REFINITIV

DELTA REPORT

10-K

RCEL - AVITA MEDICAL, INC.

10-K - DECEMBER 31, 2023 COMPARED TO 10-K - DECEMBER 31, 2022

The following comparison report has been automatically generated

TOTAL DELTAS	13891
CHANGES	118
DELETIONS	3879
ADDITIONS	9894

REFINITIV

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

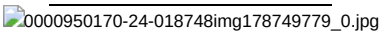
For the fiscal year ended December 31 2022, 2023

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, CA91355
(Address of principal executive offices and Zip Code)

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

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

Title of each class	Trading Symbol	Trading Symbol

Common Stock, par value $0.0001 per share	**RCEL**	The **Nasdaq Stock Capital Market LLC**

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 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 $117,461,038 $431,861,022 on June 30, 2022 June 30, 2023, using the closing price on that day of $4.75. $17.01.

The number of shares of the registrant’s $0.0001 par value common stock outstanding as of February 13, 2023 February 7, 2024 was 25,296,08625,706,662.

DOCUMENTS INCORPORATED BY REFERENCE

List hereunder the following documents if incorporated by reference and the Part of the Form 10-K (e.g., Part I, Part II, etc.) into which the document is incorporated: (1) Any annual report to security holders; (2) Any proxy or information statement; and (3) Any prospectus filed pursuant to Rule 424(b) or (c) under the Securities Act of 1933. The listed documents should be clearly described for identification purposes (e.g., annual report to security holders for fiscal year ended December 24, 1980)

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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: future revenues; solvency; future industry market conditions; future increased competition; changes in our capacity and operations; future operating and overhead costs; production capacity; failure to obtain, maintain and enforce our intellectual property rights; failure to obtain and/or maintain regulatory approvals and related approvals; comply with applicable regulations;; the conduct or outcome of pre-clinical or clinical (human) studies; operational and management restructuring activities (including implementation of methodologies activities; our ability to find and changes in the board of directors); future employment maintain partnerships relating to collaborations, strategic arrangements and contributions of personnel; licensing arrangements; our ability to expand our sales organization to address effectively existing and new markets that we intend to target; our ability to attract and retain qualified personnel,; effects on the global economy of the ongoing COVID-19 pandemic; including management; tax and interest rates;inflation, recession, financial market disruptions and other economic conditions; productivity, business process, rationalization, investment, acquisition and acquisition integrations, consulting, operational, tax, financial and capital projects and initiatives; changes in the legal or regulatory environment; the impact of a cybersecurity breach, terrorist attack, pandemic or epidemic, or natural disaster; and future working capital, costs, revenues, business opportunities, cash flows, margins, earnings and growth.

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, highly 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.

Currency

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 (including AVITA Medical Pty Limited ("AVITA Australia").

Currency

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

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PART I

Item 1. BUSINESS

GENERAL**OVERVIEW**

AVITA Medical Inc.and its subsidiaries (including AVITA Medical Pty Limited ("**AVITA Australia**") (collectively, "**AVITA Medical**", "**we**", "**our**", "**us**" or "**Company**"), is a commercial-stage regenerative medicine company leading transforming the development standard of care in wound care management and commercialization skin restoration with innovative devices. At the forefront of devices and autologous cellular therapies for skin restoration. Our our portfolio is our patented and proprietary RECELL® RECELL® System ("**RECELL System System"**" or "**RECELL**" RECELL"), approved by the United States Food & Drug Administration ("FDA") technology platform 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 Spray-On Skin™ Cells, an autologous skin cell suspension, that is sprayed onto Spray-On Skin™ Cells, delivering a transformative solution at the patient to regenerate natural healthy skin. point of care. This breakthrough technology serves as the catalyst for a new treatment paradigm enabling improved clinical outcomes.

CORPORATE HISTORY

Headquartered in Valencia, California,AVITA Australia, the Company began as a laboratory spin-off in the Australian State of Western Australia. AVITA Medical's former parent company of AVITA Medical, was founded in December 1992. AVITA Australia (formerly known as Clinical Cell Culture) was founded under the laws of the Commonwealth of Australia in December 1992 and changed its name to AVITA Medical Ltd in 2008. AVITA Australia's ordinary shares originally began trading in Australia on the Australian Securities Exchange ("**ASX**") on August 9, 1993. AVITA Australia's its American Depositary Shares ("**ADSs**") traded over the counter on the OTCQX under the ticker symbol "AVMXY" from May 14, 2012 through September 30, 2019 and its ADSs began trading on the Nasdaq on October 1, 2019, Capital Market ("Nasdaq") under the ticker symbol "RCEL".

On June 29, 2020, AVITA Australia implemented a statutory scheme of arrangement under Australian law to effect a redomiciliation of AVITA Medical from Australia to the United States (the "**Redomiciliation**") on October 1, 2019. The Redomiciliation was approved by shareholders on June 15, 2020 and approved by the Federal Court of Australia on June 22, 2020.

Pursuant to the Redomiciliation, all ordinary shares in AVITA Australia were exchanged for shares of Today, our common stock in trades on the Company (AVITA Medical, Inc.). As a result, Nasdaq under the Company became the sole shareholder of AVITA Australia. In conjunction with the Redomiciliation, an implicit consolidation or reverse split on a 1 for 100 basis was implemented whereby shareholders of AVITA Australia received one share of common stock in the Company for every 100 shares held in AVITA Australia.

Under the Redomiciliation, eligible shareholders in AVITA Australia received consideration in the form of:

- five CHESS Depositary Interests ("**CDIs**" symbol "RCEL" and our CHESS Depositary Interests ("CDIs") in the Company for every 100 ordinary shares in AVITA Australia that were held by them; or
- one share of common stock in the Company for every five ADSs in AVITA Australia that were held by them.

The Company's CDIs are quoted traded on the ASX under AVITA Australia's former ASX ticker code, "AVH". The Company's shares of common stock are quoted on Nasdaq under AVITA Australia's former Nasdaq ticker code, "RCEL". One share of common stock on Nasdaq is equivalent to five CDIs on the ASX.

As a result of the 'implicit consolidation' that occurred under the Redomiciliation, the number of shares of common stock issued and outstanding in the Company (as set out in the consolidated financial statements) is less than the number of ordinary shares of AVITA Australia that was set out in the consolidated financial statements of AVITA Australia prior to August 28, 2020.

COVID-19 IMPACT ON OUR BUSINESS

The ongoing pandemic caused by the spread of coronavirus ("COVID-19") has created significant disruptions to the U.S. and global economies and financial markets. The global impact of the pandemic has fluctuated since early 2020. At times, in the United States, state and local governmental authorities have responded by issuing orders, of varying degrees, requiring quarantines, restrictions on travel and minimizing social gathering/interactions and mandatory closures of certain non-essential businesses. Many of the restrictions have been periodically updated as infection rates in the U.S. have risen and fallen, as new variants have emerged, as vaccines have become available, and new information about transmission has been discovered.

In response to the pandemic, we acted swiftly by implementing protocols to ensure continuity of our manufacturing, increasing our safety stock and to provide for the safety of our employees. We implemented a number of measures designed to protect the health and safety of our employees, support our customers and promote business continuity. Early on, our business and operations were impacted by the ongoing effects of the pandemic with restrictions on travel and access to our customers or temporary suspension of treatment of burn patients or re-distribution of those patients to other treatment facilities and resulted in a reduction in the volume of

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burn procedures using the RECELL following the implementation of those protective measures. In addition, we experienced periodic enrollment cessation in our clinical trials due to COVID-19 as well as having individuals excluded due to contracting the virus.

STRATEGY

As of the date of this filing, we have resumed on-site work schedules for all employees. The COVID-19 pandemic has not materially adversely affected our financial results and business operations for the fiscal year-ended December 31, 2022; however, we are unable to predict the impact that COVID-19 may have

AVITA Medical is focused on our business, operations, and financial results and condition in the future because of the numerous uncertainties created by the unprecedented nature of the pandemic.

STRATEGY

Our objective is to become becoming the leading provider of regenerative medicine addressing unmet medical needs in burn injuries, trauma injuries, full-thickness skin defects, and in dermatological and aesthetics indications, skin repigmentation, such as vitiligo. We will continue to drive commercial revenue growth to generate positive cash flow and achieve operating profit. To achieve this objective, these objectives, we intend to:

- Become the standard of care in the U.S. burns industry by increasing RECELL System penetration in burn centers and with burn physicians;
- Commercialize the RECELL System in the U.S. for use in soft tissue repair following approval of our pending premarket approval ("**PMA**") supplement, which was submitted to the U.S. Food and Drug Administration ("**FDA**") in December 2022. Following anticipated FDA approval of RECELL for soft tissue repair, we plan to commence a full commercial launch in July 2023 with both inpatient and outpatient reimbursement in place;
- Commercialize the RECELL System in the U.S. for use in treatment of vitiligo following approval of our pending PMA application, which was submitted to the FDA in December 2022. Subsequent to anticipated FDA approval of RECELLfor vitiligo, we plan to commence a full commercial launch following receipt of in-office reimbursement, which we believe will occur by January 2025;
- Evaluate potential commercialization applications for the RECELL System related to skin rejuvenation and Epidermolysis Bullosa indications;
- Become the standard of care in the U.S. burns industry by increasing RECELL penetration and adoption in burn centers
- Expand into U.S. trauma centers to increase utilization of RECELL for the treatment of full-thickness skin defects
- Launch RECELL GO™ following FDA approval to increase market adoption and expand our customer base
- Expand our global presence within the European Union and Australia through the exclusive use of third-party distributors

- Further invest in our RECELL System platform to automate and improve workflow, speed, and ease of use as it relates to specific indications, as well as to build upon our intellectual property;
- Continue to build upon commercial activities in Japan through our partnership with COSMOTEC Company, Ltd (“COSMOTEC”) with our current Pharmac Medical Devices Act (“PMDA”) approval for RECELL with an indication in burns
- Continue to build upon commercial activities in Japan through our partnership with COSMOTEC Company, Ltd (“**COSMOTEC**”) with our current Pharmaceuticals and Medical Devices Act (“**PMDA**”) approval for RECELL with an indication in burns;
- Develop and Continue to pursue viable commercial activities outside of the U.S. and Japan once we have received FDA approval for RECELL System indications in soft tissue and vitiligo;
- Pursue business development opportunities that are complementary to our core RECELL System indications and/or our targeted markets; and
- Improve our margins and profitability by leveraging our current team and infrastructure across an expanding base of business in burns and in future indications.

RECELL® PLATFORM

The RECELL System has indications and/or our targeted markets, such as the agreement with Stedical Scientific, Inc. Refer to Footnote 20 for further details

- Establish commercial payor coverage for the RECELL System in the U.S. for the treatment of vitiligo lesions; initial phase of coverage expected during the fourth quar 2025

PRODUCT PORTFOLIO

RECELL Platform

RECELL is a long-established safety profile, single use, stand-alone, battery operated, autologous cell harvesting device containing enzymatic and clear potential buffer solutions, sterile surgical instruments, and actuators. RECELL is FDA approved for clinical the treatment of thermal burn wounds and health-economic value propositions across full-thickness skin defects, and for repigmentation of stable depigmented vitiligo lesions. The platform technology of the RECELL System enables a range thin split-thickness skin sample from the patient to be processed and prepared, producing an autologous cellular suspension called Spray-On Skin Cells. These Spray-On Skin Cells are prepared at the point of skin-related clinical indications. care in as little as 30 minutes, providing a new way to treat thermal burn wounds and full-thickness skin defects.

The regenerative skin cell suspension includes the patient's own skin cells, including keratinocytes, fibroblasts, and melanocytes, all of which play critical roles in skin regeneration. The application of these cells stimulates healing and repigmentation throughout the wound bed. The patented and proprietary platform technology underlying the Spray-On Skin™ Cells Skin Cell suspension originated in Australia, based on the seminal work of Professor Fiona Wood and fellow scientist Marie Stoner. RECELL was initially launched in the E.U. in 2005, and then in Australia in 2006, ahead of pivotal outcomes data demonstrating clinical performance relative to standard care. Pivotal trials were conducted in the U.S. beginning in 2010. In September 2018, the FDA approved RECELL as a Class 3 device through a PMA premarket approval (“PMA”) for the treatment of second and third-degree

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acute thermal burn injuries in patients 18 years and older. Following receipt of our original PMA, we commenced commercialization of the RECELL System in January 2019 in the United States.

In June 2021, the FDA approved expanded use of RECELL is in combination of meshed autografting for acute full-thickness thermal wounds in both pediatric and adult patients, and for full-thickness thermal burns greater than 50% total body surface area ("TBSA"). As a first-of-kind medical device approved through FDA's Center for Biologics Evaluation and Research, and the first Class 3 device approved result of having achieved an expanded indication for use in burn care in over 20 years.

The RECELL System is a single use (disposable), stand-alone, battery operated, autologous cell harvesting device containing enzymatic pediatric burns, the Biomedical Advanced Research and buffer solutions, sterile surgical instruments, and actuators Development Authority ("BARDA") funded U.S. Pediatric Burns trial has been closed to achieve the disaggregation and delivery of skin cells. The platform technology of the RECELL System allows for the preparation and delivery of Spray-On Skin Cells, an autologous cellular suspension comprised of the patient's own skin cells necessary to regenerate natural healthy epidermis. These Spray-On Skin Cells are prepared at the point of care in as little as 30 minutes, providing a new way to treat thermal burns, other wounds, skin injuries or defects of the skin. The skin cell suspension includes keratinocytes, fibroblasts, and melanocytes, all of which play critical roles in skin regeneration. The treatment of burns with RECELL yields proven and significant reduction in the harvesting of donor skin. Donor sites are of great concern amongst burn patients. Burn wounds treated using RECELL show comparable results in burn wound healing outcomes relative to conventional grafting, despite the use of less donor site tissue. The ability of RECELL to retain melanocytes in the cell suspension is notable as these cells are critical for the restoration of natural pigmentation to the area treated,

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which is being further evaluated in ongoing clinical trials. Skin cell suspension is a powerful therapeutic with the potential for addressing unmet needs in a number of clinical indications, including burns, soft tissue repair, and vitiligo.

RESEARCH & DEVELOPMENT

The launch of the RECELL System into the U.S. market provided an opportunity to gain valuable, in-depth insight into the patient care pathway, as well as the workflow for surgical management of burn wounds. We continue to commit significant and increasing resources in product development to ensure that our device continues to evolve and has robust patent protection. In February 2022, the FDA approved the a PMA supplement for the RECELL Autologous Cell Harvesting Device, an enhanced RECELL system ease-of-use device aimed at providing clinicians a more efficient user experience and simplified streamlined workflow. This new version

On June 7, 2023, the FDA approved a PMA supplement for full-thickness skin defects based on results from our pivotal trial for soft tissue repair and reconstruction. Following this approval, we commenced a commercial launch on June 8, 2023.

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 three-step framework to secure reimbursement. The first step is a post-market study called, TONE. TONE will evaluate repigmentation using the RECELL System offers improved convenience along device and will also seek to measure the improvement in the quality-of life following treatment of stable vitiligo with an opportunity RECELL. We expect to expand our intellectual property portfolio.

Further product development submit the study for publication by the end of 2024.The second step is ongoing to capture the longitudinal healthcare costs for a vitiligo patient through a health economics, which is also expected to be submitted for publication by the end of 2024. Following publication of both studies, it is expected that conversations with commercial payors will begin during the second quarter of 2025. Subsequently, we anticipate commercial coverage will be rolled out on a next generation device regional basis, considering state and geographic factors. The initial phase of coverage is likely to begin in the fourth quarter of 2025, with appropriately sized commercial support as coverage is established.

Additionally, on June 29, 2023, we submitted a PMA supplement to the FDA for more automated implementation 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 supplement is required for the continuation of a substantive review for RECELL GO. This request, which is not unique to the core Spray-On Skin Cells technology, Breakthrough Device Program, placed the application file on hold while the Company addresses the FDA's questions. A category of questions posed by the FDA requires additional in-house testing, which is substantially completed. Consequently, we expect to advance submit a response to the user experience toward less hands-on processing time. With each iteration of our RECELL System development, we anticipate preservation of FDA no later than February 28, 2024. Upon the therapeutic power of Spray-on Skin Cells, deployed submission to the FDA, the application will reenter the 180-day cycle, with 90 days remaining in devices that become appropriate for use in an increasing range of clinical settings. the review period. This is particularly important as we aim to enter the dermatology space, where there is timing would imply FDA approval on May 30, 2024, with a shift toward an emphasis product launch on the volume of patients treated in a day. May 31, 2024.

In summary, our research and development efforts are currently focused on:

- Further clinical development of the RECELL System in additional skin-focused clinical indications where the platform can be leveraged. Specifically, to expand our footprint within wounds and dermatology, such as soft tissue repair and vitiligo. These activities are generally characterized by pivotal studies for which the FDA has approved an Investigational Device Exemption ("**IDE**")
- RECELL platform technology evolution to automate and improve workflow, speed, and ease of use
- Further research and characterization of the RECELL System design and the composition and activity of the Spray-On SkinCells suspension to support further clinical development of the platform, and to expand our intellectual property estate

TARGET MARKETS

Burns

Acute thermal burns are life-threatening and debilitating injuries that are among the most challenging and expensive to manage. These injuries require complex surgical procedures, long and costly hospitalization, and have a high potential for clinical complications and requirement for rehabilitation and scar treatment. In the U.S., approximately 40,000 people have burn injuries severe enough to require hospital admission annually, and it is estimated that 3,300 patients die each year. The majority of patients treated on an inpatient basis in the U.S. are treated in specialized burn centers.

Severe burns (typically defined as second- and third-degree) are commonly treated with autologous split-thickness skin grafts ("**STSGs**" STSGs") to achieve definitive closure of the burn wound. In a STSG, or autograft, donor skin is harvested from a healthy area of the patient's skin. The donor skin is then typically perforated into a mesh that can be expanded and transferred to cover the prepared burn injury. Treatment with STSG results in additional trauma for the patient due to creation of a new donor site wound. Although the use of STSG has been a standard treatment for more than 50 years, autografting is associated with significant pain, itching, infection, dyschromia, dyspigmentation, delayed healing, and hypertrophic scarring of the donor site.

The clinical benefits of earlier wound closure are well recognized and include increased survival, reduced hospital length of stay, decreased pain duration, and reduced infection-related complications. However, in large burn injuries, the patient may have insufficient donor skin available to allow for immediate and complete treatment of the entire burn injury area when using traditional grafting techniques. The lack of available healthy donor skin in patients with large burn injuries is often the central problem impacting time to autografting and definitive closure of the wounds. In extensively burned patients, surgeons often must wait until the donor sites have healed so they can re-harvest from the sites, resulting in delays in treatment and closure, requiring multiple procedures, and extending hospital stay. While waiting for donor skin, the burn wounds may be temporarily covered by allogeneic skin (allograft, cadaver skin) or xenograft (typically pig skin). The overall cost of treatment with STSG is expensive - for example it would cost

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approximately $579,000 and 59.4 days in hospital for a patient with a 40% Total Body Surface Area ("**TBSA**") mixed-depth burn injury to recover and return to normal day to day activities.

The RECELL System was approved by the FDA in September 2018 for the treatment of second- and third-degree acute thermal burn injuries in patients 18 years and older. In June 2021, the FDA approved an expanded indication for use to also include treatment of full-thickness (third-degree) pediatric burns, which represent close to a quarter of all burn injuries in the U.S., as well as

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full-thickness burn injuries greater than 50% TBSA. As a result of having achieved an expanded indication for use in pediatric burns, the Biomedical Advanced Research and Development Authority (**"BARDA**") funded U.S. Pediatric Burns trial has been closed to new enrollment (refer to BARDA Contract section below).

The pivotal studies leading to the RECELL System's FDA PMA for the treatment of acute thermal burns demonstrated that the RECELL System treated burns used 97.5% less donor skin when used alone in second-degree burns, and 32% less donor skin when used with autograft for third-degree burns, compared to standard of care autografting. In these studies, a statistically significant reduction in donor skin required to treat burn patients with the RECELL System was realized without any associated compromise to healing or safety outcomes. Donor site outcomes from the clinical trial for second-degree burns also revealed a statistically significant reduction in patient-reported pain, increased patient satisfaction and improved scar outcomes.

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

In addition to robust clinical data, RECELL has proven health economic benefits and a compelling cost-effectiveness model which shows that treatment using the RECELL System for deep partial-thickness burns 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, treatment using the RECELL System reduced 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 cost reductions are attributed to decreasing the length of hospital stay, reducing the number of procedures required to close the burn wound, and minimizing the donor site size and associated wound care. All of these cost savings estimates are net of the cost of the RECELL System.

A budget impact model was developed and has been used to calculate the annual budget impact of current standard of care for the treatment of burns versus treatment using the RECELL System for a burn center with 200 patients. The model shows that treatment using the RECELL System reduces annual total treatment costs from approximately $39.4 million to $32.6 million, saving 17% or approximately $6.8 million per year. In addition, real world evidence has been published by the Doctors at IQVIA and funded by the Company and BARDA indicating that these economic savings are demonstrated in a wide range of burn sizes.

The market for the treatment of burns in the U.S. is highly concentrated, with approximately 150 140 burn centers and approximately 300 burn surgeons who treat the majority of severe burns burn patients in the country (i.e., ~75%). Accordingly, our target market is was predominantly focused on burn centers, of which half are trauma centers. With FDA approval for full-thickness skin defects, we are expanding into these trauma centers, with the goal of capturing approximately 30% of RECELL-eligible burn injuries that are treated outside of dedicated burn centers. Our

Looking ahead, our goal is to establish RECELL as the standard of care for any burn injury that requires grafting for patients with 5% TBSA injury or greater. In the U.S., we estimate that there are approximately 35,000 patients annually that could benefit from our technology. Each RECELL System can treat up to 10% TBSA, and many patients

require more than one device.

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 the RECELL System and then taking it through 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., several existing reimbursement codes were in place prior to the commencement of commercial sales of the RECELL System. For inpatient treatment of burn patients, U.S. hospitals are reimbursed under DRG (Diagnosis Related Group) Codes based on diagnosis of a patient's injuries. For physicians, CPT (Current Procedural Terminology) codes for use in RECELL System procedures are recommended by the American Burn Association and are the same for both inpatient and outpatient use. In August 2020, we filed a Transitional Pass-through Payment Application ("**TPT**") with The Centers for Medicare & Medicaid Services ("**CMS**") to support a separate, additional Medicare payment for use of the RECELL System in the Outpatient Setting. On November 3, 2021, the Company was informed that CMS approved our TPT submission with the code effective as of January 1, 2022. The new "C" code provides additional payment which offsets the cost of the device in hospital outpatient facilities and ambulatory surgical centers for Medicare beneficiaries over a 2-to-3-year period before converting to a permanent code. Following the granting of the code, the Company is working with commercial carriers to ensure broader coverage. The new "C" code is not indication specific and lays the foundation for growth in other indications outside of acute thermal burns (such as soft tissue repair).

Japan is the second largest healthcare market, with approximately 6,000 patients per year who suffer from severe burns in Japan. Large patient populations coupled with healthy reimbursement coverage makes Japan an attractive market for the RECELL System. In February 2019, we entered into a collaboration with COSMOTEC, an M3 Group company, to market and distribute the RECELL System in Japan. We worked with COSMOTEC to advance our application for approval of the RECELL System in Japan

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pursuant Full-Thickness Skin Defects

A wound is a breach in the integrity of the skin, with full-thickness wounds extending through the dermal layer to Japan's Pharmaceuticals and Medical Devices Act ("**PMDA**"). In February 2022, our application for regulatory approval was approved by the PMDA for both adult and pediatric burns. In September 2022, COSMOTEC commercially launched RECELL in Japan following Japan's Ministry of Health, Labor, and Welfare approval of reimbursement pricing.

Soft Tissue Repair

Soft tissue repair includes treatment of injuries caused by non-burn trauma, including deeper tissues. Full-thickness skin defects include traumatic avulsion (e.g. degloving), surgical excision of infected tissue, such as (e.g. necrotizing soft tissue infections. While minor infection), or resection (e.g., skin defects may be primarily closed cancer). The cause or origin of the wound directly impacts healing potential, response to treatment options, and likely complications.

Traumatic Wounds. Traumatic wounds are subdivided by mechanism of injury into lacerations, abrasions, avulsions, crush, penetrating, or bites. Traumatic wounds often arise in high-energy circumstances and result in extensive zones of injury with sutures 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 standard wound care, larger open defects require more complicated approaches, including 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 Excisions for Cancer. Surgical excisions for cancer are procedures used to remove and treat various skin grafts, tissue flaps cancers. In the U.S., we estimate there are approximately 136,000 annual procedures that are eligible for treatment with RECELL.

Chronic Wounds. Chronic wounds are wounds that do not heal within an expected time frame. These types of wounds include diabetic foot ulcers, venous leg ulcers, pressure ulcers, and dermal matrices. non-pressure ulcers. In the U.S., we estimate there are approximately 128,000 annual procedures that are eligible for treatment with RECELL.

Similar to the burns indication, soft tissue repair is 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 donor skin harvesting

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

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

Given the interest to reduce 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 is 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.

On September 17, 2019, the FDA approved an Investigational Device Exemption ("**IDE**") to conduct a pivotal trial evaluating the safety The study design included two co-primary endpoints based on pairwise comparisons where each subject received both RECELL treatment and effectiveness standard of the RECELL System in combination with meshed autografting for the treatment of acute full-thickness skin defects. Subsequently, on March 2, 2020, we initiated a prospective, multi-center, randomized controlled study for soft tissue repair with the enrollment of the first patient at the Arizona Burn Center at Valleywise Medical Health Center in Phoenix, AZ. Each patient care treatment: one endpoint had a control wound treated with conventional hypothesis of superiority for donor skin grafting sparing and the other co-primary endpoint had a wound treated with expanded skin grafting in combination with RECELL. Enrollment hypothesis of this pivotal study was completed in January of 2022. In August 2022, the company announced positive topline results in which the study met both of its co-primary endpoints. Subsequently, the RECELL System earned the FDA Breakthrough Device designation non-inferiority for the proposed indication of soft tissue repair in November 2022. In December 2022, the Company submitted a PMA supplement application to the FDA. The supplement, if approved, will expand the indication of RECELL to include soft tissue repair.

Open wounds associated with traumatic injuries caused over 4.5 million hospital visits in the U.S. in 2017, and traumatic wounds rank among the five most costly medical conditions. We estimate that the total annual addressable U.S. market for RECELL in soft tissue repair is approximately $1 billion. The majority of our current burn accounts represent opportunities for use of RECELL in soft tissue repair. We plan to build out our existing field team to cover approximately 1,500 acute wound accounts (representing both burn and trauma accounts). Our expansion allows for coverage of over 75% of total targeted procedures. Based on market research, degloving (a type of injury where the skin is ripped from the underlying tissue), abrasions, and infectious disease (e.g., necrotizing soft tissue infections, like flesh-eating disease) have the greatest stated intent to use. We anticipate RECELL being used in both the inpatient & outpatient settings across a wide range of wound sizes. Market research indicates that surgeons treating soft tissue injuries believe RECELL will offer benefits over current treatment options, allowing surgeons to address key unmet needs. From a reimbursement perspective, the same DRG code that is currently being used to treat inpatient burns can be applied to soft tissue repair once FDA approval is received. Additionally, pending FDA approval of the PMA supplement application, the outpatient TPT "C" code we have been granted for RECELL can also be utilized for soft tissue repair in the outpatient setting.

Clinical study data and international product usage supports clinical benefits of RECELL use in soft tissue repair. In the pivotal study, RECELL met both healing. Both co-primary endpoints were met, demonstrating statistically significant donor sparing and non-inferior healing outcomes with RECELL versus standard of care. 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 outside the U.S. for many years and there exist several case reports on the treatment of traumatic injuries (soft tissue repair) that have been the subject of peer-reviewed scientific publications and presentations at medical conferences.

Soft tissue repairIn the U.S., we estimate that there are approximately 400,000 full-thickness skin defect procedures annually that are eligible for treatment with RECELL. The majority of our current burn accounts represent opportunities for use of RECELL in the treatment of full-thickness skin defects. In the second quarter of 2023, we expanded our commercial organization from 30 to 70. Our team is targeting approximately 800 acute wound accounts, representing both burn and trauma accounts. In the first half of 2024, we plan to further expand our commercial organization from 70 to 100.

The approval for the treatment of full-thickness skin defects represents a significant opportunity in which AVITA Medical can pursue we are leveraging its our existing and future resources while also creating synergies with the burns market. As of February 23, 2023, approximately Approximately 50% of the U.S. burn centers are classified as Level 1 and Level 2 trauma centers. Those Level 1 and Level 2 trauma centers currently utilizing RECELL should be are now able to use RECELL to repair soft tissue immediately following FDA approval treat full-thickness skin defects as these centers have already approved RECELL through their respective VACs. Further, we will be are expanding our burn market opportunity by virtue of our soft tissue launch approval for full-thickness skin defects as we will be are extending our reach to include trauma centers.

We anticipate RECELL being used in both the inpatient & outpatient settings across a wide range of wound sizes. 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. The condition is not life-threatening or physically painful, but it can significantly alter physical appearance and have negative emotional and psychological consequences, thus causing a cascade of medical conditions with associated costs.

Vitiligo cannot be cured at present, and treatments generally fall into one of two categories:

1. Treatments to arrest the spread of vitiligo, such as steroid creams and non-steroidal anti-inflammatory creams. There are also a number of therapies under development designed to target the underlying autoimmune disease. One challenge in terms of achieving the desired patient outcome is that stopping the spread of vitiligo may not restore pigmentation to the areas already damaged.

1. Treatments to arrest the spread of vitiligo, such as steroid creams and non-steroidal anti-inflammatory creams. There are also a number of therapies under development designed to target the underlying autoimmune disease. One challenge in terms of achieving the desired patient outcome is that stopping the spread of vitiligo may not restore pigmentation to the areas already damaged.

2. Treatments to restore pigmentation include skin grafting, laser phototherapy (with and without topicals), and Melanocyte-Keratinocyte Transplantation Procedure ("MKTP"). MKTP requires expensive and substantial laboratory equipment and is currently only available in a handful of locations in the U.S.

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RECELL does not treat underlying autoimmune disease. Rather, it works to restore pigmentation.

According to the FDA panel in 2021, there is a high level of depression, anxiety, and negative quality of life among vitiligo patients. Interest in vitiligo treatment tends to increase in individuals who have lesions in more visible areas (such as the face, neck and hands) as well as the younger female population. In 2022, over 400,000 patients pursued treatment for vitiligo in the U.S. We estimate that there are approximately 1.3 million 1.3 million people in the U.S. with stable vitiligo and a total addressable market of approximately $5 billion. Vitiligo rates a '7.61' 7.61 on the Dermatology Life Quality Index ("**DLQI**" DLQI"), which is in the same range of other aesthetic dermatological disease analogs which receive healthy positive reimbursement such as Rosacea (5.2), Psoriasis (9.3) and Atopic Dermatitis (12.79).

The market is expected to grow, especially over the next decade, with the advent of novel treatment options including oral and topical Janus Kinase ("**JAK**" JAK") inhibitors, such as Opzelura. Although these new products will both stabilize and re-pigment some patients, it is anticipated that many patients will need additional modes of treatment for re-pigmentation. Products (immunosuppressants) working to stabilize vitiligo and RECELL (working to restore pigmentation) are complementary. Further, large pharmaceutical companies with immunosuppressant assets in development will likely invest in disease awareness campaigns which will further grow consumer awareness and the market.

On July 1, 2020,Following FDA approval, we established a three-step framework to secure reimbursement. The first step is a post-market study called, TONE. The second step is to initiate a health economics study to capture the FDA approved our IDE application longitudinal healthcare costs for a pivotal study in vitiligo which patient. We expect to submit these two studies for publication by the end of 2024. Following publication of these studies, we plan to start conversations with commercial payors during the second quarter of 2025. Consequently, we anticipate commercial coverage will be rolled out on a regional basis, considering state and geographic factors. The initial phase of coverage is titled "A Prospective Multi-Arm Blinded-Evaluator Within-Subject Randomized Controlled Clinical Study likely to Investigate the Safety and Effectiveness of RECELL for Repigmentation of Stable Vitiligo." The primary endpoint compared the incidence of successful (80%, by area) repigmentation for RECELLtreatment versus that of standard of care phototherapy. The Company commenced enrollment begin in the vitiligo pivotal study in September 2020. The last subject enrolled in the study was treated in January 2022. fourth quarter of 2025, with appropriately sized commercial support as coverage is established.

INTERNATIONAL STRATEGY

In September 2022, the Company announced positive topline results in which its primary endpoint was met. Subsequently, international markets, the RECELL System earned the FDA Breakthrough Device designation for the proposed indication of vitiligo in November 2022. In December 2022, the Company submitted a PMA application has received various approvals and registrations to the FDA. The application, if approved, will expand the indication of RECELL to include treatment of vitiligo.

More than 1,000 patients have been successfully treated with the RECELL System for stable vitiligo outside of the U.S., and to date there are eleven publications demonstrating the benefits of the RECELL System in vitiligo. We believe that RECELL would be the first point-of-care device which provides a standardized in-office treatment to durably restore depigmented areas for patients with stable (or non-progressive) vitiligo.

Epidermolysis Bullosa

The RECELL System has been studied promote skin healing in a wide variety range of indications applications including, burns, full-thickness skin defects, and has been shown to enable patients to regenerate natural healthy skin vitiligo. These endorsements include
TGA registration in instances where Australia, CE mark approval in Europe, and PMDA approval in Japan under the patient's outer skin covering, or epidermis, has been lost or damaged. In addition to these applications of Pharmaceuticals and Medical Devices Act for burns. Our global commercialization strategy is focused on Australia, the RECELL System, we are pursuing related opportunities where the RECELL System's ability to harness the natural European Union, and Japan.

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healing capabilities of the body could be augmented In February 2019, we entered into a partnership with the use of genetically-modified cells for treatment of certain genetic skin disorders. In this way, COSMOTEC, an M3 Group company, to market and distribute the RECELL System could potentially be used as a vehicle for other therapeutic offerings. in Japan. Following the approval of reimbursement pricing by the Japanese Ministry of Health, Labor, and Welfare, COSMOTEC began the commercial launch of RECELL in September 2022.

Epidermolysis Bullosa ("EB") is a rare As part of our strategic growth plans, we plan to expand our global presence within the European Union and incurable group Australia through the exclusive use of disorders caused by mutations in genes encoding structural skin proteins. EB is characterized by skin fragility and blistering leading to chronic wounds due to normal mechanical trauma. Dystrophic EB ("**DEB**") is often associated with widespread blistering, pain, pruritus, extensive scarring, increased risk of squamous cell carcinoma with increased mortality. Signs typically occur at birth and persist over a lifetime. Currently, there are no FDA-approved treatments. All treatment options are palliative—focused primarily on pain and nutritional management, itching relief, and wound care (bandaging) with a significant cost burden ranging from $200,000-$500,000 per year per patient.

third-party distributors. In November 2019, AVITA Medical 2023, we entered into our first European distribution partnership with PolyMedics Innovations GmbH. PolyMedics Innovations will lead our expansion into Germany, Austria, and Switzerland.

We plan to actively identify new distribution partners in our focused markets over the next 6 to 12 months.

RESEARCH & DEVELOPMENT

Our research and development activities are focused on advancing our innovative products and building a research agreement with the Gates Center for Regenerative Medicine at the University comprehensive portfolio of Colorado School of Medicine ("**Gates Center**") for the purpose of seeking to establish pre-clinical proof-of-concept for a spray-on treatment of genetically corrected cells. Pursuant to this agreement, recessive dystrophic bullosa ("RDEB") cells have been successfully reverse-differentiated and corrected, yielding iPSCs (induced pluripotent stem cells). Further, iPSCs have been forward-differentiated, amplified, and used to successfully regenerate skin in an immunocompromised mouse model. We have paired the RECELL System Spray-On Skin Cells technology and expertise with the Gates Center's innovative patent-pending combined reprogramming and gene-editing technology, with the intent to allow the skin cells of patients with EB to function properly. Under the arrangement with the Gates Center, we retain the option to exclusively license technologies emerging from the partnership for further development and commercialization. While we remain interested in the therapeutic potential of modified Spray-On Skin Cells, the sponsored research agreement has concluded, and the Company is currently evaluating its potential next steps.

Rejuvenation

We believe that reversing aging at a cellular level has the potential to impact rejuvenation by driving functional changes to skin cells. This will be significantly different from existing products, such as cosmeceuticals that supplement proteins to cells, and surgical approaches that do not alter cellular stat but alter tissue morphology. An approach for molecular reversal of the underlying defects resulting in aging could have a profound effect on rejuvenation.

In November 2020, AVITA Medical announced a preclinical research agreement with the Houston Methodist Research Institute ("**HMRI**") to explore molecular reversal of cellular aging through a novel cell suspension delivery system. AVITA Medical retains the option to exclusively license HMRI's patented technology solutions, as well as developing clinical applications to advance the right management of first negotiations wound care. Additionally, we continue to HMRI's technologies emerging conduct clinical studies to provide further efficacy and health economic evidence.

We continue to commit resources to product development to ensure the RECELL system continues to evolve and that we maintain robust patent protection. In June 2023, we submitted a PMA supplement to the FDA for RECELL GO™. 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. Additionally, RECELL GO offers us an opportunity to expand our intellectual property portfolio. With each iteration of our RECELL System, 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. This is particularly important as we aim to enter the dermatology space, where there is a shift toward an emphasis on the volume of patients treated in a day.

RECELL GO maintains the FDA Breakthrough Device designation from predecessor devices. On September 29, 2023, we received notice from the partnership FDA that additional information regarding the PMA supplement is required for further development 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 we address the FDA's questions. A category of questions posed by the FDA requires additional in-house testing. The testing is already underway and commercialization. we expect to submit a response to the FDA no later than February 28, 2024. Upon submitting a response to the FDA, the application will reenter the 180-day cycle, with 90 days remaining in the review period. This timing would imply a product launch on May 31, 2024.

HMRI is a compelling partner for this work. Dr. John Cooke and his team have developed a novel, patented approach of telomerase reverse transcriptase delivery to reverse cellular aging and have been widely recognized as leaders in this space with multiple peer reviewed publications, grants, and awards. Further, HMRI has a strong program in translational medicine, including the Center for Rapid Device Translation that supports preclinical testing and GLP environments which could enable rapid translation from research into clinical trials.

In collaboration with HMRI, skin cells harvestedTONE will evaluate repigmentation using the RECELL Device have been molecularly reverse-aged, device and used will also seek to regenerate skin 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 mouse model, thereby establishing proof health economics study to capture the longitudinal healthcare costs for a vitiligo patient, which is expected to be completed by the end of concept. Work 2024. The purpose of these studies is ongoing to characterize demonstrate how treating vitiligo with RECELL can significantly reduce the tissue lifetime healthcare cost of patients. As a result, commercial payors will stand to identify functional attributes associated benefit economically by providing coverage of RECELL for the repigmentation of stable depigmented vitiligo lesions. Following publication of these studies, we expect conversations with rejuvenated skin. commercial payors to begin during the second 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.

SALES AND MARKETING

A primary objective of our field sales teamOur commercial organization is to build upon burn community focused on clinical case support, staff training, and building awareness that has resulted from an extensive series of RECELL System related burn conference presentations and scientific publications to further expand interest in the clinical and economic benefits of the RECELL System. In addition, our field sales team provides robust clinical case support and staff training. RECELL. It is not uncommon in the burn community 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.

We sell the RECELL System in the U.S. through our direct commercial organization consisting of 26 field personnel who are supported by corporate marketing, reimbursement, scientific 70 individuals, which consists of 10 managers, 40 regenerative tissue specialists, and medical affairs, operations, and corporate leadership. The field sales team was recruited and hired subsequent to the September 2018 FDA PMA and trained prior to the U.S. market launch of RECELL in January 2019. 20 clinical training specialists. Our field commercial organization is composed of highly experienced medical sales representatives as well as former burn and trauma nurses.

This organization covers both thermal and non-thermal wound accounts. We anticipate the U.S. market launch of RECELL for soft tissue repair in July 2023. The majority of our current burn accounts represent opportunities for the use of RECELL in soft tissue repair; however, we plan to significantly further expand our commercial organization to 108 in the existing burns field team to cover both burn and trauma accounts prior to the market launch first half of RECELL for soft tissue repair. The expansion plan allows for coverage of over 75% of total targeted procedures. 2024.

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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, 2022 December 31, 2023, we had 126 employees 207 full-time and part-time employees. As of December 31, 2022 December 31, 2023, 98% 99% of our workforce was based in the United States, with a significant number of our management and professional employees having prior experience with leading medical product, 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, 2022 December 31, 2023, our executive leadership team was 50% the Directors of the Company were 28.5% female, our senior leadership executive team was 38% 30% female and our total employee base was 47% 50.2% female. In addition to promoting gender diversity, we encourage ethnically diverse talent when recruiting as well as providing employee training and development focusing on workplace diversity and inclusion.

INTELLECTUAL PROPERTY

We seek to protect our intellectual property, core technologies, and other know-how through a combination of patents, trademarks, trade secrets, non-disclosure and confidentiality agreements, licenses, assignments of invention and other contractual arrangements IP assignments with our employees, consultants, business partners, suppliers, customers, and others. 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.

As powerful complements to our IP rights, we also believe that the regulatory approval processes around the world will continue to provide additional and significant barriers to entry against meaningful competition.

As of December 31, 2022 December 31, 2023, we had been granted a total of 19 patents AVITA Medical's patent portfolio comprised 22 patent grants and had 27 31 pending patent applications pending worldwide. The Company's worldwide, with patent portfolio encompasses assets coverage either secured or in progress in the U.S., China, Japan, Australia, Brazil, Canada, France, Germany, Hong Kong, Italy, Spain, the United Kingdom, and applications pending before at the European Patent Office (**" ("EPO")**. Notably, as discussed more fully below, our core U.S. patent remains in force until February 6, 2024, and we expect it to be extended through April 9, 2024. In addition to patent protection, we believe that the regulatory approval processes around the world will continue to provide significant barriers to entry against meaningful competition.

AVITA Medical's patent portfolio covers AVITA Medical's core the original RECELL System, product, all-in-one RECELL, RECELL GO, methods of using the RECELL System, methods of evaluating the therapeutic potential of Regenerative Epidermal Suspension ("**RES®**" RES"), a cell-free and allogeneic RES supernate, and methods of preparing a cell suspension with exogenous agents to promote wound healing, as well as to one or more automated systems for tissue processing and preparation of cell suspensions. AVITA Medical's pending patent applications cover an all-in-one RECELL System embodiment and methods of evaluating the therapeutic potential of RES, as well as new modifications to RES that are showing potential for therapeutic results. healing. We expect that our research and development pipeline, strategic partnerships, with universities, and improvements to the RECELL System and RES will result in additional and diverse patent applications for automated tissue processing and RES-related compositions of matter, along with related methods of use, in the next calendar year.

In 2019, AVITA Medical filed a Patent Term Extension ("PTE") application with the U.S. Patent and Trademark Office requesting an extension of the patent term for U.S. Patent No. 9,029,140, "Cell suspension preparation technique and device" which covers the RECELL System, as a result of patent term lost to the FDA regulatory process. If the term extension requested in the The PTE application is was approved, and the patent term of U.S. Patent No. 9,029,140, which covers the RECELL System, will be has been extended to April 9, 2024. An interim PTE application was approved on December 12, 2022, for U.S. Patent No. 9,029,140 that extends its expiration date until February 6, 2024 while we wait for full approval of the PTE application. AVITA Medical's other patents have expected expiration dates ranging from 2032 to 2033, while AVITA Medical's pending patent applications, if granted, would have expiration dates ranging from 2032 to 2041. 2042.

Additionally, AVITA Medical owns and defends a global trademark portfolio comprising 125 142 registered trademarks, common or state law trademarks, and pending trademark applications. Recently, AVITA applications, including "AVITA Medical, received U.S. federal trademark registration on the marks "AVITA Medical" and " the AVITA Medical logo. AVITA Medical also owns trademark registrations for logo, "RECELL," "Spray-On Skin," the RECELL System logo, "RES," and others in the U.S. and international markets. In addition to patent and trademark protection, we the Company also rely relies on trade secrets, know-how, and other proprietary information to develop and maintain our competitive position. We have robust confidentiality and invention disclosure procedures in place that incentivize our employees to innovate and allow us to maintain our rights to AVITA Medical innovations.

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FACILITIES

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, 2024 September 30, 2027. The Ventura facility has two one 3-year options 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**" 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. Also included within the Ventura facility is a secure controlled-temperature warehouse that complies with the vendor-managed inventory ("**VMI**" VMI") requirements of the contract with BARDA. See below for details. The VMI contract with BARDA terminated on December 31, 2023.

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, as well as other indications under development, for the foreseeable future.

AVITA Medical serves the U.S. burn market by shipping the RECELL System directly from our Ventura facility to U.S. burn centers. 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

We have a contract with the BARDA, under the Assistant Secretary for Preparedness and Response, within the U.S. Department of Health and Human Services, valued at approximately $53.3 million. Services. The contract provided funding for the development of the RECELL System. The contract will continue to provide funding for future use of the product as a medical countermeasure to assist disaster preparedness and response in the U.S. for mass casualty events involving burn injuries. We entered into the contract on September 29, 2015, and with the scope has expanded through a number of amendments to the contract. The current original contract period continues to ending on December 31, 2023,. We have executed a contract modification with the option by BARDA to terminate earlier. extend the period of performance to September 28, 2025.

Under the original contract, BARDA has provided funding and technical support for the development of the RECELL System. BARDA funded the completion of two randomized, controlled pivotal clinical trials, as well as Compassionate Use and Continued Access programs, and development of the health economic model demonstrating the cost savings associated with the RECELL System. BARDA exercised a contract option to fund a randomized, controlled clinical trial for a pediatric early intervention study which commenced enrollment in March 2020, and closed to enrollment in June 2021, subsequent to FDA-approval of an expanded RECELL indication for use that includes treatment of pediatric patients. Currently, the The BARDA contract is supporting also supported the Company's clinical trial in soft-tissue repair. reconstruction, which led to the full-thickness skin defect indication. Also included in the BARDA contract was a provision for procurement of the RECELL System under a vendor-managed inventory system to bolster emergency preparedness in the amount of $7.6 million. Further, BARDA expanded the awarded contract to provide supplemental funding of $1.6 million $7.6 million and an additional $1.6 million to support the logistics of emergency deployment of RECELL Systems for use in mass casualty or other emergency situations. We are were contracted to manage this inventory of product until the earlier of the federal government requesting shipment or at contract termination on December 31, 2023. As of December 31, 2022 December 31, 2023, we had received cumulative payments of $37.9 $40.3million under the original BARDA contract. Under the new contract, BARDA shall have access to AVITA Medical's RECELL inventory in the event of a national emergency. BARDA shall pay for the devices requisitioned under this inventory along with a nominal annual maintenance fee to ensure first right of access.

COMPETITION

TheWe currently believe that there is no direct competition for the RECELL system. 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 intensely highly competitive and subject to significant technological developments and rapid advancements in technology, as well as changes in practice. While we believe that our innovative technology, knowledge, experience, and scientific resources provide us with competitive advantages, In the future, we may face competition from many different various sources, with respect to the

RECELL System or any product candidates that we may seek to develop and commercialize in the future. Possible competitors may include including medical device, pharmaceutical, and wound care companies, academic and medical institutions, governmental agencies, medical practitioners, and public and private research institutions, among others. Any Consequently, any product that we successfully develop and and/or commercialize will compete with both existing therapies and any new therapies that may become available emerge in the future.

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Our primary competitor in

In the burns market and non-burn wound markets, our indirect competitor is the current standard of care, primarily split-thickness autografts. Although the While RECELL System is complementary with complements autografts for the treatment of many burn various wound injuries, we face competition from this split-thickness autografts represent the traditional surgical procedure for many burn patients. and the current standard of care. However, based on our clinical trials, we believe that the RECELL System has system offers sustainable competitive clinical and economic advantages over this current standard of care. We face additional competition the traditional surgical procedure. Additionally, in the burns market, from other FDA-approved products such as Epicel® provided by Vericel Corporation markets Epicel® as well as from Stratagraft® provided by Mallinckrodt. a permanent skin replacement for deep-dermal or full-thickness burns; however, Epicel is a cultured epidermal autograft grown ex vivo and exclusively used to treat burns comprised of greater than or equal to 30% of TBSA.

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** **"FD&C Act**" 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 December 2022, June 2023, the Company submitted FDA approved a supplement to our PMA supplement to expand the use of RECELL for soft tissue repair full-thickness skin defects and an original PMA application to expand the use of RECELL for treatment the repigmentation of vitiligo. stable depigmented vitiligo lesions.

To support 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, that 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 regulations, 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 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 requirements. 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 regulations and other FDA and international agency regulatory requirements, approved supplier lists, and regular 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 product.

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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 Pharmaceuticals and Medical Devices Act (PMDA) approval for burns in Japan.

HEALTHCARE LAWS AND REGULATIONS

AVITA Medical is a manufacturer of a medical device 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**" 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

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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.

- 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 U.S. Department of Health and Human Services, Office of Inspector General. Such laws 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**" FCPA") prohibits any U.S. individual or business from paying, offering, or authorizing 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 the companies to maintain books and records that accurately and fairly reflect all transactions of the 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 annually to the Centers for Medicare and Medicaid Services within the U.S. Department of Health and Human Services. Additionally, in adhering to federal reporting requirements, all relevant state marketing reporting regulations, any payments, and transfers of value to physicians and teaching hospitals, as well as other categories of disclosures must be reported annually.

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Privacy

AVITA Medical must comply with the federal Health Insurance Portability and Accountability Act of 1996 ("**HIPAA**" HIPAA") which imposes criminal and civil liability for, among other conduct, making false statements relating to healthcare matters and executing a scheme to defraud any healthcare benefit program. It also imposes criminal and civil liability and penalties on those who violate requirements such as mandatory contractual terms which are intended to safeguard the security, transmission and use of individually identifiable health information.

Various state and foreign laws also govern the privacy and security of health information such as the European Union General Data Protection Regulation ("**GDPR**" GDPR"). GDPR governs the use of individual health data and other personal information and imposes strict obligations and restrictions on the ability to use, access, process, and disseminate health data from clinical trials and adverse event reporting, among others.

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 violations or deficiencies. These laws, regulations and permits could potentially require the expenditure by us for 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**" 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). We maintain a website at www.avitamedical.com. Since becoming a domestic U.S. issuer on July 1, 2020, 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. Information contained on our website is not part of or incorporated into this annual report.

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ORGANIZATIONAL STRUCTURE

ThePrior to the Corporate Restructuring initiated during fourth quarter, the Company has had a total of six subsidiaries and their corporate details and business activities are listed below:

Subsidiary Name	Place of Incorporation	% Held	Business Purpose
AVITA Medical Pty Limited	Australia	100	Operating Company
AVITA Medical Americas, LLC	Delaware	100	U.S. operations
AVITA Medical Europe Limited	United Kingdom	100	EMEA operations
Visiomed Group Pty Ltd	Australia	100	Asia Pacific Operations
C3 Operations Pty Ltd	Australia	100	Holding company
Infamed Pty Ltd	Australia	100	Inactive

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 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 deregistered during the course of 2024.

After the Corporate Reorganization (expected to occur by the end of the third quarter in 2024), the Company's entity structure will be as follows:

Subsidiary Name	Place of Incorporation	% Held	Business Purpose

AVITA Medical Americas, LLC	Delaware	100	U.S. operations

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, such sales have been limited to date and we have not yet obtained achieved profitability. We had a total net loss of $26.7 million $35.4 million and $25.1 million $26.7 million for the year-ended year ended December 31, 2023 and December 31, 2022 and the year-ended December 31, 2021, respectively. We have incurred a cumulative deficit of $262.6 million $298.0 million through December 31, 2022 December 31, 2023. We anticipate that we may continue to incur losses at least until U.S. 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 for which we are not presently approved.

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 the Company entered with OrbiMed Advisors, LLC ("Credit Agreement") on October 18, 2023, we incurred $40.0 million of indebtedness secured by substantially all of our assets and have the ability to incur an additional $50.0 million of indebtedness. 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.

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Our ability to make scheduled payments of interest depends on our future performance, which is subject to interest rate risk, 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 and make 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 five percent of the outstanding principal amount of its indebtedness in equal quarterly installments, in addition to a repayment fee and a prepayment fee.

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 engage in these activities on desirable 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 the agreements. The breach of any of these covenants and restrictions could result in a default under the Credit Agreement, which could result in an acceleration of the repayment of our indebtedness.

Provisions in our U.S. government contracts, including our contracts with BARDA, may affect our intellectual property rights.

Certain of our activities have been funded, and may in the future be funded, by the U.S. government, including through our previous contracts with BARDA. When new technologies are developed with U.S. government funding, the government obtains certain rights in any resulting patents, including the right to a nonexclusive license authorizing the government to use the invention and rights that may permit the government to disclose our confidential information to third parties and to exercise "march-in" rights. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the U.S. government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, U.S. government-funded inventions must be reported to the government, U.S. government funding must be disclosed in any resulting patent applications, and our rights in such inventions may be subject to certain requirements to manufacture products in the United States.

Development and commercialization of our products require successful completion of the regulatory approval process and may suffer delays or fail. We may be unsuccessful in obtaining additional approvals for our RECELL System for soft tissue repair full thickness skin defects and skin conditions such as vitiligo.

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. Although For instance, our RECELL System has been approved by the FDA and regulatory authorities in Australia, the EU and Japan for use in the treatment of acute partial-thickness thermal burn wounds in patients 18 years of age and older or application in combination with meshed autografting for acute full-thickness thermal burn wounds in pediatric and adult patients in the United States, we are looking to expand the indications of the product for use in soft tissue repair and vitiligo. In December 2022, the company

submitted a PMA supplement to expand the use of RECELL for soft tissue repair and an original PMA application for the use of RECELL for treatment of vitiligo. While clinical trials for such uses are nearing completion, there can be no assurance that we will be successful in those clinical trials or ever receive approval by the FDA for the use of our RECELL System for such additional applications. Such a failure of approval would have a material negative effect on our future prospects.

In Australia, the RECELL System is approved to use for the treatment certain treatments of burns, acute wounds, scars and vitiligo. In the EU the product has been approved for the treatment of burns, chronic wounds, scars and vitiligo. We worked with COSMOTEC to advance our application for approval of the RECELL System in Japan pursuant to Japan's Pharmaceuticals and Medical Devices Act ("**PMDA**"). In February 2022, our application for regulatory approval was approved by the PMDA for both adult and pediatric burns. We However, we will require additional clinical data or approvals from regulatory authorities within these countries to market the product for the treatment of other indications, and from any other jurisdictions in which we seek to market the product. This process can be time consuming time-consuming and complicated and may be unsuccessful or otherwise result in unanticipated delays or fail altogether. For example, on September 29, 2023, the Company received notice from the FDA that additional information regarding the Company's PMA supplement for its latest device, RECELL GO is required for the continuation of the FDA's review. This request, which is not unique to the Breakthrough Device Program, placed the application file on hold for approximately 4 to 6 months while the Company addresses the FDA's questions.

To secure marketing authorization, an applicant generally is required to submit an application that includes the data supporting preclinical 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 or facilities 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 will take to do so. 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, and we may not 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, and recordkeeping 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 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.

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 in, 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, and results of operations.

Obtaining and maintaining regulatory approval for a product candidate in one jurisdiction does not mean that we will be successful in obtaining regulatory approval for that product candidate 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, while 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 if though the FDA grants has granted marketing approval for use of our RECELL System for the treatment soft tissue repair and/or full-thickness skin defects and vitiligo, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries 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 additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a medical device must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

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. FDA including subsequent secondary approvals of the PMA outside of burns. This PMA allows us to sell our RECELL System in the United States, our current primary market. In addition, maintaining this PMA also increases the probability of approval of secondary indications for the PMA outside of burns. 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.

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

We cannot guarantee that any preclinical testing or clinical trials will be conducted as planned or completed on schedule, if 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.

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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 clinical development or a regulatory application include:

- delays in raising, or inability to raise, sufficient capital to fund the planned trials;

• 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 of the product candidates to the clinical sites;
- delays caused by clinical trial sites not completing a trial;
- failure to demonstrate adequate effectiveness;
- occurrence of serious adverse events in clinical trials that are associated

with the product candidates that are viewed to outweigh its potential benefits;
•changes in regulatory requirements and 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.

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- 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;
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- 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 of the product candidates to the clinical sites;
- delays caused by clinical trial sites not completing a trial;
- failure to demonstrate adequate effectiveness;
- occurrence of serious adverse events in clinical trials that are associated with the product candidates that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and 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 and 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 and reimbursement policies.

We cannot guarantee that we will receive favorable pricing and 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, the government largely controls pricing of medical products. In other countries, coverage negotiations must occur at the regional or hospital level. 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. Adverse pricing limitations may hinder our ability to recoup our total investment in our RECELL System or other future products, even after obtaining regulatory approval.

If we are unable to promptly obtain coverage and profitable payment rates from hospital budget, government-funded and 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.

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

- Reimbursement for hospitals in inpatient services using Medicare Severity Diagnosis-Related Groups (“**MS-DRGs**”).
- 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 to support physician reimbursement for professional healthcare services, ambulatory surgical center (“ASCs”) reimbursement for facility services and hospital reimbursement for outpatient

department services. Medicare reimburses

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ASCs for services using CPT codes and reimburses hospitals for outpatient services using Ambulatory Payment Classifications ("APCs").

- 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.
- Current Procedural Terminology ("**CPT**") codes to support physician reimbursement for professional healthcare services, ambulatory surgical center ("**ASCs**") reimbursement for facility services and hospital reimbursement for outpatient department services. Medicare reimburses ASCs for services using CPT codes and reimburses hospitals for outpatient services using Ambulatory Payment Classifications ("**APCs**").

In addition, in 2022, we were approved for a Transitional Pass-through Payment ("**TPT**") C code to support additional Medicare payment in the outpatient hospital and the ASC setting. There can be no guarantee that the above reimbursement codes will not be withdrawn, reduced, consolidated or otherwise be altered in a manner which is not supportive of ongoing commercial use of the RECELL System.

We have limited financial resources and will likely may require additional financings 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 or place restrictions on our operations. 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 the indebtedness under our Credit Agreement with OrbiMed and 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 at all. If we raise additional capital through the issuance of equity, or convertible debt securities, 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. Debt financing, if available, may involve restrictive covenants, which may limit our operating flexibility with respect to certain business matters. 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.

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 adhering to product quality standards, complying with regulatory quality system requirements and managing manufacturing costs. 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 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 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; and

- quality 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; and

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 and results of operations. In addition, we are continually identifying additional third-party suppliers who could serve if necessary as replacement manufacturers should the need arise.

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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.

We expect recent supply chain disruptions as a result of the pandemic combined with raw material shortages, and inflationary pressures, to continue for the foreseeable future. These conditions have strained our suppliers and extended supplier delivery lead times. The Life Sciences industry is experiencing market wide shortages for resin products used in our packaging. As a result of recent inflation, we are seeing increases in the costs of raw materials.

We have single-sourced some of our material components dueDue to the cost and regulatory requirements associated with qualifying multiple suppliers. suppliers, in the prior year we single-sourced some of our material components. To the extent that any of these single sourced single-sourced suppliers may have experience disruptions in deliveries due to production, quality, or other issues, we may also experience related are potentially subject to similar production delays or unfavorable cost increases associated with qualifying alternate suppliers. The impact increases. In the current year, we invested resources in obtaining additional suppliers for some of delays resulting from disruptions in our key raw materials, but these efforts only mitigate, and not eliminate, our supply for these items could negatively impact our revenue, our reputation with our customers, and our results chain risk.

Table of operations. In addition, significant price increases from single-source suppliers could have a negative impact on our profitability to the extent that we are unable to recover these cost increases on our fixed price contracts. Contents

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 regulatory approval for or commercialize our drug product candidates and our business could be substantially harmed.

We rely on clinical research organizations ("**CRO**" CRO"), and clinical trial sites to ensure our clinical trials are conducted properly and on time. While we will have agreements governing their activities, we will have limited influence over their actual performance. CROs manage and monitor the clinical trials, duties and functions, and we will control only certain aspects of our CROs' activities. Nevertheless, we will be responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory 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, enforces 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 regulatory approval for, or successfully commercialize, our product candidates. If any such event were to occur, our financial results and the commercial prospects for our product candidates 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 time and focus. 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 delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

As a result of the ongoing COVID-19 pandemic, other pandemics, inadequate funding or other reasons, the FDA and other government agencies may have resource constraints which could limit their ability to review and approve our applications in a timely manner, thus negatively impacting our business.

The FDA's ability to review and approve regulatory submissions ***can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, federal government shutdowns, and other events that may otherwise affect the FDA's ability to perform routine functions.*** The time to review submissions can vary from time to time.

If a prolonged government shutdown occurs, or if global health concerns continue to prevent or delay the FDA or other regulatory authorities from conducting, at all or in a timely manner, their regular inspections, reviews, or other regulatory activities (including pre-submission engagements), it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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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, subjects 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 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.

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 efforts internal computer and information technology systems and those of our vendors and customers are vulnerable to secure this 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 there can be no assurance that cyberattacks 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 threats from malicious persons means to affect service reliability and groups will not cause harm threaten the confidentiality, integrity and availability of information. Beyond external criminal activity, systems that access or control access to or disrupt our business services and operations. As databases may be compromised as a result cyber 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 the continued development and enhancement of our controls, processes and practices designed to protect our information systems from attack, damage or unauthorized access remain a priority for us. We may be required to expend significant additional resources to protect against cyber threats. A cyber-attack may could result in a material adverse disruption of our business operations, damage to our reputation, financial condition, results of operations, cash flows and prospects.

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We receive, collect, process, use and store a large amount of information from our customers and our own employees, including personal information, protected health 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 monetary loss and/or litigation, fines and sanctions. 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 all potential liability.

We are subject to diverse laws and regulations relating to data privacy and security, such as HIPPA and similar U.S. state data protection regulations, including the California Consumer Privacy Act (CCPA), and European data privacy laws, including the E.U.'s 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, fines, civil liability 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, employee training and engagement of third-party experts and consultants. Additionally, the costs incurred to remediate any security incident could be substantial.

We cannot assure you that any of our third-party service providers with access to our, or our customers and/or employees' personally identifiable and other sensitive or confidential information will not experience security breaches or attempts thereof, which could have a corresponding effect on our financial position and results of operations and harm our business reputation. business.

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

We rely upon complex, integrated information technology (IT) ("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, financial loss, and our operations would be adversely impacted.

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, thus negatively impacting our sales, financial conditions and business prospects. Our competitors may have significantly more financial and other resources to invest in product development. We must continue to develop and market new products, or we risk our products becoming obsolete, in which case, our revenues may decline, and our business prospects may suffer.

Product development is an expensive, uncertain and lengthy process.

We have significant product development projects ongoing that, if successful, are intended to improve the ease and use of our device in our current burn indication, as well as in soft tissue repair, full-thickness skin defects, vitiligo and future indications. The costs, timeline and ultimate success of these product development programs are subject to risk and uncertainty. If the Company is we are not able to develop and obtain regulatory approval for these products in development in a timely fashion and within budget, our business prospects and financial condition may suffer.

Compliance with environmental, health and safety requirements is costly and, if not achieved, could result in material financial fines and penalties, expensive lawsuits, cessation of business operations, and a material adverse impact on the business.

Our manufacturing and other processes may involve the use of hazardous materials subject to federal, state, and 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 environment environmental laws, or future laws, could result in significant fines, penalties and expenses which could have an adverse impact on our financial condition.

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

We are prohibited from promoting our products for uses that are inconsistent with the uses that have been approved by the FDA - also known as “off-label” uses. More specifically, we may not make claims, in our promotion materials, website or otherwise,

about the use of any RECELL products which are outside of their approved labeling and indications. If the FDA determines that our marketing activities constitute off-label promotion, the FDA could impose fines and penalties on the Company and our executives, withdraw or recall our approved product from the market, as well as limit our product from off-label usage.

Risks Relating to our Industry and Intellectual Property

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 and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we may have. Mergers and acquisitions in the pharmaceutical, medical device, and biotechnology industries or 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 complementary to, or necessary for, our programs.

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, whether or not such claims are covered by insurance or have merit. A product liability claim against us or the withdrawal of a product from the market could have a material adverse effect on our business or financial condition. 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.

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 will operate is still evolving. The amount of ongoing protection for our proprietary rights therefore is uncertain. 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 or our subsidiaries may be challenged, invalidated, held unenforceable or circumvented. In particular, 2019, we filed a patent Patent Term Extension (“PTE”) application with the U.S. Patent and Trademark Office requesting an extension of our commercial patent that for U.S. Patent No. 9,029,140, which covers the RECELL System, as a result of patent term lost to the FDA regulatory process. The PTE application was approved, and the patent term of U.S. Patent No. 9,029,140. If the term extension is approved, the patent term will be 9,029,140, has been extended to April 9, 2024. Without such approval, Our other patents have expected expiration dates ranging from 2032 to 2033, while our RECELL System pending patent will expire in February 2024, which could prevent us applications, if granted, would have expiration dates ranging from defending our patent in the event a competitor infringes on our RECELL System by producing the same type of product. 2032 to 2042.Furthermore, the patent protections we have been granted may not be broad enough to prevent competitors from producing products similar to ours.

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In markets other than the USA, where we continue to have patent protection on the RECELL System, the expiration of these patents means the Company may not be able to deter a competitor from introducing a product similar to the RECELL System in those jurisdictions. If this were to occur, our ability to successfully market and sell our products in such markets could be materially impaired.

In addition, the laws of various foreign countries in which we may compete may not protect our intellectual property to the same extent as do the laws of the United States. If we fail to obtain adequate patent protection for our proprietary technology, our ability to be commercially competitive will be materially impaired.

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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. In addition, because patent law is evolving in the life science industry, the patent positions of companies like ours are uncertain. As a result, the validity and enforceability of our patents cannot be predicted with certainty.

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, particularly in relation to biotechnology, 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.

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 these 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.

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 our management and 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 business.

Our current and future relationships with investigators, health care professionals, consultants, third-party payors, and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.

Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These

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laws regulate the business or 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:

- the federal Anti-Kickback Statute prohibits, among other things,
- the federal Anti-Kickback Statute 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

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

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 False Claims Act;

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false or fraudulent claim for purposes of the civil 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;

- HIPAA imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false or fraudulent statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information on health plans, health care clearing houses, and certain health care providers, known as

covered entities, and their business associates, defined as independent contractors or agents of covered entities that create, receive or obtain protected health information in connection with providing a service for or on behalf of a covered entity as well as their covered subcontractors;

- a number of federal, state and foreign laws, regulations, guidance and standards that impose requirements regarding the protection of health data that are applicable to or affect our operations;
- the federal transparency requirements, sometimes referred to as the “Sunshine Act,” under the Patient Protection and Affordable Care Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) to report annually

to the government information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to the government ownership and investment interests held by the physicians described above and their immediate family members. Applicable manufacturers are also required to report such information regarding their relationships with physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and certified nurse midwives during the previous year; and

- 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 otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and 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; and state and

foreign laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

- 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;
- HIPAA imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false or fraudulent statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information on health plans, health care clearing houses, and certain health care providers, known as covered entities, and their business associates, defined as independent contractors or agents of covered entities that create, receive or obtain protected health information in connection with providing a service for or on behalf of a covered entity as well as their covered subcontractors;
- a number of federal, state and foreign laws, regulations, guidance and standards that impose requirements regarding the protection of health data that are applicable to or affect our operations;
- the federal transparency requirements, sometimes referred to as the “Sunshine Act,” under the Patient Protection and Affordable Care Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to the government ownership and investment interests held by the physicians described above and their immediate family members. Beginning in 2022, applicable manufacturers are also required to report such information regarding their relationships with physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and certified nurse midwives during the previous year; and
- 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 otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and 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; and state and foreign laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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 business may be impaired.

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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 health 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 health care related organizations, who are increasingly challenging the price of medical 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. Further 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

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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 product and we cannot predict the scope of any future changes or the impact that those changes would have on our operations. operations. Cost control initiatives may decrease coverage and payment levels and, in turn, the price 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, 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 harm our business and reduce our revenue. Additionally, if rebate obligations associated with them are substantially greater than we expect, our future net revenue and profitability could be materially diminished.

Macroeconomic and Social Risks

Our business, results of operations and financial condition may be adversely impacted by the COVID-19 pandemic.

The ongoing COVID-19 pandemic has negatively affected the U.S. and global economies, disrupted global supply chains, resulted in significant travel and transport restrictions, and created significant disruption of the financial markets. We continue to closely monitor the impact of the COVID-19 pandemic on all aspects of our business, including how it is impacting our employees, product development, customers and supply chain. We continue to be unable to predict the ultimate impact that the COVID-19 pandemic may have on our business, future results of operations, financial position or cash flows. The extent to which our operations may be impacted by the COVID-19 pandemic and recovery will depend largely on future developments, which are highly uncertain and cannot be accurately predicted.

We may experience additional operating costs due to increased challenges with our workforce (including as a result of illness, absenteeism or government orders), access to supplies, capital, and fundamental support services (such as shipping and transportation). Even after the COVID-19 pandemic has subsided, we may experience materially adverse impacts to our business due to any resulting supply chain disruptions, economic recession or depression. Furthermore, the impacts of potential worsening of global economic conditions, inflation resulting from government interventions and stimulus, and continued disruptions to and volatility in the financial markets remain unknown.

The impact of the COVID-19 pandemic may also exacerbate other risks discussed in this section, any of which could have a material adverse effect on us. This situation continues to change rapidly, and additional impacts may arise that we are not aware of currently, including the emergence of additional variants which may or may not be resistant to currently available vaccines and therapeutic treatments.

Adverse changes in general economic conditions or uncertainty about future economic conditions, including economic uncertainty from the departures of critical personnel from the industry, could adversely affect us.

We are subject to the risks arising from adverse changes in general economic market conditions, including the negative impact to the U.S. and global economy from the COVID-19 pandemic. conditions. Uncertainty about future economic conditions could negatively affect our current and prospective customers causing them to delay the purchase of our products. Poor economic conditions could harm our business, financial condition, operating results and cash flows. In addition, a number of nurses and other critical personnel in burn centers who are trained and well versed in the use of the RECELL system have determined to change occupations, possibly as a result of the ongoing pandemic. occupations. Nationally, this has been termed the “great resignation”. The fact that many burn center employees

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have moved on to other positions or industries may limit our ability to increase adoption of our RECELL system as we will be required to train a new group of nurses and other personnel critical to the implementation of the RECELL system.

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 are beyond our control. Many predict that the U.S. economy will enter a recession in fiscal year 2023.

We continue to take precautions due to the COVID-19 pandemic that could negatively impact our business.

In response to the COVID-19 pandemic, we have taken measures intended to protect the health and well-being of our employees, customers, and communities, which could negatively impact our business. While the COVID-19 pandemic has not materially adversely affected our financial results and business operations through the fiscal year-ended December 31, 2022, we are unable to predict the impact that COVID-19 will have on our business, operations, and financial results and condition because of the numerous uncertainties created by the unprecedented nature of the pandemic. We are closely monitoring the evolving impact of the pandemic on all aspects of our business. We have implemented a number of measures designed to protect the health and safety of our employees, support our customers and promote business continuity. We continue to evaluate the Company's liquidity and operational performance, communicate with and monitor the actions of our customers, third-party manufacturers and suppliers, and review our near-term financial performance as we manage the Company through this period of uncertainty.

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, for our operations. If we decided to pay dividends at some future time, we may not have sufficient funds legally available to do so. 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 conditions, 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 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 our 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 and biotech sectors have often experienced fluctuations that have been unrelated or disproportionate to the operating results of these companies. 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 patient serious adverse events;
- publication of research reports by securities 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;
- issuances 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;

- 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 patient serious adverse events;
- publication of research reports by securities 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;
- issuances 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 st
- 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;
- economic and social effects of the COVID-19 virus, including any emerging variants or other pandemics;

- 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 biopharmaceutical 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.

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- natural disasters and other calamities;
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- 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.

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**" "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. We expect that the 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, our business and operating results could be harmed, 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 ("**JOBS Act**" Act"). For as long as we continue to be an emerging growth company, we may take 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. We have taken, and in the future may take, advantage of these exemptions until such time that we are no longer an emerging growth company. 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 will remain an emerging growth company until the earliest of (i) the last day of the fiscal year following the fifth anniversary of the date of the first sale of our common stock pursuant to an effective registration statement under the Securities Act which, given the filing of the S-8 Registration Statement on August 27, 2020, will be December 31, 2025, (ii) the last day of the fiscal year in which we have total annual gross revenue of at least $1.07 billion, $1.07 billion, (iii) the last day of the fiscal year in which we are deemed to

be a “large accelerated filer” as defined in Rule 12b-2 under the Exchange Act, or (iv) the date on which we have issued more than $1.0 billion $1.0 billion in non-convertible debt securities during the prior three-year period.

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 research analysts publish about us and our business and industry. If one or more research 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 research 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.

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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, which is not guaranteed, 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;

new product development;

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

- • commercial development of our RECELL System to such areas soft tissue repair and vitiligo;

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- • 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 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 integrate new personnel could prevent us from successfully growing our company.

Our operations are subject to anti-corruption laws, including Australian bribery laws, and the FCPA 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 or interpreted.

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

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. 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 2
   The ISO 27001, Information security management systems, provides a framework and guidelines for establishing, implementing and managing an ISMS and ISO 270
   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 po
   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 a
   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 level 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") 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 primarily 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

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multiple parts of the business. We have engaged an external consultant to provide oversight and technical expertise to our ISMS process. 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 (in conjunction particularly with 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 as amended, expires on October 31, 2026. Our production plant in Ventura, California is a 27,480 square foot facility that we lease through September 30, 2024 September 30, 2027 with the right to extend the lease, at our sole option, as a result of two, three-year options that allow us to extend the lease up to an additional six years in total. 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 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.

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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 31, 2023 January 31, 2024, the Company had approximately 23,190 4 unique stockholders of record of our common stock (which includes 23,120 20,497 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 prior to the Redomiciliation, to the holders of ordinary shares in the former parent company, AVITA Australia (being AVITA Medical Pty Limited). 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]

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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 year-ended December 31, 2022 years-ended December 31, 2023 and 2021, 2022, should be read in conjunction with our consolidated financial statements and related notes included in this Annual Report.

Overview

Overview

AVITA Medical Inc. is a commercial-stage regenerative medicine company leading transforming the development and commercialization standard of care for skin restoration with innovative devices and autologous cellular therapies for skin restoration. Our therapies. At the forefront of our portfolio is our patented and proprietary RECELL® System, technology platform approved by the United States Food & Drug Administration ("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 Spray-On Skin™ Cells, an autologous skin cell suspension, that is sprayed onto Spray-On Skin™ Cells, delivering a transformative solution at the patient to regenerate natural healthy skin. point of care. This breakthrough technology serves as the catalyst for a new treatment paradigm enabling improved clinical outcomes.

Our objective is to become the leading provider of regenerative medicine addressing unmet medical needs in burn injuries, trauma injuries, full-thickness skin defects, and in dermatological and aesthetics indications, skin repigmentation, such as vitiligo. To achieve this objective, we intend plan to:

- • Become the standard of care in the U.S. burns industry by increasing RECELL System penetration in burn centers and with burn physicians
- Become the standard of care in the U.S. burns industry by increasing RECELL System penetration in burn centers
- Continue to commercialize the RECELL System in the U.S. for treatment of full-thickness skin defects
- Expand our global presence within the European Union and Australia through the exclusive use of third-party distributors.
- Launch RECELL GO following FDA approval to increase market adoption, expand our customer base, and facilitate international commercialization
- Establish commercial payor coverage for the RECELL System in the U.S. for the repigmentation of stable depigmented

vitiligo lesions, which we expect will begin during the fourth quarter of 2025
- Further invest in our RECELL System platform to automate and improve workflow, speed, and ease of use as it relates to specific indications, as well as to build upon our intellectual property estate
- Continue to build upon commercial activities in Japan through our partnership with COSMOTEC Company, Ltd with our current PMDA approval for RECELL with an indication in burns
- Develop and pursue viable commercial activities outside of the U.S. and Japan following the FDA approvals of the RECELL System for full-thickness skin defects and repigmentation of stable depigmented vitiligo lesions
- Pursue business development opportunities that are complementary to our core RECELL System indications and/or our targeted markets
- Improve our margins and profitability by leveraging our current team and infrastructure across an expanding base of business in burns and in future indications
- With the successful

execution of the exclusive distribution agreement with Stedical Scientific, Inc., we will begin distribution of the PermeaDerm® Biosynthetic Wound Matrix in the United States using our existing sales force. Refer to Note 20 of our Consolidated Financial Statements for further details

- Commercialize the RECELL System in the U.S. for use in soft tissue repair following approval of our pending PMA supplement, which was submitted to the FDA in December 2022. Following anticipated FDA approval for soft tissue repair, we plan to commence a full commercial launch in July 2023 with both inpatient and outpatient reimbursement in place
- Commercialize the RECELL System in the U.S. for use in treatment of vitiligo following approval of our pending PMA application, which was submitted to the FDA in December 2022. Subsequent to FDA approval for vitiligo, we will commence a full commercial launch following receipt of in-office reimbursement, which we anticipate will occur by January 2025
- Evaluate potential commercialization applications for the RECELL System related to skin rejuvenation and Epidermolysis Bullosa indications
- Further invest in our RECELL System platform to automate and improve workflow, speed, and ease of use as it relates to specific indications, as well as to build upon our intellectual property estate
- Continue to build upon commercial activities in Japan through our partnership with COSMOTEC Company, Ltd with our current PMDA approval for RECELL with an indication in burns
- Develop and pursue viable commercial activities outside of the U.S. and Japan once we have received FDA approval with RECELL System indications in soft tissue and vitiligo
- Pursue business development opportunities that are complementary to our core RECELL System indications and/or our targeted markets
- Improve our margins and profitability by leveraging our current team and infrastructure across an expanding base of business in burns and in future indications

Business Environment and Current Trends

The outbreak of the global pandemic and the associated response measures implemented by governments and businesses around the world, as well as subsequent accelerated and robust recovery in global business activity, have increased uncertainty in the business environment. These macroeconomic environment implications, including supply chain shortages, increased cost of healthcare, increased inflation rates, competitive and tight labor market, and other related global economic conditions and geopolitical conditions, remain unknown. Additionally, there have been various economic indicators that the United States economy may be entering a recession in upcoming quarters.

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 Ukraine, in the Middle East, the continuation of the Russia-Ukraine military conflict and/or an and the conflict in the Middle East, and potential escalation of the conflict conflicts beyond its their current scope may further weaken the global economy and could result in additional inflationary pressures and supply chain constraints.

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Although we do not believe that these trends have had a material effect on our business, financial condition or results of operations, it may in the future. If these conditions continue or worsen, they could adversely impact our future operating results. An economic recession could potentially impact the general business environment and the capital markets, which may have a material negative impact on our financial results.

Results of Operations

Year-Ended December 31, 2022 December 31, 2023, compared to the Year-Ended December 31, 2021 December 31, 2022

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

Statement of Operations Data:	Year-Ended December 31, 2022	Year-Ended December 31, 2021	$ Change	% Change	Year-Ended December 31, 2023	Year-Ended December 31, 2022	$ Change	% Change
Revenues	$ 34,421	$ 33,025	$ 1,396	4%	$ 50,143	$ 34,421	15,722	46%
Cost of sales	(6,041)	(6,104)	63	1%	(7,780)	(6,041)	(1,739)	(29)%
Gross profit	28,380	26,921	1,459	5%	42,363	28,380	13,983	49%
BARDA income	3,215	1,590	1,625	102%	1,428	3,215	(1,787)	(56)%
Operating Expenses:								
Sales and marketing expenses	(21,913)	(16,267)	(5,646)	(35)%				
General and administrative expenses	(23,330)	(21,693)	(1,637)	(8)%				
Research and development expenses	(13,857)	(15,669)	1,812	12%				
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	(59,100)	(53,629)	(5,471)	(10)%	(86,446)	(59,100)	(27,346)	(46)%
Operating loss	(27,505)	(25,118)	(2,387)	(10)%	(42,655)	(27,505)	(15,150)	(55)%
Interest expense	(16)	(29)	13	45%	(1,143)	(16)	(1,127)	*nm
Other income	892	47	845	nm*				
Other income, net					8,483	892	7,591	*nm
Loss before income taxes	(26,629)	(25,100)	(1,529)	(6)%	(35,315)	(26,629)	(8,686)	(33)%
Provision for income tax	(36)	(42)	6	14%				
Income tax expense					(66)	(36)	(30)	(83)%
Net loss	$ (26,665)	$ (25,142)	(1,523)	(6)%	$ (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 is 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 are 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 is 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 $1.7 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 Sheet.

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.

Year-Ended December 31, 2022, compared to the Year-Ended December 31, 2021

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, 2022	Year-Ended December 31, 2021	$ Change	% Change
Revenues	$ 34,421	$ 33,025	1,396	4%
Cost of sales	(6,041)	(6,104)	63	1%
Gross profit	28,380	26,921	1,459	5%
BARDA income	3,215	1,590	1,625	102%
Operating expenses:				
Sales and marketing	(21,913)	(16,267)	(5,646)	(35)%
General and administrative	(23,330)	(21,693)	(1,637)	(8)%
Research and development	(13,857)	(15,669)	1,812	12%
Total operating expenses	(59,100)	(53,629)	(5,471)	(10)%
Operating loss	(27,505)	(25,118)	(2,387)	(10)%
Interest expense	(16)	(29)	13	45%
Other income, net	892	47	845	*nm
Loss before income taxes	(26,629)	(25,100)	(1,529)	(6)%
Income tax expense	(36)	(42)	6	14%
Net loss	$ (26,665)	$ (25,142)	(1,523)	(6)%

*nm = not meaningful

Total net revenue increased by 4% or $1.4 million to $34.4 million, compared to $33.0 million in the corresponding period in the prior year year-ended December 31, 2021, which included $7.9 million from our delivery of units to managed inventory for the Biomedical Advanced Research and Development Authority ("**BARDA**") (of the Office for the Assistant Secretary for Preparedness and Response) for emergency response preparedness. Total commercial revenue, which excludes BARDA revenue, increased by 36% or $9.0 million to $34.0 million in the full year-ended December 31, 2022, compared to $25.1 million in the corresponding period in the prior year. year-ended December 31, 2021. The growth in commercial revenues was largely driven by deeper penetration within individual customer accounts along with the commencement of commercial sales with our partner COSMOTEC in Japan.

Gross profit margin was 82% and relatively flat compared to the corresponding period in the prior year. year-ended December 31, 2021.

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. Under the BARDA

contract, income of $3.2 million $3.2 million was recognized during the year-ended December 31, 2022, compared to income of $1.6 million $1.6 million for the same period in the prior year. year-ended December 31, 2021. BARDA income increased as a result of funding by BARDA for the pivotal trial for use of the RECELL System for soft tissue repair.

Total operating expenses increased by 10% or $5.5 million to $59.1 million, compared to $53.6 million in the corresponding period in the prior year. year-ended December 31, 2021.

Sales and marketing expenses increased by 35%, or $5.6 million, to $21.9 million, compared to $16.3 million recognized in the corresponding period in the prior year. year-ended December 31, 2021. Increased costs in the current year were primarily driven by higher selling costs, pre-commercialization costs and higher salaries and benefits. Higher selling costs are attributable to increased commissions due to increased revenue and higher costs for travel, hands-on professional education, and training. Increased pre-commercialization costs are driven by activities related to future RECELL launches in soft tissue repair and vitiligo. Higher salaries and benefits were primarily due to additional field personnel added to deepen penetration within individual customer accounts.

General and administrative expenses increased by 8%, or $1.6 million, to $23.3 million, compared to $21.7 million recognized in the corresponding period in the prior year. year-ended December 31, 2021. The increase was primarily driven by higher salaries and benefits and share-based

compensation expenses. Higher salaries and benefits costs were due to the expansion of our workforce to support overall operations along with severance costs associated with the termination of a former executive officer. Higher share-based compensation expense was due to the new equity grants in the current period, partially offset by the reversal of expense for unvested awards related to the termination of a former executive officer in the current year.

Research and development expenses decreased by 12%, or $1.8 million, to $13.9 million, $13.9 million, compared to $15.7 million $15.7 million recognized in the corresponding period in the prior year. year-ended December 31, 2021. Research and development costs were lower due to the following: pediatric burn study was closed for enrollment, soft tissue repair and vitiligo trial participants were in less costly follow-up phases this period compared to more costly recruitment and treatment phases in the prior period, and lower expense for sponsored research toward pipeline development in the current period. This is partially offset by higher development expenses in the current year from ongoing development of next generation devices for an automated preparation of Spray-On Skin™ Cells as compared to the prior year due to early prototype development and testing.

Net loss increased by 6%, or $1.5 million, to $26.7 million, $26.7 million, over the $25.1 million $25.1 million recognized in the corresponding period in the prior year. year-ended December 31, 2021. The increase in net loss was driven by higher operating expenses as described above, partially offset by higher revenue.

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

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

Statement of Operations Data:	Transition Period July 1 - December 31, 2021	Six Months Ended December 31, 2020	$ Change	% Change
Revenues	$ 13,956	$ 10,163	3,793	37%
Cost of sales	(1,905)	(1,750)	(155)	9%
Gross profit	12,051	8,413	3,638	43%
BARDA income	580	1,045	(465)	(44)%
Operating Expenses:				
Sales and marketing expenses	(8,472)	(6,865)	(1,607)	23%
General and administrative expenses	(10,996)	(11,703)	707	(6)%
Research and development expenses	(7,586)	(6,735)	(851)	13%
Total operating expenses	(27,054)	(25,303)	(1,751)	7%
Operating loss	(14,423)	(15,845)	1,422	(9)%
Interest expense	(17)	(10)	(7)	70%
Other income	38	8	30	375%
Loss before income taxes	(14,402)	(15,847)	1,445	(9)%
Income tax benefit (expense)	(25)	(21)	(4)	19%
Net loss	$ (14,427)	$ (15,868)	1,441	(9)%

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

Gross profit margin was 86% compared with 83% in the corresponding period in the prior year, driven largely by the extension of our shelf-life and 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. Under the BARDA contract, income of $0.6 million was recognized during the transition period ended December 31, 2021, compared to income of $1.0 million for the same period in the prior year. BARDA income declined as a result of wind-down of certain activities associated with continued pivotal trials for the treatment of pediatric scald injuries.

Total operating expenses increased 7% to $27.1 million, compared to $25.3 million in the corresponding period in the prior year.

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Sales and marketing expenses increased 23%, or $1.6 million, to $8.5 million, compared to $6.9 million recognized in the corresponding period in the prior year. Increased costs in the current year are driven primarily by pre-commercialization planning for RECELL launches in soft tissue repair and vitiligo as well higher travel costs and increased hands-on professional education and training events. Higher travel costs along with professional and training events in the current period are driven by fewer COVID-19 related travel restrictions.

General and administrative expenses decreased 6%, or $0.7 million, to $11.0 million, compared to $11.7 million recognized in the corresponding period in the prior year. The decrease was driven by certain one-time professional services costs incurred in the prior period with establishing the Company as a domestic filer with the SEC following completion of the Redomiciliation, and severance costs associated with a former executive employee in the prior year.

Research and development expenses increased 13%, or $0.9 million, to $7.6 million, compared to $6.7 million recognized in the corresponding period in the prior year. The increase was primarily attributed to ongoing development of a next generation device for more automated preparation of Spray-On Skin™ Cells for vitiligo. In addition, we had higher costs associated with an increased rate of enrollment into our soft tissue repair clinical trial, as well as other research and development costs associated with furthering the Company's pipeline.

Net loss decreased 9%, or $1.4 million, to $14.4 million, over the $15.9 million recognized in the corresponding period in the prior year. The decrease in net loss was driven by higher revenue during the year, partially offset by higher operating expenses as described above.

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 historically funded its research and development activities, and more recently its substantial investment in sales and marketing activities, through raising capital by issuing securities and it is expected that similar funding will be obtained to provide working capital if and when required. the issuance of debt. As of December 31, 2022 December 31, 2023, the Company had approximately $18.2 million $22.1 million in cash and cash equivalents and $68.1 million $66.9 million in marketable securities securities.

On October 18, 2023 (the "Closing Date"), the Company entered into a Credit Agreement (the "Credit Agreement"), by and believes it has 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 (the "Initial Commitment Amount"). In addition, an aggregate of $50.0 million will be made available in two separate $25.0 million tranches, at the Company's discretion, subject to certain net revenue requirements. The first tranche of $25.0 million will be made available on or before December 31, 2024. The second tranche of $25.0 million will be made available on or prior to June 30, 2025, only if the first tranche was drawn upon. 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 indebtedness under the Credit Agreement will be 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 certain 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. 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.

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As of the date these financial statements were issued, we believe we have sufficient cash reserves to fund operations for the next 12-months. If the Company is unable to raise capital in the future, the Company may need to curtail expenditures by scaling back certain research and development or other programs. 12 months.

Financing Activities

On March 1, 2021 April 14, 2023, we entered into a Sales Agreement with Cowen and Company, LLC pursuant to which the Company issued 3,214,250 may sell from time-to-time up to 3,799,164 shares of its common stock (the "2023 ATM Program"). During the year-ended December 31, 2023, we did not make any sales under the 2023 ATM

Program.

On October 18, 2023, as discussed above, we completed a Credit Agreement with the Lender for an aggregate amount up to $90.0 million. On the closing date of the agreement we drew $40.0 million.

On October 18, 2023, as discussed above, we issued to an affiliate of the Lender a warrant to purchase up to 409,661 shares of our common stock, at an offering exercise price of $21.50 $10.9847 per share, in with a registered underwritten offering. The gross proceeds term of 10 years from the offering were approximately $69.1 million. issuance date.

AVITA Medical also benefits from cash inflows from the BARDA contract (discussed earlier in this Annual Report). We entered into the contract on September 29, 2015, and the scope has expanded through a number of amendments to the contract. The current contract period continues to December 31, 2023, with the option by BARDA to terminate earlier. The contract provided funding for the development of the RECELL System. The contract will continue to provide funding for future use of the product as a medical countermeasure to assist disaster preparedness and response in the U.S. for mass casualty events involving burn injuries.

Under the contract, BARDA has provided funding and technical support for the development of the RECELL System. BARDA funded the completion of two randomized, controlled pivotal clinical trials, as well as Compassionate Use and Continued Access programs, and development of the health economic model demonstrating the cost savings associated with the RECELL System. BARDA exercised a contract option to fund a randomized, controlled clinical trial for a pediatric early intervention study which commenced enrollment in March 2020, and closed to enrollment in June 2021, subsequent to FDA-approval of an expanded RECELL indication for use that includes treatment of pediatric patients. Currently, the BARDA contract is supporting the Company's clinical trial in soft-tissue repair. Also included in the BARDA contract was a provision for procurement of the RECELL System under a vendor-managed inventory system to bolster emergency preparedness in the amount of $7.6 million. Further, BARDA expanded the awarded contract to provide supplemental funding of $1.6 million to support the logistics of emergency deployment of RECELL Systems for use in mass casualty or other emergency situations. We are contracted to manage this inventory of product until the federal government requests shipment or at contract termination on December 31, 2023. As of December 31, 2022, we had received cumulative payments of $37.9 million under the BARDA contract. For the year-ended December 31, 2022, we recognized $370,000 of revenue related to BARDA services provided to BARDA for emergency preparedness.

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Given the above, we believe there is presently sufficient working capital to support our committed activities, our research and development programs and other activities over the next twelve months and the Company believes it has the ability to realize its assets and pay its liabilities and commitments in the normal course of business. months.

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

(In Thousands)	Year-Ended December 31, 2022	Year-Ended December 31, 2021
Net cash used in operations	$ (19,090)	$ (18,024)
Net cash used in investing activities	(19,332)	(50,208)
Net cash provided by financing activities	900	64,065
Effect of foreign exchange rate on cash and cash equivalents and restricted cash	(26)	(87)
Net increase/(decrease) in cash and cash equivalents and restricted cash	(37,548)	(4,254)
Cash and cash equivalents and restricted cash at beginning of year	55,712	59,966
Cash and cash equivalents and restricted cash at end of year	18,164	55,712

(In thousands)	Year-Ended December 31, 2023	December 31, 2022
Net cash used in operations	$ (38,011)	$ (19,090)
Net cash provided by/(used in) investing activities	1,607	(19,332)
Net cash provided by financing activities	40,374	900
Effect of foreign exchange rate on cash and cash equivalents	(16)	(26)
Net increase/(decrease) in cash and cash equivalents	3,954	(37,548)
Cash and cash equivalents at beginning of the period	18,164	55,712
Cash and cash equivalents at end of the period	22,118	18,164

Net cash used in operating activities was $19.1 million $38.0 million during the year-ended December 31, 2022 December 31, 2023, and $18.0 million $19.1 million during the year-ended December 31, 2021 December 31, 2022. The increase was primarily resulted from higher operating costs, partially offset by increased revenues.

Net cash provided in investing activities was $1.6 million during the year-ended December 31, 2023 and cash used in investing activities was $19.3 million during the year-ended December 31, 2022 and $50.2 million $19.3 million during the during the year-ended December 31, 2021 December 31, 2022. Cash flows used for provided by investing activities were primarily attributable to maturities of marketable securities. Cash flows used in investing excess cash in activities for the year-ended December 31, 2022 is primarily attributable to purchase of marketable securities in the prior year. securities.

Net cash provided by financing activities was $0.9 million $40.4 million and $64.1 million $0.9 million for the year-ended December 31, 2022 years-ended December 31, 2023 and 2021 2022, respectively. The decrease increase in cash provided by financing activities was due to the issuance of common stock during March 2021. debt.

Capital Management and Material Cash Requirements

We aim to manage capital so that the Company continues as a going concern while also maintaining 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 the Company. us. We regularly review the Company's our capital structure and seek to take advantage of available opportunities to improve outcomes for the Company us and its our stockholders.

For the annual period ended December 31, 2022 year-ended December 31, 2023, there were no dividends paid and we have no plans to commence the payment of dividends. We have no purchase commitments or long-term contractual obligations, or purchase commitments, except for lease obligations as of December 31, 2022 December 31, 2023. Refer to Note 6 7 of our Consolidated Financial Statements for further details on our lease obligations. In addition, we have no off-balance sheet arrangements (as defined in the rules and regulations of 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 that is material to investors. We have no committed plans to issue further shares on the market but will continue to assess market conditions and the Company's cash flow requirements to ensure the Company is appropriately funded in order to pursue its various opportunities. conditions.

There is no significant external borrowing at the reporting date. Neither the Company nor any

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Table of the subsidiaries are subject to externally imposed capital requirement. Contents

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.

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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

The Company adopted ASC Topic 606 – Revenue from Contracts with Customers, on July 1, 2018. Under Topic 606, the Company recognizes

We recognize revenue when its customers obtain control of promised goods or services, in an amount that reflects the consideration which the Company expects we expect to be entitled in exchange for those goods or services.

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

1. Identify the contract with a customer
2. 2. Identify the performance obligations
3. 3. Determine the transaction price
4. 4. Allocate the transaction price to the performance obligations
5. 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 the Company we will collect the consideration to which it is entitled for goods or services to be transferred. Once the contract is determined to be within the scope of ASC 606, the Company assesses we assess the goods or services promised with each contract, determines whether those are performance obligations and the related transaction price. The Company We then recognizes recognize the sale of goods based on the transaction price that is allocated to the respective performance obligation when the performance obligation is satisfied.

The Company's

Our revenue consists primarily of the sale of the RECELL System to hospitals or other treatment centers, COSMOTEC and to BARDA (collectively, “customers”), predominately in the United States. The Company We evaluated the BARDA contract and concluded that a portion of the arrangement, such as the procurement of the RECELL system and the emergency preparedness, represents a transaction with a customer and as such are in the scope of ASC 606. Amounts received from BARDA for the research and development of the Company’s our product are classified as BARDA income in the consolidated statement Consolidated Statement of operations Operations and are accounted for under IAS 20. For further details refer to BARDA Income and Receivables below.

Revenues for commercial customers (COSMOTEC, hospitals and treatment centers) are recognized as control of the product is transferred to customers, at an amount that reflects the consideration expected to be received in exchange for the product. Revenues are recognized net of volume discounts. As such, revenue is recognized only to the extent a significant reversal of revenues is not expected to occur in subsequent periods. For the Company’s our contracts that have an original duration of one year or less, the Company we used the practical expedient applicable to such contracts and does not consider the time value of money. Further, because of the short duration of these contracts, the Company has we have not disclosed the transaction price for the remaining performance obligations as of each reporting period or when the Company expects we expect to recognize this revenue. The Company has We have further applied the practical expedient to exclude sales tax in the transaction price and expense contract fulfilment acquisition costs such as commissions and shipping and handling expenses as incurred.

For revenues related to the BARDA contract with-in within the scope of ASC 606, the Company we identified two performance obligations (i) the procurement of 5,614 RECELL units, (ii) emergency preparedness services. Through this contract the Company promises we promise to procure the product through a vendor management inventory arrangement and to stand ready to provide emergency deployment services related to the product. Emergency preparedness services include procuring necessary storage containers, housing, and maintaining the containers (and product), and providing shipping and handling services in the event of an emergency situation. This stand ready obligation is a

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series of distinct services that are substantially the same and have the same pattern of transfer to the customer, overtime as services are consumed.

The total transaction price for the portion of the BARDA contract that is with-in within the scope of ASC 606, was determined to be $9.2 million, at contract inception. The transaction price was allocated on a stand-alone selling price basis as follows: $7.6 million to the procurement of the RECELL product, which is classified as revenues when recognized in the consolidated statement Consolidated Statement of operations Operations and $1.6 million to the emergency deployment services is be classified as revenues when recognized in the consolidated statement Consolidated Statement of operations. Operations. The

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$1.6 million $1.6 million for emergency deployment includes variable consideration which is deemed immaterial to the contract as a whole. The Company We estimated the stand-alone selling price of the procurement of the RECELL product based on historical pricing of the Company’s our product at the initial execution of the contract. The Company We estimated the stand-alone selling price of the emergency deployment services performed based on the Company’s our projected cost of providing the services plus an applicable profit margin as denoted in the contract.

The Company’s

Our performance obligations are either satisfied at a point in time or over time as services are provided. The product procurement performance obligation is satisfied at a point in time, upon transfer of control of the product. As such, the related revenue for these performance obligations is recognized at a point in time as revenue within the Company’s consolidated statement our Consolidated Statement of operations. Operations. In addition to guidance under ASC 606, the Company recognizes we recognize revenue from the sales of RECELL product to BARDA for placement into vaccine stockpiles in accordance with Securities and Exchange Commission (SEC) (“SEC”) Interpretation, Commission Guidance regarding Accounting for Sale of Vaccines and BioTerror Countermeasures to the Federal Government for Placement into the Pediatric Vaccine Stockpile or the Strategic National Stockpile (SNS). Under this guidance, revenue is recognized when product is placed in the BARDA vendor-managed inventory (“**VMI**” VMI”) as control of the product has been transferred to the customer at the time of delivery to the VMI. RECELL units that have been delivered to BARDA have a product replacement obligation at no cost to BARDA due to product’s limited shelf-life. The estimated cost of the expired inventory over the term of the contract is accrued on a per unit basis at the time of delivery. The liability is released upon replacement of the product along with a corresponding reduction to inventory. The emergency preparedness services performance obligation is satisfied over time. Revenue for the emergency deployment will be recognized on a straight-line basis during the term of the contract as services are consumed over time. Services recognized are included in sales within the consolidated statement Consolidated Statement of operations. Operations. Contract costs to fulfil the performance obligation are incremental and expected to be recovered are capitalized and amortized on a straight-line basis over the term of the contract. Contract costs are included in other long-term assets.

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 30-90 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.

See Note 14 5 to our Consolidated Financial Statements included in this Annual Report for additional detail on revenue recognition.

Government Grants / BARDA Income and Receivables

AVITA Medical was

We were granted a BARDA contract in September 2015, wherein BARDA provided funding to the AVITA Medical us to support the ongoing U.S. clinical regulatory program towards FDA premarket approval, Compassionate Use program, clinical and health economics research, and U.S. pediatric burn programs.

Income under the BARDA contract is earned under a cost-plus-fixed-fee arrangement in which the Company is we are reimbursed for direct costs incurred plus allowable indirect costs and a fixed-fee earned. Billings under the contracts are based on approved provisional indirect billing rates, which permit recovery of fringe benefits, general and administrative expenses and a fixed fee.

The Company has

We have concluded that grants are not within the scope of ASC 606, as they do not meet the definition of a contract with a "customer". The Company has We have 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. Government grants and related receivables are recognized when there is reasonable assurance that the grant will be received, and all attaching conditions will be complied with. When the grant relates to an expense item, it is recognized as income over the periods necessary to match the grant on a systematic basis to the costs that it is intended to compensate. When the grant relates to an asset, the fair value is credited to deferred income and is released to the profit or loss over the expected useful life of the relevant asset by equal annual installments.

Share-Based Compensation

The Company records

We measure and recognize compensation expense on a graded-vesting method, for share-based payments to employees, including grants of stock options and restricted stock units ("RSUs"), to employees, directors and performance-based awards based on the fair market value of the awards on the date of grant. The fair value of share-based compensation awards is amortized consultants over the vesting period of the award. 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.

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The Company estimates Determining the estimated fair value of tenure-based share options using the Black-Scholes option pricing model on the date of grant. The Company estimates the fair value of options with a performance condition and market condition using the Monte-Carlo simulation model. Restricted stock units are valued based on the market price on at the grant date. 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 average of the historical volatility using daily intervals over the expected term and the derived volatility using the longest term available of 12 months.

- 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 does 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 the 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 redomiciliation 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.

- Expected dividends – None, 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 stock-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, the first plan was established in 2016 and was primarily used for Executives 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.

- 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 15 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 inASC Topic 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 the Company 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 825-10, 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

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- 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.

The Company reviews its

We review our uncertain tax positions regularly. An uncertain tax position represents the Company's 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. The Company recognizes 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 16 to our Consolidated Financial Statements included in this Annual Report for additional detail on income taxes.

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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.

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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, 2022 December 31, 2023. 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, 2022 December 31, 2023.

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, 2022 December 31, 2023, 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, 2022 December 31, 2023.

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, 2022 December 31, 2023, 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.

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Item 9B. OTHER INFORMATION

None

Item 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

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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	6566	Chairman of the Board of Directors	July 2014	December 2023June 2024
Jeremy Curnock Cook	7374	Non-Executive Director	October 2012	December 2023June 2024
Professor Suzanne Crowe	7273	Non-Executive Director	January 2016	December 2023June 2024
Jan Stern Reed	6364	Non-Executive Director	July 2021	December 2023June 2024
James CorbettRobert McNamara	6467	Non-Executive Director	June 2023	June 2024
Cary Vance	58	Non-Executive Director	June 2023	June 2024
James Corbett	65	Executive Director and Chief Executive Officer	July 2021	December 2023June 2024

Lou Panaccio has served as Non-Executive 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 Non-Executive 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 a Non-Executive Director of Unison Housing Limited, was a Non-Executive Chairman of Genera Biosystems Limited until June 2019, is a Non-Executive Chairman of Adherium Limited and a Non-Executive Director of Rhythm Biosciences Limited, both of which are publicly listed (ASX) development-stage medical diagnostics/device devices companies. We believe Mr. Panaccio is qualified to serve on our board Board of directors 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 Non-Executive Director of 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 co-created founded a European-focused seed fund with Johnson & Johnson and built the International Biotechnology Trust. Mr. Curncock 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 Dragon) appointed October 2012, Adherium Ltd appointed April 2015, Bioscience Managers UK Ltd appointed August 2017, Marine Department Ltd, appointed on January 2019, JLCC Ltd appointed December 2019, CRiL 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 Board of directors Directors based on his extensive experience in the life sciences. sciences sector.

Professor Suzanne Crowe AO has served as a Non-Executive 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 Non-Executive Director of Sonic Healthcare Ltd, a large global medical diagnostic diagnostics company. Past board positions include St. Vincent's 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 (AO) 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 Board of directors 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 Non-Executive 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 pharmacy-led, 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

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General Counsel, Corporate Secretary and Chief Corporate Governance Officer at Baxter International, Inc. Ms. Reed holds

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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: (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 currently a 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 and Chair of Compensation 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 continues to serve as an independent director for Titan Medical's Board of Directors. 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* Corbett	6465	Chief Executive Officer	September 2022
Sean EkinsDavid O'Toole	4865	Interim Chief Financial Officer	JanuaryJune 2023
Erin LibertoDonna Shiroma	4861	Chief Commercial OfficerGeneral Counsel	August 2017
Andrew Quick	52	Chief Technology Officer	April 2019
Donna Shiroma	60	General Counsel	June 2018

*Mr. Corbett was appointed as President and CEO of the Company effective as of September 28, 2022.

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

Sean Ekins **has served as the interim Chief Financial Officer since January 2023. A versatile David O'Toole** an accomplished financial leader executive with more than 20 years of extensive experience in technology, high-tech manufacturing both public company operations and entertainment industries, capital markets, Mr. Ekins O'Toole joined AVITA Medical in 2017 and currently serves 2023 as Senior Vice President of Finance. Over the course of his career, its Chief Financial Officer. Mr. Ekins has demonstrated expertise across all aspects of management and operational accounting, inclusive of SEC and financial reporting, systems analysis and implementation, and team development. Prior to joining the company, Mr. Ekins O'Toole most recently served as the North American Controller CFO of Opiant Pharmaceuticals, a biopharmaceutical company developing treatments for IXIA, a test, visibility, addiction and security solutions provider, where he led all accounting operations, including the transition and successful integration into Keysight Technologies following the company's acquisition. Previously, Mr. Ekins held accounting positions with The Walt Disney Company, Countrywide Financial Corporation, and 3D Systems, Inc. Mr. Ekins is a Certified Public Accountant and earned his Bachelor Science in Accounting from the University of Southern California. drug overdose, which was acquired

Erin Liberto has served as Chief Commercial Officer since August 2017. Ms. Liberto has more than 20 years of multifaceted global commercial experience developing, launching, managing, and optimizing healthcare portfolios with products that span therapeutic and aesthetic indications for international organizations including Allergan and Johnson & Johnson. Ms. Liberto's proficiency in long-term strategic planning has led to more than a dozen successful product launches across the United States, Europe, and Asia Pacific. Ms. Liberto holds an International MBA with a concentration in Global Marketing from Thunderbird School of Global Management in Arizona and a Bachelor of Commerce from McMaster University in Canada. 42

Andrew Quick was appointed Chief Technology Officer in April 2019 and previous to that served as Senior Vice President, Clinical Development. Mr. Quick joined the company in July of 2010 and has more than 25 years of experience in medical device design, development, clinical research and medical affairs. Mr. Quick has previously held leadership positions in the development of diagnostic instrumentation and active implantable therapeutics, including most recently with Boston Scientific Neuromodulation / Advanced Bionics from 2006 to 2010 where he led U.S. investigational device and post-market clinical research in the cochlear implant business. He also served in a series of positions with SonaMed Corporation from 1994 to 2005, including Vice President, Products and Clinical Affairs. Mr. Quick has B.S. and M.S. degrees in Biomedical Engineering from Boston University.

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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).

Donna Shiroma has served as General Counsel, Chief Compliance Officer, and Corporate Secretary since June 2018. Ms. Shiroma has more than 20 years of legal and compliance experience in thepharmaceutical and medical device industries and has played an instrumental role in transitioning companies from clinical to commercial entities. Prior to joining the Company, she served in roles of increasing responsibility as corporate counsel, general counsel, vice president of legal, chief privacy and officer, chief compliance officer, and chief commercial officer for and general counsel. Her prior professional experiences are with: Astex Pharmaceuticals from 2017 to 2018, Ascend Therapeutics from 2008 to 2017, PDL BioPharma from 2006 to 2008, and several Johnson & Johnson companies. companies from 2001 to 2006. Ms. Shiroma holds a B.S. in Environmental Sciences from University of California, Berkeley, and a Juris Doctor degree from Santa Clara University School of Law. She is licensed in the State of California as an attorney.

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;

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;

- 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;
- 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.

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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

Under the 4th Edition of the ASX's Corporate Governance Principles and Recommendations the Company is required to set measurable objectives for achieving gender diversity in the composition of its board, senior executives and workforce generally.

In the Company's 2021 Form 10-KT, the Company confirmed that it had set a target of having at least 30% of its Directors being of each gender by 2024. As of the date of this Form 10-K, the Company has achieved that target as the Company's Directors of the Company are 40% 28.5% female and 60% 71.5% male.

The Company is also in the process of developing measurable objectives for achieving gender diversity in the composition of its senior executives and workforce generally in accordance with its Code of Ethics and Business Conduct. The Company will disclose its measurable objectives, the time period for achieving those objectives and the Company's progress towards achieving those objectives in future reporting periods.

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Performance Evaluations

At least annually, the Nominating and Corporate Governance Committee will lead the Board of Directors in a self-evaluation to determine whether the board, its committees and individual directors are functioning effectively. The board completed its last self-evaluation during the fiscal year-ended December 31, 2022 December 31, 2023.

Additionally, the Nominating and Corporate Governance Committee, Compensation Committee and Audit Committee conduct an annual evaluation of each Board committee as it relates to the composition of each committee, the frequency and length of meetings, each committees primary responsibilities, and the effectiveness of the each of the committee's duties. The Nominating and Corporate Governance Committee and Compensation Committee completed its self-evaluation during the fiscal year-ended December 31, 2022. December 31, 2023

The Company's Compensation Committee has historically undertaken undertakes a review of the performance of the Company's CEO and the executive management team annually during the first quarter of the calendar year. While no performance evaluation for the fiscal year-ended December 31, 2022 took place in 2023, the Company's Compensation Committee completed a performance evaluation for the fiscal year-ended December 31, 2023 on or around January 3, 2024.

Code of Ethics

We have adopted a Code of Conduct, or 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, 2022 December 31, 2023.

Election of Directors

Our Board of Directors consists of five 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 2022 2023 annual general meeting on December 12, 2022 June 6, 2023, 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.

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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

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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
Jeremy Curnock Cook	X	Member	Interim Chair	Member
Professor Suzanne CroweLou Panaccio	X	ChairMember	Member	Chair
Jeremy Curnock Cook	X	Member		Member
Professor Suzanne Crowe	X	Member		Member
Jan Stern Reed	X	Member	Member	Chair
Robert McNamara	X		Chair	Member
Cary Vance	X	Chair	Member	

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.

We have a separately-designated standing Audit Committee established 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 three four 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 Jeremy Curnock Cook, Robert McNamara, Lou Panaccio, Cary Vance and Jan Stern Reed. 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. Corbett Curnock-Cook was the interim, Chairman of the Audit Committee from February 23, 2022 September 2022 through September 28, 2022. April 2023. Mr. Corbett stepped down from his role on the Audit Committee following his appointment to President and CEO of the Company on September 28, 2022. Prior to his appointment to President and CEO, Mr. Corbett was an independent director. Mr. Curnock Cook Robert McNamara is the current Interim Audit Committee Chair and was appointed to that role as of September 28, 2022, May 2023, following Mr. Corbett's transition his appointment to President and CEO the Board of the Company. Directors. Our Board of Directors has determined that Jeremy Curnock Cook Robert McNamara is an "audit committee financial expert," expert", as defined in item 407(d)(5)(ii) of Regulations S-K. The Audit Committee meets at least two times per year. See below for summary of attendance.

The Audit Committee held a total of six five meetings during the annual period ended December 31, 2022 December 31, 2023. The meetings attended by each Director, and the number of meetings that they were each eligible to attend, is as follows:

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Audit Committee Meeting Attendance	
	Meetings attended/Eligible to attend Meetings held

Lou PanaccioRobert McNamara	(1)	4/63/5
Jeremy Curnock Cook	(2)	4/65/5
Jan Stern ReedLou Panaccio		6/64/5
James CorbettJan Stern Reed		6/65/5
Dr. Michael PerryCary Vance	(3)	3/35
James Corbett	(4)	5/5

(1) Mr. Robert McNamara was elected to the Board of Directors on April 1, 2023. Mr. McNamara was appointed by the Board of Directors to serve as Audit Committee Chair, with effect fron 10, 2023.

(2) Mr. Jeremy Curnock Cook stepped down as a member of the Audit Committee, with effect from May 10, 2023.

(3) Mr. Cary Vance was elected to the Board of Directors on April 1, 2023. Mr. Vance was appointed by the Board of Directors to serve as an Audit Committee member, with effect from May 2023.

(4) Mr. James Corbett was not a member of the Audit Committee but was in attendance at all Audit Committee meetings in 2023 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

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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, Jan Stern Reed, Cary Vance and Lou Panaccio 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. Professor Suzanne Crowe 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 10 five meetings during annual period ended December 31, 2022 December 31, 2023. 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/Eligible to attend Meetings held
Lou PanaccioProfessor Suzanne Crowe		9/105/5
Jeremy Curnock Cook		9/104/5
Professor Suzanne CroweLou Panaccio		10/105/5
Jan Stern Reed	(1)	10/105/5
James CorbettCary Vance	(2)	6/63/5
Dr. Michael PerryJames Corbett	(3)	4/45/5
Robert McNamara	(4)	3/5

(1) Ms. Jan Stern Reed stepped down from role as Compensation Committee Chair and was appointed by Board of Directors to serve as Compensation Committee member, with effect fro 10, 2023.

(2) Mr. Cary Vance was elected to the Board of Directors on April 1, 2023. Mr. Vance was appointed by the Board of Directors to serve as member of Compensation Committee, with effect May 10, 2023. Mr. Vance was then appointed to Compensation Committee Chair beginning with August 9, 2023 meeting.

(3) Mr. James Corbett was not a member of the Compensation Committee but was in attendance at all Compensation Committee meetings in 2023 as CEO.

(4) Mr. Robert McNamara was elected to the Board of Directors on April 1, 2023.

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, Lou Panaccio, 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. Professor Suzanne Crowe 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, 2022 December 31, 2023. 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/Eligible to attend Meeting held
Lou Panaccio	(1)	2/3/4
Jeremy Curnock Cook		4/4
Professor Suzanne Crowe		4/4
Jan Stern Reed		4/4
James CorbettRobert McNamara	(2)	4/3/4
Dr. Michael PerryJames Corbett	(3)	4/4
Cary Vance	(4)	3/3 4

(1) Mr. Lou Panaccio stepped down as a member of the Nominating and Corporate Governance Committee, with effect from May 10, 2023.

(2) Mr. Robert McNamara was elected to the Board of Directors on April 1, 2023. Mr. McNamara was appointed by the Board of Directors to serve as member of the Nominating and Co Governance Committee, with effect from May 10, 2023.

(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 mee 2023 as CEO.

(4) Mr. Cary Vance was elected to the Board of Directors on April 1, 2023.

Board of Directors’ Meetings

The Board of Directors held a total of 12 seven meetings during the annual period ended December 31, 2022 December 31, 2023. 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/Eligible to attend Meetings held
Lou Panaccio		10/127/7
Jeremy Curnock Cook		11/127/7
Professor Suzanne Crowe		12/127/7
Jan Stern Reed		12/127/7
James CorbettRobert McNamara	(1)	12/124/7
Dr. Michael PerryCary Vance	(2)	9/125/7
James Corbett		7/7

(1) Mr. Robert McNamara was elected to the Board of Directors on April 1, 2023.

(2) Mr. Cary Vance was elected to the Board of Directors on April 1, 2023.

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*
- Donna Shiroma, *General Counsel*

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- Michael Holder, *Chief Financial Officer**
- Erin Liberto, *Chief Commercial Officer*
- Michael Perry, *FormerChief Executive Officer*

Pursuant to the listing requirements of ASX, we are also providing the particulars of the compensation paid to the following executive officers of the Company.

- Andrew Quick, *Chief Technology Officer*
- Donna Shiroma, *General Counsel*
- Kathy McGee, *Chief Operating Officer**

*Ceased to be Executive Officers on January 19, 2023

SUMMARY COMPENSATION TABLE

The following table sets forth for our named executive officers the following information for the annual period ended December 31, 2022 December 31, 2023 and December 31, 2021 December 31, 2022.

Name and Position	Year	Salary	Bonus	Stock Awards (1)	Option Awards (2)	All Other Compensation (3)		Total
Named Executive Officers:		**($)**	**($)**	**($)**	**($)**	**($)**		**($)**
James Corbett	2023	625,000	491,188	-	912,500	39,987	(4)	2,068,675
Chief Executive Officer	2022	156,992	100,726	-	1,232,747	5,119	(4)	1,495,584
David O'Toole	2023	245,048	146,753		1,607,150	7,875	(5)	2,006,826
Chief Financial Officer	2022	-	-	-	-	-		-
Donna Shiroma	2023	431,526	209,829	-	547,500	47,249	(6)	1,236,104
General Counsel	2022	416,902	178,662	178,672	82,524	47,155	(7)	903,915

Name and Position	Year	Salary	Bonus	Stock Awards (1)	Option Awards (2)	All Other Compensation (3)		Total
		($)	**($)**	**($)**	**($)**	**($)**		**($)**
James Corbett	2022	156,992	100,726	-	1,232,747	5,119	(4)	1,495,584

(1) Amounts in this column represent awards of restricted stock units with determined at the date of grant in accordance with U.S. GAAP based awards is subject to continuation of employment over the relevant ves

Chief Executive Officer	2021	-	-	-	-	-		-
Michael Holder	2022	430,128	184,900	178,672	82,524	48,988	(5)	925,212
Chief Financial Officer	2021	335,064	148,668	97,020	2,056,809	65,333		2,702,894
Kathy McGee	2022	411,434	176,451	178,672	82,524	46,946	(6)	896,027
Chief Operating Officer	2021	353,872	119,398	97,020	1,983,811	52,490		2,606,591
Erin Liberto,	2022	421,999	180,812	178,672	82,524	42,286	(7)	906,293
Chief Commercial Officer	2021	342,063	115,413	97,020	90,337	33,088		677,921
Andrew Quick	2022	411,857	176,484	178,672	82,524	27,518	(8)	877,055
Chief Technology Officer	2021	336,024	113,376	97,020	90,337	18,665		655,422
Donna Shiroma	2022	416,902	178,662	178,672	82,524	47,155	(9)	903,915
General Counsel	2021	342,063	115,413	97,020	90,337	18,688		663,521
Michael Perry	2022	461,512	-	-	-	342,986	(10)	804,498
Former Chief Executive Officer	2021	537,006	424,637	772,244	323,137	183,365		2,240,389

(2) Amounts in this column represent awards of stock options with the aggregate grant date fair value computed in accordance with FASB ASC Topic 718. Amounts in this c 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 15- Share-Bas Payment Plans to our Consolidated Financial Statements included in Part II, Item 8. “Financial Statements and Supplementary Data” for the assumptions used in determ the grant date fair value of option awards. The vesting of these option awards are subject to various performance or tenure related criteria.

(3) 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 t 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.

(4) Relates to accommodation costs associated with the executive commuting from his home to our offices in Valencia, California (including an amount necessary to gross u these costs for income tax purposes under U.S. federal and California State laws).

(5) Represents 401(k) employer match contribution.

(6) Comprised of (a) $28,045 in non-qualified deferred compensation employer match and (b) $19,204 in 401(k) employer match contribution.

(7) Comprised of (a) $28,855 in non-qualified deferred compensation employer match and (b) $18,300 in 401(k) employer match contribution.

(1) Amounts in this column represent awards of restricted stock units with the aggregate grant date fair value computed in accordance with FASB ASC Topic 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 subject to various performance or related criteria, including continuation of employment over the relevant vesting period.

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(2) Amounts in this column represent awards of stock options with the aggregate grant date fair value computed in accordance with FASB ASC Topic 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 13- 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.

(3) 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 relocation costs, car allowance, accommodations and medical benefits, along with related taxes on grossed up fringe benefits.

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(4) Relates to accommodation costs associated with the executive commuting from his home to our offices in Valencia, California (including an amount necessary to gross up these cost for income tax purposes under U.S. federal and California State laws).

(5) Comprised of (a) $30,688 in non-qualified deferred compensation employer match and (b) $18,300 in 401(k) employer match contribution.

(6) Comprised of (a) $28,646 in non-qualified deferred compensation employer match and (b) $18,300 in 401(k) employer match contribution.

(7) Comprised of (a) $14,400 in car allowance, (b) $9,586 in non-qualified deferred compensation employer match and (c) $18,300 in 401(k) employer match.

(8) Comprised of (a) $18,300 in 401(k) employer match contribution and (b) $9,218 in non-qualified deferred compensation employer match.

(9) Comprised of (a) $28,855 in non-qualified deferred compensation employer match and (b) $18,300 in 401(k) employer match contribution.

(10) Comprised of (a) $145,585 in relation to the travel, flight and accommodation costs associated with the executive commuting from his home to our offices in Valencia, California (including an amount necessary to gross up these cost for income tax purposes under U.S. federal, California and Colorado State laws); (b) $47,359 associated with medical benefits (including an amount necessary to gross up these cost for income tax purposes under U.S. federal, California and Colorado State laws), (c) $96,154 in vacation buy-out (d) $35,588 associated with deferred compensation employer matching contributions and (e) $18,300 in employer 401(k) match contribution

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.	1218 months
Chief Financial Officer (CFO)	Michael HolderDavid O'Toole	Open ended contract	Involuntary terminationTermination by the Company or Executive with or without Cause or resignation with Good Reason: 3-month Cause– No notice period period.	912 months
Chief Operating **Officer (COO)**	Kathy McGee	Open ended contract	Involuntary termination without Cause or resignation with Good Reason: 3-month notice period	9 months
Chief Commercial Officer (CCO)	Erin Liberto	Open ended contract	Involuntary termination without Cause or resignation with Good Reason: 3-month notice period	9 months
Chief Technology Officer (CTO)	Andrew Quick	Open ended contract	Involuntary termination without Cause or resignation with Good Reason: 3-month not	9 months
General Counsel (GC)	Donna Shiroma	Open ended contract	Involuntary termination without Cause or resignation with Good Reason: 3-month notice period	9 months
(1)	Donna Shiroma	Open ended contract	Termination payments only in by the event of employment termination for involuntary termination or termination for “good reason.”	Company or Executive with or without cause 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 proprie 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 Con 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 dat 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 nol 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 contractu 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 Compa

For the GC, 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 thef 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 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 Sala 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 e 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 GC, 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 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

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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."

"Cause" - For the Former CFO, Former COO, CCO, CTO and GC, 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. 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.

(2)

(3) "Good Reason" - For the Former CFO, Former COO, CCO, CTO and GC, 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 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 the executive's employment agreement or (v) the occurrence of a change in control provided (i) through (iv) if such conduct is not cured within thirty days of receipt of written notice by the executive. 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).

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

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salary for a period of nine months 18-months for the CEO and 12-months for the CFO or twelve months (in the case of the CEO), General Counsel, following termination; termination (ii) a pro-rated target bonus for the period during which the employee was employed in the year of termination; 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. Further, in the case options and restricted stock unit awards.

Table of the Chief Executive Officer, if his employment terminates as a result of disability or death, he or his representative will be entitled to receive: (i) a lump sum payment equal to 12 months of the employee's then-current base salary, (ii) unpaid annual bonus, and (iii) any unpaid vacation. Payment in each case is subject to the employee's, or representative's execution of a release. Contents

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, 2022 December 31, 2023 (in US dollars).

	Option awards				Stock awards	
Name	Number of securities underlying unexercised options exercisable	Number of securities underlying unexercised unearned options	Option exercise price (2)	Option expiration date (2)	Number of unearned shares, units or other rights have not vested	Market or payout value of unearned shares, units or other rights have not vested (1)
James Corbett, Chief Executive Officer	5,834	1,641	$ 12.18	12/22/2031	2,891	$ 14,455
	56,574	169,722	$ 5.64	9/28/2032		
	-	100,000	$ 14.17	6/6/2033		
David O'Toole, Chief Financial Officer	-	150,000	$ 17.00	6/15/2033		
Donna Shiroma, General Counsel	17,000	-	$ 4.38	6/25/2028	29,216	$ 146,080
	26,100	-	$ 6.38	11/1/2028		
	64,700	-	$ 5.99	11/30/2028		
	3,462	3,463	$ 20.21	7/6/2031		
	6,884	13,766	$ 4.97	7/1/2032		

					-	60,000	$ 14.17	6/6/2033

	Option awards				Stock awards	
Name	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised unearned options (#)	Option exercise price ($) (2)	Option expiration date (2)	Number of unearned shares, units or other rights have not vested (#)	Market or payout value of unearned shares, units or other rights have not vested ($) (1)
James Corbett, Chief Executive Officer	4,192	3,283	$ 12.18	12/12/2031	5,783	$ 38,168
	—	226,296	$ 5.64	9/28/2032		
Michael Holder, Chief Financial Officer	9,375	28,125	$ 22.25	3/22/2031	43,825	$ 289,245
	22,500	90,000	$ 19.91	5/11/2031		
	1,731	5,194	$ 20.21	7/6/2031		
	—	20,650	$ 4.97	7/1/2032		
Kathy McGee, Chief Operating Officer	65,250	62,750	$ 21.88	3/4/2031	43,825	$ 289,245
	1,731	5,194	$ 20.21	7/6/2031		
	—	20,650	$ 4.97	7/1/2032		
Erin Liberto, Chief Commercial Officer	40,000	—	$ 5.03	9/6/2027	43,825	$ 289,245
	21,100	—	$ 6.38	11/1/2028		
	59,700	—	$ 5.99	11/30/2028		
	1,731	5,194	$ 20.21	7/6/2031		
	—	20,650	$ 4.97	7/1/2032		
Andrew Quick, Chief Technology Officer	45,187	—	$ 6.32	5/18/2027	43,825	$ 289,245
	5,000	—	$ 6.38	11/1/2028		
	30,212	—	$ 5.99	11/30/2028		
	30,300	10,100	$ 21.35	4/1/2029		
	1,731	5,194	$ 20.21	7/6/2031		
	—	20,650	$ 4.97	7/1/2032		

(1) Amounts in this column are calculated by multiplying the closing market price of the Company' awards.

Donna Shiroma, General Counsel	17,000	—	$ 4.38	6/25/2028	43,825	$ 289,245
	26,100	—	$ 6.38	11/1/2028		
	64,700	—	$ 5.99	11/30/2028		
	1,731	5,194	$ 20.21	7/6/2031		
	—	20,650	$ 4.97	7/1/2032		

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

(1) Amounts in this column are calculated by multiplying the closing market price of the Company's stock as of December 31, 2022 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.

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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, 2022 December 31, 2023 (in US dollars). We do not provide separate compensation to our executive Directors, such such as Dr. Michael Perry, James Corbett, who served as our Chief Executive Officer during the fiscal year-ended December 31, 2022 until September 28, 2022, except in December 31, 2023.

	Fees earned in cash (1)	Stock awards (2)	Option awards (3)	Total
Non-Executive Directors				
Lou Panaccio - Chairman	$ 123,983	$ 87,500	$ 23,203	$ 234,686
Jeremy Curnock Cook	89,164	87,500	23,203	199,867
Suzanne Crowe	84,580	87,500	23,203	195,283
Jan Stern Reed	100,417	87,500	23,203	211,120
Robert McNamara	70,836	234,499	63,773	369,108
Cary Vance	66,669	234,499	63,773	364,941
Total Non-Executive Directors	**$ 535,649**	**$ 818,998**	**$ 220,358**	**$ 1,575,005**

(1) Amounts are composed of the case of Mr. James Corbett who served following: $70,000 for fees as a non-executive director only until his appointment as Chief Executiv Officer effective as at September 28, 2022.

	Fees earned in cash ($) (1)	Stock awards ($) (2)	Option awards ($) (3)	Total ($)
Non-Executive Directors				
L Panaccio - Chairman	$ 126,250	$ 87,494	$ 31,248	$ 24
J Curnock Cook	90,833	87,494	31,248	20
L Drapeau*	26,667	-	-	2
S Crowe	95,000	87,494	31,248	21
J Corbett	73,542	-	-	7
J Reed	92,500	87,494	31,248	21
Total Non-Executive Directors	**$ 504,792**	**$ 349,976**	**$ 124,992**	**$ 97**

* Mr. Drapeau retired from 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 Governanc $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 Directors during April 2022.

(1) Amounts are composed of the following: $70,00 for fees as a Board Member, $35,000 for Chair of the Board, $20,000 for Audit Committee Chair, $15,0 Compensation Committee Chair, $10,000 for Nominating and Corporate Governance Chair, $10,000 for Audit Committee Member, $7,500 for Comper Committee Member, and $5,000 for Nominating and Corporate Governance Member. Note that Mr. Drapeau's and Mr. Corbett's fees are prorated based terms as non-executive Directors.

restricted stock units with the aggregate grant date fair value computed in accordance with FASB ASC Topic 718. The fair value determined at the date of grant in accor 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 contir participant as Board Members.

	Year-Ended December 31, 2022	Transition Period Ended December 31, 2021	Year-Ended June 30, 2021
Expected volatility	72% - 113%	68% - 75%	65% - 80%
Weighted-average volatility	103%	69%	73%
Expected dividends	0%	0%	0%
Expected term (in years)	5 - 9.8	5 - 10	5 - 10
Risk-free interest rate	1.42% - 3.94%	0.88% - 1.46%	0.77% - 1.64%

16. Income Taxes

Geographic sources of loss before income taxes are as follows:

(amounts in thousands)	Year- Ended December 31, 2022	Transition Period Ended December 31, 2021	Year- Ended June 30, 2021	Year-Ended December 31, 2023	Year-Ended December 31, 2022
United States	$ (26,764)	$ (14,490)	$ (26,478)	$ (44,691)	$ (26,764)
Foreign	135	88	(67)	$ 9,376	135
Loss before income taxes	$ (26,629)	$ (14,402)	$ (26,545)	$ (35,315)	$ (26,629)

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

(amounts in thousands)	Year-Ended December 31, 2023	Year-Ended December 31, 2022
Current:		
Federal	$ -	$ -
State	66	36
Foreign	-	-
Total current	66	36
Deferred:		
Federal	-	-
State	-	-
Foreign	-	-
Total deferred	-	-
Total income tax expense	$ 66	$ 36

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(amounts in thousands)	Year-Ended December 31, 2022	Transition Period Ended December 31, 2021	Year-Ended June 30, 2021
Current:			
Federal	$ -	$ -	$ -
State	36	25	38
Foreign	-	-	-
Total current	36	25	38
Deferred:			
Federal	-	-	-
State	-	-	-
Foreign	-	-	-
Total deferred	-	-	-
Total income tax expense	$ 36	$ 25	$ 38

The provision for income taxes differs from the tax computed using the statutory United States federal income tax rate of 21%21% for the year-ended December 31, 2022, transition period ended December 31, 2021, years-ended December 31, 2023 and year-ended June 30, 2021 2022 as a result of the following items:

(amounts in thousands)	Year-Ended December 31, 2023	December 31, 2022
Tax benefit at U.S. statutory rate	$ (7,416)	$ (5,592)
State income taxes	66	35
Foreign rate differential	375	5
Share-based compensation	774	719
Fair value change in debt and warrants	494	-
Foreign exchange gain/(loss) on intercompany trade balances	(2,354)	-
Gain of transfer of intellectual property	2,804	-
Permanent differences	554	(30)
Change in tax rate	(847)	-
Net change in valuation allowance	5,616	4,899
Income tax expense	$ 66	$ 36

(amounts in thousands)	Year-Ended December 31, 2022	Transition Period Ended December 31, 2021	Year-Ended June 30, 2021
Tax expense (benefit) at U.S. statutory rate	$ (5,592)	$ (3,024)	$ (5,574)
State income taxes	35	25	36
Foreign rate differential	5	5	(5)
Share-based compensation	719	997	(27)
Permanent differences	(30)	29	233
Net change in valuation allowance	4,899	1,993	5,375
Income tax expense (benefit)	$ 36	$ 25	$ 38

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

(amounts in thousands)	Year-Ended December 31, 2022	Transition Period Ended December 31, 2021	Year-Ended June 30, 2021	Year- Ended December 31, 2023	December 31, 2022
Deferred tax liabilities					
ROU Asset	$ (229)	$ (404)	$ (389)	$ (618)	$ (229)
Intangible assets	(11)	(25)	—	-	(11)
Property, plant and equipment	-	(5)	(5)	(6)	-
Total deferred tax liabilities	$ (240)	$ (434)	$ (394)	$ (624)	$ (240)
Deferred tax assets					

Property, plant and equipment	$ 3	$ —	$ —	$ -	$ 3
Accrued expenses	1,833	1,151	686	2,714	1,833
Intangible assets	—	—	262	12	-
Stock based compensation	3,405	2,739	3,215	3,763	3,405
Lease liability	247	428	415	657	247
Research and development	2,215	—	—	5,357	2,215
Net operating loss carryforward	48,413	46,918	44,282	50,438	48,413
Other	630	483	609	992	630
Total deferred tax assets	$ 56,746	$ 51,719	$ 49,469	$ 63,933	$ 56,746
Less valuation allowance	(56,506)	(51,285)	(49,075)	(63,309)	(56,506)
Net deferred tax assets	$ 240	$ 434	$ 394	624	240
Net deferred tax assets / (liabilities)	$ —	$ —	$ —	$ -	$ -

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At December 31, 2022 December 31, 2023, the Company and its subsidiaries had net operating loss carryforwards for federal, state, United Kingdom, and Australia income tax purposes of $129.5 $145.2 million, $83.5 $89.5 million, $28.4 $29.9 million and $36.0 $24.9 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 and foreign provisions. Of these carryforwards, $21.7 $19.5 million will expire, if not utilized, between 2026 2028 through 2038. 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 $56.5 $63.3 million and $51.3 million as of December 31, 2022, December 31, 2021, respectively. The Company has established a valuation allowance against its net deferred tax asset of $49.1 $56.5 million as of June 30, 2021. December 31, 2023 and 2022, 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.

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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% 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 not identified any uncertain tax positions as of December 31, 2022, December 31, 2021, December 31, 2023 and June 30, 2021. 2022.

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, 2006 and forward. The Company also remains subject to income tax examinations for international income taxes for fiscal years ended June 30, 2018 June 30, 2019 through December 31, 2021 December 31, 2022, and for certain other U.S. state and local income taxes generally for the fiscal years ended June 30, 2018 June 30, 2019 through December 31, 2021 December 31, 2022.

17. Loss per Share

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

	Year-Ended December 31, 2022	Transition Period Ended December 31, 2021	Year-Ended June 30, 2021
	(in thousands, except per share amounts)		
Net Loss	$ 26,665	$ 14,427	$ 26,583
Weighted-average common shares—outstanding, basic	25,000	24,915	22,674
Weighted-average common shares—outstanding, diluted	25,000	24,915	22,674

Net loss per common share, basic	$ 1.07	$ 0.58	$ 1.17
Net loss per common share, diluted	$ 1.07	$ 0.58	$ 1.17

	Year-Ended	
	December 31, 2023	December 31, 2022
(in thousands, except per share amounts)		
Net loss	$ 35,381	$ 26,665
Weighted-average common shares—outstanding, basic and diluted	25,331	25,000
Net loss per common share, basic and diluted	$ 1.40	$ 1.07

	Year-Ended	
	December 31, 2023	December 31, 2022
Anti-dilutive shares excluded from diluted net loss per common share:		
Stock options	2,690,158	2,235,446
Restricted stock units	235,132	460,518
ESPP	91,152	-
Warrants	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 710-10 17,927*Compensation - General*, shares of common stock held by the rabbi trust are excluded from the denominator in the basic and diluted EPS net loss per common share calculations. As of December 31, 2023 and 2022 a total of 99,106 and 17,927, shares of common stock were excluded, respectively. For details on shares of common stock held by the rabbi trust refer to Note 18. 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. As Because the Company has reported a net loss for all periods presented years-ended December 31, 2023 and 2022, diluted net loss per common share is the same as the basic net loss per share. share for those periods.

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18. Retirement Plans

The Company offers a 401(k)-retirement savings plan (the "**401(k) Plan**" "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%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 $1,027,000, $966,000, $1.2 million and $733,000 in $1.0 million for the year-ended December 31, 2022 years-ended December 31, 2023, the transition period ended December 31, 2021 and the year-ended June 30, 2021. 2022, respectively.

Non-qualified deferred compensation plan

The Company's non-qualified deferred compensation plan (the "**NQDC plan**" "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

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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%4% to 6%6% (depending on level) of employee contributions. These matching employer contributions are vested over a two-year period with 25%25% vesting on year one and 75%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 year-ended December 31, 2022 years-ended December 31, 2023 and the transition period ended December 31, 2021 2022 were $258,000 $171,000 and $16,000, $258,000, respectively. The Company's deferred compensation plan liability was $1,348,000 $3.8 million and $262,000 $1.3 million as of the year-ended December 31, 2022 December 31, 2023 and 2021. As of December 31, 2022, the Company has $1.27 million in non-qualified deferred compensation plan liability 2022, respectively. These amounts are split between current and $78,000 in other current liabilities in long term on the Consolidated Balance Sheets. As of December 31, 2021 amounts are recorded December 31, 2023 and 2022, $168,000 and $78,000 is included in Current non-qualified deferred compensation plan liability and $3.7 million and $1.3 million in Non-qualified deferred compensation liability, respectively. During the

years-ended December 31, 2023 and 2022, the Company had a payout of approximately $950,000 in the Consolidated Balance Sheets. The Company did not have a NQDC plan deferred compensation liability for the year-ended June 30, 2021. 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.

The Refer to Note 4, Fair Value Measurements for the fair values of the Company's deferred compensation plan assets and liability are included in the table below. Note that the Company did not have NQDC plan for the year-ended June 30, 2021. For additional information on the fair value hierarchy COLI policies and the inputs used to measure fair value, see Note 5, Fair Value Measurements. NQDC liability.

	Fair Value as of December 31, 2022				Fair Value as of December 31, 2021			
(in thousands)	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Corporate-owned life insurance policies (1)	-	1,238	-	1,238	-	304	-	304
Non-qualified deferred compensation plan liability	-	1,348	-	1,348	-	262	-	262

(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.

(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.

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,*Compensation — Stock Compensation*, 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, 2023 and December 31, 2022, a total of 81,052 and 253,048, shares awards have been deferred, and during the quarter-ended September 30, 2022, a total of 17,927 awards vested. 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. A For the years-ended December 31, 2023 and December 31, 2022 a total of 99,106 and 17,927 shares were vested at the redemption value of $127,000. $1.1 million and $127,000, respectively.

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TheThe following table summarizes the eligible share award activity as of December 31, 2023 and December 31, 2022. There was no activity as of December 31, 2021 and June 30, 2021.

	As of
(in thousands)	December 31, 2022
Non-qualified deferred compensation share awards:	
Balance at inception/beginning of period	-
Change in classification of deferred compensation share awards	192
Share-based compensation expense	471
Change in redemption value	21
Vesting of share awards held by NDQC	(127)
Ending Balance	557

	As of	
(in thousands)	December 31, 2023	December 31, 2022
Non-qualified deferred compensation share awards:		
Balance at inception/beginning of period	$ 557	$ -
Change in classification of deferred compensation share awards	-	192
Stock-based compensation expense	518	471
Change in redemption value	1,019	21
Vesting of share awards held by NDQC	(1,401)	(127)
Ending Balance	$ 693	$ 557

19. Deed of Cross Guarantee

The Company (as the parent entity of the AVITA Group) is party to a deed of cross guarantee dated June 29, 2020 ("**Deed**") with each of its Australian wholly-owned subsidiaries, namely:

- AVITA Medical Pty Ltd (ACN 058 466 523);
- C3 Operations Pty Ltd (ACN 090 161 505);
- Visiomed Group Pty Ltd (ACN 003 010 580); and
- Infamed Pty Limited (ACN 084 800 653),

(together, the "**Australian Subsidiaries**" "Australian Subsidiaries").

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The Company and the Australian Subsidiaries were the only parties to the Deed at December 31, 2022 December 31, 2023 and comprise the "closed group" for the purposes of the Deed (and also the "extended closed group"). No parties were added to or removed from the Deed, or subject to a notice of disposal, during or since the financial year-ended December 31, 2022 December 31, 2023. Since December 31, 2022 December 31, 2023, there has been no change in ownership of any of the Australian Subsidiaries.

By entering into the Deed, the Company and the Australian Subsidiaries have guaranteed the debts of each other.

Relief under ASIC Corporations (Wholly-owned Companies) Instrument 2016/785

By entering into the Deed, the Australian Subsidiaries have been relieved from the requirement to prepare a financial report and directors' report for the financial year-ended December 31, 2022 December 31, 2023 under *ASIC Corporations (Wholly-owned Companies) Instrument 2016/785*.

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Consolidated financial information of parties to the Deed

The financial statements below are additional disclosure items specifically required by the Australian Securities and Investments Commission and represent the consolidated financial statements of the entities that are party to the Deed only (being the 'closed group' and also the 'extended closed group' under the Deed).

	Year-Ended
(in thousands)	**December 31, 2023**
Revenues	$ 222
Cost of sales	(263)
Gross profit	(41)
Operating Expenses:	
Sales and marketing expenses	(206)
General and administrative expenses	(79)
Product development expense	(28)
Total operating expenses	(313)
Other income	21,717

Net Income	$ 21,363

(in thousands)	As of December 31, 2023
ASSETS	
Cash	$ 25
Prepaids and other current assets	1
Total assets	26
LIABILITIES AND STOCKHOLDERS' EQUITY	
Accounts payable and accrued liabilities	1
Accrued wages and fringe benefits	4
Other current liabilities	7
Total liabilities	12
Accumulated equity	14
Total stockholders' equity	14
Total liabilities and stockholders' equity	$ 26

20. Subsequent Events

Ventura Lease Extension

On January 1, 2024, the Company executed the second amendment to the Ventura Warehouse to extend the lease for an additional three years until September 30, 2027. The lease was set to expire in September 30, 2024. The average monthly rent payment on the extended lease is approximately $36,000 per month. The Company will account for the lease extension during the three months ended March 31, 2024.

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Stedical Scientific Distributor Agreement

On January 26, 2024, the Company entered into an exclusive multi-year distribution agreement with Stedical Scientific, Inc. ("Stedical") to commercialize PermeaDerm® Biosynthetic Wound Matrix 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 agreement, the Company will 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. During February 2024, the Company purchased a total of $2.5 million in inventory from Stedical Scientific.

OVIK Health was the distributor for Stedical from March 20, 2020 until January 26, 2024. As part of the distribution agreement with Stedical, the Company entered into a separate agreement with OVIK Health. As part of this agreement Stedical and OVIK Health agreed to terminate their previous distribution agreement and all rights thereunder, transfer customer lists to the Company and the purchase by the Company of existing inventory held by OVIK Health for $1.2 million. As consideration for the covenants, agreements, undertakings and purchase of the inventory the Company paid OVIK Health a total of $1.75 million. The inventory purchased from OVIK is included in the purchase by Stedical.

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.

Exhibit 10.30

STANDARD INDUSTRIAL/COMMERCIAL MULTI-TENANT LEASE GROSS

AMERICAN INDUSTRIAL REAL ESTATE ASSOCIATION

1. **Basic Provisions ("Basic Provisions").**

1.1 **Parties:** This Lease ("Lease"), dated for reference purposes only, December 06, 2023 is made by and between **Hartco Ventura Inc.**_____**(“Lessor”)** and **Avita Medical Americas**_____**(“Lessee”),** (collectively the **"Parties,"** or individually a **"Party**").

1.2(a) Premises: That certain portion of the Building, including all improvements therein or to be provided by Lessor under the terms of this Lease, commonly known by the street address of 3007 Bunsen Avenue, Unit G , located in the City of ___Ventura_____, County of ____Ventura_____, state of California with zip code___93003__, as outlined on Exhibit ___A_____attached hereto ("Premises"). The "Building" is that certain building containing the Premises and generally described as (describe briefly the nature of the Building):An approximately 3360 square feet (unit -G) ,Part of a larger 88,080 square feet multi-tenant industrial complex located on approximately 192,500 square feet of MPD zoned land.

In addition to Lessee's rights to use and occupy the Premises as hereinafter specified, Lessee shall have non-exclusive rights to the Common Areas (as defined in Paragraph 2.7 below) as hereinafter specified, but shall not have any rights to the roof, exterior walls or utility raceways of the Building or to any other buildings in the Industrial Center. The Premises, the Building, the Common Areas, the land upon which they are located, along with all other buildings and improvements thereon, are herein collectively ref to as the "industrial Center." (Also see Paragraph 2.)

1.2(b) **Parking**: _Four (4) unreserved vehicle parking spaces ("**Unreserved Parking Spaces**"); and __Twelve (2)___ _____ reserved vehicle parking spaces ("**Reserved Parking Spaces**"). (Also see Paragraph 2.6.)

(in thousands)	Year-ended December 31, 2022
Revenues	$ 568
Cost of sales	(243)

1.3 **Term**:____1____years and _____0___months ("**Original Term**") commencing__January 1,2024 ("**Commencement Date**") and ending __December 31,2024_____ (**Date**"). (Also see Paragraph 3.)

(in thousands)	As of December 31, 2022
ASSETS	
Cash	$ 337

Cost of sales	(248)
Gross profit	325
Operating Expenses:	
Sales and marketing expenses	(231)
General and administrative expenses	(14)
Product development expense	(9)
Total operating expenses	(254)
Other Income	1
Net loss	$ 72

Cash	$ 301
Accounts receivable, net	2
Prepaids and other current assets	1,440
Inventory	46
Total assets	1,825
LIABILITIES AND STOCKHOLDERS' EQUITY	
Accounts payable and accrued liabilities	7
Accrued wages and fringe benefits	75
Other current liabilities	1,728
Total liabilities	1,810
Contributed equity	232,747
Reserves	31,476
Accumulated deficit	(264,208)
Total stockholders' equity (deficit)	15
Total liabilities and stockholders' equity (deficit)	$ 1,825

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