarily attributable to headcount growth to support the expansion of our business. The decrease in the deferred compensation expense is driven by a lower stock price used to calculate the deferred compensation liability for the deferred restricted stock awards.

Research and development expenses decreased by 2%, or $0.5 million, to $20.3 million, compared to $20.8 million in the year-ended December 31, 2023. The decrease in research and development expenses is primarily due to lower professional fees and development expenses of approximately $4.0 million related to RECELL GO and full-thickness skin defects plus lower other development expenses, net of $0.3 million, partially offset by an increase in salaries and benefits of $2.8 million, an increase in stock-based compensation of $0.7 million, and an increase of $0.3 million in travel expenses, primarily due to the increase in headcount resulting from the deployment of Medical Science Liaisons.

Interest expense increased approximately $4.2 million in comparison to the prior year due to the interest expense related to the long-term debt as part of the OrbiMed Credit Agreement for the full year, for an aggregate principal amount owed of $40.0 million.

Other income, net decreased by $8.3 million to $0.2 million. In the current year, other income, net consisted of $2.7 million in income related to our investments and $0.3 million in other gains, net offset by non-cash charges of $2.5 million due to the change in fair value of the debt and $0.3 million due to the change in fair value of warrant liability. In the prior period, income consisted of $3.1 million in income from our investment activities, dissolution of certain foreign subsidiaries that resulted in a $9.4 million gain, plus other gains, net of $0.3 million, partially offset by a loss on debt issuance of $1.2 million, debt issuance costs of $0.8 million and the change of fair value for our debt of $1.6 million and change in fair value of warrants for $0.7 million.

Net loss increased by $26.5 million, to $61.8 million, over the $35.4 million recognized in the year ended December 31, 2023. The increase in net loss was driven by the higher operating expenses and lower other income, net, partially offset by higher gross profit as described above.

Year-Ended December 31, 2023, compared to the Year-Ended December 31, 2022

The table below summarizes the results of our operations for each of the periods presented (in thousands).

Statement of Operations Data:	Year-Ended December 31, 2023	Year-Ended December 31, 2022	$ Change	% Change
Revenues	$ 50,143	$ 34,421	15,722	46 %
Cost of sales	(7,780)	(6,041)	(1,739)	(29)%
Gross profit	42,363	28,380	13,983	49 %
BARDA income	1,428	3,215	(1,787)	(56)%
Operating expenses:				
Sales and marketing	(37,291)	(21,913)	(15,378)	(70)%
General and administrative	(28,334)	(23,330)	(5,004)	(21)%
Research and development	(20,821)	(13,857)	(6,964)	(50)%
Total operating expenses	(86,446)	(59,100)	(27,346)	(46)%
Operating loss	(42,655)	(27,505)	(15,150)	(55)%
Interest expense	(1,143)	(16)	(1,127)	*nm
Other income, net	8,483	892	7,591	*nm
Loss before income taxes	(35,315)	(26,629)	(8,686)	(33)%
Income tax expense	(66)	(36)	(30)	(83)%
Net loss	$ (35,381)	$ (26,665)	(8,716)	(33)%

*nm = not meaningful

Total net revenues increased by 46%, or $15.7 million, to $50.1 million, compared to $34.4 million in the year-ended December 31, 2022. Our commercial revenue, which excludes BARDA revenue, was $49.8 million for the year-ended December 31, 2023, an increase of $15.8 million, or 46%, compared to $34 million in the year-ended December 31, 2022. The growth in commercial revenues was largely driven by deeper penetration within individual customer accounts and the full-thickness skin defects launch along with the commencement of commercial sales with our partner COSMOTEC in Japan.

Gross profit margin increased by 2% to 84.5% compared to 82.4% in the year-ended December 31, 2022. The increase in gross profit margin was largely driven by higher production along with lower shipping costs.

BARDA income consisted of funding from BARDA, under the Assistant Secretary for Preparedness and Response, within the U.S. Department of Health and Human Services, under ongoing USG Contract No. HHSO100201500028C. BARDA income decreased 56% or $1.8 million to $1.4 million, compared to $3.2 million in the year-ended December 31, 2022, due to reimbursable clinical trials winding down.

Total operating expenses increased by 46% or $27.3 million to $86.4 million, compared with $59.1 million in the year-ended December 31, 2022.

Sales and marketing expenses increased by 70%, or $15.4 million, to $37.3 million, compared to $21.9 million incurred in the year-ended December 31, 2022. Higher costs in the current year were primarily attributed to higher salaries and benefits, commissions, recruitment fees and travel costs. The increase in salaries and benefits and recruitment fees were due to the preparation of the commercial launch of full-thickness skin defects in June 2023. Higher commissions and travel costs were directly associated with the increase in revenues.

General and administrative expenses increased by 21%, or $5.0 million, to $28.3 million, compared to $23.3 million incurred in the year-ended December 31, 2022. The increase was attributable to salaries and benefits, deferred compensation expense, stock-based compensation, and severance costs. Higher salary and benefits are driven by the increase in headcount. The increase in deferred compensation expense was driven by our deferred compensation liability which generally tracks the movements in the stock market. Severance costs in the current year were due to the termination of three former executive officers, partially offset by the termination of a former executive officer in the prior year.

Research and development expenses increased by 50%, or $6.9 million, to $20.8 million, compared to $13.9 million incurred in the year-ended December 31, 2022. The increase was primarily due to higher clinical trial costs associated with the TONE study as well as other research and development costs associated with furthering our pipeline, and the development of the next generation RECELL GO for preparation of Spray-On Skin Cells, which resulted in a PMA submission in June 2023. We also had increased expenses associated with building out a team of Medical Science Liaisons in support of the new full-thickness skin defects indication.

Interest expense increased by $1.1 million due to the new Credit Agreement entered into with OrbiMed Advisors, LLC on October 18, 2023.

Other income, net increased by $7.6 million in the current year primarily due to an increase of $2.1 million in income from our investment activities, wind down of certain foreign subsidiaries that resulted in a $9.4 million gain, partially offset by a loss on debt issuance of $1.2 million, debt issuance costs of $0.8 million and the change of fair value for our debt of $1.6 million and change in fair value of warrants for $0.7 million. We had an increase of approximately $2.1 million in interest income due to higher investment yields. By the end of the fourth quarter of 2023 the business activities of AVITA Medical Pty Limited, AVITA Medical Europe Limited, Visiomed Group Pty Ltd, C3 Operations Pty Ltd and Infamed Pty Ltd were essentially dissolved. As part of the liquidation the company recognized $9.4 million of non-cash foreign currency exchange gains associated with the elimination of the foreign subsidiaries. The gains were offset by expenses related to issuance of debt. We recognized approximately $1.2 million loss on debt issuance as the fair value of the debt and the warrants on the issuance date exceeded the proceeds received on October 18, 2023, the closing date. In addition, we incurred approximately $0.8 million in debt issuance costs. We also recognized $1.6 million and $0.7 million of non-cash charges due to the change in fair value of the debt and the warrant liability, respectively. As permitted under ASC 825, we elected the fair value option to account for the debt, and recorded the debt and warrants at fair value with changes in fair value recorded in the Consolidated Statements of Operations. Changes in fair value related to instrument specific credit risk for the debt are included in Other comprehensive income in the Consolidated Balance Sheets.

Net loss increased by $8.8 million, to $35.4 million, over the $26.7 million recognized in the year ended December 31, 2022. The increase in net loss was driven by the higher operating expenses, partially offset by higher revenues and the non-cash charges as described above.

Liquidity and Capital Resources

Overview

We expect to utilize cash reserves until U.S. sales of our products reach a level sufficient to fund ongoing operations. AVITA Medical has funded its research and development activities, and more recently its substantial investment in sales and marketing activities, through the issuance of debt. As of December 31, 2024, the Company had approximately $14.1 million in cash and cash equivalents and $21.8 million in marketable securities.

On October 18, 2023 (the "Closing Date"), the Company entered into a Credit Agreement (the "Credit Agreement"), by and between the Company, as borrower, and an affiliate of OrbiMed Advisors, LLC, as the lender and administrative agent (the "Lender"). The Credit Agreement provides for a five-year senior secured credit facility in an aggregate principal amount of up to $90.0 million (the "Loan Facility"), of which $40.0 million was borrowed on the Closing Date, less certain fees and expenses payable to or on behalf of the Lender. On November 7, 2024, the Lender and the Company mutually agreed to a third amendment (the "Third Amendment") to the Credit Agreement. Under the terms of the Third Amendment and subject to the payment by the Company of a consent fee to the Lender, the Company and the Lender mutually agreed to (1) terminate two additional tranches of available debt in the aggregate amount of $50.0 million and (2) remove the trailing 12-month revenue covenant for the fourth quarter of 2024, which was set at $67.5 million. All revenue covenants for subsequent quarters remain in effect. The indebtedness under the Credit Agreement is secured by substantially all of our assets and will accrue interest at a rate equal to the greater of (a) forward-looking one-month term SOFR rate and (b) four percent (4%) per annum, plus eight percent (8%). In the event that the Company does not meet certain twelve-month trailing revenue targets at the end of future fiscal quarters, the outstanding balance of the loan must be repaid in equal quarterly installments of 5% of the funded amount through the maturity date. In addition, if we don't maintain a minimum cash and cash equivalents balance at the end of each reporting period, we may have to repay amounts outstanding in full as a result of an event of default. The Credit Agreement contains representations, warranties and covenants that are customary for this type of agreement.

On the Closing Date, we issued to an affiliate of the Lender a warrant (the "Warrant") to purchase up to 409,661 shares of our common stock, at an exercise price of $10.9847 per share, with a term of 10 years from the issuance date. The Warrant contains customary share adjustment provisions, as well as weighted average price protection in certain circumstances.

Subsequent to December 31, 2024, on February 13, 2025, we entered into a fourth amendment to the Credit Agreement (the "Fourth Amendment"), which amended the trailing 12-month revenue covenant to $73.0 million for the quarter ending March 31, 2025, to $78.0 million for the quarter ending June 30, 2025, to $84.0 million for the quarter ending September 30, 2025, to $92.0 million for the quarter ending December 31, 2025 and to $103.0 million for the quarter ending March 31, 2026. The $115.0 million revenue covenant for all subsequent quarters through the date of debt maturity remains in effect.

As a condition to the execution of the Fourth Amendment, we issued to the Lender a warrant to purchase up to 145,180 shares of our common stock, at an exercise price of $0.01 per share, with a term of 10 years from the issuance date.

As of the date these financial statements were issued, we believe we have sufficient cash reserves to fund operations for the next 12 months.

The following table summarizes our cash flows for the periods presented:

	Year Ended	
(in thousands)	December 31, 2024	December 31, 2023
Net cash used in operations	$ (48,939)	$ (38,011)
Net cash provided by investing activities	37,363	1,607
Net cash provided by financing activities	3,508	40,374
Effect of foreign exchange rate on cash and cash equivalents	-	(16)
Net increase/(decrease) in cash and cash equivalents	(8,068)	3,954
Cash and cash equivalents at beginning of the period	22,118	18,164
Cash and cash equivalents at end of the period	14,050	22,118

Net cash used in operating activities was $48.9 million and $38.0 million during the years-ended December 31, 2024 and 2023, respectively. The increase primarily resulted from higher operating costs, partially offset by increased revenues.

Net cash provided by investing activities was $37.4 million and $1.6 million during the years-ended December 31, 2024 and 2023, respectively. The increase in cash provided by investing activities is primarily attributable to lower cash outflows from purchases of marketable securities offset by lower cash inflows from maturities of marketable securities and an increase in cash

outflow for capital expenditures in the current year compared to the prior year. The increase in capital expenditures in the current year is primarily related to the leasehold improvement in the Ventura production facility to enhance manufacturing output and materials related to our RECELL GO RPDs.

Net cash provided by financing activities was $3.5 million and $40.4 million for the years-ended December 31, 2024 and 2023, respectively. The decrease in cash provided by financing activities was due to the issuance of debt in the prior year offset by increases in the proceeds from the exercises of stock options and purchases of stock under the ESPP in the current year.

Capital Management and Material Cash Requirements

We aim to manage capital to maintain optimal returns to stockholders and benefits for other stakeholders. We also aim to maintain a capital structure that ensures the lowest cost of capital available to us. We regularly review our capital structure and seek to take advantage of available opportunities to improve outcomes for us and our stockholders.

For the year-ended December 31, 2024, there were no dividends paid and we have no plans to commence the payment of dividends. On December 19, 2024, Regenity received 510(k) clearance, as such, we accrued $2.0 million to be paid in January 2025 and recorded $3.0 million in Contingent liability and $5.0 million in Intangible assets, net in the Consolidated Balance Sheets. Under the terms of our exclusive development and distribution agreement with Regenity, we have a further obligation to make up to an additional $3.0 million payment on or before January 4, 2026 to guarantee development and manufacturing capacity (and related resources), contingent on positive results of certain clinical studies. With the exception of the milestone payments related to our exclusive development and distribution agreement with Regenity, we do not have any other purchase commitments or long-term contractual obligations, except for lease obligations as of December 31, 2024. Refer to Note 7 of our Consolidated Financial Statements for further details on our lease obligations.

In addition, we have no material off-balance sheet arrangements (as defined in the applicable rules and regulations established by the SEC) that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources. While we have no committed plans to issue further shares on the market, we will continue to assess market conditions.

Critical Accounting Policies and Estimates

The SEC defines “critical accounting policies” as those that require the application of management’s most difficult, subjective, or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods.

The preparation of consolidated financial statements in conformity with U.S. Generally Accepted Accounting Practices, or U.S. GAAP, requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. We base those estimates on historical experience and on various assumptions that are believed to be reasonable under the circumstances. Actual results could differ from those estimates.

The following listing is not intended to be a comprehensive list of all of our accounting policies. Our significant accounting policies are described in Note 2 to our Consolidated Financial Statements contained elsewhere in this Annual Report. In many cases, the accounting treatment of a particular transaction is dictated by U.S. GAAP, with no need for our judgment in its application. There are also areas in which our judgment in selecting an available alternative would not produce a materially different result. We have identified the following as our critical accounting policies.

Revenue Recognition

We generate revenues primarily from:

- The sale of RECELL EOU, RPK, and PermeaDerm products to hospitals, other treatment centers, and distributors.
- Maintenance fee received from BARDA to ensure first right of access to our inventory. In the prior year, the Company recorded service revenue for the emergency preparedness services provided to BARDA.
- Lease revenue for the RPD.

Our sale of the RECELL EOU and PermeaDerm products are accounted for under ASC 606, *Revenue from contracts with customers* (“ASC 606”). Revenue for the RECELL GO system is disaggregated between two accounting standards: (1) ASC 606 for the RPK and (2) ASC 842, *Leases* (“ASC 842”) for the RPD. Revenues from BARDA are accounted for under ASC 606, and are included in Sales revenues within the Consolidated Statements of Operations.

To determine revenue recognition for arrangements that are within the scope of Topic 606, *Revenue from contracts with customers*, (“ASC 606”), we perform the following five steps:

1. Identify the contract with a customer
2. Identify the performance obligations
3. Determine the transaction price
4. Allocate the transaction price to the performance obligations
5. Recognize revenue when/as performance obligation(s) are satisfied

In order for an arrangement to be considered a contract, it must be probable that we will collect the consideration to which it is entitled for goods or services to be transferred. We then assess the goods or services promised within the contract to determine whether each promised good or service is a performance obligation. Performance obligations are promises in a contract to transfer a distinct good or service to the customer that (i) the customer can benefit from on its own or together with other readily available resources, and (ii) is separately identifiable from other promises in the contract.

We determine the transaction price based on the amount of consideration we expect to receive for providing the promised goods or services in the contract. Consideration may be fixed, variable, or a combination of both. At contract inception for arrangements that include variable consideration, we estimate the probability and extent of consideration we expect to receive under the contract utilizing either the most likely amount method or expected amount method, whichever best estimates the amount expected to be received. We then consider any constraints on the variable consideration and include in the transaction price variable consideration to the extent it is deemed probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

When accounting for a contract that contains multiple performance obligations, we must develop judgmental assumptions to determine the estimated stand-alone selling price ("SSP") for each performance obligation identified in the contract. We utilize the observable SSP when available, which represents the price charged for the promised product or service when sold separately. When the SSP for our products or services are not directly observable, we determine the SSP using relevant information available and apply suitable estimation methods including, but not limited to, the cost-plus margin approach. We then allocate the transaction price to each performance obligation based on the relative SSP and recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) control is transferred to the customer and the performance obligation is satisfied.

Most of our contracts have a single performance obligation. As such, we recognize revenue when our customers obtain control of promised goods or services, in an amount that reflects the consideration which we expect to be entitled in exchange for those goods or services. Revenue is recognized net of volume discounts (variable consideration). For our contracts that have an original duration of one year or less, since contract inception and customer payment occur within the same period we do not consider the time value of money. Further, because of the short duration of these contracts, we have not disclosed the transaction price for the remaining performance obligations as of each reporting period or when we expect to recognize this revenue. We have further applied the practical expedient to exclude sales tax in the transaction price and expense contract acquisition costs such as commissions and shipping and handling expenses as incurred.

Revenue recognition for contracts that are within the scope of ASC 606 and ASC 842

We enter into contracts with customers where we receive consideration for the RPK and do not receive additional consideration for the RPD. As a result, judgment and analysis are required to determine the appropriate accounting, including: (i) whether the arrangement contains an embedded lease, and if so, whether such embedded lease is a sales-type lease or an operating lease, (ii) the amount of the total consideration, as well as variable consideration, (iii) the identification of the distinct performance obligations contained within the arrangement, (iv) how the arrangement consideration should be allocated to each performance obligation when multiple performance obligations exist, including the determination of standalone selling price, and (v) when to recognize revenue on the performance obligations.

For these contracts we consider the guidance under ASC 842 to determine if furnishing the RPD to the customer during the period of use establishes an embedded lease. To determine if the contract contains a lease, we evaluate the customer’s rights and ability to control the use of the underlying equipment throughout the contract term, including any equipment substitution rights

retained by us. As the contract conveys the right to control the use of an identified asset for a period of time, the contract was determined to contain a lease. We then evaluated the lease classification based on the below:

- Pursuant to ASC 842-30, we will classify a lease as a sales-type lease if: (i) the lease transfers ownership of the underlying asset to the lessee by the end of the lease term, (ii) the lease grants the lessee an option to purchase the underlying asset that the lessee is reasonably certain to exercise, (iii) the lease term is for the major part of the remaining economic life of the underlying asset, (iv) the present value of the sum of the lease payments and any residual value guaranteed by the lessee that is not already reflected in the lease payments equals or exceeds substantially all (90% or more) of the fair value of the underlying asset, or (v) the underlying asset is of such a specialized nature that it is expected to have no alternative use to the lessor at the end of the lease term.
- Pursuant to ASC 842-30, when none of the sales-type lease classification criteria are met, a lessor would classify the lease as a direct financing lease when both of the following criteria are met: (i) the present value of the sum of the lease payments and any residual value guaranteed by the lessee that is not already reflected in the lease payments and/or any other third party unrelated to the lessor equals or exceeds substantially all (90% or more) of the fair value of the underlying asset and (ii) it is probable that the lessor will collect the lease payments plus any amount necessary to satisfy a residual value guarantee.
- Pursuant to ASC 842-30, a lessor would classify a lease as an operating lease when none of the sales-type or direct financing lease classification criteria are met. Further, per ASC 842, a lessor is required to classify a lease with variable lease payments that do not depend on an index or rate as an operating lease at lease commencement if the lease would have been classified as a sales-type lease or a direct financing lease in accordance with the classification criteria of ASC 842 and the lessor would have otherwise recognized a loss at the lease commencement date.

In determining whether the lease components are related to a sales-type lease or an operating lease, we evaluate if the lease transfers ownership at the end of the lease term, the existence of purchase options, the lease term in relation to the economic life of the asset, if the lease payments exceed the fair value of the asset, and if the asset is of a specialized nature. We also evaluate if the lease results in a loss at the lease commencement date. As the lease term is for the major part of the economic life, the lease meets the classification criteria for sales-type lease. However, to determine if the contract results in a loss at the lease commencement date we evaluated the consideration in the contract. The consideration at lease commencement does not contain fixed payments, purchase options, penalty payments or residual value guarantees. The variable consideration is related to the sale of the RPK. As the variable lease payments are not dependent on an index or rate, the variable consideration is excluded from consideration at contract inception resulting in a loss at lease commencement. As such, we classify the lease as an operating lease.

The contracts contain a lease component, the RPD, and a non-lease component, the RPK. The lease component will be accounted for under ASC 842 and the non-lease component will be accounted for under ASC 606, as described above. In accordance with ASC 842, the consideration in the contract will be allocated to each separate lease component and non-lease component of the contract. The consideration is allocated to these lease and non-lease components based on the SSP (as described above for contracts within the scope of ASC 606). In accordance with ASC 842, variable lease payments will be recognized once the sale of the RPK occurs and control has transferred to the customer. Consideration will be allocated to the RPD and RPK based on the SSP. Consideration related to the RPD will be recognized as Lease revenue and consideration related to the RPK will be recognized as Sales revenues in accordance with guidance in ASC 606, as described above, upon transfer of control of the RPK, which generally occurs at the time the product is shipped or delivered depending on the customer's shipping terms.

Assets in our lease program are reported in Plant and equipment, net on our Consolidated Balance Sheets and are depreciated over the useful life of the RPD device's 200 uses, as indicated in the Instructions for Use that were approved by the FDA and expensed as Costs of goods sold in the Consolidated Statements of Operations. The RPD depreciation has a direct relationship to the number of RPK units sold. Based on customer usage, each purchase of an RPK unit results in a 1/200 depreciation to the RPD.

See Note 5 to our Consolidated Financial Statements included in this Annual Report for additional detail on revenue recognition.

Share-Based Compensation

We measure and recognize compensation expense on a graded-vesting method, for stock options and restricted stock units (“RSUs”), to employees, directors and consultants over the vesting period based on their grant date fair values. Compensation expense for performance-based awards is measured based on the number of shares ultimately expected to vest, estimated at each reporting date based on management’s expectations regarding the relevant performance criteria. We estimate the fair value of stock options on the

date of grant using the Black-Scholes option pricing model. The fair value of RSUs is based on the closing stock price as determined per Nasdaq at the date of grant.

Determining the estimated fair value at the grant date requires judgment in determining the appropriate valuation model and assumptions, including, risk-free rate, volatility rate, annual dividend yield and the expected term.

The following assumptions were used in the valuation of stock options:

- Expected volatility – determined using the historical volatility using daily intervals over the expected term.
- Expected dividends – None, based on the fact that we have never paid cash dividends and do not expect to pay any cash dividends in the foreseeable future.
- Expected term – the expected term of our stock options for tenure-only vesting has been determined utilizing the "simplified" method as described in the SEC's Staff Accounting Bulletin No. 107 relating to stock-based compensation. The simplified method was chosen because we have limited historical option exercise experience due to its short operating history of awards granted, the first plan was established in 2016 and was primarily used for Executives awards. Further, we do not have sufficient history of exercises in the U.S. market given our re-domiciliation from Australia to the United States in 2020.
- Risk-free interest rate – the risk-free interest rate is based on the U.S. Treasury yield in effect at the time of grant for a period approximately equal to the expected term of the award.

See Note 14 to our Consolidated Financial Statements included in this Annual Report for additional detail on share-based compensation.

Warrants

Warrants are accounted for in accordance with applicable accounting guidance provided in ASC 815*, Derivatives and Hedging – Contracts in Entity's Own Equity* ("ASC 815"), as a liability based on the specific terms of the warrant agreement and recorded at fair value. The warrants are subject to re-measurement at each settlement date and at each balance sheet date and any change in fair value is recognized in earnings. The fair value of the warrant liability, which is reported within Warrant liability on the Consolidated Balance Sheets, is estimated by us based on the Black-Scholes option pricing model with the following inputs (Level 3):

- Price of common stock
- Estimated expected term
- Estimated exercise price
- Estimated expected volatility
- Estimated risk free interest rate
- Estimated expected dividend rate

Long-term debt

We elected the fair value option ("FVO") of accounting under ASC 825-10*, Financial Instruments* ("ASC 825"), to account for the debt. ASC 825 provides FVO election that allows companies an irrevocable election to use fair value at the date of issuance and subsequently remeasure every reporting period. The fair value of the debt is reported in the Consolidated Balance Sheets. Changes in fair value are reported in earnings in Other income in the Consolidated Statements of Operations. Any changes in fair value caused by instrument-specific credit risk are presented separately in other comprehensive income. We have elected to present interest expense separately from changes in fair value and therefore will present interest expense associated with the debt. All costs associated with the issuance of the Credit Agreement accounted for using the fair value option were expensed upon issuance. Refer to Note 6 for further details.

The fair value of the debt was determined using a Monte Carlo simulation in order to capture the probability of different potential cash flows outcomes associated with the contractual terms of the instrument. The below assumptions were used in the Monte Carlo simulation (Level 3):

- Estimated risk free interest rate
- Estimated revenue volatility
- Estimated revenue discount rate
- Estimated future revenue projection
- Estimated expected dividend rate

Income Taxes

Income taxes are accounted for using the liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Deferred tax assets are reduced by a valuation allowance if it is more-likely-than-not that a portion of the deferred tax asset will not be realized.

We review our uncertain tax positions regularly. An uncertain tax position represents our expected treatment of a tax position taken in a filed return or planned to be taken in a future tax return or claim that has not been reflected in measuring income tax expense for financial reporting purposes. We recognize the tax benefit from an uncertain tax position when it is more-likely-than-not that the position will be sustained upon examination on the basis of the technical merits or the statute of limitations for the relevant taxing authority to examine and challenge the tax position has expired.

See Note 15 to our Consolidated Financial Statements included in this Annual Report for additional detail on income taxes.

Recent accounting pronouncements

See discussion of recent accounting pronouncements in Note 2 of the Consolidated Financial Statements located in Item 8 in this Annual Report.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As a smaller reporting company, we are not required to provide the information required by this item.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our financial statements and supplementary data are attached hereto beginning on Page F-1 and are incorporated by reference herein.

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

Item 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Disclosure controls and procedures are controls and other procedures of a company that are designed to ensure that information required to be disclosed by the company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its chief executive officer and chief financial officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. As required by Rules 13a-15(b) and 15d-15(b) under the Exchange Act, our management, with the participation of our chief executive officer and chief financial officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures as of December 31, 2024. Based on this evaluation, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures were effective as of December 31, 2024.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting for our company, as this term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. As required by Rules 13a-15(e) and 15d-15(e) under the Exchange Act, our management, with the participation of our chief executive officer and chief financial officer, conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2024, based on the criteria set forth in the Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2024.

This report does not include an attestation report of our independent registered public accounting firm regarding our internal control over financial reporting, in accordance with applicable SEC rules that permit us to provide only management's report in this report.

Changes in Internal Control over Financial Reporting

During the three-months ended December 31, 2024, there were no material changes made in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act).

Inherent Limitations on Disclosure Controls and Procedures

Management recognizes that any controls and procedures, no matter how well-designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the benefits of possible controls and procedures relative to their costs. Because of these inherent limitations, our disclosure controls and procedures may not prevent or detect all instances of fraud, misstatements, or other control issues. In addition, projections of any evaluation of the effectiveness of disclosure or internal controls to future periods are subject to risks, including, among others, that controls may become inadequate because of changes in conditions or that the degree of compliance with policies or procedures may deteriorate.

Item 9B. OTHER INFORMATION

None

Item 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Identification of Directors

Name	Age	Position with the Company and Principal Occupation	Director Since	Board Term Expires
Lou Panaccio	67	Chairman of the Board of Directors	July 2014	June 2025
Jeremy Curnock Cook	75	Non-Executive Director	October 2012	June 2025
Professor Suzanne Crowe	74	Non-Executive Director	January 2016	June 2025
Jan Stern Reed	65	Non-Executive Director	July 2021	June 2025
Robert McNamara	68	Non-Executive Director	June 2023	June 2025
Cary Vance	59	Non-Executive Director	June 2023	June 2025
James Corbett	66	Executive Director and Chief Executive Officer	July 2021	June 2025

Lou Panaccio has served as Chairman of the Board of Directors since July 2014. Mr. Panaccio is a successful healthcare businessman with extensive experience leading companies from concept to commercialization. Mr. Panaccio possesses more than 35 years of executive leadership experience in healthcare services and life sciences, including more than 25 years of board-level experience. Mr. Panaccio is currently a Director of ASX50 company and one of the world's largest medical diagnostics companies, Sonic Healthcare Limited, where he has served since 2005. In addition, Mr. Panaccio is Director of Unison Housing Limited, was a Chairman of Genera Biosystems Limited until June 2019, is a Chairman of Adherium Limited and a Director of Rhythm Biosciences Limited, both of which are publicly listed (ASX) development-stage medical diagnostics/devices companies. We believe Mr. Panaccio is qualified to serve on our Board of Directors based on his extensive experience in the healthcare services and life sciences sectors and his experience in serving on boards.

Jeremy Curnock Cook has served as a Director since October 2012. He is a veteran in the life sciences/healthcare industry and has been actively supporting the commercialization of healthcare innovations and helping entrepreneurs build their international businesses over the past 45 years. Founder and Managing Director of BioScience Managers, Mr. Curnock Cook brings his decades of international experience to our Board of Directors. Over his career, Mr. Curnock Cook has successfully managed in excess of US $1 billion in equity investments. He launched the first dedicated biotechnology fund for the Australian market and is a former head of the life science private equity team at Rothschild Asset Management, an early pioneer and significant investor in the sector. In his early career he founded the International Biochemicals Group which he successfully sold to Royal Dutch Shell. Mr. Curnock Cook founded a European-focused seed fund with Johnson & Johnson and built the International Biotechnology Trust. Mr. Curnock Cook has served on more than 40 boards of directors in the life science sector in the UK, Europe, USA, Canada, Japan and Australia. In addition to serving on our Board of Directors, Mr. Curnock Cook currently serves on the following boards: International BioScience Managers Ltd appointed March 2000, Bioscience Managers Pty Ltd appointed January 2003, REX Bionics Pty Ltd appointed February 2012, Sheldon LTD (formerly Sea Dragon) appointed October 2012, Adherium Ltd appointed April 2015, Bioscience Managers UK Ltd appointed August 2017, Marine Department Ltd, appointed January 2019, JLCC Ltd appointed December 2019, Tidal Sense LTD (formally CRiL) appointed November 2020 and Humanetix Ltd appointed September 2021. We believe Mr. Curnock Cook is qualified to serve on our Board of Directors based on his extensive experience in the life sciences sector.

Professor Suzanne Crowe AO has served as a Director since January 2016. Australian-based, she is a physician-scientist and ASX/Nasdaq-listed company director with expertise in supporting companies with their medical and scientific strategies. A Fellow of the Australian Institute of Company Directors, and Emeritus Professor, Monash University Melbourne, she is currently a Director of Sonic Healthcare Ltd, a large global medical diagnostics company. Past board positions include St. Vincent's Health Australia Ltd (2012-2021), the country's largest not-for-profit health and aged care provider. After 35 years at both, she has recently retired from the Burnet Institute, having served as Associate Director Clinical Research, and The Alfred Hospital Melbourne, where she held the appointment of Senior Specialist Physician in Infectious Diseases. She was appointed as Officer of the Order of Australia in June 2020 in recognition of her distinguished services to health, clinical governance, biomedical research, and education. We believe Professor Crowe is qualified to serve on our Board of Directors based on her technical experience and extensive expertise in supporting companies with their medical and scientific strategies.

Jan Stern Reed has served as a Director since July 2021. She has more than 35 years of legal, management and business leadership experience primarily within the healthcare industry, and brings significant expertise in corporate governance, compliance, and risk management. Ms. Reed served as Senior Vice President, General Counsel and Corporate Secretary at Walgreens Boots Alliance, Inc., a global health and wellbeing company. Prior to Walgreens, Ms. Reed was Executive Vice President, Human Resources, General Counsel and Corporate Secretary of Solo Cup Company, where she was responsible for the legal, human resources, internal audit, corporate communications, and compliance functions. Prior to Solo Cup Company, she was Associate General Counsel, Corporate Secretary and Chief Corporate Governance Officer at Baxter International, Inc. Ms. Reed holds a Bachelor of Arts degree from the University of Michigan and a Juris Doctor from the Northwestern University Pritzker School of Law. Ms. Reed currently serves as a board member of Stepan Co. (NYSE: SCL), a major manufacturer of specialty and intermediate chemicals used in a broad range of industries, and AngioDynamics, Inc. (NASDAQ: ANGO), an industry-leading and transformative medical technology company focused on restoring healthy blood flow in the body's vascular system, expanding cancer treatment options, and improving quality of life for patients. We believe Ms. Reed is qualified to serve on our Board of Directors based on her extensive experience in legal, human resources, corporate governance, general management and business leadership, primarily within the healthcare industry.

Robert McNamara has served as a Director since April 2023. He is an accomplished senior executive with over 25 years of leadership experience in public and privately held companies in the medical device and technology industries. His extensive experience in operations and financial management spans across early stage, high growth, and mature companies. He is a former member of the Board of Directors and Chair of Audit Committee for Axonics, Inc. Additionally, Mr. McNamara is a member of the Board of Directors, Chair of the Compensation Committee, and member of the Audit Committee for Xtant Medical Holdings. Prior to these appointments, Mr. McNamara served as Executive Vice President, Chief Financial Officer of LDR Holding/Spine. Prior to this role, he served as the Chief Financial Officer of three publicly traded medical device companies including Accuray, Somnus Medical Technologies, and Target Therapeutics. Mr. McNamara holds a Bachelor of Science in Accounting from the University of San Francisco and an MBA from The Wharton School, University of Pennsylvania. We believe Mr. McNamara is qualified to serve on our Board of Directors because of his experience with financial management and other requirements of U.S. public and private companies, and considerable expertise in the medical device and technology industries.

Cary Vance has served as a Director since April 2023. Mr. Vance has over 25 years of extensive leadership experience with commercial and operational expertise in the healthcare industry. He is currently the President and Chief Executive Officer of PhotoniCare, Inc., a position he has held since May 2023. Prior to this appointment, he was President and CEO of Titan Medical, and he served as an independent director for its Board of Directors through November 2024. Previously, Mr. Vance served as President and CEO of XCath, a privately held neurovascular robotics company, having also served in similar roles at OptiScan Biomedical, Myoscience, and Hansen Medical. He strategically transformed and commercialized these businesses and markets with disruptive, enabling, and game-changing novel technologies. Mr. Vance has also executed on equity and debt financing strategies as an integral step to successful value creation and M&A events. Prior to his role at Hansen Medical, he served in various global executive leadership roles at Teleflex, Covidien, and GE HealthCare. Mr. Vance is Lean/Six Sigma Black Belt Certified, NACD Certified, and holds both a Bachelor of Arts degree in Economics and an MBA from Marquette University. We believe Mr. Vance is qualified to serve on our Board of Directors based on his leadership experience and extensive expertise in commercial and operations in the healthcare industry.

James Corbett was appointed as President and CEO of the Company effective as of September 28, 2022. Mr. Corbett served as a Non-Executive Director from July 2021 to September 28, 2022. He has approximately 40 years of leadership experience in the medical device field, most recently, as CEO of CathWorks Ltd., a software-based medical technology company. Mr. Corbett has extensive global commercial and operating experience, serving as an expatriate General Manager of Baxter Japan and later as General Manager and President of Scimed Life Systems Inc. and Boston Scientific International, respectively. During his career he has served as CEO of three publicly listed companies; Microtherapeutics Inc (MTIX), ev3 Inc (evvv), Alphatec Spine (ATEC). Mr. Corbett has also led two privately funded companies as CEO: Home Diagnostics Inc. and Vertos Medical. Mr. Corbett has extensive capital market and governance experience from both public and private environments. Mr. Corbett holds a Bachelor of Science in Business Administration from the University of Kansas. Mr. Corbett is a board member of two privately held medical device companies. We believe Mr. Corbett is qualified to serve on our Board of Directors based on his global commercial and operating expertise in supporting companies with their medical and scientific strategies.

Identification of Named Executive Officers

Name	Age	Position	Date First Elected or Appointed
James Corbett	66	Chief Executive Officer	September 2022
David O'Toole	66	Chief Financial Officer	June 2023
Nicole Kelsey	58	Chief Legal and Compliance Officer and Corporate Secretary	July 2024

James Corbett is discussed above under "Identification of Directors".

David O'Toole an accomplished financial executive with extensive experience in both public company operations and capital markets, Mr. O'Toole joined AVITA Medical in 2023 as its Chief Financial Officer. Mr. O'Toole most recently served as CFO of Opiant Pharmaceuticals, a biopharmaceutical company developing treatments for addiction and drug overdose, which was acquired by Indivior in March of 2023. Prior to that, he served as CFO of Soleno Therapeutics, a company focused on the development and commercialization of novel therapeutics for the treatment of rare diseases. Prior to Soleno, Mr. O'Toole held the role of CFO for three publicly traded life sciences companies where he built and led high-performance teams. Prior to his CFO experience, he spent over 24 years in public accounting, including 16 years with Deloitte & Touche. He holds a Bachelor of Science in accounting from the University of Arizona and is a Certified Public Accountant (non-active).

Nicole Kelsey has served as Chief Legal and Compliance Officer, and Corporate Secretary since July 2024. Ms. Kelsey has over 25 years of executive legal experience with expertise in M&A, securities, and corporate governance. Ms. Kelsey previously served as Chief Legal Officer and Secretary for Amyris, Inc., a leading biotech company, and as General Counsel and Secretary of Criteo, a global leader in commerce marketing based in Paris with global operations. Prior to joining Criteo, Ms. Kelsey was the senior securities lawyer for Medtronic, a global leader in medical technology; she served as head M&A attorney for CIT Group, Inc.; was the general counsel and chief compliance officer of a private merchant bank; and was the senior corporate attorney for the international conglomerate Vivendi. Before going in-house, Ms. Kelsey practiced with the law firms of White & Case and Willkie, Farr & Gallagher, in Paris and New York. A Fulbright scholar, Ms. Kelsey holds a Juris Doctor degree from Northwestern Pritzker School of Law and a Bachelor of Arts degree in Political Science and International Studies from The Ohio State University, and is admitted to practice law in New York and Minnesota.

Term of Office

Our Directors are elected for a term of one year and until their respective successors are elected and qualified, or until their earlier resignation, disqualification, or removal. Our executive officers are appointed by our Board of Directors and hold office for such terms as may be prescribed by our Board of Directors and until their successors are appointed, or until their earlier resignation or removal.

Family Relationships

There are no family relationships between our Directors or executive officers.

Involvement in Certain Legal Proceedings

None of our Directors or executive officers has been involved in any of the following events during the past ten years:

a) any bankruptcy petition filed by or against any business or property of such person or any partnership or business in which such person was a general partner or executive officer either at the time of the bankruptcy or within two years prior to that time;

b) any conviction in a criminal proceeding or being a named subject of a pending criminal proceeding (excluding traffic violations and other minor offences);

c) being the subject of any order, judgment, or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction, permanently or temporarily enjoining, barring, suspending or otherwise limiting his or her involvement in any type of business, securities or banking activities;

d) being found by a court of competent jurisdiction (in a civil action), the SEC or the Commodity Futures Trading Commission to have violated a federal or state securities or commodities law, and the judgment has not been reversed, suspended, or vacated;

e) being the subject of, or a party to, any federal or state judicial or administrative order, judgment, decree, or finding, not subsequently reversed, suspended or vacated, relating to an alleged violation of: (i) any federal or state securities or commodities law or regulation; or (ii) any law or regulation respecting financial institutions or insurance companies including, but not limited to, a temporary or permanent injunction, order of disgorgement or restitution, civil money penalty or temporary or permanent cease- and-desist order, or removal or prohibition order; or (iii) any law or regulation prohibiting mail or wire fraud or fraud in connection with any business entity; or

f) being the subject of, or a party to, any sanction or order, not subsequently reversed, suspended or vacated, of any self-regulatory organization (as defined in Section 3(a)(26) of the Exchange Act), any registered entity (as defined in Section 1(a)(40) of the Commodity Exchange Act), or any equivalent exchange, association, entity or organization that has disciplinary authority over its members or persons associated with a member.

Gender Diversity

The 4th Edition of the ASX's Corporate Governance Principles and Recommendations recommend we set measurable objectives for achieving gender diversity in the composition of our Board of Directors, senior executives and workforce generally. As of the date of this Form 10-K, the non-executive Directors of the Company are 33% female, our senior executive team members are 40% female, and our total employee base is 52.5% female.

In light of the Company's gender diversity as represented by the current composition of our Board of Directors, senior executives, and general workforce, together with the Company's requirement to follow U.S. laws when making employment decisions without regards to gender (or any other factors about an individual other than such individual's qualifications to perform the relevant job functions), the Company's employment objectives do not currently reference gender diversity. We will continue to track gender diversity throughout our organization and, in coordination with the oversight of the Board of Directors's Nominating and Corporate Governance Committee, may set one or more measurable objectives relating to gender diversity at a later date.

Performance Evaluations

At least annually, the Nominating and Corporate Governance Committee Chair guides the Board of Directors in a self-evaluation process to assess the functioning of the Board of Directors, its committees', and its individual directors.

Additionally, the Nominating and Corporate Governance Committee, Compensation Committee, and Audit Committee conduct annual self-evaluations regarding their composition, the frequency and length of their meetings, their responsibilities, and the effectiveness of their respective duties.

The Company's Compensation Committee undertakes a review of the performance of the Company's CEO and the executive management team annually during the first quarter of each calendar year. The Company's Compensation Committee completed these performance evaluations for the fiscal year ended December 31, 2024 on or around January 6, 2025.

Code of Ethics

We have adopted a Code of Business Conduct and Ethics (the "Code"), that constitutes a "code of ethics" as that term is defined in paragraph (b) of Item 406 of Regulation S-K and that applies to our executive officers, non-executive Directors, management and employees of the Company. A copy of the Code is available on our website at www.avitamedical.com.

If we make any amendments to the Code or grant any waivers, including any implicit waiver, from a provision of the Code, we will disclose the nature of such amendment or waiver on our website. The information on our website is not incorporated by reference into this Annual Report.

Section 16(a) Beneficial ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act requires the Company's Directors and certain of its executive officers and persons who beneficially own more than 10% of the Company's common shares to file reports of and changes in ownership with the SEC. Based solely on the Company's review of copies of SEC filings it has received or filed, the Company believes that each of its Directors, executive officers, and beneficial owners of more than 10% of the shares satisfied the Section 16(a) filing requirements during the fiscal year-ended December 31, 2024.

Election of Directors

Our Board of Directors consists of seven members. Directors are elected at our annual general meeting of stockholders and hold office for a term of one year and until their successors have been elected and qualified or until the earlier of their resignation or removal. Our Directors were most recently elected at our 2024 annual general meeting on June 5, 2024, to hold office for a term of one year or until his or her successor is duly elected and qualified. Any newly created directorship or any vacancy occurring on our Board of Directors may be filled only by a majority of the remaining members of our Board, even if such majority is less than a quorum, and each Director so elected shall hold office until the expiration of the term of office of the Director whom he or she has replaced or until his or her successor is elected and qualified. Under ASX Listing Rule 14.4, any Directors of the Company (except a managing Director) must not hold office without re-election past the third annual general meeting following the Director's appointment or three years, whichever is longer.

Stockholder Nominees for Director

There have been no material changes to the procedures by which stockholders may recommend nominees to the Board of Directors.

Committees of the Board of Directors

Our Board of Directors has established an audit committee, a compensation committee, and a nominating and corporate governance committee, each of which operates pursuant to a written charter adopted by our Board of Directors. Our Board of Directors may also establish other committees from time to time to assist the Board of Directors. The composition and functioning of all of our committees comply with all applicable requirements of the Sarbanes-Oxley Act, Nasdaq and SEC rules and regulations and the ASX Listing Rules and also align with the ASX Corporate Governance Council's 4th Edition Corporate Governance Principles and Recommendations. Each committee has a charter, which is available on our website at www.avitamedical.com. As of the date of this report, the composition of our audit, compensation, and nominating and corporate governance committees were as follows:

Director	Independent	Compensation Committee		Audit Committee		Nominating and Corporate Governance Committee	
Lou Panaccio	X	Member		Member		Member	(1)
Jeremy Curnock Cook	X	Member		Member	(1)	Member	
Professor Suzanne Crowe	X	Member		Member	(1)	Member	
Jan Stern Reed	X	Member		Member		Chair	
Robert McNamara	X	Member	(1)	Chair		Member	
Cary Vance	X	Chair		Member		Member	(1)

(1) Committee membership effective as of the fourth quarter Board meeting (November 5, 2024).

Audit Committee

Nasdaq Marketplace Rules require us to establish an audit committee comprised of at least three members, each of whom is financially literate and satisfies the respective "independence" requirements of the SEC and Nasdaq and one of whom has accounting or related financial management expertise at senior levels within a company. In addition, the ASX Listing Rules and the 4th Edition of the ASX's Corporate Governance Principles and Recommendations require us to have an Audit Committee comprised of at least three members, all of whom are non-executive Directors and a majority of whom are "independent" Directors, and which is chaired by an independent Director who is not the chair of the Board of Directors.

We have an Audit Committee in accordance with Section 3(a)(58)(A) of the Exchange Act. Our Audit Committee assists our Board of Directors in overseeing the accounting and financial reporting processes of our company and audits of our financial statements, including the integrity of our financial statements, compliance with legal and regulatory requirements, our registered public accounting firm's qualifications and independence, and such other duties as may be directed by our Board of Directors. The Audit Committee is also required to assess risk management in conjunction with the Board of Directors.

Our Audit Committee currently consists of six Board members, each of whom satisfies the "independence" requirements of the SEC, Nasdaq Marketplace Rules, the ASX Listing Rules and the 4th Edition of the ASX's Corporate Governance Principles and Recommendations. Our Audit Committee is currently composed of Robert McNamara, Jeremy Curnock Cook, Lou Panaccio, Jan Stern Reed, Cary Vance, and Professor Suzanne Crowe. Each qualifies as an "independent director" within the meaning of Nasdaq Marketplace Rules and the 4th Edition of the ASX's Corporate Governance Principles and Recommendations. Mr. Robert McNamara is the current Audit Committee Chair and was appointed to that role as of May 2023, following his appointment to the Board of Directors. Our Board of Directors has determined that Robert McNamara is an "audit committee financial expert", as defined in item 407(d)(5)(ii) of Regulations S-K. The Audit Committee meets at least four times per year. See below for summary of attendance.

The Audit Committee held a total of four meetings during the annual period ended December 31, 2024. The meetings attended by each Director, and the number of meetings that they were each eligible to attend, is as follows:

Audit Committee Meeting Attendance		
		Meetings attended/Meetings held
Robert McNamara (Chair)		4/4
Professor Suzanne Crowe	(1)	4/4
Jeremy Curnock Cook	(2)	4/4
Lou Panaccio		4/4
Jan Stern Reed		4/4
Cary Vance	(2)	4/4
James Corbett	(3)	4/4

(1) Professor Suzanne Crowe was appointed by the Board of Directors to serve as member of the Audit Committee, with effect from November 5, 2024. Prior to her appointment, Ms. Crowe was in attendance at all Audit Committee meetings in 2024 as non-executive director.

(2) Mr. Jeremy Curnock Cook was appointed by the Board of Directors to serve as member of the Audit Committee, with effect from November 5, 2024. Prior to his appointment, Mr. Curnock Cook was in attendance at all Audit Committee meetings in 2024 as non-executive director.

(3) Mr. James Corbett was not a member of the Audit Committee but was in attendance at all Audit Committee meetings in 2024 as CEO.

Compensation Committee

Our Board of Directors has established a Compensation Committee, which is comprised of independent Directors, within the meaning of Nasdaq Marketplace Rules and also the 4th Edition of the ASX's Corporate Governance Principles and Recommendations. The Compensation Committee must be comprised solely of non-executive directors in accordance with the ASX Listing Rules and must also be chaired by an independent Director in accordance with the 4th Edition of the ASX's Corporate Governance Principles and Recommendations. The Compensation Committee is responsible for reviewing the salary, incentives, and other benefits of our directors, senior executive officers and employees, and to make recommendations on such matters for approval by our Board of Directors. The Compensation Committee is also responsible for overseeing and advising our Board of Directors with regard to the adoption of policies that govern our compensation programs. Professor Suzanne Crowe, Jeremy Curnock Cook, Robert McNamara, Lou Panaccio, Jan Stern Reed, and Cary Vance are the current members of the Compensation Committee, and each qualifies as an "independent Director" within the meaning of Nasdaq Marketplace Rules and the 4th Edition of the ASX's Corporate Governance Principles and Recommendations. Cary Vance is the chair of this committee (being an independent Director who is not the chair of the Board).

The Compensation Committee held a total of five meetings during annual period ended December 31, 2024. The meetings attended by each Director, and the number of meetings that they were each eligible to attend, is as follows:

Compensation Committee Meeting Attendance		
		Meetings attended/Meetings held
Cary Vance (Chair)		5/5
Jeremy Curnock Cook		5/5
Professor Suzanne Crowe		5/5
Robert McNamara	(1)	5/5
Lou Panaccio		5/5
Jan Stern Reed		5/5
James Corbett	(2)	5/5

(1) Mr. Robert McNamara was appointed by the Board of Directors to serve as member of the Compensation Committee, with effect from November 5, 2024. Prior to his appointment, Mr. McNamara was in attendance at all Compensation Committee meetings in 2024 as non-executive director.

(2) Mr. James Corbett was not a member of the Compensation Committee but was in attendance at all Compensation Committee meetings in 2024 as CEO.

Nominating and Corporate Governance Committee

Our Board of Directors has established a Nominating and Corporate Governance Committee. Under the 4th Edition of the ASX's Corporate Governance Principles and Recommendations, our Nominating and Corporate Governance Committee should have at least three members, a majority of whom are independent, and should also be chaired by an independent Director. Professor Suzanne Crowe, Robert McNamara, Jan Stern Reed and Jeremy Curnock Cook are the current members of the Nominating and Corporate Governance Committee and each qualifies as an "independent Director" within the meaning of Nasdaq Marketplace Rules and the 4th Edition of the ASX's Corporate Governance Principles and Recommendations. Jan Stern Reed is the Chair of this committee (being an independent Director). The Nominating and Corporate Governance Committee is responsible for identifying individuals qualified to become members of our Board of Directors, recommending nominees for election at the stockholders meetings or to fill vacancies that arise on our Board of Directors, and recommending qualified and experienced directors to serve on the committees of our Board of Directors. In addition, the Nominating and Corporate Governance Committee is responsible for leading the Board of Directors to complete a self-evaluation of the board, its committees, and the individual directors.

The Nominating and Corporate Governance Committee held a total of four meetings during the annual period ended December 31, 2024. The meetings attended by each Director, and the number of meetings that they were each eligible to attend, is as follows:

Nominating and Corporate Governance Committee Meeting Attendance		
		Meetings attended/Meeting held
Jan Stern Reed (Chair)		4/4
Jeremy Curnock Cook		4/4
Professor Suzanne Crowe		4/4
Robert McNamara		4/4
Lou Panaccio	(1)	4/4
Cary Vance	(2)	4/4
James Corbett	(3)	4/4

(1) Mr. Lou Panaccio was appointed by the Board of Directors to serve as member of the Nominating and Corporate Governance Committee, with effect from November 5, 2024. Prior to his appointment, Mr. Panaccio was in attendance at all Nominating and Corporate Governance Committee meetings in 2024 as non-executive director.

(2) Mr. Cary Vance was appointed by the Board of Directors to serve as member of the Nominating and Corporate Governance Committee, with effect from November 5, 2024. Prior to his appointment, Mr. Vance was in attendance at all Nominating and Corporate Governance Committee meetings in 2024 as non-executive director.

(3) Mr. James Corbett was not a member of the Nominating and Corporate Governance Committee but was in attendance at all Nominating and Corporate Governance Committee meetings in 2024 as CEO.

Board of Directors' Meetings

The Board of Directors held a total of seven meetings during the annual period ended December 31, 2024. The meetings attended by each Director, and the number of meetings that they were each eligible to attend, is as follows:

Board of Directors' Meeting Attendance	
	Meetings attended/Meetings held
Lou Panaccio (Chair)	6/6
Jeremy Curnock Cook	6/6
Professor Suzanne Crowe	6/6
Robert McNamara	6/6
Jan Stern Reed	6/6
Cary Vance	6/6
James Corbett	6/6

Item 11. EXECUTIVE COMPENSATION

The particulars of the compensation paid to the below listed "named executive officers" of our company are set out in the summary compensation below.

- *James Corbett, Chief Executive Officer*
- *David O'Toole, Chief Financial Officer*
- *Nicole Kelsey, Chief Legal and Compliance Officer, and Corporate Secretary*

SUMMARY COMPENSATION TABLE

The following table sets forth for our named executive officers the following information for the annual periods ended December 31, 2024 and December 31, 2023.

Name and Position	Year	Salary	Bonus	Option Awards (1)	All Other Compensation (2)		Total
Named Executive Officers:		**($)**	**($)**	**($)**	**($)**		**($)**
James Corbett	2024	684,231	459,000	2,080,166	20,487		3,243,885
Chief Executive Officer	2023	625,000	491,188	912,500	39,987		2,068,675
David O'Toole	2024	459,253	195,500	1,068,666	54,109		1,777,528
Chief Financial Officer	2023	245,048	146,753	1,607,150	7,875		2,006,826
Nicole Kelsey	2024	228,475	95,625	784,700	179,390	(3)	1,288,190
Chief Legal and Compliance Officer	2023	-	-	-	-		-

(1) Amounts in this column represent awards of stock options with the aggregate grant date fair value computed in accordance with ASC 718. Amounts in this column represent option awards issued to the individuals noted, based on the fair value determined at the date of grant in accordance with U.S. GAAP. See Note 14, Share-Based Payment Plans to our Consolidated Financial Statements included in Part II, Item 8. "Financial Statements and Supplementary Data" for the assumptions used in determining the grant date fair value of option awards. The vesting of these option awards are subject to various performance or tenure related criteria.

(2) Amounts in this column represent all other compensation for the covered fiscal year that the smaller reporting company could not properly report in any other column of the Summary Compensation Table. This includes the non-qualified deferred compensation employer match, 401(k) match, and fringe benefits such as car allowance, accommodations and medical benefits, along with related taxes on grossed up fringe benefits.

(3) Primarily relates to relocation assistance.

Employment Contracts

The following table outlines the specified terms of the relevant employment contracts for the named executive officers of the Company. For compensation information of named executives refer to the table above.

Role	Name	Contract Duration	Period of Notice (2) (3)	Termination payments provided for by contract (1)
Chief Executive Officer (CEO)	James Corbett	Three years with automatic one-year extensions on each anniversary.	Termination by the Company with or without Cause– No notice period. Termination by executive- with or without Good Reason - 90 days prior written notice.	18 months
Chief Financial Officer (CFO)	David O'Toole	Open-ended contract	Termination by the Company or Executive with or without Cause– No notice period.	12 months
Chief Legal and Compliance Officer, and Corporate Secretary (CLCO)	Nicole Kelsey	Open-ended contract	Termination by the Company or Executive with or without Cause– No notice period.	12 months

(1) Termination payments only in the event of employment termination for involuntary termination without cause or termination for "Good Reason."

(2) "Cause" - For the CEO, "Cause" shall mean the occurrence of any of the following events: (i) Executive's unauthorized misuse of the Company's trade secrets or proprietary information, (ii) Executive's conviction or plea of nolo contendere to a felony or a crime involving moral turpitude, (iii) Executive's committing an act of fraud against the Company, or (iv) Executive's gross negligence or willful misconduct in the performance of his duties that has had or is likely to have a material adverse effect on the Company. Except for a failure, breach or refusal which, by its nature, cannot reasonably be expected to be cured, Executive shall have ten (10) business days from the delivery date of the Company's written notice of termination within which to cure any acts constituting Cause. For the CFO, Cause is defined as (i) conviction of, or a plea of guilty or nolo contendere to, a felony or crime involving moral turpitude; (ii) participation in an act of fraud or theft against the Company; (iii) willful and material breach of any contractual, statutory, fiduciary, or common law duty owed to the Company including without limitation Section 4.1 of this Agreement; (iv) willful and repeated failure to satisfactorily perform job duties; or (v) any willful act that is likely to and which does in fact have the effect of injuring the reputation, business, or a business relationship of the Company. For the CLCO, Cause is defined as: conviction of, or a plea of guilty or nolo contendere to, a felony or crime involving moral turpitude; participation in an act of fraud or theft; willful and material breach of any contractual, statutory, fiduciary or common law duty owed to the Company; intentional and repeated failure of Executive to perform Executive's job duties after receiving notice of the stated deficiencies and Executive willfully falling to address the deficiencies and deliberately continuing to not perform stated job duties; or any willful, deliberate, premeditated act by Executive that materially and demonstrably injures the reputation, business or a business relationship of the Company.

(3) "Good Reason" - For the CEO, Good Reason is defined as (i) a material reduction in Executive's Base Salary unless a proportionate reduction is made to the Base Salary of all members of the Company's senior management, (ii) a permanent relocation of Executive's principal place of employment by more than 50 miles from the location in effect immediately prior to such relocation, (iii) any material by the Company of any material provision of this Agreement, or (iv) a material diminution in the nature or scope of Executive's authority or responsibilities from those applicable to Executive as of the Effective Date (date of hire). For the CFO and CLCO, Good Reason is defined as (i) a material diminution in Executive's authority, duties, or responsibilities in effect at the time of this Agreement; (ii) any reduction in the Executive's then current base salary; (iii) relocation of Executive's principal place of work by a distance of fifty (50) miles or more from the Executive's then current principal place of work without the Executive's consent; (iv) material breach by the Company of any provision of this Agreement; provided, however, that the conduct described in the foregoing subsections (i) through (iv) will only constitute Good Reason if such conduct is not cured within thirty (30) days after the Company's receipt of written notice from the Executive specifying the particulars of the conduct the Executive believes constitutes Good Reason."

Compensation Principles

The Compensation Committee has a formal Compensation Governance Framework which, at the core, consists of a Compensation Committee Charter (the "Charter"). The Charter outlines responsibilities and duties of the members, sets forth the frequency of meetings, establishes and reviews the overall compensation policies and practices of the Company, and also sets forth the process to review and approve the executive compensation program for the Chief Executive Officer and other executive officers, and make appropriate recommendations to the Board of Directors.

Compensation Committee

The Compensation Committee approves or makes recommendations to our Board of Directors on decisions concerning compensation of the executive management team and Board of Directors on a periodic basis to ensure that it is consistent with our short-term and long-term goals. The Compensation Committee assess the appropriateness of the nature and amount of compensation of our executives by reference to relevant employment market conditions with the overall objective of ensuring maximum stakeholder benefit from the recruitment and retention of a high-quality board and executive team.

Additionally, the Compensation Committee is responsible for evaluating the performance of the Company's key senior executives. The Company's Chief Executive Officer and other members of management regularly discuss the Company's compensation issues with Compensation Committee members. The Compensation Committee reviews and recommends to the Board of Directors the overall bonus and equity incentive awards for employees of the Company Additionally, the Company's Chief Executive Officer makes recommendations to the Compensation Committee for review, modification (if applicable) and approval in relation to bonuses and equity incentive awards for members of the executive management team.

Resignation, Retirement, Termination for Cause, or Resignation without Good Reason Arrangements

The Company does not have any agreements or plans other than the current employment contracts in place for the named executive officers that would provide additional compensation in connection with a retirement.

Potential Payments upon Involuntary Termination, Resignation without Good Reason or Change-In-Control

The employment contract provides for the following severance payments upon termination by us without cause or by the employee for good reason (as defined in the particular employment agreement): (i) payment of the employee's then-current base salary for a period of 18-months for the CEO and 12-months for the CFO or CLCO, following termination (ii) a pro-rated target bonus for the period during which the employee was employed in the year of termination and (iii) continued coverage under our group health and benefits plan consistent with the term of the base salary; and (iv) immediate acceleration of unvested stock options and restricted stock unit awards.

Outstanding Equity Awards at Fiscal Year-End

The following table presents information regarding outstanding equity awards held by our named executive officers as of December 31, 2024 (in US dollars).

	Option awards			
Name	Number of securities underlying unexercised options exercisable	Number of securities underlying unexercised unearned options	Option exercise price (2)	Option expiration date (2)
James Corbett, Chief Executive Officer	-	350,000	$12.64	6/5/2034
	113,148	113,148	$5.64	9/28/2032
	33,334	66,666	$14.17	6/6/2033
David O'Toole, Chief Financial Officer	-	125,000	$12.64	1/3/2034
	50,000	100,000	$17.00	6/15/2033
Nicole Kelsey, Chief Legal and Compliance Officer	-	150,000	$7.72	7/1/2034

(1) Amounts in this column are calculated by multiplying the closing market price of the Company's stock as of December 31, 2024 by the number of shares or units of stock awards.

(2) Represents range of exercise price and expiration dates as options were granted on different dates throughout their tenure.

Director Compensation

The following table sets forth certain information regarding the compensation earned by or awarded to each non-employee Director who served on our Board during the fiscal year-ended December 31, 2024 (in U.S. Dollars). We do not provide separate compensation to our executive Director, James Corbett, who served as our Chief Executive Officer during the fiscal year-ended December 31, 2024.

	Fees earned in cash (1)	Stock awards (2)	Option awards (3)	Total
Non-Executive Directors				
Lou Panaccio - Chairman	$ 127,500	$ 87,492	$ 24,482	$ 239,474
Jeremy Curnock Cook	92,500	87,492	24,482	204,474
Suzanne Crowe	92,500	87,492	24,482	204,474
Jan Stern Reed	97,500	87,492	24,482	209,474
Robert McNamara	102,500	87,492	24,482	214,474
Cary Vance	100,000	87,492	24,482	211,974
Total Non-Executive Directors	**$ 612,500**	**$ 524,952**	**$ 146,893**	**$ 1,284,345**

(1) Amounts are composed of the following: $70,000 for fees as a Board Member, $35,000 for Chair of the Board, $20,000 for Audit Committee Chair, $15,000 for Compensation Committee Chair, $10,000 for Nominating and Corporate Governance Chair, $10,000 for Audit Committee Member, $7,500 for Compensation Committee Member, and $5,000 for Nominating and Corporate Governance Member.

(2) Amounts in this column represent awards of restricted stock units with the aggregate grant date fair value computed in accordance with ASC 718. The fair value determined at the date of grant in accordance with U.S. GAAP based on the closing price of our common stock on the applicable grant date. The vesting of these stock awards are service based and subject to continued participant as Board Members.

(3) Amounts in this column represent awards of stock options with the aggregate grant date fair value computed in accordance with ASC 718. Amounts in this column represent option awards issued to the individuals noted, based on the fair value determined at the date of grant in accordance with U.S. GAAP. See Note 14, Share-Based Payment Plans to our Consolidated Financial Statements included in Part II, Item 8. “Financial Statements and Supplementary Data” for the assumptions used in determining the grant date fair value of option awards. The vesting of these option awards are service based and subject to continued participant as Board Members.

Equity Compensation Plan Information as of December 31, 2024

Plan Category		Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)		Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)	
Equity compensation plans approved by security holders						
2016 Equity Incentive Plan	(2)				-	(1)
Stock Options		458,196	$	12.53		
2020 Equity Incentive Plan					1,422,101	
Stock Options		2,313,110	$	12.46		
RSUs		48,164	$	-		
2021 AGM Awards					-	
Stock Options		22,600	$	12.18		
2022 AGM Awards					-	
Stock Options		247,876	$	5.75		
2023 AGM Awards					-	
Stock Options		124,768	$	14.17		
RSUs		13,832	$	-		
2024 AGM Awards						
Stock Options		373,658	$	12.44		
RSUs		55,200				
Equity compensation plans not approved by security holders		-		-	-	
Total		3,657,404			1,422,101	

(1) Upon closing of the Redomiciliation, the 2016 Plan was terminated with respect to future grants and accordingly, there are no more shares available to be issued under the 2016 Plan.

(2) The 2016 Plan was previously approved and adopted by the shareholders of AVITA Australia, the former parent company.

No securities were purchased on-market:

- under or for the purposes of an employee incentive plan; or
- to satisfy the entitlements of the holders of options or other rights to acquire securities granted under an employee incentive plan.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

For common stockholders, the information required with respect to this item will be incorporated herein by reference to our Definitive Proxy Statement for our 2025 Annual Meeting of Stockholders or an amendment of this report to be filed with the SEC no later than 120 days after the close of our year ended December 31, 2024.

In addition to the Company's primary listing on the Nasdaq Capital Market, the Company's shares of common stock are also quoted in the form of CDIs on the ASX and trade under the ticker symbol "AVH". As part of our ASX listing, we are required to comply with the various disclosure requirements as set out under the ASX Listing Rules. The following information is intended to comply with the ASX Listing Rules (where that information has not been provided elsewhere in this Annual Report).

Australian Disclosure Requirements

Principal Stockholders and Management

The following table provides certain information regarding the ownership of our common stock (including our CDIs), as of January 27, 2025 by each person or group of affiliated persons known to us to be the beneficial owner of more than 5% of our common stock (including our CDIs); each of our named executive officers; each of our Directors; and all of our named executive officers and Directors as a group. The table also sets out the names of all persons (to the best of the Company's knowledge) who have disclosed pursuant to the *Corporations Act 2001* (Cth) that they are "substantial shareholders" of the Company and carry 5% or more of the voting rights attached to the issued securities of the Company.

Unless otherwise indicated in the table or the related notes, the address for each person named in the table is c/o AVITA Medical, Inc., 28159 Avenue Stanford Suite 220, Valencia, CA 91355.

Title of Class	Name and Address of Beneficial Owner	Amount and Nature of Beneficial Ownership [1]		Percentage of Class [2]
	More than 5% stockholders:			
	BlackRock, Inc. 50 Hudson Yards New York, NY 10001	1,806,519	(3)	6.85%
	The Vanguard Group, Inc. 100 Vanguard Blvd., Malvern, PA 19355	1,417,672	(4)	5.38%
	Directors and named executive officers:			
Common Stock	Lou Panaccio	53,769	(5)	*
Common Stock	Jeremy Curnock Cook	31,205	(6)	*
Common Stock	Professor Suzanne Crowe	38,303	(7)	*
Common Stock	Jan Stern Reed	47,305	(8)	*
Common Stock	Cary Vance	13,761	(9)	*
Common Stock	Robert McNamara	23,761	(10)	*
Common Stock	James Corbett	282,204	(11)	1.07%
Common Stock	David O'Toole	115,401	(12)	*
Common Stock	Nicole Kelsey	-		*
	All executive officers and directors as a group (9 persons)	**605,709**		**2.30%**

* Represents beneficial ownership of less than 1% of the outstanding common stock.

(1) Except as otherwise indicated, we believe that the beneficial owners of the common stock listed above, based on information furnished by such owners, have sole investment and voting power with respect to such shares, subject to community property laws where applicable. Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities.

(2) Percentage of ownership is based on 26,357,542 shares of our common stock issued and outstanding as of January 27, 2025 (including common stock represented by CDIs). Common stock subject to options or RSUs exercisable within 60 days of January 27, 2025 are deemed outstanding for purposes of computing the percentage ownership of the person holding such option or RSUs but are not deemed outstanding for purposes of computing the percentage ownership of any other person.

(3) Represents shares beneficially owned by BlackRock, Inc, as of December 31, 2024, obtained from Schedule 13G filed by BlackRock, Inc. with the SEC on January 26, 2024.

(4) Represents shares beneficially owned by Vanguard, Inc, as of December 31, 2024, as obtained from Schedule 13G filed by Vanguard, Inc. with the SEC on February 13, 2024.

(5) Reflects 23,114 shares of common stock and 100,320 CDIs, which translates into 20,064 shares of common stock, and 10,591 shares of stock options to acquire 10,591 shares of our common stock exercisable within 60 days of January 27, 2025. CDIs include 29,860 CDIs which translates into 5,972 shares of common stock that are held by The Panaccio Superannuation Fund.
(6) Reflects 20,614 shares of common stock, and 10,591 shares of stock options to acquire 10,591 shares of our common stock exercisable within 60 days of January 27, 2025.
(7) Reflects 23,114 shares of common stock, 22,990 CDIs, which represent 4,598 shares of our common stock, and 10,591 shares of stock options to acquire 10,591 shares of our common stock exercisable within 60 days of January 27, 2025.
(8) Reflects 31,789 shares of common stock, and 15,516 shares of stock options to acquire 15,516 shares of our common stock exercisable within 60 days of January 27, 2025.
(9) Reflects 9,633 shares of common stock and 4,128 shares of stock options to acquire 4,128 shares of our common stock exercisable within 60 days of January 27, 2025.
(10) Reflects 19,633 shares of common stock and 4,128 shares of stock options to acquire 4,128 shares of our common stock exercisable within 60 days of January 27, 2025.
(11) Reflects 11,580 shares of common stock and 270,624 shares of stock options to acquire 270,624 shares of our common stock exercisable within 60 days of January 27, 2025.
(12) Reflects 23,734 shares of common stock and 91,667 shares of stock options to acquire 91,667 shares of our common stock exercisable within 60 days of January 27, 2025.

Jurisdiction of incorporation and restrictions on the acquisition of securities

The Company is incorporated in the State of Delaware in the United States of America. As a foreign company registered in Australia, the Company is not subject to Chapters 6, 6A, 6B and 6C of the *Corporations Act 2001* (Cth) dealing with the acquisition of its shares (including substantial holdings and takeovers).

Under the Delaware General Corporation Law, the Company's shares are generally freely transferable, subject to restrictions imposed by United States federal or state securities laws, by the Company's certificate of incorporation or by-laws or by an agreement signed with the holders of shares on issue. The Company's certificate of incorporation and bylaws do not impose any specific restrictions on the transfer of its shares. Repurchases of the Company's securities are governed by the safe harbor provisions set forth in Rule 10b-18 of the Securities Exchange Act of 1934. However, provisions of the Delaware General Corporation Law, the Company's certificate of incorporation and the Company's by-laws could make it more difficult to acquire the Company by means of a tender offer (takeover), a proxy contest or otherwise, or to remove incumbent officers and directors of the Company. These provisions could discourage certain types of coercive takeover practices and takeover bids that the Company's Board of Directors may consider inadequate and encourage persons seeking to acquire control of the Company to first negotiate with the Board of Directors.

Australian Corporate Governance Statement

The Board of Directors and employees of the Company are committed to developing, promoting and maintaining a strong culture of good corporate governance and ethical conduct. The Board of Directors confirm that the Company's corporate governance framework is generally consistent with the ASX's Corporate Governance Council's "Corporate Governance Principles and Recommendations" (4th Edition) ("ASX Governance Recommendations"). The Company's Corporate Governance Statement is available for viewing at https://ir.avitamedical.com/corporate-governance. The Corporate Governance Statement sets out the ASX Governance Recommendations and the Company's response as to how and whether it follows those recommendations. Where the Company's practices depart from a recommendation, the Board of Directors has disclosed in the Corporate Governance Statement the departure along with reasons for the adoption of its own practices. The Company's most recent Corporate Governance Statement, dated February 22, 2024 and approved by the Board of Directors remains accurate as of the date of this Annual Report on Form 10-K.

Issued Capital

As of January 27, 2025, the Company's issued share capital was as follows:

- 26,357,542 shares of common stock, of which:
  - 12,515,008 shares of common stock were held by 4 stockholders of record quoted on Nasdaq; and
  - 13,842,534 shares of common stock were held by CHESS Depositary Nominees Pty Limited ("Authorized Nominee") (on behalf of 19,321 CDI securityholders) representing 69,212,670 CDIs quoted on ASX.

As of January 27, 2025, the following unquoted securities were on issue, which entitle the holders of those securities, upon vesting of their conversion rights, to be issued shares of common stock (including in certain cases in the form of CDIs) of the Company:

- the equivalent of 4,686,196 unquoted options held amongst 124 option holders. Specifically:
  - the equivalent of 683,771 options are on issue to Mr. James Corbett, CEO;
  - the equivalent of 4,002,425 options were granted (and are on issue) to 123 employees and directors of the Company under Avita Australia's 2016 Equity Incentive Plan and 2020 Equity Incentive Plan and the Company's 2021, 2022, 2023, and 2024 AGM Awards; and
- the equivalent of 117,196 RSUs held by 21 employees of the Company under Avita Australia's 2020 Employee Incentive Plan and the Company's 2021, 2022, 2023, and 2024 AGM Awards.

As of January 27, 2025, the Company does not have any restricted securities that are on issue or any securities subject to voluntary escrow that are on issue.

Voting Rights

The Company's bylaws provide that each stockholder has one vote for every share of common stock entitled to vote held of record by such stockholder. If holders of CDIs wish to attend and vote at the Company's general meetings, they will be able to do so, provided, in case of voting, that the relevant steps as set out below are complied with by the CDI holder. Under the ASX Listing Rules and ASX Settlement Operating Rules, the Company must allow CDI holders to attend any meeting of the holders of the underlying securities, unless relevant United States laws at the time of the meeting prevent CDI holders from attending those meetings.

In order to vote at such meetings, CDI holders have the following options:

- instruct the Authorized Nominee (as the legal owner of the shares of common stock) to vote the common stock represented by their CDIs in a particular manner. A voting instruction form will be sent to CDI holders with the notice of meeting or proxy statement for the meeting and that instruction form must be completed and returned to the Company's registry prior to the record date fixed for the relevant meeting ("CDI Voting Instruction Receipt Time"), which is notified to the CDI holder in the voting instructions included in the notice of meeting; or
- inform the Company that they wish to nominate themselves or a third party to be appointed as the Authorized Nominee's proxy with respect to their common stock underlying their CDIs for the purposes of attending and voting at the meeting. The instruction form must be completed and returned to the Company's registry prior to the CDI Voting Instruction Receipt Time.

Alternatively, a CDI holder can convert their CDIs into a holding of common stock and vote those shares of common stock at a meeting of stockholders. Such a conversion must be undertaken prior to the record date fixed by the Company's Board of Directors for determining the entitlement of stockholders to attend and vote at the meeting. However, if the former CDI holder later wishes to sell their investment on the ASX, it would be necessary to convert those shares of common stock back to CDIs.

As CDI holders will not appear on the Company's register as the legal holders of the underlying common stock, they will not be entitled to vote at a stockholder meeting unless one of the above steps is undertaken. As each CDI represents 1/5 of a share of common stock, if the CDI holder takes one of the steps noted above to allow it to vote at a stockholder meeting, the CDI holder will be entitled to one vote for every five CDIs it holds.

Holders of options, warrants and RSUs are not entitled to vote at the Company's general meetings.

Substantial Stockholders

The information required in relation to the substantial shareholders of the Company is included in this Annual Report at Item 12 of Part III.

Distribution of Common Stock and CDI Holders as of January 27, 2025

Below is a distribution schedule of the number of holders of common stock and CDIs, categorized by the size of their holdings, based on the Company's registers as of January 27, 2025.

	Common Stock		
	Number of Holders of Record	Shares of common stock	Percentage of total common stock ownership (1)
1 - 1,000	1	20	0.00%
1,001 - 5,000	-	-	
5,001 - 10,000	-	-	
10,001 - 100,000	1	56,944	0.22%
100,001 - and over	2	12,458,044	47.27%
	4	12,515,008	

(1) Percentage of ownership is based on 26,357,542 shares of our common stock issued and outstanding as of January 27, 2025 (including common stock represented by CDIs).

	CDIs		
	Number of Holders	Number of common stock equivalents (CDIs divided by 5) (1)	Percentage of total common stock ownership (2)
1 - 1,000	12,252	867,746	3.29%
1,001 - 5,000	4,903	2,411,580	9.15%
5,001 - 10,000	1,129	1,714,911	6.51%
10,001 - 100,000	977	4,738,952	17.98%
100,001 - and over	60	4,109,347	15.59%
	19,321	13,842,536	

(1) Assuming all CDIs are held as common stock of the Company, with 5 CDIs representing a beneficial ownership interest in one share of common stock of the Company.

(2) Percentage of ownership is based on 26,357,542 shares of our common stock issued and outstanding as of January 27, 2025 (including common stock represented by CDIs).

The number of holders holding less than a marketable parcel of securities

The number of stockholders and/or CDI holders holding less than a marketable parcel of shares of common stock and/or CDIs (where a "marketable parcel" means a parcel of securities worth at least A$500, pursuant to the ASX Operating Rules) as of January 27, 2025 was as follows:

- 4,470 holders of less than a marketable parcel of CDIs.
- No common stockholders owning less than a marketable parcel of shares of common stock.

Buy-back of securities

There is no current on-market buy-back of our securities.

Twenty Largest Holders as of January 27, 2025

Below are statements of the 20 largest stockholders and CDI holders, and the number and percentage of issued common stock held by those holders, based on the Company's registers as of January 27, 2025 (assuming all CDIs are held as common stock of the Company, with 5 CDIs representing a beneficial ownership interest in one share of common stock of the Company).

		Common Stock	
Rank	**Name**	**Shares of common stock**	**Percentage of total common stock outstanding (1)**
1	CEDE & CO	26,171,266	99.29%
2	DR MIKE PERRY	129,312	0.49%
3	ARLENE O E PERRY	56,944	0.22%
4	GARY L ORLOFF	20	0.00%
	Total	**26,357,542**	

(1) Percentage of ownership is based on 26,357,542 shares of our common stock issued and outstanding as of January 27, 2025 (including common stock represented by CDIs).

	CDIs		
Rank	Name	Number of Common stock equivalents (CDIs divided by 5) (1)	Percentage of total common stock outstanding (2)
1	WASHINGTON H SOUL PATTINSON AND COMPANY LIMITED	392,529	1.49%
2	CITICORP NOMINEES PTY LIMITED	391,741	1.49%
3	BNP PARIBAS NOMINEES PTY LTD <HUB24 CUSTODIAL SERV LTD>	388,055	1.47%
4	UBS NOMINEES PTY LTD	345,782	1.31%
5	ABN AMRO CLEARING SYDNEY NOMINEES PTY LTD <CUSTODIAN A/C>	177,865	0.67%
6	MR EVAN PHILIP CLUCAS + MS LEANNE JANE WESTON <KURANGA NURSERY SUPER A/C>	177,013	0.67%
7	J P MORGAN NOMINEES AUSTRALIA PTY LIMITED	113,074	0.43%
8	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED	112,967	0.43%
9	TAGGART INVESTMENTS PTY LTD <TAGGART INVESTMENT A/C>	86,000	0.33%
10	BNP PARIBAS NOMINEES PTY LTD <IB AU NOMS RETAILCLIENT>	76,729	0.29%
11	IOOF INVESTMENT SERVICES LIMITED <IPS SUPERFUND A/C>	71,116	0.27%
12	NEWECONOMY COM AU NOMINEES PTY LIMITED <900 ACCOUNT>	70,808	0.27%
13	BNP PARIBAS NOMINEES PTY LTD <CLEARSTREAM>	70,704	0.27%
14	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED	65,237	0.25%
15	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED <GSCO CUSTOMERS A/C>	61,465	0.23%
16	MR ANDRE WALL ELLIS + MRS OLIVIA LOUISE ELLIS	60,000	0.23%
17	MRS ARLENE PERRY	60,000	0.23%
18	WAIRAHI INVESTMENTS LIMITED	60,000	0.23%
19	MR DAVID ANTHONY DEELEN	57,200	0.22%
20	DENTAL UNION OF AUSTRALIA PTY LTD <IAN WEATHERLAKE S/F A/C>	56,000	0.21%
	Total	2,894,285	
	Remaining CDI Holders	10,948,249	
	Total common stock held with CDI shares	13,842,534	

(1) Assuming all CDIs are held as shares of common stock of the Company, with 5 CDIs representing a beneficial ownership interest in one share of common stock in the Company.

(2) Percentage of ownership is based on 26,357,542 shares of our common stock issued and outstanding as of January 27, 2025 (including common stock represented by CDIs).

General Information

The name of our Secretary is Nicole Kelsey.

The Company's ASX liaison officer who is responsible for communications with the ASX is Mark Licciardo.

The complete mailing address, including zip code, of our principal executive office is 28159 Avenue Stanford, Suite 220, Valencia, CA 91355, USA. The telephone number is +1(661) 367-9170.

The address of our registered office in Australia is c/o Acclime Ltd (formerly Merton's Corporate Services), Level 7, 330 Collins Street, Melbourne VIC 3000, Australia and our telephone number there is +61 3 8689 9997.

Registers of securities are held as follows:

- for CDIs in Australia at Computershare Investor Services Pty Limited, Level 2, 45 St Georges Terrace, Perth WA 6000 Australia, Investor Enquiries +61 8 9323 2000 (within Australia) +61 3 9415 4677 (outside Australia); and
- for common stock in the United States at Computershare Investor Services, 250 Royall Street, Canton, MA 02021 USA, Tel: +1 866-644-4127.

Application of funds

The Company advises that it has used the cash and assets in a form readily convertible to cash that it had at the time of the Company's admission to the Official List of ASX in a way that is consistent with its business objectives.

Item 13. CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Transactions with Related Persons

SEC rules require us to disclose any transaction or currently proposed transaction in which the Company is a participant and in which any related person has or will have a direct or indirect material interest involving the lesser of $120,000 or 1% of the average of the Company's total assets as of the end of the last two completed fiscal years. A related person is any executive officer, director, nominee for director, or holder of 5% or more of the Company's Common Stock, or an immediate family member of any of those persons. Since January 1, 2023, the Company has not participated in any such related party transaction.

Director Independence

The Company's Board of Directors has determined that all members of our Board of Directors, except Mr. James Corbett, are independent directors for purposes of the rules of Nasdaq and the SEC and for the purposes of the ASX Listing Rules and the ASX Corporate Governance Council's 4th Edition Corporate Governance Principles and Recommendations. In making this determination, our Board of Directors considered the relationships that each non-executive director has with us and all other facts and circumstances that our Board of Directors deemed relevant, including the beneficial ownership of our common stock by each non-executive director and Mr. Corbett's executive role within AVITA Medical.

The composition and functioning of the Company's Board of Directors and each of its committees complies with all applicable requirements of Nasdaq and the rules and regulations of the SEC as well as the ASX Listing Rules and the ASX Corporate Governance Council's 4th Edition Corporate Governance Principles and Recommendations.

Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Principal Accounting Fees and Services

Grant Thornton LLP, the U.S. member of Grant Thornton International Ltd, independent registered public accountants have served as our independent public accountant for the years-ended December 31, 2024 and 2023. The following table sets forth fees billed or accrued by our independent registered public accountants during the years-ended December 31, 2024 and 2023.

	Year-Ended December 31, 2024	Year-Ended December 31, 2023
Audit fees - Grant Thornton LLP (1)	$ 726,716	$ 775,020
Grant Thornton UK LLP (1)	-	47,301
Tax fees - Grant Thornton LLP (2)	175,652	137,812
Total fees	$ 902,368	$ 960,133

(1) Audit fees consist of fees for the professional services by the principal accountant for the audit of the registrant's annual financial statements and review of financial statements included in the registrant's Form 10-Q or services that are normally provided by the accountant in connection with statutory and regulatory filings or engagements.

(2) Tax fees include the aggregate fees billed in each of the last two fiscal years for professional services rendered by the principal accountant for tax compliance, tax advice, and tax planning.

Pre-Approval Policies and Procedures

The Audit Committee's policy is for the Audit Committee to approve all audit and non-audit services prior to such services being performed by the independent registered public accounting firm. Before engaging an independent registered public accountant firm to render audit or non-audit services, the engagement is approved by the Company's Audit Committee or the engagement to render services is entered into pursuant to pre-approval policies and procedures established by the audit committee. The Audit Committee pre-approved all audit services provided by independent registered public accountants during the years-ended December 31, 2024 and 2023.

PART IV

Item 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this Annual Report:

(1) All Financial Statements

See Index to Financial Statements in Part II, Item 8 of this Annual Report.

(2) Financial Statement Schedules

All financial statement schedules have been omitted since the required information was not applicable or was not present in amounts sufficient to require submission of the schedules, or because the information required is included in the financial statements or the accompanying notes.

(3) Exhibits

The exhibits listed in the following Index to Exhibits are filed, furnished or incorporated by reference as part of this Annual Report

EXHIBITS

Exhibit Number	Exhibit Description
2.1	Scheme Implementation Agreement (incorporated by reference to Exhibit 99.2 of Form 6-K of Avita Medical Limited dated April 20, 2020)
3.1	Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the registrant's Form 8-K12B filed on June 30, 2020)
3.2	Certificate of Amendment of Certificate of Incorporation (incorporated by reference to Exhibit 3.2 to the registrant's Form 10-KT filed on February 28, 2022)
3.3	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.3 to the registrant's Form 10-KT filed on February 28, 2022)
4.1	Description of Capital Stock (incorporated by reference to Exhibit 4.1 to the registrant's Form 10-K filed on February 23, 2023)
10.1	Employee Incentive Option Plan (incorporated by reference to Exhibit 4.1 of the Form 20-F of Avita Medical Limited filed September 27, 2019)†
10.2	Employee Share Plan (incorporated by reference to Exhibit 4.2 of the Form 20-F of Avita Medical Limited filed September 27, 2019)†
10.3	Award Contract dated September 29, 2015 by and between the registrant and the U.S. Department of Health and Human Services Biomedical Advanced Research and Development Authority (BARDA) (incorporated by reference to Exhibit 4.3 of the Form 20-F of Avita Medical Limited filed September 27, 2019)*
10.4	Award Contract dated September 29, 2015 by and between the registrant and BARDA (incorporated by reference to Exhibit 4.4 of the Form 20-F of Avita Medical Limited filed September 27, 2019) *
10.5	Amendment of Solicitation/Modification of Contract dated June 24, 2016 by and between the registrant and BARDA (incorporated by reference to Exhibit 4.5 of the Form 20-F of Avita Medical Limited filed September 27, 2019) *
10.6	Amendment of Solicitation/Modification of Contract dated September 28, 2017 by and between the registrant and BARDA (incorporated by reference to Exhibit 4.6 of the Form 20-F of Avita Medical Limited filed September 27, 2019) *
10.7	Amendment of Solicitation/Modification of Contract dated July 2, 2018 by and between the registrant and BARDA (incorporated by reference to Exhibit 4.7 of the Form 20-F of Avita Medical Limited filed September 27, 2019) *
10.8	Lease Agreement between the registrant and Hartco Ventura Inc. dated January 25, 2018 (incorporated by reference to Exhibit 4.8 of the Form 20-F of Avita Medical Limited filed September 27, 2019)
10.9	Lease Agreement between the registrant and RIF-Avenue Stanford LLC, dated October 3, 2016, as amended (incorporated by reference to Exhibit 4.9 of the Form 20-F of Avita Medical Limited filed September 27, 2019)

Exhibit Number	Exhibit Description
10.10	Third Amendment to the Lease Agreement between the registrant and RIF III-Avenue Stanford LLC, dated November 17, 2020, as amended) (incorporated by reference to Exhibit 10.10 to the registrant's Form 10-KT filed on February 28, 2022)
10.11	Executive Employment Agreement between the registrant and James Corbett dated September 26, 2022 (incorporated by reference to Exhibit 10.1 of the registrant's Form 10Q filed on November 10, 2022)
10.12	Amendment One to Employment Agreement between the registrant and James Corbett, dated March 16, 2023 (incorporated by reference to Exhibit 10.1 of the registrant's Form 8-K filed on March 22, 2023) †
10.13	Executive Employment Agreement between the registrant and David O'Toole dated June 17, 2023 (incorporated by reference to Exhibit 10.3 to the registrants Form 10Q filed August 10, 2023) †*
10.14	Amendment No. 1 to the 2020 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.1 of the Registrant's Form 8-K filed on June 7, 2023) †
10.15	AVITA Medical, Inc. Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.2 of the Registrant's Form 8-K filed on June 7, 2023) †
10.16	Form of Stock Option Grant (incorporated by reference to Exhibit 10.19 to the registrant's Form 10-K filed on February 23, 2023)†
10.17	Form of RSU Agreement (incorporated by reference to Exhibit 10.20 to the registrant's Form 10-K filed on February 23, 2023)†
10.18	2020 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.29 to the registrant's Form 10-KT filed on February 28, 2022) †
10.19	Fourth Amendment to the Lease Agreement between the registrant and RIF III-Avenue Stanford LLC, dated August 25, 2021, as amended) (incorporated by reference to Exhibit 10.30 to the registrant's Form 10-KT filed on February 28, 2022)
10.20	Stock Option Grant Agreement between the registrant and James Corbett, dated effective September 28, 2022 (incorporated by reference to Exhibit 10.23 of Form 10-K filed on February 23, 2023).
10.21	Fifth Amendment to the Lease Agreement between the registrant and 28159 Avenue Stanford Properties, LLC, (formerly RIF III-Avenue Stanford LLC), dated January 26, 2023, as amended) (incorporated by reference to Exhibit 10.24 to the registrant's Form 10-K filed on February 23, 2023)
10.22	Engagement Letter dated March 15, 2023, between the registrant and Mr. Cary Vance (incorporated by reference to Exhibit 10.1 of the registrant's Form 8-K filed on March 21, 2023) †
10.23	Non-Qualified Deferred Compensation Plan (incorporated by reference to Exhibit 10.4 on Form 10Q issued May 11, 2023) †
10.24	Lease agreement between URP X LLC and AVITA Medical, Inc. dated May 11, 2023 (incorporated by reference to Exhibit 10.5 on Form 10Q issued May 11, 2023)
10.25	Engagement Letter dated March 22, 2023, between AVITA Medical, Inc. and Mr. Robert McNamara (incorporated by reference to Exhibit 10.1 on Form 8K issued March 27, 2023)
10.26	Warrant Certificate, dated October 18, 2023, by and between the Company, and OrbiMed Royalty & Credit Opportunities IV, LP (incorporated by reference to Exhibit 4.1 to the registrant's Form 8-K filed on October 18, 2023)
10.27	Credit Agreement, dated October 18, 2023, by and between the Company, as borrower, and ORCO IV LLC as lender and administrative agent (incorporated by reference to Exhibit 10.1 to the registrant's Form 8-K filed on October 18, 2023)
10.28	Pledge and Security Agreement, dated October 18, 2023, by and among the Company, the guarantors party thereto and ORCO IV LLC (incorporated by reference to Exhibit 10.2 to the registrant's Form 8-K filed on October 18, 2023)
10.29	Lease Agreement between the registrant and Hartco Ventura Inc. dated December 6, 2023 (incorporated by reference to Exhibit 10.30 to the registrant's Form 10-K filed on February 22, 2024)
10.30	Amendment One to Employment Agreement between the registrant and David O'Toole, dated August 9, 2023 (incorporated by reference to Exhibit 10.33 to the registrant's Form 10-K filed on February 22, 2024) †

Exhibit Number	Exhibit Description
10.31	Waiver and First Amendment to Orbimed Credit Agreement (incorporated by reference to Exhibit 10.34 to the registrant's Form 10-K filed on February 22, 2024)
10.32	Trademark Security Agreement (incorporated by reference to Exhibit 10.35 to the registrant's Form 10-K filed on February 22, 2024)
10.33	Supplement to Guarantee (incorporated by reference to Exhibit 10.36 to the registrant's Form 10-K filed on February 22, 2024)
10.34	Patent Security Agreement (incorporated by reference to Exhibit 10.37 to the registrant's Form 10-K filed on February 22, 2024)
10.35	Supplement to Pledge and Security Agreement (incorporated by reference to Exhibit 10.38 to the registrant's Form 10-K filed on February 22, 2024)
10.36	Security Trust Deed (incorporated by reference to Exhibit 10.39 to the registrant's Form 10-K filed on February 22, 2024)
10.37	Specific security Deed (marketable securities) (incorporated by reference to Exhibit 10.40 to the registrant's Form 10-K filed on February 22, 2024)
10.38	General Security Deed (incorporated by reference to Exhibit 10.41 to the registrant's Form 10-K filed on February 22, 2024)
10.39	Exclusive Distribution Agreement between the registrant and PolyMedics Innovation GmbH (incorporated by reference to Exhibit 10.42 to the registrant's Form 10-K filed on February 22, 2024)
10.40	Exclusive Distribution Agreement between the registrant and Stedical Scientific, Inc, dated January 10, 2024 (incorporated by reference to Exhibit 10.1 on Form 10-Q issued May 13, 2024)
10.41	Second Amendment to Lease Agreement between the registrant and Hartco Ventura Inc. dated January 1, 2024 (incorporated by reference to Exhibit 10.2 on Form 10-Q issued May 13, 2024)
10.42	Amendment of Solicitation/Modification of Contract dated February 16, 2024 by and between the registrant and BARDA (incorporated by reference to Exhibit 10.3 on Form 10-Q issued May 13, 2024)
10.43	Exclusive Development and Distribution Agreement between the registrant and Collagen Matrix, Inc. dba Regenity Biosciences dated July 31, 2024 (incorporated by reference to Exhibit 10.1 on Form 10-Q issued November 7, 2024)
10.44	Executive Employment Agreement between the registrant and Nicole Kelsey dated June 28, 2024 (incorporated by reference to Exhibit 10.2 on Form 10-Q issued November 7, 2024) †
10.45	Separation Agreement and Release between the registrant and Donna Shiroma dated June 28, 2024 (incorporated by reference to Exhibit 10.3 on Form 10-Q issued November 7, 2024) †
10.46	First Amendment to Lease Agreement between the registrant and Hartco Ventura Inc. dated September 12, 2024 (incorporated by reference to Exhibit 10.4 on Form 10-Q issued November 7, 2024)
10.47	First Amendment to Lease Agreement between the registrant and Hartco Ventura Inc. dated November 5, 2020 **
10.48	Second Amendment to OrbiMed Credit Agreement dated May 28, 2024 **
10.49	Third Amendment to Orbimed Credit Agreement dated November 7, 2024**
19	AVITA Medical, Inc. Insider Trading and Securities Dealing Policy **
21.1	Subsidiaries of the Registrant **
97.1	Incentive-Based Compensation Recovery Policy †
23.1	Consent of Independent Registered Public Accounting Firm **
31.1	Certification of CEO pursuant to Section 302 of The Sarbanes-Oxley Act of 2002 **
31.2	Certification of CFO pursuant to Section 302 of The Sarbanes-Oxley Act of 2002 **
32.1	Certification of CEO and CFO pursuant to Section 906 of The Sarbanes-Oxley Act of 2002 ***
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

† Management contract or compensation plan or arrangement.
* Certain identified confidential information has been redacted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.
** Filed herewith

*** Furnished herewith

Item 16. Form 10-K Summary

None

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

AVITA Medical, Inc.
(Registrant)

Date: February 13, 2025

/s/ James Corbett
James Corbett
Chief Executive Officer (Principal Executive Officer)

Date: February 13, 2025

/s/ David O'Toole
David O'Toole
Chief Financial Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Name	Title	Date
/s/ James Corbett James Corbett	Chief Executive Officer and Director (Principal Executive Officer)	February 13, 2025
/s/ David O'Toole David O'Toole	Chief Financial Officer (Principal Financial and Accounting Officer)	February 13, 2025
/s/ Lou Panaccio Lou Panaccio	Chairman of the Board of Directors	February 13, 2025
/s/ Jeremy Curnock Cook Jeremy Curnock Cook	Director	February 13, 2025
/s/ Suzanne Crowe Suzanne Crowe	Director	February 13, 2025
/s/ Jan Stern Reed Jan Stern Reed	Director	February 13, 2025
/s/ Robert McNamara Robert McNamara	Director	February 13, 2025
/s/ Cary Vance Cary Vance	Director	February 13, 2025

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Shareholders
AVITA Medical, Inc.

Opinion on the financial statements

We have audited the accompanying consolidated balance sheets of AVITA Medical, Inc. (a Delaware corporation) and subsidiaries (the "Company") as of December 31, 2024 and 2023, the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2024, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2024, in conformity with accounting principles generally accepted in the United States of America.

Basis for opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ GRANT THORNTON LLP

We have served as the Company's auditor since 2020.

Los Angeles, California
February 13, 2025

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

	As of	
	December 31, 2024	**December 31, 2023**
ASSETS		
Cash and cash equivalents	$ 14,050	$ 22,118
Marketable securities	21,835	66,939
Accounts receivable, net	11,786	7,664
BARDA receivables	56	30
Prepaids and other current assets	2,004	1,659
Inventory	7,269	5,596
Total current assets	57,000	104,006
Plant and equipment, net	10,018	1,877
Operating lease right-of-use assets	3,571	2,440
Corporate-owned life insurance (“COLI”) asset	3,006	2,475
Intangible assets, net	5,570	487
Other long-term assets	546	355
Total assets	$ 79,711	$ 111,640
LIABILITIES, NON-QUALIFIED DEFERRED COMPENSATION PLAN SHARE AWARDS AND STOCKHOLDERS’ EQUITY		
Accounts payable and accrued liabilities	$ 6,294	$ 3,793
Accrued wages and fringe benefits	10,451	7,972
Current non-qualified deferred compensation (“NQDC”) liability	2,094	168
Other current liabilities	1,319	1,266
Total current liabilities	20,158	13,199
Long-term debt	42,245	39,812
Non-qualified deferred compensation liability	2,969	3,663
Contract liabilities	324	357
Operating lease liabilities, long term	2,840	1,702
Warrant liability	3,432	3,158
Contingent liability	3,000	-
Total liabilities	74,968	61,891
Non-qualified deferred compensation plan share awards	244	693
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Common stock, $0.0001 par value per share, 200,000,000 shares authorized, 26,354,042 and 25,682,078, shares issued and outstanding at December 31, 2024 and December 31, 2023, respectively	3	3
Preferred stock, $0.0001 par value per share, 10,000,000 shares authorized, no shares issued or outstanding at December 31, 2024 and December 31, 2023	-	-
Company common stock held by the non-qualified deferred compensation plan	(1,319)	(1,130)
Additional paid-in capital	367,568	350,039
Accumulated other comprehensive loss	(1,939)	(1,887)
Accumulated deficit	(359,814)	(297,969)
Total stockholders’ equity	4,499	49,056
Total liabilities, non-qualified deferred compensation plan share awards and stockholders’ equity	$ 79,711	$ 111,640

The accompanying notes form part of the consolidated financial statements

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

	Year Ended	
	December 31, 2024	**December 31, 2023**
Sales revenue	$ 63,893	$ 50,143
Lease revenue	358	-
Total revenues	64,251	50,143
Cost of sales	(9,094)	(7,780)
Gross profit	55,157	42,363
BARDA income	-	1,428
Operating expenses:		
Sales and marketing	(58,195)	(37,291)
General and administrative	(33,195)	(28,334)
Research and development	(20,360)	(20,821)
Total operating expenses	(111,750)	(86,446)
Operating loss	(56,593)	(42,655)
Interest expense	(5,361)	(1,143)
Other income, net	163	8,483
Loss before income taxes	(61,791)	(35,315)
Income tax expense	(54)	(66)
Net loss	$ (61,845)	$ (35,381)
Net loss per common share:		
Basic and diluted	$ (2.39)	$ (1.40)
Weighted-average common shares:		
Basic and diluted	25,883,056	25,331,264

The accompanying notes form part of the consolidated financial statements

AVITA MEDICAL, INC.
Consolidated Statements of Comprehensive Loss
(In thousands)

	Year Ended	
	December 31, 2024	December 31, 2023
Net loss	$ (61,845)	$ (35,381)
Cumulative translation adjustment recognized in earnings as part of the reorganization of foreign subsidiaries	-	(9,415)
Change in fair value due to credit risk on long-term debt	30	(621)
Net unrealized gain/(loss) on marketable securities	(82)	522
Comprehensive loss	$ (61,897)	$ (44,895)

The accompanying notes form part of the consolidated financial statements

AVITA MEDICAL, INC.
Consolidated Statements of Stockholders' Equity
(In thousands, except shares)

	Common Stock						
	Shares	Amount	Company common stock held by the NQDC Plan	Additional Paid-in Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2022	**25,208,436**	**$ 3**	**$ (127)**	**$ 339,825**	**$ 7,627**	**$ (262,588)**	**$ 84,740**
Net loss	-	-	-	-	-	(35,381)	(35,381)
Stock-based compensation	-	-	-	7,866	-	-	7,866
Exercise of stock options	166,675	-	-	957	-	-	957
Vesting of restricted stock units	106,476	-	-	-	-	-	-
Company common stock held by the NQDC Plan	128,172	-	(1,401)	1,401	-	-	-
Distribution/diversification of Company common stock held by the NQDC Plan	-	-	398	354	-	-	752
Change in redemption value of share awards in NQDC plan	-	-	-	(1,019)	-	-	(1,019)
ESPP purchases	72,319	-	-	655	-	-	655
Net unrealized gain on marketable securities	-	-	-	-	522	-	522
Change in fair value due to credit risk on long-term debt	-	-	-	-	(621)	-	(621)
Cumulative translation adjustments recognized in earnings as part of the reorganization of foreign subsidiaries	-	-	-	-	(9,415)	-	(9,415)
Balance at December 31, 2023	**25,682,078**	**3**	**(1,130)**	**350,039**	**(1,887)**	**(297,969)**	**49,056**
Net loss	-	-	-	-	-	(61,845)	(61,845)
Stock-based compensation	-	-	-	13,419	-	-	13,419
Vesting of restricted stock units	99,905	-	-	-	-	-	-
Exercise of stock options	352,208	-	-	2,135	-	-	2,135
ESPP purchase	171,224	-	-	1,373	-	-	1,373
Distribution/diversification of Company common stock held by the NQDC Plan	-	-	245	76	-	-	321
Vesting of Company common stock held by the NQDC Plan	48,627	-	(434)	434	-	-	-
Change in redemption value of share awards in NQDC Plan	-	-	-	92	-	-	92
Net unrealized loss on marketable securities	-	-	-	-	(82)	-	(82)
Change in fair value due to credit risk on long-term debt	-	-	-	-	30	-	30
Balance at December 31, 2024	**26,354,042**	**$ 3**	**$ (1,319)**	**$ 367,568**	**$ (1,939)**	**$ (359,814)**	**$ 4,499**

The accompanying notes form part of the consolidated financial statements

AVITA MEDICAL, Inc.
Consolidated Statement of Cash Flows
(In thousands)

	Year Ended	
	December 31, 2024	**December 31, 2023**
Cash flow from operating activities:		
Net loss	$ (61,845)	$ (35,381)
Adjustments to reconcile net loss to net cash used in operating activities:		
Cumulative translation adjustments recognized in earnings as part of the reorganization of foreign subsidiaries	-	(9,415)
Loss on issuance under credit agreement	-	1,238
Change in fair value of long-term debt	2,463	1,616
Change in fair value of warrant liability	274	733
Depreciation and amortization	1,126	632
Stock-based compensation	13,496	8,384
Non-cash lease expense	843	748
Loss on fixed asset disposal	107	83
Investment losses	-	17
Loss on patent disposal	16	4
Remeasurement and foreign currency transaction gain/(loss)	21	37
Excess and obsolete inventory related charges	487	221
BARDA deferred costs	-	(194)
Contract cost amortization	-	341
Provision for credit losses	23	24
Amortization of premium of marketable securities	(1,674)	(1,381)
Non-cash changes in the fair value of NQDC plan	402	856
Changes in operating assets and liabilities:		
Trade and other receivables	(4,145)	(4,172)
BARDA receivables	(26)	868
Prepaids and other current assets	(345)	(451)
Inventory	(2,160)	(3,693)
Operating lease liability	(906)	(713)
Corporate-owned life insurance (“COLI”) asset	(271)	(1,008)
Other long-term assets	(191)	(233)
Accounts payable and accrued expenses	340	809
Accrued wages and fringe benefits	2,479	1,347
Current non-qualified deferred compensation liability	1,785	(1,504)
Other current liabilities	122	266
Non-qualified deferred compensation plan liability	(1,327)	2,251
Contract liabilities	(33)	(341)
Net cash used in operations	(48,939)	(38,011)
Cash flows from investing activities:		
Purchase of marketable securities	(24,504)	(78,757)
Sale of marketable securities	-	2,372
Maturities of marketable securities	71,200	79,439
Purchase of plant and equipment	(9,171)	(1,381)
Patent filing fees	(162)	(66)
Net cash provided by investing activities	37,363	1,607
Cash flow from financing activities:		
Proceeds from long-term debt	-	38,762
Proceeds from exercise of stock options	2,135	957
Employee stock purchase plan (“ESPP”) purchases	1,373	655
Net cash provided by financing activities	3,508	40,374
Effect of foreign exchange rate on cash and cash equivalents	-	(16)
Net increase/(decrease) in cash and cash equivalents	(8,068)	3,954
Cash and cash equivalents beginning of the period	22,118	18,164
Cash and cash equivalents end of the period	$ 14,050	$ 22,118

Supplemental Disclosure of Cash Flow Information:				
Income taxes paid during the period	$	41	$	44
Interest paid during the period	$	5,359	$	1,143
Non-cash investing and financing activities:				
Intangible asset purchase not yet paid	$	5,000	$	-
Plant and equipment purchases not yet paid	$	115	$	6
Right-of-use-asset obtained in exchange for lease liabilities	$	2,043	$	2,337
Warrant liability recognized upon issuance of term loan	$	-	$	2,425

The accompanying notes form part of the consolidated financial statements

AVITA MEDICAL, INC.
Notes to Consolidated Financial Statements

1. The Company

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). These financial statements include the assets, liabilities, revenues and expenses of all wholly-owned subsidiaries.

Nature of the Business

AVITA Medical and its subsidiaries (collectively, "AVITA Medical" or the "Company") is a leading therapeutic acute wound care company delivering transformative solutions. The Company's technologies are designed to optimize skin restoration procedures, effectively accelerating patient healing and recovery. The Company's solutions improve the healing outcomes for patients with traumatic injuries and surgical repairs, addressing critical healing needs that arise from unpredictable and life-changing events. At the forefront of the Company's portfolio is the patented and proprietary RECELL® System ("RECELL System" or "RECELL"), approved by the U.S. Food and Drug Administration (the "FDA") for the treatment of thermal burn wounds and full-thickness skin defects, and for repigmentation of stable depigmented vitiligo lesions. RECELL harnesses the regenerative properties of a patient's own skin to create an autologous skin cell suspension, Spray-On Skin™ Cells, delivering a transformative solution at the point of care. This breakthrough technology serves as the catalyst for a new treatment paradigm enabling improved clinical outcomes. In September 2018, the FDA granted PMA to the RECELL System for use in the treatment of acute thermal burns in patients eighteen years and older. Following receipt of the original PMA, the Company commenced commercialization of the RECELL System in January 2019 in the United States. In June 2021, the FDA approved the expanded use of the RECELL System in combination of meshed autografting for acute full-thickness thermal wounds in pediatric and adult patients. In February 2022, the FDA approved a PMA supplement for the RECELL Autologous Cell Harvesting Device, an enhanced ease-of-use device aimed at providing clinicians a more efficient user experience and simplified workflow. On June 7, 2023, the FDA approved a PMA supplement for full-thickness skin defects based on results of the Company's pivotal trial for soft tissue repair and reconstruction. Following this approval, the Company commenced a commercial launch on June 8, 2023.

The single-use RECELL Autologous Cell Harvesting Device ("RECELL Ease-of-Use" or "RECELL EOU") is approved by the FDA for the treatment of thermal burn wounds and full-thickness skin defects, and repigmentation of stable depigmented vitiligo lesions. The Company's next-generation device, RECELL GO™ Autologous Cell Harvesting Device ("RECELL GO"), is FDA-approved to treat thermal burn wounds and full-thickness skin defects. RECELL GO introduces enhanced features that streamline the preparation of Spray-On Skin Cells and improves workflow efficiency in the operating room. It consists of two components: a multi-use, AC-powered RECELL GO Processing Device (the "RPD") and a RECELL GO Preparation Kit (the "RPK"). The RPK contains the single-use RECELL GO Cartridge, disaggregation head, RECELL Enzyme™, and other components. The RPD provides the control for the RPK, manages the pressure applied to disaggregate the donor skin cells, and precisely regulates the incubation times of the RECELL Enzyme and solutions to optimize cell yield and promote cell viability.

On June 16, 2023, the FDA approved a PMA application for the repigmentation of stable depigmented vitiligo lesions. Following FDA approval, the Company established a framework, which consists of three steps, to secure reimbursement for vitiligo. The first step is to conduct the 100-patient post market study called TONE. TONE will evaluate repigmentation using the RECELL device and will also seek to measure the improvement in the quality-of-life following treatment of stable vitiligo with RECELL. TONE, including publication, is expected to be complete by the end of 2024. The second step is to initiate a health economics study to capture the longitudinal healthcare costs for a vitiligo patient, which is expected to be completed by the end of 2024. The purpose of these studies is to demonstrate how treating vitiligo with RECELL can significantly reduce the lifetime healthcare cost of patients. As a result, commercial payors will stand to benefit economically by providing coverage of RECELL for the repigmentation of stable depigmented vitiligo lesions. Conversations with commercial payors will begin during the first quarter of 2025. Commercial coverage will be rolled out on a tiered basis based on state and geographic factors. The Company anticipates that the initial phase of reimbursement coverage will likely begin in the fourth quarter of 2025 with appropriately sized commercial support as coverage is established.

Additionally, on June 29, 2023, the Company submitted a PMA supplement to the FDA for RECELL GO™. RECELL GO maintains the FDA Breakthrough Device designation from predecessor devices. On September 29, 2023, the Company received notice from the FDA that additional information regarding the PMA is required for the continuation of a substantive review for RECELL GO. This request, which is not unique to the Breakthrough Device Program, placed the application file on hold while the Company addressed the FDA's questions. A category of questions posed by the FDA required additional in-house testing. The Company submitted the complete response to the FDA on February 28, 2024. On May 29, 2024, the FDA approved the premarket approval PMA supplement for RECELL GO. Following this approval, the Company shipped the first RECELL GO order on May 30, 2024, to accommodate the first case for its use on May 31, 2024.

In February 2019, the Company entered into a collaboration with COSMOTEC, an M3 Group company, to market and distribute the RECELL System in Japan. Under the terms of the agreement, AVITA Medical will supply the RECELL product, and COSMOTEC will be the sole distributor of the product in Japan. The Company worked with COSMOTEC to advance its application for approval of the RECELL System in Japan pursuant to PMDA. In February 2022, COSMOTEC's application for regulatory approval was approved by the PMDA with labeling for burns only. In September 2022, COSMOTEC commercially launched RECELL in Japan following Japan's Ministry of Health, Labor, and Welfare approval of reimbursement pricing.

The Company also holds the right to market, sell, and distribute PermeaDerm®, a biosynthetic wound matrix, in the United States under the terms of an exclusive multi-year distribution agreement with Stedical Scientific, Inc. ("Stedical") (the "Stedical Agreement"). In July 2024, the Company entered into an exclusive multi-year development and distribution agreement with Collagen Matrix, Inc. dba Regenity Biosciences ("Regenity") (the "Regenity Agreement"). Following 510(k) approval, Regenity will manufacture and supply Cohealyx™, a unique collagen-based dermal matrix, and the Company will hold the exclusive marketing, sales, and distribution rights to this product under its private label in the U.S., and potentially in countries in the European Union, as well as in Australia and Japan.

Liquidity and Capital Resources

The Company has incurred operating losses and negative cash flows from operations since its inception and has an accumulated deficit of $359.8 million as of December 31, 2024. For the years ended December 31, 2024 and 2023, the Company used $48.9 million and $38.0 million of cash, respectively, in its operating activities. As of December 31, 2024, the Company had cash, cash equivalents, and marketable securities of $35.9 million. Historically, the Company has funded its operations principally through the sales of its products, issuance of equity securities, and debt financing.

The Company's Consolidated Financial Statements have been prepared on the basis of the Company continuing as a going concern for the next 12 months. Management believes that the Company's cash, cash equivalents, and marketable securities will allow the Company to continue its planned operations for at least the next 12 months from the date of the issuance of these Consolidated Financial Statements.

In connection with the Long-term debt described in Note 6, the Company will need to be in compliance with a minimum trailing twelve month net revenue (see Note 18 for amendment providing for lowered revenue covenants) at the end of each quarter and maintain a minimum quarterly cash and cash equivalents balance. If the Company cannot generate sufficient revenue in the future or maintain the cash balance, the Company may not be in compliance with the covenants and additional repayments may be necessary or the lender may call the debt. As of December 31, 2024, the Company was in compliance with all financial covenants.

2. Summary of Significant Accounting Policies

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany transactions and balances have been eliminated upon consolidation.

Recent Accounting Pronouncements

In November 2023, the Financial Accounting Standards Board (the "FASB") issued ASU 2023-07, S*egment Reporting (Topic 280): Improvements to Reportable Segment Disclosures.* The ASU expands public entities' segment disclosures by requiring disclosure of significant segment expenses that are regularly reviewed by the Chief operating decision maker ("CODM") and included within each reported measure of segment profit or loss, an amount and description of its composition for other segment items, and interim disclosures of a reportable segment's profit or loss and assets. The ASU also allows, in addition to the measure that is most consistent with U.S. GAAP, the disclosure of additional measures of segment profit or loss that are used by the CODM in assessing segment performance and deciding how to allocate resources. All disclosure requirements under ASU 2023-07 are also required for public entities with a single reportable segment. The Company adopted ASU 2023-07 during the year-ended December 31, 2024. For further details refer to Note 11.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures.* The amendments require (i) enhanced disclosures in connection with an entity's effective tax rate reconciliation and (ii) income taxes paid disaggregated by jurisdiction. The amendments are effective for annual periods beginning after December 15, 2024. The Company is currently evaluating the impact of adopting this ASU on its Consolidated Financial Statements and disclosures.

Use of Estimates

The preparation of the accompanying Consolidated Financial Statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts (including the stand-alone selling price ("SSP") for the RPD, allowance for credit losses, reserves for inventory excess and obsolescence, carrying value of long-lived assets, the useful lives of long-lived assets, accounting for marketable securities, income taxes, fair value of debt, fair value of warrants and stock-based compensation) and related disclosures. Estimates have been prepared based on the current and available information. However, actual results could differ from estimated amounts.

Foreign Currency Translation and Foreign Currency Transactions

The financial position and results of operations of the Company's operating non-U.S. subsidiaries are generally determined using the respective local currency as the functional currency of that subsidiary. Assets and liabilities of these subsidiaries are translated at the exchange rate in effect at each period end. Income statement accounts are translated at the average rate of exchange prevailing during the period. Adjustments arising from the use of differing exchange rates from period to period are included in Accumulated other comprehensive loss in the Consolidated Balance Sheets.

The Company's non-operating subsidiaries that use the U.S. Dollar as their functional currency remeasure monetary assets and liabilities at exchange rates in effect at the end of each period and nonmonetary assets and liabilities at historical rates. Gains and losses resulting from these remeasurements are included in earnings in the Consolidated Statement of Operations. Gains and losses for remeasurement were minimal for the year-ended December 31, 2024 and $22,000 for the year-ended December 31, 2023.

The Company records certain revenues and operating expenses in foreign currencies. These revenues and expenses are translated into U.S. Dollars based on the average exchange rate for the reporting period. Assets and liabilities denominated in foreign currencies are translated into U.S. Dollars at the exchange rate in effect as of the balance sheet date. For the years-ended December 31, 2024 and 2023, the Company incurred losses of approximately $21,000 and $15,000, respectively, included in Other income, net in the Consolidated Statement of Operations.

Comprehensive Loss

The components of comprehensive loss consist of net loss, foreign currency translation adjustments ("CTA") from its subsidiaries not using the U.S. dollar as their functional currency, unrealized gains and losses in investments available for sale and changes in fair value due to instrument specific credit risk on the debt. During the year-ended December 31, 2023, the Company liquidated the Company's foreign subsidiaries. In accordance with ASC 830-30, *Foreign Currency Matters* ("ASC 830"), the CTA was reclassified into earnings. As such, the Company reclassified $9.4 million from comprehensive loss to earnings for the winding down of the foreign subsidiaries. The amount is recorded in Other income, net in the Consolidated Statement of Operations.

Reorganization of Foreign Subsidiaries and Deed of Cross Guarantee

During the year-ended December 31, 2023, the business activities of AVITA Medical Pty Limited, AVITA Medical Europe Limited, Visiomed Group Pty Ltd, C3 Operations Pty Ltd and Infamed Pty Ltd were liquidated. AVITA Medical Americas LLC was transferred from C3 Operations Pty Ltd to be directly held by the Company in preparation for each of AVITA Medical Pty Limited, AVITA Medical Europe Limited, Visiomed Group Pty Ltd, C3 Operations Pty Ltd and Infamed Pty Ltd to be de-registered during the year-ended December 31, 2024. In March 2024, the Company's deed of cross guarantee, dated June 29, 2020, with each of its Australian wholly-owned subsidiaries was revoked as part of the Company's reorganization of foreign subsidiaries. In January 2025, the Company was notified that the de-registration of each of its wholly-owned Australian subsidiaries listed above was completed.

Revenue Recognition

The Company generates revenues primarily from:

- The sale of RECELL EOU, RPK, and PermeaDerm products to hospitals, other treatment centers, and distributors.
- Maintenance fee received from BARDA to ensure first right of access to our inventory. In the prior year, the Company recorded service revenue for the emergency preparedness services provided to BARDA.
- Lease revenue for the RPD.

The Company's sale of the RECELL EOU and PermeaDerm products are accounted for under ASC 606, *Revenue from contracts with customers* ("ASC 606"). Revenue for the RECELL GO system is disaggregated between two accounting standards: (1) ASC 606 for the RPK and (2) ASC 842, *Leases* ("ASC 842") for the RPD. Revenues from BARDA are accounted for under ASC 606, and are included in Sales revenues within the Consolidated Statements of Operations.

To determine revenue recognition for contracts that are within the scope of ASC 606, the Company performs the following five steps:

1. Identify the contract with a customer
2. Identify the performance obligations
3. Determine the transaction price
4. Allocate the transaction price to the performance obligations
5. Recognize revenue when/as a performance obligation(s) is(are) satisfied

In order for an arrangement to be considered a contract, it must be probable that the Company will collect the consideration to which it is entitled for goods or services to be transferred. The Company then assesses the goods or services promised within the contract to determine whether each promised good or service is a performance obligation. Performance obligations are promises in a contract to transfer a distinct good or service to the customer that (i) the customer can benefit from on its own or together with other readily available resources, and (ii) is separately identifiable from other promises in the contract.

The Company determines the transaction price based on the amount of consideration the Company expects to receive for providing the promised goods or services in the contract. Consideration may be fixed, variable, or a combination of both. At contract inception for arrangements that include variable consideration, the Company estimates the probability and extent of consideration it expects to receive under the contract utilizing either the most likely amount method or expected amount method, whichever best estimates the amount expected to be received. The Company then considers any constraints on the variable consideration and includes in the transaction price variable consideration to the extent it is deemed probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

When accounting for a contract that contains multiple performance obligations, the Company must develop judgmental assumptions to determine the estimated SSP for each performance obligation identified in the contract. We utilize the observable SSP when available, which represents the price charged for the promised product or service when sold separately. When the SSP for our products or services are not directly observable, we determine the SSP using relevant information available and apply suitable estimation methods including, but not limited to, the cost-plus margin approach. The Company then allocates the transaction price to each performance obligation based on the relative SSP and recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) control is transferred to the customer and the performance obligation is satisfied.

Most of the Company's contracts have a single performance obligation. As such, the Company recognizes revenue when its customers obtain control of promised goods or services, in an amount that reflects the consideration which the Company expects to be entitled in exchange for those goods or services. Revenue is recognized net of volume discounts (variable consideration). For the Company's contracts that have an original duration of one year or less, since contract inception and customer payment occur within the same period the Company does not consider the time value of money. Further, because of the short duration of these contracts, the Company has not disclosed the transaction price for the remaining performance obligations as of each reporting period or when the Company expects to recognize this revenue. The Company has further applied the practical expedient to exclude sales tax in the transaction price and expense contract acquisition costs such as commissions and shipping and handling expenses as incurred.

Revenue recognition for contracts that are within the scope of ASC 606 and ASC 842

The Company enters into contracts with customers where it receives consideration for the RPK and does not receive additional consideration for the RPD. As a result, judgment and analysis are required to determine the appropriate accounting, including: (i) whether the arrangement contains an embedded lease, and if so, whether such embedded lease is a sales-type lease or an operating lease, (ii) the amount of the total consideration, as well as variable consideration, (iii) the identification of the distinct performance obligations contained within the arrangement, (iv) how the arrangement consideration should be allocated to each performance obligation when multiple performance obligations exist, including the determination of standalone selling price, and (v) when to recognize revenue on the performance obligations.

For these contracts the Company considers the guidance under ASC 842 to determine if furnishing the RPD to the customer during the period of use establishes an embedded lease. To determine if the contract contains a lease, the Company evaluates the customer's rights and ability to control the use of the underlying equipment throughout the contract term, including any equipment substitution rights retained by the Company. As the contract conveys the right to control the use of an identified asset for a period of time, the contract was determined to contain a lease. The Company then evaluated the lease classification based on the below:

- Pursuant to ASC 842-30, the Company will classify a lease as a sales-type lease if: (i) the lease transfers ownership of the underlying asset to the lessee by the end of the lease term, (ii) the lease grants the lessee an option to purchase the underlying asset that the lessee is reasonably certain to exercise, (iii) the lease term is for the major part of the remaining economic life of the underlying asset, (iv) the present value of the sum of the lease payments and any residual value guaranteed by the lessee that is not already reflected in the lease payments equals or exceeds substantially all (90% or more) of the fair value of the underlying asset, or (v) the underlying asset is of such a specialized nature that it is expected to have no alternative use to the lessor at the end of the lease term.
- Pursuant to ASC 842-30, when none of the sales-type lease classification criteria are met, a lessor would classify the lease as a direct financing lease when both of the following criteria are met: (i) the present value of the sum of the lease payments and any residual value guaranteed by the lessee that is not already reflected in the lease payments and/or any other third party unrelated to the lessor equals or exceeds substantially all (90% or more) of the fair value of the underlying asset and (ii) it is probable that the lessor will collect the lease payments plus any amount necessary to satisfy a residual value guarantee.
- Pursuant to ASC 842-30, a lessor would classify a lease as an operating lease when none of the sales-type or direct financing lease classification criteria are met. Further, per ASC 842, a lessor is required to classify a lease with variable lease payments that do not depend on an index or rate as an operating lease at lease commencement if the lease would have been classified as a sales-type lease or a direct financing lease in accordance with the classification criteria of ASC 842 and the lessor would have otherwise recognized a loss at the lease commencement date.

In determining whether the lease components are related to a sales-type lease or an operating lease, the Company evaluates if the lease transfers ownership at the end of the lease term, purchase options, the lease term in relation to the economic life of the asset, if the lease payments exceed the fair value of the asset, and if the asset is of a specialized nature. The Company also evaluates if the lease results in a loss at the lease commencement date. As the lease term is for a major part of the economic life, the lease meets the classification criteria for sales-type lease. However, to determine if the contract results in a loss at the lease commencement date the Company evaluated the consideration in the contract. The consideration at lease commencement does not contain fixed payments, purchase options, penalty payments or residual value guarantees. The variable consideration is related to the sale of the RPK. As the variable lease payments are not dependent on an index or rate, the variable consideration is excluded from consideration at contract inception resulting in a loss at lease commencement. As such, the Company classifies the lease as an operating lease.

The contracts contain a lease component, the RPD, and a non-lease component, the RPK. The lease component will be accounted for under ASC 842 and the non-lease component will be accounted for under ASC 606, as described above. Per ASC 842, the consideration in the contract will be allocated to each separate lease component and non-lease component of the contract. The consideration is allocated to these lease and non-lease components based on the SSP (as described above for contracts within the scope of ASC 606). In accordance with ASC 842, variable lease payments will be recognized once the sale of the RPK occurs and control has transferred to the customer. Consideration will be allocated to the RPD and RPK based on the SSP. Consideration related to the RPD will be recognized as Lease revenue and consideration related to the RPK will be recognized as Sales revenues in accordance with guidance in ASC 606, as described above, upon transfer of control of the RPK, which generally occurs at the time the product is shipped or delivered depending on the customer's shipping terms.

Assets in the Company's lease program are reported in Plant and equipment, net on its Consolidated Balance Sheets and are depreciated over the useful life of the RPD device's 200 uses, as indicated in the Instructions for Use that were approved by the FDA, and expensed as Costs of goods sold in the Consolidated Statements of Operations. The RPD depreciation has a direct relationship to the number of RPK units sold. Based on customer usage, each purchase of an RPK unit results in a 1/200 depreciation to the RPD.

Contract Liabilities

The Company receives payments from customers based on contractual terms. Trade receivables are recorded when the right to consideration becomes unconditional. The Company satisfies its performance obligation on product sales when the products are shipped or delivered, depending on the terms of the sale. Payment terms on invoiced amounts are typically 30 days, and do not include a financing component. Contract liabilities are recorded when the Company receives payment prior to satisfying its obligation to transfer goods to a customer.

Cost of Sales

Cost of sales related to products includes costs to manufacture or purchase, package, and ship the Company's products. Costs also include relevant production overhead and depreciation and amortization. These costs are recognized when control of the product is transferred to the customer and revenue is recognized.

Income Taxes

Income taxes are accounted for using the liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of assets and liabilities and their respective tax basis. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income or loss in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment date. Deferred tax assets are reduced by a valuation allowance if it is more likely than not that a portion of the deferred tax asset will not be realized. We recognize interest and penalties related to unrecognized tax benefits on the income tax expense line in the accompanying Consolidated Statement of Operations. Accrued interest and penalties are included on the related tax liability line in the Consolidated Balance Sheets.

The Company reviews its uncertain tax positions regularly. An uncertain tax position represents the Company's expected treatment of a tax position taken in a filed return, or planned to be taken in a future tax return or claim that has not been reflected in measuring income tax expense for financial reporting purposes. The Company recognizes the tax benefit from an uncertain tax position when it is more-likely-than-not that the position will be sustained upon examination on the basis of the technical merits or the statute of limitations for the relevant taxing authority to examine and challenge the tax position has expired.

Cash and Cash Equivalents

Cash and cash equivalents consists of cash held at deposit institutions, money market funds and short-term highly liquid investments with original maturities of three months or less from the date of purchase. As of December 31, 2024 and 2023, the Company holds cash at deposit institutions in the amount of $2.3 million and $10.7 million, respectively. The Company holds no cash denominated in foreign currencies in foreign institutions as of December 31, 2024 and $69,000 denominated in foreign currencies in foreign institutions as of December 31, 2023. As of December 31, 2024 and 2023, the Company held cash equivalents in the amount of $11.7 million and $11.4 million, respectively.

Concentrations

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents, marketable securities, trade receivables, BARDA receivables and other receivables. As of December 31, 2024 and 2023, substantially all of the Company's cash was deposited in accounts at financial institutions, and those deposited amounts may exceed federally insured limits and are subject to the risk of bank failure.

As of December 31, 2024, two commercial customers accounted for more than 10% of accounts receivable. Customer A accounted for 21% and Customer B for 11% of accounts receivable. As of December 31, 2023, no single commercial customer accounted for more than 10% of accounts receivable. For the years-ended December 31, 2024 and 2023, no single commercial customer accounted for more than 10% of total revenues.

BARDA revenues for the procurement of the RECELL system accounted for zero and 1% of total revenues for the years-ended December 31, 2024 and 2023, respectively. BARDA receivables for the procurement of the RECELL system and emergency preparedness accounted for 100% and 27% of BARDA receivables as of December 31, 2024 and 2023, respectively. As of December 31, 2024 and 2023, BARDA receivables were $56,000 and $30,000, respectively,

Fair Value of Financial Instruments

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1 — Quoted prices in active markets for identical assets or liabilities.

- Level 2 — Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.

- Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The asset's or liability's fair value measurement level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. Valuation techniques used need to maximize the use of observable inputs and minimize the use of unobservable inputs. For further details refer to Note 4.

At December 31, 2024 and 2023, the Company's financial instruments included cash, accounts payable, accrued expenses, long-term debt and warrant liabilities. The carrying amounts of accounts payable and accrued expenses approximate fair value due to the short-term maturities of these instruments.

Long-term Debt

The Company elected the fair value option ("FVO") of accounting under ASC 825-10, *Financial Instruments* ("ASC 825"), to record the debt at fair value at issuance and subsequently remeasures to fair value each reporting period. The Company elected the fair FVO option of accounting of ASC 825 for the debt from the issuance date in order to not have to bifurcate any embedded derivatives in accordance with ASC 815, *Derivatives and Hedging – Contracts in Entity's Own Equity* ("ASC 815"). The debt accounted for under the FVO represents a financial instrument containing embedded features which would otherwise be required to be bifurcated from the debt-host and recognized as separate derivative liabilities subject to initial and subsequent periodic estimated fair value measurements under ASC 815. The Company has elected to present interest expense separately from changes in fair value and therefore will present interest expense associated with the debt as Interest expense in the Consolidated Statement of Operations. Any changes in fair value caused by instrument-specific credit risk are presented separately in Accumulated other comprehensive loss in the Consolidated Balance Sheets. Changes in fair value attributable to changes in credit risk are determined using observable option adjusted spreads for the issuer or comparable companies with similar credit ratings. All costs associated with the issuance of the Credit Agreement accounted for using the FVO were expensed upon issuance. The fair value of the debt is determined using a Monte Carlo Simulation and classified as Level 3 in the fair value hierarchy. For further details refer to Note 4.

Presentation and Valuation of the Warrants

Warrants are accounted for as liabilities in accordance with ASC 815-40 and were presented within Warrant liability on the Consolidated Balance Sheets. The initial fair value of the warrant liability is measured at fair value at the date of issuance and are remeasured at each reporting date until settlement. Changes in the fair value of the warrant liability is recognized in Other income, net in the Consolidated Statement of Operations.

The Company established the fair value of the warrants utilizing the Black-Scholes pricing model. Assumptions used in the valuation are the price of the company stock, expected share-price volatility, expected term, risk-free interest rate and dividend yield. The Company estimates the volatility based on historical volatility that matches the expected remaining life of the warrants. The expected term of the warrants is assumed to be equivalent to their remaining contractual term. The dividend rate is based on the historical rate, which the Company anticipates to remain at zero. The warrants were classified Level 3 fair value measurement, due to the use of unobservable inputs. For further details refer to Note 4.

Marketable Securities

The Company classifies all highly liquid investments with original maturities of three months or less from the date of purchase as cash equivalents and all highly liquid investments with stated maturities of greater than three months as marketable securities. The Company classifies marketable securities as short-term when they have remaining contractual maturities of one year or less from the balance sheet date, and as long-term when the investments have remaining contractual maturities of more than one year from the balance sheet date. Classification is determined at the time of purchase and re-evaluated each balance sheet date. Short-term marketable securities represent investment of cash available for current operations. The Company accounts for our marketable securities as available-for-sale securities.

All marketable securities, which consist of corporate debt securities, asset backed securities, U.S treasury and commercial paper are denominated in the U.S. dollars, have been classified as “available for sale”, and are carried at fair value. Unrealized gains and losses, net of any related tax effects, are excluded from earnings and are included in other comprehensive income (loss) and reported as a separate component of stockholders equity until realized. Realized gains and losses on marketable securities are included in Other income, net, in the accompanying Consolidated Statements of Operations. The cost of any marketable securities sold is based on the specific identification method. The amortized cost of marketable securities is adjusted for amortization of premiums and accretion of discounts to maturity. Interest on marketable securities is included in Other income, net in the Consolidated Statements of Operations. In accordance with the Company’s investment policy, management invests to diversify credit risk and only invests in securities with high credit quality, including U.S. government securities, and the maximum final maturity from the date of purchase is thirty-seven months.

If necessary, the Company will recognize an allowance for credit losses on available-for-sale debt securities on an individual basis, and will no longer consider other than-temporary impairment or immediately reduce the cost basis of the investment provided that it is more likely than not that the security will be held to recovery or maturity. Further, the Company will recognize any improvements in estimated credit losses on available-for-sale debt securities immediately in earnings and reduce the existing allowance for credit losses. The Company will disaggregate its available-for-sale marketable securities into the following categories: commercial paper, corporate debt, government and agency securities and money market funds. The Company’s government and agency securities are U.S. treasury bonds, and U.S. agency bonds. The Company has analyzed government and agency securities and identified that both types of securities have similar risk characteristics in that they are traded infrequently and have contractual interest rates and maturity dates.

To evaluate for impairment, management reviews credit rating changes, securities trends, interest rate movements and unrealized loss at the security level of the Company’s available for sale debt securities. If any of these give rise to a potential credit concern, the Company performs a discounted cash flow analysis to determine the credit portion of the impairment. The discounted cash flow analysis will be performed either internally or through the assistance of a qualified third party. Once the credit component of the impairment is determined, the Company will record the impaired amount as an allowance to the available-for-sale debt securities balance and as a charge to other income in the accompanying Consolidated Statements of Operations, not to exceed the amount of the unrealized loss. The Company assesses expected credit losses at the end of each reporting period and adjusts the allowance through Other income, net.

Accounts Receivable

Accounts receivable are recorded net of customer allowances for expected credit losses. The Company estimates an allowance for expected credit losses (i.e., the inability of our customers to make required payments). These estimates are based on a combination of past experience and current trends. In estimating the allowance for expected credit losses, consideration is given to the current aging of receivables, a specific review for potential bad debts and an evaluation of historic write-offs. The resulting bad debt expense is included in Sales and marketing expenses in the Consolidated Statement of Operations. Receivables are written-off when deemed uncollectible. As of December 31, 2024 and 2023, the allowance for expected credit losses was $71,000 and $48,000, respectively.

A rollforward of the activity in the Company's allowance for expected credit losses is as follows (in thousands):

	Year-ended	
	December 31, 2024	**December 31, 2023**
Balance at beginning of year	$ 48	$ 24
Additions: change to cost and expense	23	24
Deductions: write-offs, net of recovery	-	-
Balance at end of year	$ 71	$ 48

BARDA Income and Receivables

The Company has concluded that grants under the BARDA grant are not within the scope of ASC 606, as they do not meet the definition of a contract with a "customer." The Company has further concluded that Subtopic 958-605, *Not-for-Profit-Entities-Revenue Recognition* also does not apply, as the Company is a business entity and the grants are with governmental agencies or units. With respect to the BARDA grant, the Company considered the guidance in IAS 20, *Accounting for Government Grants and Disclosure of Government Assistance,* by analogy. BARDA income and related receivables are recognized when there is reasonable assurance that the grant will be received, and all attaching conditions have been complied with. When the grant relates to an expense item, the grant received is recognized as income over the period when the expense was incurred.

Inventory

Inventory is valued at the lower of cost or estimated net realizable value and is reflected in cost of sales. Costs incurred in bringing each product to its present location and condition are accounted for at purchase cost on a first-in, first-out basis ("FIFO"). The Company capitalizes inventory costs associated with the Company's products when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized; otherwise, such costs are expensed as research and development. Inventory is evaluated for impairment periodically to identify inventory obsolescence when an inventory item's cost basis is in excess of its net realizable value. These adjustments are based upon multiple factors, including inventory levels, projected demand, and product shelf life.

Net realizable value is the estimated selling price in the ordinary course of business, less estimated costs of completion and costs to complete the sale.

Lessee Right-of-Use Assets and Lease Liabilities

The Company has operating leases for corporate office space, manufacturing and warehouse facility. The Company's operating leases have remaining lease terms of one year to five years, some of which include options to renew the lease. At contract inception, the Company determines whether the contract is a lease or contains a lease. A contract contains a lease if the Company is both able to identify an asset and can conclude it has the right to control the identified asset for a period of time. Leases with an initial term of twelve months or less are not recorded on the Consolidated Balance Sheet.

Right-of-use ("ROU") assets represent the Company's right to control an underlying asset for the lease term, and lease liabilities represent the Company's obligation to make lease payments arising from the lease. ROU assets and lease liabilities are recognized at commencement date based on the present value of lease payments over the lease term. As the Company's leases do not provide an explicit rate, the Company used its incremental borrowing rate ("IBR") based on the information available at commencement date in determining the discount rate used to present value lease payments. In determining the IBR, the Company considered its credit rating and current market interest rates. The IBR used approximates the interest that the Company would be required to pay for a collateralized loan over a similar term. The Company's leases typically do not include any residual value guarantees or asset retirement obligations.

The Company's lease terms are only for periods in which it has enforceable rights. A lease is no longer enforceable when both the lessee and the lessor each have the right to terminate the lease without permission from the other party with no more than an insignificant penalty. The Company has options to renew some of these leases for three years after their expiration. The Company considers these options, which may be elected at the Company's sole discretion, in determining the lease term on a lease-by-lease basis. Lease expense is recognized on a straight-line basis over the lease term and is primarily included in General and administrative expenses in the accompanying Consolidated Statements of Operations.

The Company has lease agreements with lease and non-lease components, which are accounted for as a single lease component for all underlying asset classes. Some leases require variable payments for common area maintenance, property taxes, parking, insurance and other variable costs. The variable portion of lease payments is not included in operating lease assets or liabilities. Variable lease costs are expensed when incurred.

Plant and Equipment

The Company's plant and equipment are stated at cost, net of accumulated depreciation and amortization. Depreciation is computed based on the straight-line method over the estimated useful lives of the various asset classes, generally three to seven years. Depreciation for the leased RECELL GO RPD devices, which have a useful life of 200 uses, is computed based on customer usage as determined by orders placed for the sales of RPK units. Leasehold improvements are amortized over the shorter of the life of the related asset or the remaining term of the lease. Costs associated with customized internal-use software systems that have reached the application development stage and technological feasibility are capitalized and include external direct costs utilized in developing or obtaining the applications and payroll and payroll-related expenses for employees who are directly associated with the application development. Maintenance and repairs are expensed as incurred.

Intangible Assets

The Company maintains definite-lived intangible assets related to patents and a license initially measured at cost and amortized over estimated useful lives of approximately 2—19 years. The Company had capitalized patent costs of $770,000 and $616,000 as of December 31, 2024 and 2023, respectively, related to regulatory approval of the RECELL System, and are being amortized over their estimated useful lives. The Company also had a capitalized license of $5.0 million as of December 31, 2024, related to the Regenity Agreement and the 510(k) approval for Cohealyx. For further details see Note 12.

Impairment of Long-Lived Assets

The Company evaluates long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If the sum of the estimated, undiscounted future cash flows is less than the carrying amount of the asset, then an impairment is recognized for the amount by which the carrying value of the asset exceeds its estimated fair value. Fair value is determined using the market, income, or cost approaches as appropriate for the asset. Any write-downs are treated as permanent reductions in the carrying amount of the asset and recognized as an operating loss. The Company did not have any impairments in long-lived assets for the year-ended December 31, 2024 and 2023.

Sales and Marketing Expenses

Sales and marketing expenses consist primarily of compensation and employee benefits of sales and marketing personnel and related field sales organization, marketing events, advertising costs, travel, trade shows and other marketing materials. The Company expenses all selling and marketing costs as incurred. Advertising expenses were $539,000 and $398,000 for the years-ended December 31, 2024 and 2023, respectively.

Research and Development Expenses

Research and development expenses represent costs incurred to develop the Company's products. Research and development expenses consist primarily of salaries and other personnel costs, clinical trial costs, regulatory costs and manufacturing costs for non-commercial products. The Company expenses all research and development costs in the periods in which they are incurred.

Stock-Based Compensation

The Company records compensation expense for stock options and restricted stock units ("RSU") based on the fair market value of the awards on the date of grant. The fair value of stock-based compensation awards is amortized over the vesting period of the award. Compensation expense for performance-based awards is evaluated based on the number of shares ultimately expected to vest, evaluated each reporting period and based on management's expectations regarding the relevant performance criteria. The Black-Scholes option pricing model and Monte Carlo Simulation are used to estimate the fair value of the time-based and performance-based options, respectively. Under ASU 2016-09, *Compensation – Stock Compensation Improvements to Employee Share-Based Payment Accounting*, the Company elected to account for forfeitures as they occur.

The following assumptions were used in the valuation of stock options.

- Expected volatility – determined using the historical volatility using daily intervals over the expected term.
- Expected dividends - based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future
- Expected term – the expected term of the Company's stock options for tenure only vesting has been determined utilizing the "simplified" method as described in the SEC's Staff Accounting Bulletin No. 107 relating to share-based compensation. The simplified method was chosen because the Company has limited historical option exercise experience due to its short operating history of awards granted, with the first plan being established in 2016 which was primarily used for executive awards. Further, the Company does not have sufficient history of exercises in the U.S. market given the Company's redomiciliation from Australia to the United States in 2020. The expected term of options with a performance condition or market condition was set to the contractual term of 10 years. The contractual term was used for options with a performance or market condition as these are primarily awarded to executives and the Company assumes that they will hold them longer than rank and file employees.
- Risk-free interest rate – the risk-free interest rate is based on the U.S. Treasury yield in effect at the time of grant for a period approximately equal to the expected term of the award.

Employee Stock Purchase Plan

The Company's Employee Stock Purchase Plan ("ESPP"), features two six-month offering periods per year, running from June 1 to November 30 and December 1 to May 31. The ESPP provides eligible employees with an opportunity to purchase shares of the Company's common stock through payroll deductions of up to 15% of their eligible compensation. Under the ESPP, employees can purchase the Company's Common Stock at the lower of 85% of the fair value of shares on either the first or last day of the offering period. Amounts deducted and accumulated by the participant are recorded as ESPP liability and included in Accrued wages and fringe benefits in the Consolidated Balance Sheets. This amount is used to purchase shares of common stock at the end of each six-month purchase period. Once the shares are purchased, the ESPP liability is reclassified to stockholders' equity on the purchase date. The ESPP is a compensatory plan accounted for under the expense recognition provision of share-based payment accounting standards. Compensation expense is recorded based on the fair market value at the grant date, which corresponds to the first day of each purchase period. The Black-Scholes option pricing model is used to estimate the grant date fair value.

Loss per Share

Basic net loss per share is computed by dividing net loss by the weighted-average number of common shares outstanding during the period. Diluted earnings per share is computed by dividing net loss by the weighted-average number of common shares outstanding during the period, assuming potentially dilutive ordinary shares from option exercises, employee share awards, ESPP and warrants and other dilutive instruments that have been issued. For periods where the Company has presented a net loss, potentially dilutive securities are excluded from the computation of diluted net loss per share as they would be anti-dilutive. In accordance with ASC 710-10, *Compensation – General* ("ASC 710"), shares of common stock held by the rabbi trust are excluded from the denominator in the basic and diluted EPS calculations.

Non-Qualified Deferred Compensation Plan Liability and Corporate-Owned Life Insurance Asset

The Company's non-qualified deferred compensation plan (the "NQDC plan"), which became effective in October 2021, allows highly compensated key employees to elect to defer a portion of their salary, bonus and RSU awards to later years. Management determined that the cash deferrals under the NQDC plan shall be accounted for similarly to a defined benefit plan under ASC 715, *Compensation – Retirement Benefits* ("ASC 715"), and should follow accounting treatment that is similar to a cash balance plan. Management determined that the employee portion and employer portion of the deferred compensation should be recognized as a compensation expense with a corresponding credit to deferred compensation liability. The matching contribution will be accrued over the vesting period of two years with 25% vesting in the first year and 75% vesting in the second year. Employees aged 55 or older immediately vest in employer matching contributions. The change in the liability between each reporting period is accounted for as compensation expense with a corresponding adjustment to deferred compensation liability. Upon distribution, the Company will record the distribution as a decrease to deferred compensation liability with a corresponding credit to cash. The Company funds the NQDC plan through a Corporate-Owned Life Insurance ("COLI"). Per the ASC 325-30-25-1A*, Investments – Other*, COLI is recorded as an asset on the Consolidated Balance Sheets as it does not meet the definition of a plan asset under ASC 715. The Company invests in COLI policies relating to its deferred compensation plan. Investments in COLI policies are recorded at their cash surrender values as of each balance sheet date. Changes in the cash surrender value during the period are recorded as a gain or loss in the Consolidated Statements of Operations in Other income, net.

Rabbi Trust

During April 2022, the Company established a rabbi trust for a select group of participants in which share awards granted under the 2020 Omnibus Incentive Plan ("2020 Plan") and deferred under the NQDC plan may be deposited. In addition to the deferral of shares, the rabbi trust holds the assets in the COLI for the NQDC plan. The rabbi trust is an irrevocable trust, and no portion of the trust fund may be used for any purpose other than the delivery of those assets to the participants. The assets held in the rabbi trust are subject to the claims of our general creditors in the event of bankruptcy or insolvency. The value of the assets of the rabbi trust is consolidated into our financial statements.

The NQDC plan permits diversification of vested shares (common stock) into other equity securities subject to a six-month and one day holding period subsequent to vesting. Per ASC 710-10-25-15, accounting for deferred common stock will be under plan type C or D. Accounting will depend on whether or not the employee has diversified the common stock. Under plan type C, diversification is permitted but the employee has not diversified. Under plan type D, diversification is permitted, and the employee has diversified.

For common stock that has not been diversified, the employer stock held in the rabbi trust is classified in a manner similar to treasury stock and presented separately on the Consolidated Balance Sheets as Company common stock held by the NQDC plan. The common stock will be recorded at the fair value of the stock at the time it vested, subsequent changes in the value of the common stock will not be recognized. The deferred compensation obligation is measured independently at fair value of the common stock with a corresponding charge or credit to compensation cost. The fair value is calculated as the product of the common stock and the closing price of the stock each reporting period.

Under plan type D, the accounting for the assets held by the rabbi trust is subject to the accounting pronouncements under applicable GAAP for each asset type. The deferred compensation obligation is measured independently at fair value of the underlying assets. During the years-ended December 31, 2024 and 2023, the diversified stock was invested in funds under the COLI policy.

Non-Qualified Deferred Compensation Stock Awards

In accordance with ASC 718*, Compensation — Stock Compensation* ("ASC 718"), the deferred RSU awards under the NQDC plan are classified as an equity instrument and changes in fair value of the amount owed to the participant are not recognized. As the plan permits diversification, presentation outside of permanent equity in accordance with ASR 268, *Redeemable Preferred Stock* is appropriate. The redemption amounts are based on the vested percentage and are recorded outside of equity as Non-qualified deferred compensation share awards on the Consolidated Balance Sheets. Deferred awards will be presented outside of permanent equity until the awards are vested. For further details refer to Note 17.

Segment Reporting

Operating segments are defined as components of an enterprise for which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. The Company's chief operating decision-maker is its Chief Executive Officer, who reviews consolidated financial results when making resource allocation decisions or evaluating Company performance. To date, the Company has viewed its operations and manages its business as one segment. As of December 31, 2024, the Company has no material long-lived assets outside of the U.S. and approximately 3% of its total revenues for the year-ended December 31, 2024 are from foreign countries. For further details refer to Note 11.

3. Marketable Securities

The following table summarizes the amortized cost and estimated fair values of debt securities available for sale:

	As of December 31, 2024			
(in thousands)	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Carrying Value
Cash equivalents:				
Money market funds	$ 11,720	$ -	$ -	$ 11,720
Total cash equivalents	$ 11,720	$ -	$ -	$ 11,720
Current marketable securities:				
U.S. Treasury securities	$ 21,821	$ 14	$ -	$ 21,835
Total current marketable securities	$ 21,821	$ 14	$ -	$ 21,835

	As of December 31, 2023			
(in thousands)	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Carrying Value
Cash equivalents:				
Money market funds	$ 8,427	$ -	$ -	$ 8,427
U.S. Treasury securities	2,992	-	-	2,992
Total cash equivalents	$ 11,419	$ -	$ -	$ 11,419
Current marketable securities:				
U.S. Treasury securities	$ 65,145	$ 100	$ (3)	$ 65,242
U.S. Government agency obligations	1,699	-	(2)	1,697
Total current marketable securities	$ 66,844	$ 100	$ (5)	$ 66,939

The maturities of marketable securities available for sale are summarized in the following table using contractual maturities. Actual maturities may differ from contractual maturities due to obligations that are called or prepaid.

	As of December 31, 2024		As of December 31, 2023	
(in thousands)	Amortized Cost	Carrying Value	Amortized Cost	Carrying Value
Due in one year or less	$ 21,821	$ 21,835	$ 66,844	$ 66,939

Gross unrealized gains and losses on the Company's marketable securities were an unrealized gain of $14,000 as of December 31, 2024. Gross unrealized gains and losses on the Company's marketable securities were an unrealized gain of $100,000 and an unrealized loss of $5,000 as of December 31, 2023 which resulted in a net unrealized loss of $95,000.

During the years-ended December 31, 2024 and 2023, the Company did not recognize credit losses. The Company has accrued interest income of $121,000 and $227,000 as of December 31, 2024 and, 2023, respectively, recorded in Prepaids and other current assets on the Consolidated Balance Sheets. Money market funds were included in Cash and cash equivalents on the Consolidated Balance Sheets.

4. Fair Value Measurements

The authoritative guidance on fair value measurements establishes a framework with respect to measuring assets and liabilities at fair value on a recurring basis and non-recurring basis. Under the framework, fair value is defined as the exit price, or the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants, as of the measurement date. The framework also establishes a three-tier hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. Observable inputs are inputs market participants would use in valuing the asset or liability and are developed based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the factors market participants would use in valuing the asset or liability and are developed based on the best information available in the circumstances. The hierarchy consists of the following three levels:

Level 1: Inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities that the reporting entity can access at the measurement date.

Level 2: Inputs are inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly.

Level 3: Inputs are unobservable inputs for the asset or liability

The following tables present information about the Company's financial assets measured at fair value on a recurring basis, based on the three-tier fair value hierarchy:

	As of December 31, 2024			
(in thousands)	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 11,720	$ -	$ -	$ 11,720
Total cash equivalents	$ 11,720	$ -	$ -	$ 11,720
Current marketable securities:				
U.S. Treasury securities	$ -	$ 21,835	$ -	$ 21,835
Total current marketable securities	$ -	$ 21,835	$ -	$ 21,835
Total marketable securities and cash equivalents	$ 11,720	$ 21,835	$ -	$ 33,555
Financial liabilities:				
Long-term debt	$ -	$ -	$ 42,245	$ 42,245
Warrant liability	-	-	3,432	$ 3,432
Non-qualified deferred compensation plan liability	-	5,063	-	$ 5,063
Total financial liabilities	$ -	$ 5,063	$ 45,677	$ 50,740
Financial assets:				
Corporate-owned life insurance policies	$ -	$ 3,006	$ -	$ 3,006
Total financial assets	$ -	$ 3,006	$ -	$ 3,006

	As of December 31, 2023			
(in thousands)	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 8,427	$ -	$ -	$ 8,427
U.S. Treasury securities	-	2,992	-	2,992
Total cash equivalents	$ 8,427	$ 2,992	$ -	$ 11,419
Current marketable securities:				
U.S. Treasury securities	$ -	$ 65,242	$ -	$ 65,242
U.S. Government agency obligations	-	1,697	-	1,697
Total current marketable securities	$ -	$ 66,939	$ -	$ 66,939
Total marketable securities and cash equivalents	$ 8,427	$ 69,931	$ -	$ 78,358
Financial liabilities:				
Long-term debt	$ -	$ -	$ 39,812	$ 39,812
Warrant liability	-	-	3,158	3,158
Non-qualified deferred compensation plan liability	-	3,831	-	$ 3,831
Total financial liabilities	$ -	$ 3,831	$ 42,970	$ 46,801
Financial assets:				
Corporate-owned life insurance policies	$ -	$ 2,475	$ -	$ 2,475
Total financial assets	$ -	$ 2,475	$ -	$ 2,475

The following table presents the summary of changes in the fair value of our Level 3 financial instruments:

	As of December 31, 2024		As of December 31, 2023	
(in thousands)	Long-term debt	Warrant liability	Long-term debt	Warrant liability
Balance beginning of period	$ 39,812	$ 3,158	$ -	$ -
Fair value on issuance date			37,575	2,425
Change in fair value in earnings	2,463	274	1,616	733
Change in fair value in other comprehensive loss	(30)	-	621	-
Balance end of period, at fair value	$ 42,245	$ 3,432	$ 39,812	$ 3,158

The Company's Level 1 assets include money market instruments and are valued based upon observable market prices. Level 2 assets consist of U.S. Government agency obligations and U.S Treasury securities. Level 2 securities are valued based upon observable inputs that include reported trades, broker/dealer quotes, bids and offers. There were no transfers between fair value measurement levels during the years-ended December 31, 2024 and 2023. Cash equivalents consist of money market funds and are classified as a Level 1. The corporate-owned life insurance contracts are recorded at cash surrender value, which is provided by a third party and reflects the net asset value of the underlying publicly traded mutual funds and are categorized as Level 2. Non-qualified deferred compensation plan liability is measured at fair value based on quoted prices of identical instruments to the investment vehicles selected by the participants.

Long-term debt

The fair value of the debt was determined using a Monte Carlo Simulation ("MCS") in order to predict the probability of different outcomes. The valuation was performed based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The fair value of the debt is recorded in the Consolidated Balance Sheets. The fair value is estimated by the Company each reporting period and the change in the fair value is recorded in both earnings and other comprehensive loss depending on the instrument's inherent credit risk and market risk related to the debt valuation. The assumptions used in the MCS were risk-free interest rate, revenue volatility, revenue discount rate, future revenue projection, and expected dividend rate.

As the debt is subject to net revenue requirements, the valuation of the debt was determined using MCS. The underlying metric to be simulated is the projected Trailing Twelve Month ("TTM") revenues at each quarter end through the maturity date of October 18, 2028. Based on the simulated metric, the different levels of simulated TTM revenues may trigger different discounted cash flow scenarios in which the TTM revenues are lower than the targeted revenues per the Credit Agreement or the TTM revenues are equal to or higher than the targeted revenues per the Credit Agreement, as discussed in Note 6 of the Consolidated Financial Statements. MCS performs 100,000 iterations of various simulated revenues to determine the fair value of the debt.

The below assumptions were used in the MCS:

	December 31, 2024	December 31, 2023
Risk-free interest rate	4.25%	3.81%
Revenue volatility	63.00%	64.00%
Revenue discount rate	14.11%	16.58%

Warrant Liability

The fair value of the warrant liability is recognized in connection with the Credit Agreement, as discussed in Note 6 of the Consolidated Financial Statements. The fair value of the warrant liability was determined based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The fair value of the warrant liability, which is reported within Warrant liability on the Consolidated Balance Sheets, is estimated by the Company based on the Black-Scholes option pricing model with the following key inputs:

	December 31, 2024	December 31, 2023
Price of common stock	$ 12.80	$ 13.72
Expected term	8.80 years	9.81 years
Expected volatility	48.89%	31.07%
Exercise price	$ 10.9847	$ 10.9847
Risk-free interest rate	4.49%	3.84%
Expected dividends	0.00%	0.00%

5. Revenues

The Company generates revenues primarily from:

- The sale of RECELL Ease of Use ("EOU"), RECELL GO RPK, and PermeaDerm products to hospitals, other treatment centers, and distributors.
- Maintenance fee received from BARDA in exchange for first right of access to our inventory. In the prior year, the Company recorded service revenues for the emergency preparedness services provided to BARDA.
- Lease revenue for the RECELL GO RPD.

The Company's sale of the EOU and PermeaDerm products are accounted for under ASC 606, as discussed in Note 2 of the Company's Consolidated Financial Statements. Revenue for the RECELL GO device is disaggregated between two accounting standards: (1) ASC 606 for the RPK and (2) ASC 842 for the RPD.

RECELL GO

The RECELL GO device consists of a single-use RPK and a durable AC powered device, RPD. The Company enters into contracts with customers where it receives consideration for the single-use RPK and does not receive additional consideration for the RPD. The consideration in the contract is allocated based on the SSP. Upon sale of the RPK the consideration is allocated to the lease and non-lease components. Consideration received for the RPK is recorded in Sales revenues in the Consolidated Statement of Operations and consideration for the lease is recorded in Lease revenue in the Consolidated Statement of Operations. During the year-ended December 31, 2024, the Company recorded approximately $17.5 million in Sales revenue related to the RPK and $358,000 in Lease revenue related to the RPD in the Consolidated Statement of Operations.

Distributor Transactions

For international markets, the Company exclusively partners with third-party distributors (currently, COSMOTEC in Japan, PolyMedics Innovation GmbH in Germany, and Revolution Surgical Pty Ltd in Australia and New Zealand). Revenue recognition occurs when the distributors obtain control of the product. The terms of sales transactions through distributors are generally consistent with the terms of direct sales to customers and do not contain return rights. These transactions are accounted for in accordance with the Company's revenue recognition policy described in Note 2, Summary of Significant Accounting Policies in the Company's Consolidated Financial Statements.

PermeaDerm Sales

As provided in the Stedical Agreement, the Company's gross margin from the sale of PermeaDerm is 50% of the average sales price ("ASP"). The Company and Stedical share the gross revenue from the sale of the products evenly at 50% of ASP. The Company recognizes revenue when the customer obtains control of promised goods, in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods.

Remaining Performance Obligations

Contract liabilities are calculated as the dollar value of the remaining performance obligations on executed contracts and primarily relate to COSMOTEC and other customers. The estimated revenue expected to be recognized in the future once the performance obligation is satisfied under the Company's existing customer agreements is $357,000 and $390,000 as of December 31, 2024 and December 31, 2023, respectively. These amounts are classified between current and long-term in Other current liabilities and Contract liabilities in the Consolidated Balance Sheets.

Variable Consideration

The Company evaluates its contracts with customers for forms of variable consideration, which may require an adjustment to the transaction price based on their estimated impact. For commercial customers, revenue from the sale of goods is recognized net of volume discounts. The Company uses the expected value method when estimating variable consideration. Revenue is only recognized to the extent that it is probable that a significant reversal will not occur. Variable consideration under the BARDA contract is not material to the Consolidated Financial Statements.

Volume Discounts — The Company generally provides contracted customers with volume discounts that are explicitly stated in the Company's customer contracts. The RECELL system is sold with respective volume discounts based on aggregated sales over a 12-month period on a customer-by-customer basis. Revenue from these sales is recognized based on the price specified in the contract, net of estimated volume discounts, and net of any sales tax charged. Goods sold are not eligible for return. The Company has determined such discounts are not distinct from the Company's sale of products to the customer and, therefore, these payments have been recorded as a reduction of revenue and as a reduction to accounts receivable, net.

Contract Assets and Contract Liabilities

Contract assets include amounts related to the Company's contractual right to consideration for both completed and partially completed performance for which the Company does not have the right to payment. As of December 31, 2024 and December 31, 2023, the Company does not have any contract assets.

Contract liabilities are recorded when the Company receives payment prior to satisfying its obligation to transfer goods to a customer. The Company had a total of $357,000 and $390,000 in contract liabilities as of December 31, 2024 and December 31, 2023, respectively. These amounts split between Other current liabilities and Contract liabilities in the Consolidated Balance Sheets. The Company had $33,000 in Other current liabilities as of December 31, 2024 and December 31, 2023. The Company had $324,000 and $357,000 in Contract liabilities as of December 31, 2024 and December 31, 2023, respectively. The balance relates to the unsatisfied performance obligation for emergency preparedness under the BARDA contract and COSMOTEC. Performance obligations will be recognized over time over the term of the contracts. For the years-ended December 31, 2024 and 2023, the Company recognized $195,000 and $335,000 of BARDA revenue from amounts included in the beginning balance of contract liabilities, respectively. For the years-ended December 31, 2024 and 2023, the Company recognized $33,000 of revenue for COSMOTEC for amounts included in the beginning balance of contract liabilities.

Cost to Obtain and Fulfill a Contract

Contract fulfillment costs include commissions and shipping expenses. The Company has opted to immediately expense the incremental cost of obtaining a contract when the underlying related asset would have been amortized over one year or less. The Company generally does not incur costs to obtain new contracts.

BARDA Contract

On February 16, 2024, the Company executed a contract modification with BARDA to extend the period of performance, under the original contract dated September 29, 2015, from December 31, 2023 to September 28, 2025. Under the modified contract, BARDA shall have access to AVITA Medical's RECELL inventory in the event of a national emergency. No additional inventory build will be required. In the case of a national emergency, BARDA shall pay for RECELL devices at a reduced price for the first 1,000 units and retail price for any units over 1,000 requested. BARDA will pay AVITA Medical approximately $333,000 in maintenance fee over the term of the contract to ensure first right of access.

Cost to fulfill the BARDA emergency preparedness performance obligation, which primarily consist of billed costs to BARDA incurred in connection with the emergency deployment services, are incremental and expected to be recovered. Costs are capitalized and amortized on a straight-line basis over the term of the contract. As of December 31, 2024 and 2023, the Company did not have any contract costs remaining in Prepaid and other current assets on the Consolidated Balance Sheets. Amortization expense related to deferred contract costs was $341,000 during the year-ended December 31, 2023 and are classified as Cost of sales on the Consolidated Statements of Operations. There was no impairment loss in relation to deferred contract costs during the years-ended December 31, 2024 and 2023.

Disaggregated Revenue

The Company disaggregates revenue from contracts with customers into geographical regions and by customer type. As noted in the segment footnote, the Company's business consists of one reporting segment. A reconciliation of disaggregated revenue by geographical region and customer type is provided in Note 11.

6. Long-term debt

On October 18, 2023 ("Closing Date") the Company entered into a credit agreement, by and between the Company, as borrower, and an affiliate of OrbiMed Advisors, LLC (the "Lender") as the lender and administrative agent (the "Credit Agreement"). The Credit Agreement provides for a five-year senior secured credit facility in an aggregate principal amount of up to $90.0 million, of

which (i) $40.0 million was made available on the Closing Date (the “Initial Commitment Amount”), (ii) $25.0 million will be made available, at the Company’s discretion, on or prior to December 31, 2024, subject to certain net revenue requirements, and (iii) $25.0 million will be made available, at the Company’s discretion, on or prior to June 30, 2025, subject to certain net revenue requirements (the “Loan Facility”). The maturity date of the Credit Agreement is October 18, 2028 (“Maturity Date”). On the Closing date, the Company closed on the Initial Commitment Amount, less certain fees and expenses payable to or on behalf of the Lender. The Company received net proceeds of $38.8 million upon closing after deducting the Lender's transaction costs in connection with the Loan Facility. On November 7, 2024, the Lender and the Company mutually agreed to a third amendment (the “Third Amendment”) to the Credit Agreement. Under the terms of the Third Amendment and subject to the payment by the Company of a consent fee to the Lender, the Company and the Lender mutually agreed to (1) terminate the two additional tranches of available debt in the aggregate amount of $50.0 million and (2) remove the trailing 12-month revenue covenant for the fourth quarter of 2024, which was set at $67.5 million. All revenue covenants for subsequent quarters remain in effect.

All obligations under the Credit Agreement will be guaranteed by all of the Company’s wholly owned subsidiaries (subject to certain exceptions) and secured by substantially all of the Company's and each guarantor's assets. The loan will be due in full on the Maturity Date unless the Company elects to repay the principal amount at any time prior to the Maturity Date. Upon prepayment, the Company will owe the applicable repayment premium and exit fee of 3% on the principal amount of the Loans. The repayment premium varies between 0% - 3%, depending on certain conditions that are defined in the Credit Agreement. Note that the Repayment premium incorporates the make-whole amount. The make-whole amount represents the remaining scheduled interest payments on the Loan Facility during the period commencing on the prepayment date through the 24-month anniversary of the closing date. The Credit Agreement further states that the Company will be required to repay the principal amount of the Loan Facility if the Company does not achieve certain net revenue thresholds. If, for any quarter until the maturity date, the Company’s net revenue does not equal or exceed the applicable trailing twelve-month amount as set forth in the Credit Agreement, then the Company shall repay in equal quarterly installments equal to 5.0% of the outstanding principal amount of the Loan Facility on the date the net revenue amount was not satisfied, together with a repayment premium and exit fee. In addition, the Company will be required to maintain at least $10.0 million of unrestricted cash and cash equivalents at the end of each reporting period. The Company shall repay amounts outstanding in full immediately upon an acceleration as a result of an event of default as set forth in the Credit Agreement, together with a repayment premium and other fees. As of December 31, 2024, the Company has not made any repayments on the outstanding debt balance.

During the term of the Credit Agreement, interest payable in cash by the Company shall accrue on any outstanding debt at a rate per annum equal to the greater of (x) the SOFR rate for such period and (y) 4.00% plus, in either case, 8.00%. As of December 31, 2024, the interest rate was 12.55%. During an event of default, any outstanding amount will bear interest at a rate of 4.00% in excess of the otherwise applicable rate of interest. The Company will pay certain fees with respect to the Credit Agreement, including an upfront fee, an unused fee on the undrawn portion of the Loan Facility, an administration fee, a repayment premium and an exit fee, as well as certain other fees and expenses of the Lender. The unused fee accrues at 0.5% of the undrawn balance and its recorded as an asset in the Consolidated Balance Sheets. After the execution of the Third Amendment, the unused fee is no longer payable.

The Credit Agreement contains certain customary events of default, including with respect to nonpayment of principal, interest, fees or other amounts; material inaccuracy of a representation or warranty; failure to perform or observe covenants; material defaults on other indebtedness; bankruptcy and insolvency events; material monetary judgments; loss of certain key permits, persons and contracts; material adverse effects; certain regulatory matters; and any change of control. As of December 31, 2024, the Company was in compliance with all financial covenants in the Credit Agreement.

Each of the Credit Agreement and a Pledge and Security Agreement entered into by the Company, the guarantors and the Lender on October 18, 2023 (the “Pledge and Security Agreement”) contains a number of customary representations, warranties and covenants that, among other things, will limit or restrict the ability of the Company and its subsidiaries to (subject to certain qualifications and exceptions): create liens and encumbrances; incur additional indebtedness; merge, dissolve, liquidate or consolidate; make acquisitions, investments, advances or loans; dispose of or transfer assets; pay dividends or make other payments in respect of their capital stock; amend certain material documents; redeem or repurchase certain debt; engage in certain transactions with affiliates; and enter into certain restrictive agreements.

On the Closing Date, the Company issued to an affiliate of the Lender a warrant (the “Warrant”) to purchase up to 409,661 shares of the Company’s common stock, par value $0.0001 per share, at an exercise price of $10.9847 per share, with a term of 10 years from the issuance date. The Warrant contains customary share adjustment provisions, as well as weighted average price protection in certain circumstances.

As permitted under ASC 825, the Company elected the fair value option to account for the Credit Agreement, and recorded the Credit Agreement and warrants at fair value with changes in fair value recorded in the Consolidated Statements of Operations in Other income, net. Changes related to instrument specific credit risk are recorded in Accumulated Other comprehensive income in the Consolidated Balance Sheet. For changes in fair value, refer to Note 4. During the years-ended December 31, 2024, and 2023, the

Company incurred debt issuance costs of $206,000 and $775,000, respectively, which were expensed as incurred and recorded in Other income, net. During the year-ended December 31, 2023, the Company also incurred a loss on issuance of $1.2 million as the fair value of the debt and warrant exceeded the proceeds received.

See Note 18 for details regarding an amendment to the Credit Agreement.

7. Leases

During January 2024 and April 2024, the Company modified the lease agreement of the Ventura production facility to extend the lease term. The modifications resulted in an aggregate increase of approximately $2.1 million to the operating lease ROU assets and operating lease liabilities. There was no impact on earnings as a result of the lease modification.

During September 2024, the Company modified the lease agreement for the expanded Ventura Warehouse to extend the lease term. The modification resulted in an increase of approximately $50,000 in the operating lease ROU asset and operating lease liabilities.

The following table sets forth the Company's operating lease expenses which are included in operating expenses in the Consolidated Statements of Operations (in thousands):

	Year Ended	
	December 31, 2024	December 31, 2023
Operating lease cost	$ 821	$ 929
Variable lease cost	174	101
Total lease cost	$ 995	$ 1,030

Supplemental cash flow information related to operating leases was as follows (in thousands):

	Year Ended	
	December 31, 2024	December 31, 2023
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash outflows from operating leases	$ 1,185	$ 815

Supplemental balance sheet information, as of December 31, 2024 and 2023, related to operating leases was as follows (in thousands, except for operating lease weighted average remaining lease term and operating lease weighted average discount rate):

	As of	
	December 31, 2024	December 31, 2023
Reported as:		
Operating lease right-of-use assets	$ 3,571	$ 2,440
Total right-of-use assets	$ 3,571	$ 2,440
Other current liabilities:		
Operating lease liabilities, short-term	$ 900	$ 895
Operating lease liabilities, long term	2,840	1,702
Total operating lease liabilities	$ 3,740	$ 2,597
Operating lease weighted average remaining lease term (years)	4.34	3.31
Operating lease weighted average discount rate	9.74%	8.75%

As of December 31, 2024, maturities of the Company's operating lease liabilities are as follows (in thousands):

	Operating Leases
2025	$ 1,218
2026	1,125
2027	773
2028	658
2029	483
Thereafter	371
Total lease payments	4,628
Less imputed interest	(888)
Total operating lease liabilities	$ 3,740

As of December 31, 2024, there were no leases entered into that had not yet commenced.

Lessor Arrangements

As discussed in Note 5, the contracts for the RECELL GO device include an operating lease for the customer's right to use the RPD. The lease arrangement does not contain fixed consideration. Variable lease payments are not included in consideration at lease inception. The variable consideration related to the lease is allocated based on the SSP and is recognized when control of the RPK is transferred to the customer. Variable lease revenue was $358,000 for the year ended December 31, 2024.

Assets held for lease and included in Plant and equipment consisted of the following (in thousands):

	As of December 31, 2024
Rental RPD assets	$ 1,384
Accumulated depreciation	(47)
Net rental RPD assets	$ 1,337

8. Inventory

The composition of inventories is as follows (in thousands):

	As of	
	December 31, 2024	December 31, 2023
Raw materials	$ 2,449	$ 3,683
Work in process	389	878
Finished goods	4,431	1,035
Total inventory	$ 7,269	$ 5,596

The Company has reduced the carrying value of its inventories to reflect the lower of cost or net realizable value. Charges for estimated excess and obsolescence are recorded in Cost of sales in the Consolidated Statement of Operations and were $487,000 and $221,000 for the years-ended December 31, 2024 and 2023, respectively. The inventory balance as of December 31, 2024, includes inventory purchased from Stedical for the sales of PermeaDerm.

9. Intangible Assets

The composition of intangible assets is as follows (in thousands):

		As of December 31, 2024			As of December 31, 2023		
	Weighted Average Useful Life	Gross Amount	Accumulated Amortization	Net Carry Amount	Gross Amount	Accumulated Amortization	Net Carry Amount
Patent 1	-	$ -	$ -	$ -	$ 17	$ (17)	$ -
Patent 2	12	136	(46)	90	141	(39)	102
Patent 3	13	238	(61)	177	206	(54)	152
Patent 5	18	108	(25)	83	99	(11)	88
Patent 6	19	67	(9)	58	56	(6)	50
Patent 7	-	-	-	-	2	-	2
Patent 8	17	46	(3)	43	29	(1)	28
Patent 9	2	121	(42)	79	3	-	3
Patent 10	-	-	-	-	3	-	3
Patent 11	-	-	-	-	6	(1)	5
Regenity License	10	5,000	(14)	4,986	-	-	-
Trademarks	Indefinite	54	-	54	54	-	54
Total intangible assets		$ 5,770	$ (200)	$ 5,570	$ 616	$ (129)	$ 487

There was no impairment of intangibles assets recognized for the years-ended December 31, 2024 and 2023. Amortization expense of intangibles included in the Consolidated Statements of Operations was $93,000 and $35,000 for the years-ended December 31, 2024 and 2023, respectively. Due to Regenity receiving 510(k) clearance for Cohealyx, the Company recorded a license (the "Regenity License") of $5.0 million. For further details refer to Note 12.

The Company estimated the future amortization of amortizable intangible assets held as of December 31, 2024 to be (in thousands):

	Estimated Amortization Expense
2025	$ 597
2026	564
2027	541
2028	541
2029	541
Thereafter	2,732
Total	$ 5,516

10. Plant and Equipment, net

The composition of plant and equipment, net is as follows (in thousands):

	Useful Lives	As of December 31, 2024	As of December 31, 2023
Computer equipment	3 - 5 years	$ 1,645	$ 984
Computer software	3 years	836	840
Construction in progress ("CIP")		442	87
Furniture and fixtures	7 years	1,177	824
Laboratory and other equipment	3 - 5 years	954	769
Leasehold improvements	Lesser of life or lease term	4,607	367
RECELL moulds	5 years	503	438
RECELL GO RPD CIP		1,464	-
RECELL GO RPD		453	-
Operating lease assets - RPD	200 uses	1,384	-
Less: accumulated amortization and depreciation		(3,447)	(2,432)
Total plant and equipment, net		$ 10,018	$ 1,877

Construction in progress consists primarily of leasehold improvements for the renovations to the Ventura production facility, and RECELL GO RPD CIP consists of materials for the manufacture of the RPDs. RPDs have a useful life of 200 uses and are being amortized based on customer usage as determined by orders placed for the sales of RPK units. RECELL GO RPD represents assets available to be leased by customers and are not depreciated until leased. Additional information on Operating lease assets - RPD is provided in Note 7.

Depreciation expense related to plant and equipment was $1.0 million and $597,000 for the years-ended December 31, 2024 and 2023, respectively. The Company recorded a loss on disposal of fixed assets of approximately $107,000 and $83,000 for the years-ended December 31, 2024 and 2023, respectively.

11. Reporting Segment and Geographic Information

The Company views its operations and manages its business in one reporting segment. Long-lived assets were primarily located in the United States as of December 31, 2024 and December 31, 2023 with an insignificant amount located in Australia and the United Kingdom.

Revenues by region and customer location were as follows (in thousands):

	Year Ended	
	December 31, 2024	December 31, 2023
Revenue by region:		
United States	$ 62,157	$ 46,359
Japan	1,431	3,370
European Union	155	51
Australia	312	222
United Kingdom	196	141
Total	$ 64,251	$ 50,143

Revenues by customer type were as follows (in thousands):

	Year Ended	
	December 31, 2024	December 31, 2023
Revenue by customer type:		
Commercial sales	$ 64,023	$ 49,775
Deferred commercial revenue recognized	33	33
BARDA revenue for right of first access	195	335
Total	$ 64,251	$ 50,143

Commercial revenue by product were as follows (in thousands):

	Year Ended	
	December 31, 2024	December 31, 2023
Commercial revenue by product:		
RECELL	$ 62,611	$ 49,775
Other wound care products	1,054	-
Lease revenue	358	-
Total commercial sales	$ 64,023	$ 49,775

Cost of sales by customer type were as follows (in thousands):

	Year Ended	
	December 31, 2024	December 31, 2023
Cost of sales:		
Commercial cost	$ 9,094	$ 7,544
BARDA:		
Product cost	-	(105)
Emergency preparedness service cost	-	341
Total	$ 9,094	$ 7,780

Consolidated net loss by segment (in thousands):

	Year Ended	
	December 31, 2024	December 31, 2023
Total revenues	$ 64,251	$ 50,143
Purchases of inventory	(7,861)	(6,418)
Other cost of sales	(1,233)	(1,362)
Gross profit	55,157	42,363
BARDA income	-	1,428
Operating expenses:		
Sales and marketing	(58,195)	(37,291)
General and administrative	(33,195)	(28,334)
Research and development	(20,360)	(20,821)
Total operating expenses	(111,750)	(86,446)
Operating loss	(56,593)	(42,655)
Interest expense	(5,361)	(1,143)
Other income, net	163	8,483
Loss before income taxes	(61,791)	(35,315)
Income tax expense	(54)	(66)
Net loss	$ (61,845)	$ (35,381)

12. Contingencies

The Company is subject to certain contingencies arising in the ordinary course of business. The Company records accruals for these contingencies to the extent that a loss is both probable and reasonably estimable. If some amount within a range of loss appears to be a better estimate than any other amount within the range, that amount is accrued. Alternatively, when no amount within a range of loss appears to be a better estimate than any other amount, the lowest amount in the range is accrued. The Company expenses legal costs associated with loss contingencies as incurred. As of December 31, 2024, the Company does not have any outstanding or threatened litigation that would have a material impact to the financial statements.

Minimum Purchase Commitments with Stedical

The Company is subject to minimum purchases of PermeaDerm product for the initial term of five years. For 2024, the Company has an obligation to purchase enough products from Stedical to achieve $5.0 million in customer sales of that purchased inventory. As of September 30, 2024, this obligation had already been achieved. For the first three years of the Stedical Agreement, the minimum purchase will increase annually by an amount equal to the percentage growth in the Company's annual U.S.-based revenues excluding PermeaDerm revenue, or a minimum increase of at least 20% over the prior year purchase commitment. After the third year, the minimum purchase obligation will increase annually by an amount equal to the percentage growth of the Company's annual U.S.-based revenues excluding PermeaDerm sales. The minimum purchase obligation cannot decrease from the previous year.

Development and Distribution Agreement with Regenity

On July 31, 2024, the Company entered into the Regenity Agreement to market, sell, and distribute Cohealyx™, a unique collagen-based dermal matrix under the Company's private label in the U.S., with the potential to commercialize the product in countries in the European Union, as well as in Japan and Australia. The initial term of the agreement is five years, with an automatic extension of an additional five years, contingent upon meeting certain criteria. Under the terms of the agreement, the Company will make a $2.0 million payment upon receipt of 510(k) clearance by Regenity. The Company has a further obligation to make up to an additional $3.0 million payment on or before January 4, 2026 to guarantee development and manufacturing capacity (and related resources), contingent on positive results of certain clinical studies related to the new dermal matrix. On December 19, 2024, Regenity received 510(k) clearance, as such, the Company has accrued $2.0 million to be paid in January 2025, recorded $3.0 million in Contingent liabilities and $5.0 million in Intangible assets, net in the Consolidated Balance Sheets.

13. Common and Preferred Stock

The Company’s shares of common stock are quoted on Nasdaq under AVITA Medical’s previous Nasdaq ticker code, “RCEL”. The Company’s CDIs are quoted on the Australian Securities Exchange (“ASX”) under AVITA Medical’s previous ASX ticker code, “AVH”. One share of common stock on Nasdaq is equivalent to five CDIs on the ASX.

The Company is authorized to issue 200,000,000 shares of common stock, par value $0.0001 per share, and 10,000,000 shares of preferred stock, par value $0.0001 per share, issuable in one or more series as designated by the Company's board of directors. No other class of capital stock is authorized. The Company has 26,354,042 and 25,682,078 shares of common stock issued and outstanding as of December 31, 2024 and December 31, 2023, respectively. The Company has no shares of preferred stock outstanding during any period.

14. Share-Based Payment Plans

Overview of Employee Share-Based Compensation Plans

The Company's former parent company, AVITA Medical Pty Limited, adopted the Employee Share Plan and the Incentive Option Plan (collectively, the "2016 Plans"). Upon completion of the redomiciliation of the Company from Australia to the United States in June 2020 ("Redomiciliation"), the 2016 Plans were terminated with respect to future grants and accordingly, there are no more shares available to be issued under the 2016 Plans. During November 2020, the Company filed a registration statement on Form S-8 to register a total of 1,750,000 shares of common stock which may be issued pursuant to the terms of the 2020 Plan. During June 2023, the Company filed a registration statement on Form S-8 to register an additional 2,500,000 shares of common stock under the 2020 Plan. The increase in shares available for issuance was a result of the stockholders of AVITA Medical, Inc. approving an amendment to the 2020 Plan on June 6, 2023 at the Company's 2023 Annual Meeting of Stockholders (the "2023 Annual Meeting"). During August 2024, the Company filed a registration statement on Form S-8 to register 428,858 shares of common stock that are issuable upon the exercise of stock options and the vesting of RSUs granted pursuant to individual stock option award and RSU award agreements approved by the Company's stockholders at the Company's 2024 Annual Meeting of Stockholders (the "2024 Annual Meeting").

On December 22, 2021, the Company's stockholders approved the issuance of options and RSUs to the Board of Directors in accordance with ASX rules. These awards are subject to the vesting and performance conditions as denoted in the individual agreements (collectively, the "2021 Annual Meeting Awards"). On December 12, 2022, the Company's stockholders approved the issuance of options and RSUs to the Board of Directors and the CEO in accordance with ASX rules. These awards are subject to vesting conditions as denoted in the individual agreements (collectively, the "2022 Annual Meeting Awards"). On June 6, 2023, the Company's stockholders approved the issuance of options and RSUs to the Board of Directors and the CEO in accordance with ASX rules. These awards are subject to vesting conditions as denoted in the individual agreements (collectively, the "2023 Annual Meeting Awards"). On June 5, 2024, the Company's stockholders approved the issuance of options and RSUs to the Board of Directors and the CEO in accordance with ASX rules. These awards are subject to vesting conditions as denoted in the individual agreements (collectively, the "2024 Annual Meeting Awards").

The 2020 Plan provides for the grant of the following Grants: (a) Incentive Stock Options, (b) Nonstatutory Stock Options, (c) Stock Appreciation Rights, (d) Restricted Stock Grants, (e) Restricted Stock Unit Grants, (f) Performance Grants, and (g) Other Grants. The 2020 Plan will be administered by the Compensation Committee or by the Board acting as the Compensation Committee. Subject to the general purposes, terms and conditions of the 2020 Plan, applicable law and any charter adopted by the Board governing the actions of the Compensation Committee, the Compensation Committee will have full power to implement and carry out the 2020 Plan. Without limitation, the Compensation Committee will have the authority to interpret the plan, approve persons to receive grants, determine the terms and number of shares of the grants, determine vesting and exercisability of grants, and make all other determinations necessary or advisable in connection with the administration of this Plan.

The contractual term of stock option awards granted under the 2020 Plan is ten years from the grant date. Unless otherwise specified, the vesting periods of options and RSUs granted under the 2020 Plan are: (i) vest over a three-year or four-year period in equal installments at the end of each year from the date of grant, and /or (ii) subject to other performance criteria, as determined by the Compensation Committee.

Modifications

During the fourth quarter of 2023, the Company had administrative changes to employment agreements of five executives. Changes included clarification that equity awards are inclusive of options and RSUs, and a change in the post-termination exercise period from 6-months to 3-months. In addition, four employees received employment agreements for the first time as a result of a promotion. Per the terms of the employment agreement outstanding awards (options and RSUs) will immediately accelerate upon a qualifying termination. These employees were previously governed by the terms of the 2020 Plan, which upon separation from service, unvested awards will forfeit. The Company accounted for these changes in the accelerated vesting provision upon termination and the decrease in the post-termination exercise period as modifications. The modifications did not result in incremental expense.

The following table summarizes information about the Company's stock-based award plans as of December 31, 2024:

	Outstanding Options	Outstanding Restricted Stock Units	Shares Available For Future Issuance
2016 Equity Incentive Plan	458,196	—	-
2020 Equity Incentive Plan	2,313,110	48,164	1,422,101
2021 AGM Awards	22,600	—	-
2022 AGM Awards	247,876	—	-
2023 AGM Awards	124,768	13,832	-
2024 AGM Awards	373,658	55,200	-

Share-Based Payment Expenses

Stock-based payment transactions are recognized as compensation expense based on the fair value of the instrument on the date of grant. The Company uses the graded-vesting method to recognize compensation expense. Compensation cost is reduced for forfeitures as they occur in accordance with ASU 2016-09, *Simplifying the Accounting for Share-Based Payment.* The Company recorded stock-based compensation expense of $13.5 million and $8.4 million for the years-ended December 31, 2024 and 2023, respectively. No income tax benefit was recognized in the Consolidated Statements of Operations for stock-based payment arrangements for the years-ended December 31, 2024 and 2023.

The Company has included stock-based compensation expense and ESPP expense as part of operating expenses in the accompanying Consolidated Statements of Operations as follows:

	Year Ended	
	December 31, 2024	December 31, 2023
Sales and marketing expenses	$ 3,338	$ 1,401
General and administrative expenses	8,376	5,948
Research and development expenses	1,782	1,035
Total	$ 13,496	$ 8,384

A summary of share option activity as of December 31, 2024 and changes during the year then ended is presented below:

	Service Only Share Options	Performance-Based Share Options	Total Share Options
Outstanding shares at December 31, 2023	2,397,571	292,587	2,690,158
Granted	1,887,658	55,000	1,942,658
Exercised	(263,479)	(88,729)	(352,208)
Expired	(427,478)	(58,915)	(486,393)
Forfeited	(245,235)	(8,772)	(254,007)
Outstanding shares at December 31, 2024	3,349,037	191,171	3,540,208
Exercisable at December 31, 2024	1,084,364	173,449	1,257,813
Vested and expected to vest - December 31, 2024	3,349,037	191,171	3,540,208

The weighted-average grant-date fair value of options granted during the years-ended December 31, 2024 and 2023 was $7.55 and $9.46, respectively. The total intrinsic value of options exercised during the years-ended December 31, 2024 and 2023 was $2.1 million and $1.7 million, respectively. Intrinsic value is measured using the fair market value at the date of exercise for options exercised, or at balance sheet date for outstanding options, less the applicable exercise price.

Cash received from the exercise of options was approximately $2.1 million and $957,000, for the years-ended December 31, 2024 and 2023, respectively.

As of December 31, 2024, there was approximately $7.6 million of total unrecognized compensation cost related to share-based compensation expense. Of this amount $7.6 million relates to service only share options to be recognized over a weighted average period of 0.84 years, $14,000 relates to performance-based share options to be recognized over a weighted average period of 0.20 years.

Restricted Stock Units

Restricted stock units are granted to executives as part of their long-term incentive compensation. RSUs granted to directors as a result of stockholder approval 2021 Annual Meeting, 2022 Annual Meeting, 2023 Annual Meeting and 2024 Annual Meeting are issued pursuant to award agreements between the Company and the holders of such securities. These RSU awards were approved by the Compensation Committee. All RSU awards vest in accordance with the tenure or performance conditions as determined by the Compensation Committee and set out in the contracts between the Company and the holders of such securities. The grant date fair value is determined based on the price of the Company stock price on the date of grant (stock price determined on Nasdaq).

A summary of the status of the Company's unvested RSUs as of December 31, 2024, and changes that occurred during the year is presented below:

Unvested Shares	Tenure-Based RSUs	Performance Condition RSUs	Total RSUs
Unvested RSUs outstanding at December 31, 2023	207,112	28,020	235,132
Granted	55,200	-	55,200
Vested	(131,897)	(16,635)	(148,532)
Forfeited	(21,100)	(3,504)	(24,604)
Unvested RSUs outstanding at December 31, 2024	109,315	7,881	117,196

The weighted-average grant-date fair value of the RSUs granted during the years-ended December 31, 2024 and 2023, was $9.51 and $14.17, respectively. The total fair value of shares vested during the years-ended December 31, 2024 and 2023, was $1.4 million and $2.9 million, respectively.

As of December 31, 2024, there was $346,000 of total unrecognized compensation cost related to RSU awards. Of this amount $333,000 relates to service only RSUs to be recognized over a weighted average period of 0.29 years, $14,000 related to performance-based awards to be recognized over a weighted average period of 0.13 years.

2021 Annual Meeting Awards

Awards to non-executive members of the Board of Directors ("Director awards") under the 2021 Annual Meeting Awards

The Director awards that were granted in 2021 consist of an aggregate 68,600 options and RSUs. A total of 41,400 tenure-based options are RSUs (15,300 options and 26,100 RSUs) vested 12 months from the grant date. A total of 27,200 tenure-based options and RSUs (9,850 options and 17,350 RSUs) vest over 3 three years in equal installment each year.

2022 Annual Meeting Awards

Awards to the CEO under the 2022 Annual Meeting Awards

On December 12, 2022, the CEO was issued an aggregate 226,296 options with 25% of those options vesting annually commencing on September 28, 2023.

Non-Executive Director awards under the 2022 Annual Meeting Awards

The Director awards consist of an aggregate 71,936 options and RSUs (21,580 options and 50,356 RSUs) vesting 12 months from the grant date.

2023 Annual Meeting Awards

Awards to the CEO under the 2023 Annual Meeting Awards

On June 6, 2023, the CEO was issued an aggregate 100,000 options with 33.3% of those options vesting annually commencing on June 6, 2024.

Non-Executive Director awards under the 2023 Annual Meeting Awards

The Director awards consist of an aggregate 82,566 options and RSUs. A total of 52,926 tenure-based options and RSUs (15,876 options and 37,050 RSUs) vest 12 months from the grant date. A total of 29,640 tenure-based options and RSUs (8,892 options and 20,748 RSUs) vest over three years in equal installments each year.

2024 Annual Meeting Awards

Awards to the CEO under the 2024 Annual Meeting Awards

On June 5, 2024, the CEO was issued an aggregate 350,000 options with 33.3% of those options vesting annually commencing on January 3, 2025.

Non-Executive Director awards under the 2024 Annual Meeting Awards

The Director awards consist of an aggregate 78,858 options and RSUs (23,658 tenure-based options and 55,200 RSUs) vesting 12 months from the grant date.

Option Pricing Model

The Company estimates the fair value of tenure-based share options using the Black-Scholes option pricing model on the date of grant.

The valuation of the options is affected by the Company's share price as well as assumptions regarding a number of highly complex and subjective variables. These variables include, but are not limited to, expected share price volatility over the term of the awards and actual and projected employee share option exercise behaviors. The risk-free rate is based on the U.S. Treasury rate for the expected term at the time of grant, volatility is based on the historical volatility. For tenure-based options, the expected term is based on the estimated average of the life of options using the simplified method as prescribed by SAB 107. The Company utilizes the simplified method for plain vanilla options to determine the expected term of the options due to insufficient exercise activity during recent years. The expected dividend assumption is based on the Company's history and expectation of dividend payouts.

Included in the following table is a summary of the related assumptions used in the Black-Scholes Option pricing model for the years-ended December 31, 2024 and 2023.

	Year-Ended	
	December 31, 2024	**December 31, 2023**
Expected volatility	73% - 75%	66% - 114%
Weighted-average volatility	74%	71%
Expected dividends	0%	0%
Expected term (in years)	5.5 - 6.5	5.0 - 7.0
Risk-free interest rate	3.43% - 4.64%	3.51% - 4.44%

Employee Stock Purchase Plan

In June 2023, the stockholders approved the AVITA Medical, Inc. Employee Stock Purchase Plan (the "ESPP"). The ESPP became effective on July 1, 2023. On June 30, 2023, the Company filed Registration Statement on Form S-8 to register 1,000,000 shares of common stock under the ESPP, as a result of the Company's stockholders approving the ESPP at the 2023 Annual Meeting. The ESPP features two six-month offering periods per year, from June 1 to November 30 and December 1 to May 31. The first offering period for the ESPP was July 1 – November 30, 2023. Subsequent offering periods will begin the first trading day of December and June each year. For the year-ended December 31, 2024, 171,224 shares were issued under the ESPP at a purchase price of $8.02, and total proceeds received from the purchase of shares under the ESPP were approximately $1.4 million. For the year-ended December 31, 2023, 72,319 shares, were issued under the ESPP at a purchase price of $9.06, and total proceeds received from the purchase of shares under the ESPP were approximately $655,000. During the years-ended December 31, 2024 and 2023, the Company recorded $735,000 and $382,000, respectively in ESPP expense and had unamortized expense remaining of $275,000 and $327,000, respectively, to be recognized over a term of 0.42 years. As of December 31, 2024 and 2023, the Company had accrued payroll contributions for future ESPP purchases of approximately $89,000 and $122,000, respectively.

The Company estimates the fair value of the ESPP using the Black-Scholes option pricing model on the date of grant. The valuation is affected by the Company's share price as well as assumptions regarding a number of highly complex and subjective variables. These variables include, but are not limited to, expected term, expected share price, volatility over the expected term and risk-free rate. The risk-free interest rate is based on the U.S. Treasury rate for the expected term at the time of grant, volatility is based on the historical volatility. The expected dividend assumption is based on the Company's history and expectation of dividend payouts.

Included in the following table is a summary of the related assumptions used in the Black-Scholes Option pricing model for the years-ended December 31, 2024 and 2023.

	Year-Ended	
	December 31, 2024	December 31, 2023
Expected volatility	57.59% - 73.26%	81.98% - 82.00%
Weighted-average volatility	63.81%	81.99%
Expected dividends	0%	0%
Expected term (in years)	0.5	0.5
Risk-free interest rate	4.33% - 5.28%	5.19% - 5.31%

15. Income Taxes

Geographic sources of loss before income taxes are as follows:

	Year-Ended	
(amounts in thousands)	December 31, 2024	December 31, 2023
United States	$ (61,778)	$ (44,691)
Foreign	(13)	9,376
Loss before income taxes	$ (61,791)	$ (35,315)

Income tax expense as shown in the accompanying Consolidated Statements of Operations includes the following:

	Year-Ended	
(amounts in thousands)	December 31, 2024	December 31, 2023
Current:		
Federal	$ -	$ -
State	54	66
Foreign	-	-
Total current	54	66
Deferred:		
Federal	-	-
State	-	-
Foreign	-	-
Total deferred	-	-
Total income tax expense	$ 54	$ 66

The provision for income taxes differs from the tax computed using the statutory United States federal income tax rate of 21% for the years-ended December 31, 2024 and 2023 as a result of the following items:

	Year-Ended	
(amounts in thousands)	December 31, 2024	December 31, 2023
Tax benefit at U.S. statutory rate	$ (12,976)	$ (7,416)
State income taxes	54	66
Foreign rate differential	(1)	375
Share-based compensation	2,911	774
Fair value change in debt and warrants	576	494
Foreign exchange gain/(loss) on intercompany trade balances	3	(2,354)
Gain of transfer of intellectual property	-	2,804
Foreign tax loss carryforward write off	14,999	-
Permanent differences	264	554
Change in tax rate	-	(847)
Net change in valuation allowance	(5,776)	5,616
Income tax expense	$ 54	$ 66

A summary of deferred income tax assets is as follows (in thousands):

	Year- Ended	
(amounts in thousands)	December 31, 2024	December 31, 2023
Deferred tax liabilities		
ROU asset	$ (904)	$ (618)
Intangible assets	-	-
Property, plant and equipment	-	(6)
Total deferred tax liabilities	$ (904)	$ (624)
Deferred tax assets		
Property, plant and equipment	$ 41	$ -
Accrued expenses	3,365	2,714
Intangible assets	-	12
Stock-based compensation	3,044	3,763
Lease liability	947	657
Research and development	7,077	5,357
Net operating loss carryforward	45,233	50,438
Other	1,567	992
Total deferred tax assets	$ 61,274	$ 63,933
Less valuation allowance	(60,370)	(63,309)
Net deferred tax assets	904	624
Net deferred tax assets / (liabilities)	$ -	$ -

At December 31, 2024, the Company and its subsidiaries had net operating loss carryforwards for federal and state income tax purposes of $180.4 million and $92.7 million, respectively. The net operating loss carryforwards may be subject to limitation regarding their utilization against taxable income in future periods due to “change of ownership” provisions of the Internal Revenue Code and similar state provisions. Of these carryforwards, $19.4 million will expire, if not utilized, between 2028 through 2038. The remaining carryforwards have no expiration.

In assessing the recoverability of its deferred tax assets, the Company considers whether it is more likely than not that its deferred assets will be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income in those periods in which temporary differences become deductible and/or net operating losses can be utilized. The Company considers all positive and negative evidence when determining the amount of the net deferred tax assets that are more likely than not to be realized. This evidence includes, but is not limited to, historical earnings, scheduled reversal of taxable temporary differences, tax planning strategies and projected future taxable income. Based upon the weight of available evidence including the uncertainty regarding the Company’s ability to utilize certain net operating losses and tax credits in the future, the Company has established a valuation allowance against its net deferred tax assets of $60.4 million and $63.3 million as of December 31, 2024 and 2023, respectively. The deferred tax assets are primarily net operating loss carryforwards for which management has determined it is more likely than not that the deferred tax assets will not be realized.

The Company recognizes the tax benefit from an uncertain tax positions only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities based on the technical merits of the position. The tax benefits recognized in the consolidated financial statements related to a particular tax position are measured based on the largest benefit that has a greater than a 50% likelihood of being realized upon settlement. The amount of unrecognized tax benefits is adjusted as appropriate for changes in facts and circumstances, such as significant amendments to existing tax law, new regulations or interpretations by the taxing authorities, new information obtained during a tax examination, or resolution of an examination.

The Company has not identified any uncertain tax positions as of December 31, 2024 and 2023.

The Company files income tax returns in the U.S. federal, California and certain other state and foreign jurisdictions. The Company remains subject to income tax examinations for its U.S. federal and state income taxes generally for fiscal years ended June 30, 2008 and forward. The Company also remains subject to income tax examinations for international income taxes for fiscal years ended June 30, 2020 through December 31, 2023, and for certain other U.S. state and local income taxes generally for the fiscal years ended June 30, 2020 through December 31, 2023.

16. Loss per Share

The following is a reconciliation of the basic and diluted loss per share computations:

	Year Ended	
	December 31, 2024	December 31, 2023
(in thousands, except per share amounts)		
Net loss	$ (61,845)	$ (35,381)
Weighted-average common shares—outstanding, basic and diluted	25,883	25,331
Net loss per common share, basic and diluted	$ (2.39)	$ (1.40)

	Year Ended	
	December 31, 2024	December 31, 2023
Anti-dilutive shares excluded from diluted net loss per common share:		
Stock options	3,540,208	2,690,158
Restricted stock units	117,196	235,132
ESPP	81,675	91,152
Warrants	409,661	409,661

The Company's basic net loss per share is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding for the relevant period. In accordance with ASC 710, shares of common stock held by the rabbi trust are excluded from the denominator in the basic and diluted net loss per common share calculations. As of December 31, 2024 and 2023 a total of 127,270 and 99,106, shares of common stock were excluded, respectively. For details on shares of common stock held by the rabbi trust refer to Note 17. For the purposes of the calculation of diluted net loss per share, options to purchase common stock, restricted stock units and unvested shares of common stock issued upon the early exercise of stock options have been excluded from the calculation of diluted net loss per share as their effect is anti-dilutive. Because the Company has reported a net loss for years-ended December 31, 2024 and 2023, diluted net loss per common share is the same as the basic net loss per share for those periods.

17. Retirement Plans

The Company offers a 401(k)-retirement savings plan (the "401(k) Plan") for its employees, including its executive officers, who satisfy certain eligibility requirements. The Internal Revenue Code of 1986, as amended, allows eligible employees to defer a portion of their compensation, within prescribed limits, on a pre-tax basis through contributions to the 401(k) Plan. The Company matches contributions to the 401(k) Plan based on the amount of salary deferral contributions the participant makes to the 401(k) Plan. The Company will match up to 6% of an employee's compensation that the employee contributes to his or her 401(k) Plan account. Total Company matching contributions to the 401(k) Plan were $2.5 million and $1.2 million for the years-ended December 31, 2024, and 2023, respectively.

Non-qualified deferred compensation plan

The Company's non-qualified deferred compensation plan (the "NQDC plan"), which became effective on October 2021 allows for eligible management and highly compensated key employees to elect to defer a portion of their salary, bonus, commissions and RSU awards to later years. Cash deferrals are immediately vested and are subject to investment risk and a risk of forfeiture under certain circumstances. RSU deferrals are subject to the vesting conditions of the award. Once RSUs vest, subject to a six-month and one day holding period, employees are allowed to diversify the common stock into other investment options offered by the plan. For cash deferrals, the Company matches 4% to 6% (depending on level) of employee contributions. These matching employer contributions are vested over a two-year period with 25% vesting on year one and 75% vesting on year two for employees under 55 years of age. Employer contributions for employees over 55 years of age are immediately vested. Employer contributions to the NQDC plan for the years-ended December 31, 2024 and 2023 were $154,000 and $171,000, respectively. The Company's deferred compensation plan liability was $5.1 million and $3.8 million as of December 31, 2024 and 2023, respectively. These amounts are split between current and long term on the Consolidated Balance Sheets. As of December 31, 2024 and 2023, $2.1 million and $168,000 is included in Current non-qualified deferred compensation liability and $3.0 million and $3.7 million in Non-qualified deferred compensation liability, respectively. During the years-ended December 31, 2024 and 2023, the Company had a payout of approximately $744,000 and $950,000, respectively, in the deferred compensation liability for terminated employees.

The Company established a COLI to fund the NQDC plan. Amounts in the COLI are invested in a number of funds. The securities are carried at the cash surrender value on the Consolidated Balance Sheets. We record investment gains and losses of the COLI as other income. Refer to Note 4, Fair Value Measurements for the fair values of the COLI policies and the NQDC liability.

Rabbi Trust

During April 2022, we established a rabbi trust to hold the assets of the NQDC plan. The rabbi trust holds the COLI asset and the common stock from deferred RSU awards that have vested. The NQDC permits diversification of fully vested shares into other equity securities subject to a six month and one day holding period. In accordance with ASR 268, *Redeemable Preferred Stock*, and ASC 718, prior to vesting, the deferred share awards are classified as an equity instrument and changes in fair value of the amount owed to the participant are not recognized. The redemption amounts of the deferred awards are based on the vested percentage and are recorded outside of permanent equity as Non-qualified deferred compensation share awards on the Consolidated Balance Sheets. As of December 31, 2024 and December 31, 2023, a total of 244,218 and 81,052, shares awards have been deferred, respectively. Vested shares are converted to common stock and are reclassified to permanent equity. Common stock held in the rabbi trust is classified in a manner similar to treasury stock and presented separately on the Consolidated Balance Sheets as Common stock held by the NQDC plan. For the years-ended December 31, 2024 and December 31, 2023 a total of 127,270 and 99,106 shares were vested at the redemption value of $1.3 million and $1.1 million, respectively.

The following table summarizes the eligible share award activity as of December 31, 2024 and December 31, 2023.

	As of	
(in thousands)	**December 31, 2024**	**December 31, 2023**
Non-qualified deferred compensation share awards:		
Balance at beginning of period	$ 693	$ 557
Stock-based compensation expense	77	518
Change in redemption value	(92)	1,019
Vesting of share awards held by NDQC	(434)	(1,401)
Ending Balance	$ 244	$ 693

18. Subsequent Events

The Company has evaluated subsequent events through the filing of this Annual Report on Form 10-K and determined that except as disclosed below, no events have occurred that would require adjustment to, or disclosures in, the Consolidated Financial Statements.

On February 13, 2025, an affiliate of OrbiMed Advisors, LLC (the "Lender") and the Company mutually agreed to a fourth amendment (the "Fourth Amendment") to the Credit Agreement (See Note 6. Long-term debt). Under the terms of the Fourth Amendment, the Company and the Lender mutually agreed to amend the trailing 12-month revenue to $73.0 million for the quarter ending March 31, 2025, to $78.0 million for the quarter ending June 30, 2025, to $84.0 million for the quarter ending September 30, 2025, to $92.0 million for the quarter ending December 31, 2025 and to $103.0 million for the quarter ending March 31, 2026. The $115.0 million revenue covenant for all subsequent quarters through the date of debt maturity remains in effect.

As a condition to the execution of the Fourth Amendment, on February 13, 2025, the Company issued to the Lender a warrant to purchase up to 145,180 shares of the Company's common stock, par value $0.0001 per share, at an exercise price of $0.01 per share, with a term of 10 years from the issuance date.