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, 2023

☐ 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: 001-40254

MOVANO INC.
(Exact name of registrant as specified in its charter)

Delaware	**82-4233771**
(State of incorporation)	*(I.R.S. Employer Identification No.)*

6800 Koll Center Parkway, Pleasanton, CA 94566
(Address of principal executive office) (Zip code)

(415) 651-3172
(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	MOVE	The Nasdaq Stock Market LLC

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, 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 elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

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

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

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

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter. $52,910,782.

As of April 10, 2024, there were 98,225,068 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The registrant intends to file a definitive proxy statement pursuant to Regulation 14A or an amendment to this Form 10-K within 120 days after the end of the fiscal year ended December 31, 2023. Portions of such proxy statement or amendment to this Form 10-K are incorporated by reference into Part III of this Form 10-K.

MOVANO, INC.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that are intended to be covered by the "safe harbor" created by those sections. Forward-looking statements, which are based on certain assumptions and describe our future plans, strategies and expectations, can generally be identified by the use of forward-looking terms such as "believe," "expect," "may," "will," "should," "would," "could," "seek," "intend," "plan," "goal," "project," "estimate," "anticipate," "strategy", "future", "likely" or other comparable terms and references to future periods. All statements other than statements of historical facts included in this Annual Report on Form 10-K regarding our strategies, prospects, financial condition, operations, costs, plans and objectives are forward-looking statements. Examples of forward-looking statements include, among others, statements we make regarding: expectations for revenues, cash flows and financial performance, the anticipated results of our development efforts and the timing for receipt of required regulatory approvals and product launches.

Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. Important factors that could cause our actual results and financial condition to differ materially from those indicated in the forward-looking statements include, among others, the following:

- our limited operating history and our ability to achieve profitability;
- our ability to continue as a going concern and our need for and ability to obtain additional capital in the future;
- our ability to demonstrate the feasibility of and develop products and their underlying technologies;
- the impact of competitive or alternative products, technologies and pricing;
- our ability to attract and retain highly qualified personnel;
- our dependence on consultants to assist in the development of our technologies;
- our ability to manage the growth of our Company and to realize the benefits from any acquisitions or strategic alliances we may enter in the future;
- the impact of macroeconomic and geopolitical conditions, including increases in prices caused by rising inflation;
- our dependence on the successful commercialization of the Evie Ring;
- our dependence on third parties to design, manufacture, market and distribute our products;
- the adequacy of protections afforded to us by the patents that we own and the success we may have in, and the cost to us of, maintaining, enforcing and defending those patents;
- our ability to obtain, expand and maintain patent protection in the future, and to protect our non-patented intellectual property;
- the impact of any claims of intellectual property infringement, trade secret misappropriation, product liability, product recalls or other claims;
- our need to secure required FCC, FDA and other regulatory approvals from governmental authorities in the United States;
- the impact of healthcare regulations and reform measures;
- the accuracy of our estimates of market size for our products;
- our ability to implement and maintain effective control over financial reporting and disclosure controls and procedures;
- our success at managing the risks involved in the foregoing items; and
- other factors discussed in the Management's Discussion and Analysis of Financial Condition and Results of Operations and Risk Factors sections of this Form 10-K.

Any forward-looking statement made by us in this report is based only on information currently available to us and speaks only as of the date on which it is made. We undertake no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

PART I

As used in this Annual Report on Form 10-K, unless otherwise stated or the context otherwise requires, the terms "Movano," "Movano Health," "we," "us," "our" and the "Company" refer to Movano Inc.

Item 1. Business

Overview

Movano Inc., dba Movano Health, a Delaware corporation, is developing a platform to deliver purpose-driven healthcare solutions to bring medical-grade, high-quality data to the forefront of consumer health devices.

Our initial commercial product in development is the Evie Ring, a wearable designed specifically for women that was launched in November 2023. The Evie Ring combines health and wellness metrics to give a full picture of one's health, which includes resting heart rate, heart rate variability ("HRV"), blood oxygen saturation ("SpO_2"), respiration rate, skin temperature variability, period and ovulation tracking, menstrual symptom tracking, activity profile, including steps, active minutes and calories burned, sleep stages and duration, and mood tracking. The device provides women with continuous health data distilled down to simple, yet meaningful, insights to help them make manageable lifestyle changes and take a more proactive approach that could mitigate the risks of chronic disease.

We launched the Evie Ring as a general wellness device without any FDA premarket clearances. Separately, we are planning to seek FDA clearances on our medical device, which will be sold under the brand name Evie Med. We believe Evie Med will be one of the first patient wearables with FDA clearance on the entire system, both hardware and software, differing from our competition which sometimes gets FDA clearance on an individual algorithm under "Software as a Medical Device" guidance. In July 2023, we filed our first 510(k) submission to the FDA for the Evie Med Ring's pulse oximeter to monitor pulse and SpO_2 data, following a successful pivotal hypoxia trial during the fourth quarter of 2022. The submission was reviewed by the FDA, and the Company is working with the agency to address the review commentary. With progressive changes in the device and significant additional requirements from FDA since the initial submission, we opted to withdraw the 2023 510(k). Armed with FDA's review of the initial 510(k) and excellent results from a second pivotal hypoxia trial using the production model ring completed in the first quarter of 2024, we plan to resubmit in April 2024 and expect a decision by July 2024. The FDA clearance of these metrics, sold via prescription under the brand name Evie Med, would ensure clinical-level confidence in Evie Med's monitoring capabilities and could make the device attractive to clinicians and to facilities engaged in clinical trials for at-home and/or long-term patient monitoring.

In addition to the Evie Ring and Evie Med Ring, we are developing the smallest ever patented and proprietary System-on-a-Chip ("SoC") designed specifically for blood pressure or continuous glucose monitoring ("CGM") systems. We built the integrated sensor from the ground up with multiple antennas and a variety of frequencies to achieve an unprecedented level of precision in health monitoring. We are currently conducting clinical studies with the SoC and developing algorithms that, if successful, will enable us to develop wearables that can monitor glucose non-invasively and blood pressure without a cuff. To that end, we are currently conducting a longitudinal study (n=100) to program the effects of stress on blood pressure over time, with results pending. Our end goal is to bring a Class II FDA-cleared device to the market that includes CGM and cuffless blood pressure monitoring capabilities. Over time, our technology could also enable the measurement and continuous monitoring of other health data.

Problem

The scale of the chronic disease health crisis is enormous, and we believe the need to address it is immediate. The United States spent over 17% of its GDP on healthcare in 2022, and according to the Centers for Disease Control and Prevention (CDC), six in ten Americans live with at least one chronic disease.

Coronavirus disease ("COVID-19") has disproportionately affected the wellbeing of those with chronic conditions and the pandemic has created a heightened awareness about the importance of health and the high risk of complications. People have become more sensitive to the fact that managing health is not just about being physically fit but may also be a predictor of future quality of life and even lifespan. There is a need for optimized, accurate monitoring and maintenance of high-risk populations, such as those living with, or at heightened risk of, chronic conditions.

Wearable medical technology today, including CGMs and blood pressure monitors, have made it easier for those affected by chronic diseases, but many devices are still invasive, inconvenient and/or expensive.

Diabetes

Diabetes is a chronic, life-threatening disease for which there is no known cure. The disease is caused by the body's inability to produce or effectively utilize the hormone insulin, which prevents the body from adequately regulating blood glucose levels. If glucose levels are not managed properly, it can lead to serious health conditions and complications, including heart disease, limb amputations, loss of kidney function, blindness, seizures, coma and even death. According to the 2021 International Diabetes Federation Atlas, an estimated 537 million people worldwide had diabetes as of the date of the report. The number of people with diabetes ("PWDs") worldwide is estimated to grow to 783 million by 2045, driven primarily by growth in type 2 diabetes and due to various reasons, including a change in dietary trends, an aging population and increased prevalence of the disease in younger people.

To maintain blood glucose levels within the normal range, many PWDs seek to actively monitor their blood glucose levels. The traditional method of self-monitoring of blood glucose requires lancing the fingertips, commonly referred to as finger sticks, multiple times per day to obtain a blood drop to be applied to a test strip inside a blood glucose meter. This method of monitoring glucose levels is inconvenient and can be painful. Additionally, because each measurement represents a single blood glucose value at a single point in time, it provides limited information regarding trends in blood glucose levels over the course of the day, month, or year.

In contrast, CGMs are generally less painful and typically involve the insertion of a microneedle sensor into the body to measure glucose levels in the interstitial fluid throughout the day and night, providing real-time data that shows trends in glucose measurements. As a result, CGMs improve glycemic control and quality of life, particularly in individuals with type 1 diabetes treated with continuous subcutaneous insulin infusion or multiple daily insulin injection therapy and help support avoidance of hypoglycemia.

However, most of today's CGMs are still invasive, inconvenient, and expensive. Many require an implant that must be replaced after 10-14 days. This process can be uncomfortable, increases susceptibility to infections, and is expensive to manage. As a result, the vast majority of PWDs do not use a CGM. Moreover, the broader health-conscious population, including individuals with prediabetes, lacks the ability to easily monitor blood glucose levels, which can serve as a proxy for metabolic health and risk for chronic diseases. Notwithstanding the above, demand for CGMs, in general, continues to increase, with approximately three million worldwide users and industry sales estimated at more than $4.7 billion in 2021, according to published Wall Street analyst estimates.

Hypertension

Blood pressure is the pressure on the walls of arteries caused by the heart pumping blood through the circulatory system. When the force against blood vessel walls becomes too high, the heart works harder, which can cause damage to blood vessels, ultimately leading to a condition called hypertension, or high blood pressure.

According to the American Heart Association, high blood pressure affects nearly one third of the adult population worldwide. Called "the silent killer," many people are not aware that they have high blood pressure until it is too late because there are typically no symptoms. However, hypertension can lead to life-threatening conditions like heart attacks, strokes, kidney damage, amongst other problems. While there is no cure, using prescription medications, making dietary changes, increasing activity levels and maintaining awareness of blood pressure can significantly reduce the risks associated with hypertension.

Because hypertension usually has no symptoms, the only way to detect hypertension is through a blood pressure test. The test traditionally requires placement of a cuff with a pressure gauge around the upper arm that is inflated to squeeze the blood vessels. When the cuff is fully inflated, no blood flow occurs through the artery. As the cuff is deflated below the systolic pressure, the reducing pressure exerted on the artery allows blood to flow through it and sets up a detectable vibration in the arterial wall. When the cuff pressure falls below the patient's diastolic pressure, blood flows smoothly through the artery in the usual pulses, without any vibration being set up in the wall.

In recent years, blood pressure monitoring devices have become available for personal, in-home use, so people can gain an understanding of their blood pressure in between their regular doctor visits. While there are medical device and consumer electronic companies selling blood pressure monitors today, they still have limitations and tend to be cumbersome. Some provide blood pressure estimates, rather than exact readings. Often times, blood pressure cuffs require a very specific fit based on arm size and can be very sensitive to placement on the arm, movement and body position. If not used properly, errors in measuring blood pressure can occur. Most blood pressure cuffs are not continuous, which require the user to remember to take readings at the same general time of day to avoid inconsistencies when looking at trends over time. Notwithstanding the above, demand for blood pressure monitoring devices, in general, continues to increase, with industry sales estimated at approximately $3.9 billion in 2022, according to Grand View Research.

If we can develop a device that can successfully integrate blood pressure measurements continuously and non-invasively, the device could potentially help individuals understand in real-time how food intake, sleep, activity levels, stress and more can directly impact their blood pressure and their heart health. With the ability to get actionable feedback, people should be able to be more engaged in making better decisions for their health.

Solution

As the healthcare market transitions from a practice of treating the sick to a consumer-driven market focused on preventative care and longevity, consumers' appetite for digital health offerings is increasing and there is a significant and growing interest in digital health technology that allows users to address their unique needs and life circumstances. We believe women are particularly impacted by the state of healthcare today and are looking for tools that give them greater control over their health and confidence in their ability to self-manage and optimally prepare for potential health risks. To maximize their utility, we believe these tools should be intelligent, affordable, and fit seamlessly into every woman's lifestyle.

Consequently, we are creating intelligent, sleek and comfortable solutions that sit at the intersection of the medical and consumer device market, providing medical-grade diagnostics in addition to lifestyle fitness monitoring. Our first product is the Evie Ring, which is a wearable designed specifically for women.

The Evie Ring combines health and wellness metrics to give a full picture of one's health, which includes resting heart rate, HRV, SpO_2, respiration rate, skin temperature variability, period and ovulation tracking, menstrual symptom tracking, activity profile, including steps, active minutes and calories burned, sleep stages and duration, and mood tracking. This data is delivered through a mobile app which aims to simplify how data is presented, moving away from complex graphs and charts, and turning biometric data into actionable insights that will help women make manageable lifestyle changes and take a more proactive approach to mitigating the risks of chronic disease.

In future iterations of this product or another wearable device developed by Movano Health, we plan to measure glucose, blood pressure and heart rate without a needle or cuff. We will do this directly from the blood vessel by utilizing mmWave RF to probe the arteries to identify various RF properties, including RF connectivity, permittivity, and reflectivity. As these properties change, we can measure the changes in glucose and blood pressure concentrations in the blood vessels. Using our signal processing algorithms, we intend to separate the pulse pressure and glucose waveforms to jointly solve for blood pressure, pulse, and glucose. With additional sensors and an accelerometer, we expect we will also be able to estimate SpO_2 measurements and measure steps and calories. We intend to provide the user real-time data, including trending, through our proprietary cloud-based network app, and enable data sharing with healthcare providers, caregivers, and family to optimize care and reinforce positive behaviors and behavioral change. By providing knowledge about glucose levels, blood pressure, heart rate, HRV, sleep, respiration, temperature, blood oxygen, steps and calories, we believe our end-to-end solution will be a valuable preventative care tool that will help users make smarter health decisions, ultimately increasing a person's ability to self-manage chronic conditions and reducing the frequency of doctor and hospital visits.

The Evie Ring, pictured above, is currently in market and available in three finishes.

Proprietary Technology

The Evie Ring uses a multitude of optical sensors to estimate a variety of analytics, including SpO_2 and heart rate measurements, an accelerometer to measure steps and calories, as well as a battery, a charging integrated circuit, flash to store data, and Bluetooth to communicate with our mobile application.

In future products, we plan to incorporate our patented RF technology that leverages ultra-wideband multi-antenna RF with advanced signal processing and interference cancellation, machine learning and the cloud. Our RF technology is deeply rooted in military and telecom applications, and key members of our engineering team worked with the pioneers of this technology.

We intend to leverage the potential of this technology to design miniature, dynamic integrated circuits ("ICs") and proprietary algorithms that, if small and low-powered enough, may be embeddable into a variety of devices including a wearable, standalone phone case, ring or skin patch. These devices could communicate on a minute-by-minute basis, using Bluetooth Low Energy ("BLE") to a smartphone or a mobile device. Our intention is to design the system to be capable of connecting to Movano Health's cloud service, which is currently in development. Combined with our cloud analytics, we expect the technology will allow medical professionals, family members, caregivers and individuals to understand trends related to heart rate, HRV, glucose and blood pressure and make educated decisions about health, care and treatment based on that data. The goal of our development efforts is to combine machine learning with different statistical signal processing algorithms, which we believe will enable us to take advantage of multiple strains of continuous, real time Movano Health sensor data to generate advanced analytics like predictive alerts, risk profiles, and more, which are personalized for each wearer.

We believe that the main advantage of our technology under development, as compared to certain existing technologies like cameras and infrared ("IR") sensors, will be the ability to achieve fine RF mapping in a cost-effective and small form factor. As it relates to CGM and blood pressure monitor applications, we believe that our competitive edge will be that our technology solution can be deployed on a non-invasive and cuffless basis, packaged in a wearable device, so wearers feel like people, not patients, and priced more affordably for users and payers compared to existing devices.

Our Planned Solution

Our initial commercial product is the Evie Ring, which is a wearable designed specifically for women that was launched in November 2023. The Evie Ring combines health and wellness metrics to give a full picture of one's health, which includes resting heart rate, HRV, SpO_2, respiration rate, skin temperature variability, period and ovulation tracking, menstrual symptom tracking, activity profile, including steps, active minutes and calories burned, sleep stages and duration, and mood tracking. The device provides women and their network of caregivers with continuous health data distilled down to simple, yet meaningful, insights to help them make manageable lifestyle changes and take a more proactive approach to help mitigate the risks of chronic disease.

We initially launched the Evie Ring as a general wellness device without any FDA premarket clearances, but we are planning to seek FDA clearances on our medical device sold under the brand Evie Med for vital signs monitoring capabilities which would make it one of the first patient wearables that offers an FDA cleared device—hardware and software—and not only software for medical use.

We are also testing a wrist-worn wearable prototype that contains our proprietary and patented SoC. In its current state, this prototype allows us to collect data, which we are using to generate glucose, blood pressure and heart rate estimates. The accuracy of the technology will be refined as our algorithms are improved and as we test larger cross sections of people in our external studies.

In October 2023, we announced the results of our Institutional Review Board (IRB)-approved blood pressure clinical study, which incorporated our SoC and demonstrated a level of accuracy within the standards recognized by the FDA for blood pressure monitoring devices. Our algorithm for blood pressure monitoring utilized data from its prototype system combined with the subject's demographic information and a recent blood pressure reading.

Our prototype achieved an overall mean absolute difference (MAD) of 5.9 mmHg, which is below the 7 mmHg MAD required per a standard for wearable, cuffless blood pressure measuring devices (IEEE1708a-2019). We announced that we are also evaluating AI-based individual calibration methods to further enhance the future performance of the device. The 44-participant study, conducted at the Movano Health Clinical Lab, assessed the accuracy of our wrist-worn wearable prototype compared to a hospital-grade FDA-cleared blood pressure monitor. The study measured the blood pressure of each participant multiple times, including while under stress, which resulted in an average participant systolic blood pressure range of 25 mmHg and a total study range of 85 - 171 mmHg.

Our 4 x 6.7 mm SoC combines multiple antennas and a variety of frequencies in the smallest ever RF-enabled integrated circuit designed specifically for blood pressure and glucose monitoring. After shrinking our multi-chip architecture from four chips into one in mid-2022, we began using the patented SoC in clinical studies in 2023, which has materially improved the accuracy of our blood pressure measurements as seen by the results of this most recent study. In its current form factor, our wearable prototype represents one of the smallest and most accessible ways to measure blood pressure.

In February 2022, we completed our second IRB-approved glucose pilot study, which was conducted on ten participants with type 1 diabetes of varying gender, age, ethnicity and weight in conjunction with an independent Clinical Laboratory Improvement Amendments ("CLIA") certified clinical lab. During each four-hour session, participants wore our wrist-worn wearable prototype and either an FDA cleared finger stick glucose tester, a subject's existing CGM device, and/or a vital sign monitoring device. We expect the data collected in the study will ultimately allow us to further refine the algorithms we use to calculate glucose values and vital sign measurements and will also help guide us as to what specific follow-on studies will be done in support of future FDA clearances.

To date, we have completed three prospective, self-controlled clinical trials with the Evie Med Ring. Following a successful pilot hypoxia study in July 2022, which compared the accuracy of our heart rate and SpO_2 data to arterial blood gas samples and to reference devices, we completed a pivotal hypoxia study in October 2022. A second pivotal hypoxia study was completed in January 2024. During the pilot and pivotal studies, our solution has consistently achieved a margin of error well below the FDA's 3.5% requirement for SpO_2, and the ring also estimated heart rate with accuracy commensurate with the FDA's standards. In conjunction with the positive results of these studies, we plan to resubmit for FDA clearance on these metrics in April 2024 with clearance expected by July 2024. If clearance is received, the Evie Med Ring would be deemed a medical device. This unique competitive advantage is not only a key pillar in building brand trust and loyalty but will also redefine the expectations of wearable devices.

Having our product cleared as a medical device would also open a host of incremental opportunities for us beyond what you see in the market today. Currently, many wearable devices sell-in to companies for employee benefits or partner with payors. As an FDA-cleared medical device, the Evie Ring may be used with pharmaceutical companies for post-market surveillance or with medical device companies looking to determine the efficacy of their offering.

The direct-to-consumer launch of the Evie Ring occurred in November 2023 prior to any FDA decision regarding medical device clearance. Beginning with an in-depth research exercise, the marketing team spoke with over 1,000 women to understand what they were looking for in a medical device and what features and messaging were most important to them. They then partnered with a best in class design agency and site developer to build out the commercial experience which included a fully functional website, the launch of social channels Instagram and Facebook and YouTube, a paid media campaign to generate awareness and leads, and the buildout of an email engagement campaign. Heading into the November launch the team had established a lead list of over 130,000 prospective buyers and a social following of 10,000. The Evie Ring was sold exclusively on eviering.com and generated over $1,000,000 in sales in the first ten days of launch.

To prepare for the consumer launch of the Evie Ring, we conducted initial beta test programs to evaluate the fit and functionality of the ring with a number of strategic partners, including Stanford University's Applied Sports Science Department, Novant Health, a top-3 payor and one of the largest pharmaceutical companies in the U.S. Another emerging trend in healthcare is Remote Patient Monitoring (RPM), and a large player in that market is also testing the Evie Ring.

Intellectual Property

We are committed to developing and protecting our intellectual property and, where appropriate, filing patent applications to protect our technology. We rely on a combination of patent, copyright, trademark and trade secret laws and other agreements with employees and third parties to establish and protect our proprietary intellectual property rights. We require our officers, employees and consultants to enter into standard agreements containing provisions requiring confidentiality of proprietary information and assignment to us of all inventions made during the course of their employment or consulting relationship. We also enter into nondisclosure agreements with our commercial counterparties and limit access to, and distribution of, our proprietary information.

As of December 31, 2023, we own, jointly own, or have exclusive rights to 28 issued and in-force patents (that cover one or more of our products or product candidates for method, system and device development) that expire at various times between November 12, 2039 and December 18, 2039. Furthermore, as of December 31, 2023, we own, jointly own, or have exclusive rights to 18 pending U.S. patent applications, 4 pending foreign patent applications, and one pending Patent Cooperation Treaty ("PCT") International patent application.

While we have not registered any of the copyrights in our software code, our software code, once written, would be protected by applicable U.S. copyright law.

Regulation

FDA Regulation

While the first iteration of the Evie Ring is a general wellness device and therefore does not require FDA premarket clearance, over time we plan to execute accuracy studies to gain FDA clearances on its vital signs monitoring capabilities including heart rate, SpO_2 and respiration rate under the brand name Evie Med. In addition, we are currently conducting clinical trials with our proprietary and noninvasive RF-enabled technology and developing algorithms to enable us to add non-invasive CGM and cuffless blood pressure monitoring to our technology platform. Our end goal is to bring a Class II FDA-cleared device to the market, which may include additional form factors, and that includes CGM and cuffless blood pressure monitoring capabilities.

Before and after approval or clearance in the U.S., these subsequent iterations of our planned solution will be subject to extensive regulation by FDA under the Federal Food, Drug and Cosmetic Act (the "FD&C Act") and/or the Public Health Service Act, as well as by other regulatory bodies. FDA regulations govern, among other things, the development, testing, manufacturing, labeling, safety, storage, record-keeping, market clearance or approval, advertising and promotion, import and export, marketing and sales, and distribution of medical devices and pharmaceutical products. There may be certain commercial applications for our technology that require less regulatory scrutiny than described below.

FDA Approval or Clearance of Medical Devices

In the U.S., medical devices are subject to varying degrees of regulatory control and are classified in one of three classes depending on the extent of controls FDA determines are necessary to reasonably ensure their safety and efficacy:

- Class I: general controls, such as labeling, establishment registration, device listing, and, for some devices, adherence to quality system regulations;
- Class II: the general controls plus certain special controls, FDA clearance via a premarket notification, or 510(k) submission, specific controls such as performance standards, patient registries and post-market surveillance and additional controls such as labeling and adherence to quality system regulations; and
- Class III: general and special controls and approval of a premarket approval ("PMA") application.

Our end goal for our planned solution in development is to bring to market a product that will be classified as a Class II medical device and thus require FDA clearance prior to marketing by means of a 510(k) clearance rather than a PMA application.

To request marketing authorization by means of a 510(k) clearance, we must submit a notification demonstrating that the proposed device is substantially equivalent to another legally marketed medical device, a "predicate device," has the same intended use, and is as safe and effective as the predicate device and does not raise different questions of safety and effectiveness than a legally marketed device. 510(k) submissions generally include, among other things, a description of the device and its manufacturing, device labeling, medical devices to which the device is substantially equivalent, safety and biocompatibility information and the results of performance testing. In this case, the 510(k) submission will likely also include data from human clinical studies demonstrating performance and other parameters. Marketing may commence only when FDA issues a clearance letter finding substantial equivalence. The typical duration to receive a 510(k) clearance is approximately six to twelve months from the date of the initial 510(k) submission, although there is no guarantee that the timing will not be longer.

In some instances, the 510(k) pathway for product marketing may be used with only proof of substantial equivalence in technology for a given indication with a predicate device. In other instances, FDA may require additional clinical work to prove efficacy in addition to technological equivalence and basic safety. Whether clinical data is provided or not, FDA may decide to reject the substantial equivalence argument we present. If that happens, the device is automatically designated as a Class III device. The device sponsor must then fulfill more rigorous PMA requirements or can request a risk-based classification determination for the device in accordance with the "de novo" process, which may determine that the new device is of low to moderate risk and that it can be appropriately regulated as a Class I or II device. If a de novo request is granted, the device may be legally marketed, and a new classification is established. If the device is classified as Class II, the device may serve as a predicate for future 510(k) submissions. If the device is not reclassified through de novo review, then it must go through the standard PMA process for Class III devices.

After a device receives 510(k) clearance, any product modification that could significantly affect the safety or effectiveness of the product, or that would constitute a significant change in intended use, requires a new 510(k) clearance or, if the device would no longer be substantially equivalent, a PMA.

A PMA application must provide a demonstration of safety and effectiveness, which generally requires extensive pre-clinical and clinical trial data. Information about the device and its components, device design, manufacturing, and labeling, among other information, must also be included in the PMA. As part of the PMA review, FDA will inspect the manufacturer's facilities for compliance with quality system regulation requirements, which govern testing, control, documentation, and other aspects of quality assurance with respect to manufacturing, testing, and storage of medical devices. If FDA determines the application or manufacturing facilities are not acceptable, FDA may outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. During the review period, an FDA advisory committee, typically a panel of clinicians and statisticians, may be convened to review the application and recommend to FDA whether, or upon what conditions, the device should be approved. FDA is not bound by the advisory panel decision. While FDA often follows the panel's recommendation, there have been instances in which FDA has not. FDA must find the information to be satisfactory to approve the PMA. The PMA approval can include post-approval conditions, including, among other things, restrictions on labeling, promotion, sale and distribution, or requirements to do additional clinical studies after approval. Even after approval of a PMA, a new PMA or PMA supplement is required to authorize certain modifications to the device, its labeling, or its manufacturing process. Supplements to a PMA often require the submission of the same type of information required for an original PMA, except that the supplement is generally limited to that information needed to support the proposed change from the product covered by the original PMA. The typical duration to receive PMA approval is approximately two years from the date of submission of the initial PMA application, although there is no guarantee that the timing will not be longer.

Clinical Trials of Medical Devices

One or more clinical trials are generally required to support a PMA application and are sometimes necessary to support a 510(k) submission. Clinical studies of unapproved or uncleared medical devices or devices being studied for uses for which they are not approved or cleared (investigational devices) must be conducted in compliance with FDA requirements. If an investigational device could pose a significant risk to patients, the sponsor company must submit an investigational device exemption application to FDA prior to initiation of the clinical study. If an institutional review board determines that a device study does not present a significant risk, an investigational device exemption submission to FDA is not required. An investigational device exemption application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device on humans and that the testing protocol is scientifically sound. Except for studies involving certain banned devices, the investigational device exemption will automatically become effective 30 days after receipt by FDA unless FDA notifies the company that the investigation may not begin. Clinical studies of investigational devices may not begin until an institutional review board has approved the study.

During the study, the sponsor must comply with FDA's investigational device exemption requirements. These requirements include investigator selection, trial monitoring, adverse event reporting, and record keeping. The investigators must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of investigational devices, and comply with reporting and record keeping requirements. The sponsor, FDA, or the institutional review board at each institution at which a clinical trial is being conducted may suspend a clinical trial at any time for various reasons, including a belief that the subjects are being exposed to an unacceptable risk. During the approval or clearance process, FDA typically inspects the records relating to the conduct of one or more investigational sites participating in the study supporting the application.

Post-Approval Regulation of Medical Devices

After a device is cleared or approved for marketing, numerous and pervasive regulatory requirements continue to apply. These include:

- FDA quality systems regulation, which governs, among other things, how manufacturers design, test, manufacture, exercise quality control over, and document manufacturing of their products;

- labeling and claims regulations, which prohibit the promotion of products for unapproved or "off-label" uses and impose other restrictions on labeling; and

- the Medical Device Reporting regulation, which requires reporting to FDA of certain adverse experiences associated with use of the product.

Good Manufacturing Practices Requirements

Manufacturers of most medical devices are required to comply with the good manufacturing practices set forth in the quality system regulation promulgated under Section 520 of the FD&C Act. Current good manufacturing practices regulations require, among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation. The manufacturing facility for an approved product must be registered with FDA and meet current good manufacturing practices requirements to the satisfaction of FDA pursuant to a pre-PMA approval inspection before the facility can be used. Manufacturers, including third party contract manufacturers, are also subject to periodic inspections by FDA and other authorities to assess compliance with applicable regulations. Failure to comply with statutory and regulatory requirements subjects a manufacturer to possible legal or regulatory action, including the seizure or recall of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations, and civil and criminal penalties. Adverse experiences with the product must be reported to FDA and could result in the imposition of marketing restrictions through labeling changes or in product withdrawal. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product occur following the approval.

Federal Communication Commission ("FCC") Regulations

Our RF-based technology involves the transmission of RF energy, and as such, will be subject to regulation by the FCC, including the FCC's equipment authorization regulations and its regulations governing human exposure to RF energy. In particular, we expect the planned solution to be regulated under Part 18 of the FCC's rules governing industrial, scientific, and medical (ISM) equipment, and to be classified as consumer ISM equipment under that rule part. Based on the expected frequency and power of operation, we expect that the product will comply with the Part 18 technical specifications for these type of devices, which we will be required to verify under FCC equipment authorization procedures. We also expect, based on the device's frequency and power of operation, that the product will comply with the FCC's requirements governing human exposure to RF energy.

Environmental

The cost of compliance with federal, state, and local provisions related to the protection of the environment has had no material effect on our business. There were no material capital expenditures for environmental control facilities in the year ended December 31, 2023, and there are no material expenditures planned for such purposes for the year ended December 31, 2024.

Strategy

We are a public emerging growth company without a history of operations or revenue, and therefore intend to explore alternative business strategies, including:

- selling directly to consumers and enterprise customers through our website to start and then through retail or other distribution channels;
- partnering with OEMs, and value-added resellers ("VARs"); and
- partnering with industry partners to incorporate our technology into new and existing devices.

Selling our products directly to consumers would not depend on locating a suitable OEM or VAR but would require us to complete the development and manufacture of our planned solution and commercialize the product on our own without the assistance a suitable OEM or VAR could provide. We may use distributors to help distribute our product to consumers, and the costs of working with such distributors, including without limitation the compensation to such distributors and the administrative and other costs of working with such distributors, would reduce our profit margin.

We expect that partnering with OEMs and VARs may accelerate product acceptance into our target market and allow us to take advantage of the sales and marketing and distribution infrastructure of those OEMs or VARs. In particular, we believe that a maker of ICs or a manufacturer of wearables would be an ideal strategic partner for us.

One of the challenges of IC development is ensuring the ability to source quality ICs with enough volume and competitive pricing. In order to strengthen our supply chain and prepare for the future, we formed a strategic partnership with a leading specialty foundry for manufacturing and supplying our ICs.

Competition

The technology industry, generally, and the general wellness, continuous glucose and blood pressure monitoring markets, in particular, are intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities by industry participants. To compete successfully, we will need to demonstrate the advantages of our products and technologies over well-established alternative solutions, products, and technologies, as well as newer ones, and convince consumers and enterprises of the advantages of our products and technologies.

With respect to a potential solution that is targeted at the general wellness market, we would face direct and indirect competition from a number of competitors who have developed and commercialized similar products. These competitors include Apple, Samsung, Garmin, Fitbit, WHOOP and Oura Health. Many of such potential competitors enjoy significantly greater name recognition and have significantly greater financial resources and expertise in research and development, manufacturing, and sales and marketing than we have.

With respect to our planned CGM solution, we will face direct and indirect competition from a number of competitors who have developed or are developing products for continuous monitoring of glucose levels. These competitors include DexCom, Inc., Abbott Laboratories, Medtronic plc, Roche Diagnostics, LifeScan, Inc., Ascensia Diabetes Care Holdings AG, Senseonics Holdings, Inc., Integrity Applications, Inc., Nemaura Medical, Biolinq Inc., and Profusa, Inc. Our planned solution will also compete with traditional glucometers, which remain an inexpensive alternative. Many of the companies we will compete with enjoy significantly greater name recognition and have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and sales and marketing of approved products than we have.

We will also face direct and indirect competition from a number of competitors who have developed or are developing products that monitor blood pressure. These competitors include OMRON Corporation, Welch Allyn, A&D Medical, American Diagnostic Corporation, GE Healthcare, Masimo Corporation, Philips, SunTech Medical Inc., Aktiia, Biobeat and Blumio. Many of the companies we will compete with enjoy significantly greater name recognition and have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and sales and marketing of approved products than we have.

Mergers and acquisitions in the medical device, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Other small or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. There are also several academic and other institutions involved in various phases of technology development regarding blood glucose monitoring devices.

We believe the ability to deploy our technology on a non-invasive basis, packaged in a wearable that is painless, cuffless, simple, smart and competitively priced, will provide us with a competitive advantage. We cannot however assure you that we will be able to compete successfully.

Employees and Human Capital Resources

As of December 31, 2023, we had 30 employees, all of whom are employed on a full-time basis. None of our employees are covered by a collective bargaining agreement, and we believe our relationship with our employees is good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing, and integrating our existing and new employees, advisors, and consultants. The principal purposes of our equity incentive plans are to attract, retain and reward personnel through the granting of stock-based compensation awards, to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

Available Information

We were incorporated in the State of Delaware in January 2018 under the name Maestro Sensors Inc. On August 3, 2018, we changed our name to Movano Inc. Our principal executive offices are located at 6800 Koll Center Pkwy., Pleasanton, CA 94566, and our telephone number is (415) 651-3172. Our Internet website address is www.movanohealth.com. Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, including exhibits, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 are available free of charge through the investor relations page of our Internet website as soon as reasonably practicable after we electronically file such material with, or furnish it to, the U.S. Securities and Exchange Commission (the "SEC"). Our Internet website and the information contained therein or connected thereto are not intended to be incorporated into this Annual Report on Form 10-K.

Item 1A. Risk Factors

Risk Factors Summary

The following is a summary of the principal risks that could adversely affect our business, operations, and financial results.

Risks Related to Our Business

- We are a development-stage technology company with no history of generating revenue, have a history of operating losses, and we may never achieve or maintain profitability.
- We may be unable to continue as a going concern if we do not successfully raise additional capital on favorable terms, or at all, or if we fail to generate sufficient revenue from operation.
- Our efforts may never demonstrate the feasibility of our proposed CGM and blood pressure monitoring solution.
- We face competition from other technology companies and our operating results will suffer if we fail to compete effectively.
- If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.
- We are subject to risks associated with our utilization of consultants.
- We will need to grow the size of our organization, and we may experience difficulties in managing this growth.
- We may acquire businesses or products, or form strategic alliances, in the future, and we may not realize the benefits of such acquisitions.
- Our business is affected by macroeconomic conditions.
- Our business and operations are subject to risks related to climate change.
- Our business could be negatively impacted by corporate social responsibility and sustainability matters.

Risks Related to Product Development, Manufacturing and Commercialization

- We are highly dependent on the success of our first product, the Evie Ring, and cannot give any assurance that it will receive regulatory approval or clearance or be successfully commercialized.
- We will depend on third parties to design, manufacture, market and distribute our products. If any third party fails to successfully design, manufacture, market or distribute any of our products, our business will be materially harmed.
- Our business and operations would suffer in the event of information technology system failures, including cyber-attacks.

Risks Related to Intellectual Property and Other Legal Matters

- It is difficult and costly to protect our intellectual property and our proprietary technologies, and we may not be able to ensure their protection.
- If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.
- We may in the future be a party to intellectual property litigation or administrative proceedings that could be costly and could interfere with our ability to develop our products.
- We may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of their former employers or other third parties or claims asserting ownership of what we regard as our own intellectual property.
- We could become subject to product liability claims, product recalls and warranty claims that could be expensive, divert management's attention and harm our business.

Risks Related to Regulation

- We are seeking FDA clearance with respect to certain of the Evie Ring's monitoring capabilities and expect to seek FDA clearance or approval for our planned CGM and blood pressure monitoring solution, which may be difficult to achieve, and existing laws or regulations or future legislative or regulatory changes may affect our business.
- If any OEMs contracted to manufacture our products fail to comply with FDA's Quality System Regulations or other regulatory bodies' equivalent regulations, manufacturing operations could be delayed or shut down and the development of our products could suffer.
- We expect our planned solution to be subject to certain Federal Communication Commission ("FCC") regulations.
- Our current or future products may be subject to product recalls that could harm our reputation.
- Healthcare reform measures could hinder or prevent our commercial success.
- Failure to comply with privacy and security laws and regulations could result in fines, penalties and damage to our reputation and have a material adverse effect on our business.

Risks Related to Owning Our Securities and Our Financial Results

- Our quarterly and annual results may fluctuate significantly, may not fully reflect the underlying performance of our business and may result in decreases in the price of our securities.
- The issuance of additional stock in connection with financings, acquisitions, our equity incentive plan, upon exercise of outstanding warrants or otherwise will dilute our existing stockholders.
- Our stock price has fluctuated widely and is likely to continue to be volatile.
- Our failure to meet the continued listing requirements of Nasdaq could result in a de-listing of our common stock.
- Our Certificate of Incorporation designates specific courts as the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us.
- We have not paid dividends in the past and have no immediate plans to pay dividends.
- Concentration of ownership among our existing executive officers, directors and significant stockholders may prevent new investors from influencing significant corporate decisions.
- We are an "emerging growth company" under the JOBS Act and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.
- We are incurring increased costs as a public company that reports to the SEC and our management is required to devote substantial time to meet compliance obligations.
- If securities or industry analysts do not publish research reports about our business, or if they issue an adverse opinion about our business, the price of our common stock and trading volume could decline.
- Our charter documents and Delaware law may inhibit a takeover that stockholders consider favorable.

We operate in a rapidly changing environment that involves a number of risks that could materially affect our business, financial condition or future results, some of which are beyond our control. This discussion highlights some of the risks that may affect future operating results. These are the risks and uncertainties we believe are most important for you to consider. We cannot be certain that we will successfully address these risks. If we are unable to address these risks, our business may not grow, our stock price may suffer, and we may be unable to stay in business. Additional risks and uncertainties not presently known to us, which we currently deem immaterial or which are similar to those faced by other companies in our industry or business in general, may also impair our business operations.

Risks Related to Our Business

We are an early-stage technology company with no history of generating revenue, have a history of operating losses, and we may never achieve or maintain profitability.

We are a technology company that was formed in January 2018. We have a limited operating history and no revenue and to-date have largely focused our efforts and resources towards research and development activities relating to our development of the Evie Ring and the SoC. The likelihood of success of our business plan must be considered in light of the challenges, substantial expenses, difficulties, complications and delays frequently encountered in connection with developing and expanding early-stage businesses and the regulatory and competitive environment in which we operate. Technology product development is a highly speculative undertaking, involves a substantial degree of risk and is a capital-intensive business.

As of December 31, 2023, we had an accumulated deficit of approximately $124.4 million. We expect that our losses will continue for the foreseeable future as we continue to invest significant additional resources toward the commercialization of our products and ongoing research and development. We have experienced these losses and accumulated deficit primarily due to the investments we have made in developing our proprietary technologies and products, building our team and manufacturing capabilities and commercially launching our first product, the Evie Ring. Without additional capital our existing cash and cash equivalents will be insufficient to fully fund our business plan. We expect to continue to incur losses for the foreseeable future, and these losses will likely increase as we prepare for and begin to commercialize our first product. Our ability to achieve revenue-generating operations and, ultimately, achieve profitability will depend on whether we can obtain additional capital when we need it, complete the development of our technology, receive regulatory approval of our technology, potentially find strategic collaborators that can incorporate our technology into applications which can be successfully commercialized and achieve market acceptance. There can be no assurance that we will ever generate revenues or achieve profitability. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods.

We may be unable to continue as a going concern if we do not successfully raise additional capital on favorable terms, or at all, or if we fail to generate sufficient revenue from operations.

Primarily as a result of our lack of revenue, history of losses to date and our lack of liquidity, there is substantial doubt as to our ability to continue as a going concern. As of December 31, 2023, we had total assets of approximately $9.4 million and total liabilities of approximately $6.0 million. We believe that our cash and cash equivalents as of December 31, 2023 will not be sufficient to fund our projected operating requirements for the twelve-month period following the issuance of our consolidated financial statements for the fiscal year ended December 31, 2023. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. Our forecast of the period through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this “Risk Factors” section. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect.

We do not have any prospective arrangements or credit facilities as a source of future funds, and there can be no assurance that we will be able to raise sufficient additional capital on acceptable terms, or at all. If we are unable to raise additional capital or if we are unable to generate sufficient revenue from our operations, we may not stay in business. We may seek additional capital through a combination of private and public equity offerings, debt financings and strategic collaborations. If we raise additional funds through the issuance of equity or convertible debt securities, the percentage ownership of our existing stockholders could be significantly diluted and these newly-issued securities may have rights, preferences or privileges senior to those of holders of the common stock offered hereby. Debt financing, if obtained, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, which could increase our expenses and require that our assets secure such debt. Moreover, any debt we incur must be repaid regardless of our operating results. However, we do not own any significant assets that we expect could serve as acceptable collateral for a bank or other commercial lender. The above circumstances may discourage some investors from purchasing our stock, lending us money or from providing alternative forms of financing. In addition, the current economic instability in the world’s equity and credit markets may materially adversely affect our ability to sell additional securities and/or borrow cash. There can be no assurance that we will be able to raise additional working capital on acceptable terms or at all.

If we are unable to raise additional capital when needed, we may be required to curtail the development of our technology or materially curtail or reduce our operations. We could be forced to sell or dispose of our rights or assets. Any inability to raise adequate funds on commercially reasonable terms would have a material adverse effect on our business, results of operation and financial condition, including the possibility that a lack of funds could cause our business to fail and liquidate with little or no return to investors.

Even if we take these actions, they may be insufficient, particularly if our costs are higher than projected or unforeseen expenses arise. Additionally, if we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or products or to grant licenses on terms that may not be favorable to us. If we choose to expand more rapidly than we presently anticipate, we may also need to raise additional capital sooner than expected.

Our efforts may never demonstrate the feasibility of our proposed CGM and blood pressure monitoring solution.

We have developed a working prototype of our proposed solution that is capable of generating data we believe will be able to be used to measure various health vital signs and measurements, including heart rate, HRV, sleep, respiration, temperature, blood oxygen, steps, calories, blood glucose and blood pressure levels, but significant additional research and development activity will be required before we achieve a commercial product. We have conducted limited studies to compare the data our prototype device generates to measurements from conventional blood glucose and blood pressure measuring tools, and we are using the data generated in those studies to refine our product design and to develop the algorithms our product in development will utilize. However, we have not yet conducted any studies that demonstrate that our planned product is able to measure blood glucose or blood pressure levels at any particular accuracy level and we may never be able to complete any clinical studies that demonstrate accuracy levels that would be necessary for a commercial product. Our research and development efforts remain subject to all of the risks associated with the development of new products based on emerging technologies, including unanticipated technical or other problems and the possible insufficiency of funds needed in order to complete development of these products and enable us to execute our business plan. Any such problems may result in delays and cause us to incur additional expenses that would increase our losses. If we cannot complete, or if we experience significant delays in, developing our technology and products and services based on such technology for use in potential commercial applications, particularly after incurring significant expenditures, our business may fail. To our knowledge, the technological concepts we are applying to develop commercial applications have not previously been successfully applied by anyone else.

Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies in the early stages of development, especially technology companies such as ours. Potential investors should carefully consider the risks and uncertainties that a company with a limited operating history typically faces. In particular, potential investors should consider that we cannot assure you that we will be able to:

- successfully implement or execute our current business plan, or that our business plan is sound;
- successfully develop the technology necessary to develop our planned solution having the functionality and characteristics we discuss herein;
- successfully develop a practical, efficient or economical commercial version of one or more products;
- obtain any additional issued patents;
- successfully develop proprietary technology and trade secrets and secure market exclusivity and/or adequate intellectual property protection for our products by way of patent protection or otherwise;
- successfully protect any such proprietary technology and trade secrets from competitors and third parties claiming infringement or misappropriation;
- attract and retain an experienced management and advisory team; and
- raise sufficient funds in the capital markets to effectuate our business plan, including for the development and commercialization of our products.

If we cannot successfully execute any one of the foregoing, our business may not succeed and your investment will be adversely affected.

We face competition from other technology companies and our operating results will suffer if we fail to compete effectively.

The technology industry, generally, and the general wellness, continuous glucose and blood pressure monitoring markets, in particular, are intensely competitive, subject to rapid change, and significantly affected by new product introductions and other market activities by industry participants. To compete successfully, we will need to demonstrate the advantages of our products and technologies over well-established alternative solutions, products and technologies, as well as newer ones, and convince consumers and enterprises of the advantages of our products and technologies. With respect to our Evie Ring and other planned solutions, we face or will face direct and indirect competition from a number of competitors who have developed or are developing products for general wellness and continuous or periodic monitoring of glucose and blood pressure levels, and we anticipate that other companies will develop additional competitive products in the future. Traditional glucometers and blood pressure monitors remain an inexpensive alternative to our proposed solution. We have existing competitors and potential new competitors, many of which have or will have substantially greater name recognition, financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and sales and marketing of approved products than we have. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Established competitors may invest heavily to quickly discover and develop novel technologies that could make obsolete or uneconomical the technology or the products that we plan to develop. Other small or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Any new product that we develop that competes with a competitor's existing or future product may need to demonstrate compelling advantages in cost, convenience, quality, and safety to be commercially successful. In addition, new products developed by others could emerge as competitors to our proposed product development candidates. If our technology under development or our future products are not competitive based on these or other factors, our business would be harmed, and our financial condition and operations will suffer.

If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to implement our business plan depends in large part upon our ability to attract and retain highly qualified managerial and engineering personnel. We will need to hire additional personnel as we further develop our products. Competition for skilled personnel in our market is intense and competition for experienced engineers may limit our ability to hire and retain highly qualified personnel on acceptable terms. Despite our efforts to retain valuable employees, members of our management and engineering teams may terminate their employment with us on short notice. The loss of the services of any of our executive officers or other key employees could potentially harm our business, operating results or financial condition. Currently, we do not maintain key man insurance policies with respect to any of our executive officers or employees.

Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior engineering personnel. Other technology companies with which we compete for qualified personnel have greater financial and other resources, different risk profiles and longer histories than we have. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can develop and commercialize products would be limited.

We are subject to risks associated with our utilization of consultants.

To improve productivity and accelerate our development efforts while we build out our own engineering team, we use experienced consultants to assist in selected business functions, including the development of our integrated circuits. We take steps to monitor and regulate the performance of these independent third parties. However, arrangements with third party service providers may make our operations vulnerable if these consultants fail to satisfy their obligations to us as a result of their performance, changes in their own operations, financial condition or other matters outside of our control. Effective management of our consultants is important to our business and strategy. The failure of our consultants to perform as anticipated could result in substantial costs, divert management's attention from other strategic activities or create other operational or financial problems for us. Terminating or transitioning arrangements with key consultants could result in additional costs and a risk of operational delays, potential errors and possible control issues as a result of the termination or during the transition.

We will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As we expand our activities, there will be additional demands on our financial, technical, operational and management resources. To manage our anticipated future growth, we must continue to implement and improve our financial, technical, operational and management systems and continue to recruit and train additional qualified personnel. Due to our limited financial resources and operating history, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

We may acquire businesses or products, or form strategic alliances, in the future, and we may not realize the benefits of such acquisitions.

We may acquire additional businesses or products, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new products resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure you that, following any such acquisition, we will achieve the expected synergies to justify the transaction.

Our business is affected by macroeconomic conditions.

Various macroeconomic factors could adversely affect our business and the results of our operations and financial condition, including changes in inflation, interest rates and foreign currency exchange rates and overall economic conditions and uncertainties, including those resulting from the current and future conditions in the global financial markets. Cost inflation, including increases in raw material prices, labor rates, and transportation costs may impact our profitability. Global financial markets and the banking sector can experience extreme volatility, disruption and credit contraction, which adversely affect global economic conditions. The volatility of the capital markets could also affect the value of our investments and our ability to liquidate our investments or access our cash and cash equivalents in order to fund our operations. For example, on March 10, 2023, Silicon Valley Bank was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation, or the FDIC, as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership followed by First Republic Bank on May 1, 2023. While we have not experienced material challenges accessing our cash and cash equivalents to date as a result of these bank failures, we do maintain deposits in excess of federally insured limits at financial institutions as a part of doing business that could be at risk if there are further bank failures or disruptions in the banking sector. Our ongoing cash management strategy is to maintain diversity in our deposit accounts at multiple financial institutions, but there can be no assurance that this strategy will be successful. If our banking partners are negatively impacted by financial conditions affecting the banking system and financial markets, then our ability to access our cash and cash equivalents may be threatened which could have a material adverse effect on our business and financial condition.

Increasing interest rates, reduced access to capital markets and bank failures could also adversely affect the ability of our suppliers, OEMs, VARs, distributors, licensors, collaborators and other strategic partners to remain effective business partners or to remain in business. The loss of a strategic partner, or a failure to perform by a strategic partner, could have a disruptive effect on our business and could adversely affect our results of operations.

Our business and operations are subject to risks related to climate change.

The effects of global climate change present risks to our business. Natural disasters, extreme weather and other conditions caused by or related to climate change could adversely impact our supply chain, the availability and cost of raw materials and components, energy supply, transportation, or other inputs necessary for the operation of our business. Climate change and natural disasters could also result in physical damage to our facilities as well as those of our suppliers, and strategic partners, which could cause disruption in our business and operations. Our facilities and our equipment would be costly to replace and could require substantial lead time to repair or replace. Although we believe we possess adequate insurance for the disruption of our business related to climate change, such insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, or at all.

Our business could be negatively impacted by corporate social responsibility and sustainability matters.

There has been an increased focus from investors, customers, employees and other stakeholders concerning corporate social responsibility and sustainability matters, which may result in increases in our costs to operate our business or restrict certain aspects of our activities. The standards by which corporate social responsibility and sustainability efforts and related matters are measured are developing and evolving, and certain areas are subject to assumptions that could change over time. We could be criticized for the scope of such initiatives or goals or perceived as not acting responsibly in connection with these matters. In addition, with anti-ESG sentiment gaining momentum in some of our markets, we could experience reputational harm if we are targeted by groups or influential individuals who disagree with our positions on social or environmental issues. Additionally, lawsuits or regulatory actions based on allegations that certain public statements regarding ESG-related matters by companies are false and misleading “greenwashing” campaigns could significantly impact our operations and could have an adverse impact on our financial condition. Any such matters could have a material adverse impact on our future results of operations, financial position and cash flows.

Risks Related to Product Development, Manufacturing and Commercialization

We are highly dependent on the success of our first product, the Evie Ring, and cannot give any assurance that it will receive regulatory approval or clearance or be successfully commercialized.

We are highly dependent on the success of our first commercial product, the Evie Ring. There is no guarantee that we will be successful in the commercialization of this or any other future product. While we may successfully commercialize our first iteration of the Evie Ring without FDA clearance, subsequent iterations of the Evie Ring will require substantial additional clinical development, extensive preclinical testing and clinical trials in order to receive regulatory clearance or approval. We cannot give any assurance that the Evie Ring will receive regulatory clearance or approval or be successfully commercialized. Any failure to obtain regulatory clearance or approval of or to successfully commercialize the Evie Ring would have a material adverse effect on our business.

We depend on third parties to design, manufacture, market and distribute our products. If any third party fails to successfully design, manufacture, market or distribute any of our products, our business will be materially harmed.

We depend and expect to continue to depend on strategic partners such as third-party OEMs, VARs and other distributors to complete the design, manufacture, market and distribute the Evie Ring and other future products. If these strategic partners fail to successfully design, manufacture, market or distribute our current or future products, our business will be materially harmed.

The products that we intend to develop are complex and will require the integration of a number of components that are themselves complex. In light of this complexity, we expect that we may determine not to complete the design of or manufacture these products ourselves and instead develop relationships with suitable third-party OEMs to complete these tasks. Similarly, we do not anticipate building a sales or marketing function and instead expect that our products under development will be marketed and sold through strategic partners such as OEMs, VARs or other distributors. We do not currently have a relationship with any OEM, VAR or other distributor, and may never be able to find any OEMs, VARs or other distributors that are willing to work with us on acceptable terms, or at all. We will have limited control over the efforts and resources that any third-party OEMs, VARs and other distributors would devote to designing, manufacturing, marketing or distributing our products under development. An OEM may not be able to successfully design and manufacture our products and such failure by an OEM could substantially harm the value of our business. Similarly, the OEMs, VARS or other distributors we engage with to market and sell our product under development may not be successful at marketing and selling such product. If we cannot find suitable strategic partners or our strategic partners do not perform as expected, our potential for revenue may be dramatically reduced and our business could be harmed.

Our business and operations would suffer in the event of information technology system failures, including cyber-attacks.

Our information technology computer systems, as well as those of our contractors and consultants, are vulnerable to damage from computer viruses, unauthorized access, natural disasters (including earthquakes), terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs. In the ordinary course of our business, we collect and store sensitive data, including intellectual property, proprietary business information, personal data and personally identifiable information of our clinical trial subjects and employees, on our networks. The secure processing, maintenance and transmission of this information is critical to our operations. High-profile security breaches at other companies and in government agencies have increased in recent years, and security industry experts and government officials have warned about the risks of hackers and cyber-attacks targeting businesses such as ours. Cyber-attacks are becoming more sophisticated and frequent, and in some cases have caused significant harm. Computer hackers and others routinely attempt to breach the security of technology products, services and systems, and to fraudulently induce employees, customers, or others to disclose information or unwittingly provide access to systems or data. While we devote significant resources to security measures to protect our systems and data, these measures cannot provide absolute security, and our information technology and infrastructure may be vulnerable to attacks by hackers or internal bad actors, or breached due to employee error, a technical vulnerability, malfeasance or other disruptions. Although, to our knowledge, we have not experienced any such material security breach to date, any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information and significant regulatory penalties, and such an event could disrupt our operations, damage our reputation and cause a loss of confidence in us and our ability to conduct clinical trials, which could adversely affect our reputation and delay our development of our products.

Risks Related to Intellectual Property and Other Legal Matters

It is difficult and costly to protect our intellectual property and our proprietary technologies, and we may not be able to ensure their protection.

Our success depends significantly on our ability to obtain, maintain and protect our proprietary rights to the technologies used in our products. Patents and other proprietary rights provide uncertain protections, and we may be unable to protect our intellectual property. As of December 31, 2023, we own, jointly own, or have exclusive rights to 28 issued and in-force patents (that cover one or more of our products or product candidates for method, system and device development). Furthermore, as of December 31, 2023, we own, jointly own, or have exclusive rights to 18 pending U.S. patent applications, 4 pending foreign patent applications, and one pending PCT International patent application.

While we plan to file additional patent applications, we may never develop any invention that results in any additional issued patents. Even if we obtain patents, we may be unsuccessful in defending our patents (and other proprietary rights) against third party challenges. Although we expect to attempt to obtain patent coverage for our technology where available and where we believe appropriate, there may be aspects of the technology for which patent coverage may never be sought or received. We may not possess the resources to or may not choose to pursue patent protection outside the United States or any or every country other than the United States where we may eventually decide to sell our future products. Our ability to prevent others from making or selling duplicate or similar technologies will be impaired in those countries in which we have no patent protection.

Any patent applications we have filed or may file in the future may never result in issued patents, or patents issued based upon such applications may issue only with limited coverage or may issue and be subsequently successfully challenged by others and held invalid or unenforceable. There may exist prior art that may prevent our patent applications from resulting in issued patents, and there may be other inventors who file patent applications on inventions that are the same or similar to ours or that otherwise may be found to anticipate our inventions before we file patent applications of our own on our inventions, which may result in the issue of patents on our inventions or similar or anticipatory inventions to those other inventors.

Even if patents issue based on our current or any future applications, any issued patents may not provide us with any competitive advantages. Competitors may be able to design around our patents or develop products that provide outcomes comparable or superior to ours. Our patents may be held invalid or unenforceable as a result of legal challenges by third parties, and others may challenge the inventorship or ownership of our patents and pending patent applications. In addition, if we choose to and are able to secure protection in countries outside the United States, the laws of some foreign countries may not protect our intellectual property rights to the same extent as do the laws of the United States. In the event a competitor infringes upon our patents or other intellectual property rights, enforcing those rights may be difficult, expensive and time consuming and we may elect not to enforce our patents or other intellectual property rights based on the facts and circumstances known to us at the time. Even if successful, litigation to enforce our intellectual property rights or to defend our patents against challenge could be expensive and time consuming and could divert our management's attention. We may not have sufficient resources to enforce our intellectual property rights or to defend our patents against a challenge.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.

In addition to our patent activities, we rely upon, among other things, unpatented proprietary technology, processes, trade secrets and know-how. Any involuntary disclosure to or misappropriation by third parties of our confidential or proprietary information could enable competitors to duplicate or surpass our technological achievements, potentially eroding our competitive position in our market. While we require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information and technology to enter into confidentiality agreements, we cannot be certain that this know-how, information and technology will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. These agreements may be terminated or breached, and we may not have adequate remedies for any such termination or breach. Furthermore, these agreements may not be enforceable or provide meaningful protection for our trade secrets and know-how in the event of unauthorized use or disclosure. The disclosure of trade secrets or other proprietary information would impair our competitive position and may materially harm our business.

We may in the future be a party to intellectual property litigation or administrative proceedings that could be costly and could interfere with our ability to develop our products.

Because our industry is characterized by competing intellectual property, we may be sued for violating the intellectual property rights of others. Determining whether a product infringes a patent involves complex legal and factual issues, and the outcome of patent litigation actions is often uncertain. We have not conducted any significant search of patents issued to third parties, and no assurance can be given that third party patents containing claims covering our product under development, parts of our product under development, technology or methods do not exist, have not been filed, or could not be filed or issued. Because of the number of patents issued and patent applications filed in our technical areas or fields, our competitors or other third parties may assert that our products and the methods we plan to employ in the use of our products are covered by United States or foreign patents held by them. In addition, because patent applications can take many years to issue and because publication schedules for pending applications vary by jurisdiction, there may be applications now pending of which we are unaware, and which may result in issued patents that our product under development or other future products would infringe. Also, because the claims of published patent applications can change between publication and patent grant, there may be published patent applications that may ultimately issue with claims that we infringe. There could also be existing patents that one or more of our future products or parts may infringe and of which we are unaware. As the number of competitors in our market increases, and as the number of patents issued in this area grows, the possibility of patent infringement claims against us increases. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

In the event that we become subject to a patent infringement or other intellectual property lawsuit and if the relevant patents or other intellectual property were upheld as valid and enforceable and we were found to infringe or violate the terms of a license to which we are a party, we could be prevented from selling any infringing products of ours unless we could obtain a license or were able to redesign the product to avoid infringement. If we were unable to obtain a license or successfully redesign, we might be prevented from selling our product under development or other future products. If there is an allegation or determination that we have infringed the intellectual property rights of a competitor or other person, we may be required to pay damages, or a settlement or ongoing royalties. In these circumstances, we may be unable to sell our products at competitive prices or at all, and our business could be harmed.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of their former employers or other third parties or claims asserting ownership of what we regard as our own intellectual property.

We do and may employ and contract with individuals who were previously employed by other technology companies. Although we seek to protect our ownership of intellectual property rights by ensuring that our agreements with our employees, collaborators and other third parties with whom we do business include provisions requiring such parties to assign rights in inventions to us and to not use the know-how or confidential information of their former employer or other third parties, we cannot guarantee that we have executed such agreements with all applicable parties. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable personnel or intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

In addition, while it is our policy to require our employees, contractors and other third parties who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights under such agreements may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

We could become subject to product liability claims, product recalls and warranty claims that could be expensive, divert management's attention and harm our business.

Our business exposes us to potential liability risks that are inherent in the manufacturing, marketing and sale of products used by consumers. We may be held liable if our product under development or other future products cause injury or death or are found otherwise unsuitable during usage. Our future products to be developed are expected to incorporate sophisticated components and computer software. Complex software can contain errors, particularly when first introduced. In addition, new products or enhancements may contain undetected errors or performance problems that, despite testing, are discovered only after installation. While we believe our technology will be safe, because our proposed solution is an RF-based technology that is being designed to be used in close proximity to users, users may allege or possibly prove defects, some of which could be alleged or proved to cause harm to users or others. A product liability claim, regardless of its merit or eventual outcome, could result in significant legal defense costs. We cannot guarantee that we will be able to obtain products liability insurance; if we do, however, the coverage limits of any insurance policies that we may choose to purchase to cover related risks may not be adequate to cover future claims, and the cost of insurance, if obtainable, could be prohibitive. If sales of our products increase or we suffer future product liability claims, we may be unable to maintain product liability insurance in the future at satisfactory rates or with adequate amounts. A product liability claim, any product recalls or excessive warranty claims, whether arising from defects in design or manufacture or otherwise, could negatively affect our sales or require a change in the design or manufacturing process, any of which could harm our reputation and result in a decline in revenue, each of which would harm our business.

In addition, if a product we designed or manufactured is defective, whether due to design or manufacturing defects, improper use of the product or other reasons, we may be required to notify regulatory authorities and/or to recall the product. A required notification to a regulatory authority or recall could result in an investigation by regulatory authorities of our products, which could in turn result in required recalls, restrictions on the sale of the products or other penalties. The adverse publicity resulting from any of these actions could adversely affect the perception of customers and potential customers. These investigations or recalls, especially if accompanied by unfavorable publicity, could result in our incurring substantial costs, losing revenues and damaging our reputation, each of which would harm our business.

Risks Related to Regulation

We are seeking FDA clearance with respect to certain of the Evie Ring's monitoring capabilities and expect to seek FDA clearance or approval for our planned CGM and blood pressure monitoring solution, which may be difficult to achieve, and existing laws or regulations or future legislative or regulatory changes may affect our business.

While we commercialized our first iteration of the Evie Ring without FDA clearance, we expect subsequent iterations of the Evie Ring and our other future products will be subject to current and future regulation by the FDA and may be subject to regulation by other federal, state and local agencies. These agencies and regulations require manufacturers of medical devices to comply with applicable laws and regulations governing development, testing, manufacturing, labeling, marketing and distribution of medical devices. Devices are generally subject to varying levels of regulatory control, based on the risk level of the device. Governmental regulations specific to medical devices are wide-ranging and govern, among other things:

- product design, development and manufacture;
- laboratory, pre-clinical and clinical testing, labeling, packaging, storage and distribution;
- premarketing clearance or approval;
- record keeping;
- product marketing, promotion and advertising, sales and distribution; and
- post-marketing surveillance, including reporting of deaths, serious injuries and certain malfunctions, as well as corrections and removals (recalls).

Before a new medical device or a new intended use for an existing product can be marketed in the United States, a company must first submit and receive either 510(k) clearance or PMA from FDA, unless an exemption applies. The typical duration to receive a 510(k) clearance is approximately nine to twelve months from the date of the initial 510(k) submission and the typical duration to receive a PMA approval is approximately two years from the date of submission of the initial PMA application, although there is no guarantee that the timing will not be longer.

Our end goal is to bring to market a solution that would be classified as a Class II medical device that will require a 510(k) clearance prior to marketing. In some instances, the 510(k) pathway for product marketing may be used with only proof of substantial equivalence in technology for a given indication with a lawfully marketed device (a "predicate device"). In other instances, FDA may require additional clinical work to prove efficacy in addition to technological equivalence and basic safety. Whether clinical data is provided or not, FDA may decide to reject the substantial equivalence argument we present. If that happens, our device would be automatically designated as a Class III device and we would have to fulfill the more rigorous PMA requirements or request a "de novo" reclassification of the device into Class I or II. Thus, although at this time we do not anticipate that we will be required to do so, it is possible that one or more of our planned products may require PMA approval de novo reclassification.

We may not be able to obtain the necessary clearances or approvals or may be unduly delayed in doing so, which could harm our business. Furthermore, even if we are granted regulatory clearances or approvals, they may include significant limitations on the indicated uses for the product, which may limit the market for the product. Delays in obtaining clearance or approval could increase our costs and harm our revenues and growth.

In addition, we will be required to timely file various reports with FDA, including reports required by the medical device reporting regulations that require us to report to FDA if our devices may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur. If these reports are not filed timely, regulators may impose sanctions and sales of our products may suffer, and we may be subject to regulatory enforcement actions, all of which could harm our business.

If we initiate a correction or removal for one of our devices to reduce a risk to health posed by the device, we would be required to submit a publicly available Correction and Removal report to FDA and, in many cases, similar reports to other regulatory agencies. This report could be classified by FDA as a device recall which could lead to increased scrutiny by FDA, other international regulatory agencies and our customers regarding the quality and safety of our devices. Furthermore, the submission of these reports has been and could be used by competitors against us in competitive situations and cause customers to delay purchase decisions or cancel orders and would harm our reputation.

FDA and FTC also regulate the advertising and promotion of our products to ensure that the claims we make are consistent with our regulatory clearances, that there are adequate and reasonable data to substantiate the claims and that our promotional labeling and advertising is neither false nor misleading in any respect. If FDA or FTC determines that any of our advertising or promotional claims are misleading, not substantiated or not permissible, we may be subject to enforcement actions, including warning letters, and we may be required to revise our promotional claims and make other corrections or restitutions.

FDA and state authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by FDA or state agencies, which may include any of the following sanctions:

- adverse publicity, warning letters, fines, injunctions, consent decrees and civil penalties;
- repair, replacement, refunds, recall or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- refusing our requests for 510(k) clearance or PMA of new products, new intended uses or modifications to existing products;
- withdrawing 510(k) clearance or PMAs that have already been granted;
- refusal of importation or exportation; and
- criminal prosecution and/or civil penalties.

If any of these events were to occur, our business and financial condition would be harmed.

The cost of compliance with new laws or regulations governing our technology or future products could adversely affect our financial results. New laws or regulations may impose restrictions or obligations on us that could force us to redesign our technology under development or other future products and may impose restrictions that are not possible or practicable to comply with, which could cause our business to fail. We cannot predict the impact on our business of any legislation or regulations related to our technology or future products that may be enacted or adopted in the future.

If any OEMs contracted to manufacture our products fail to comply with FDA's Quality System Regulations or other regulatory bodies' equivalent regulations, manufacturing operations could be delayed or shut down and the development of our products could suffer.

The manufacturing processes of third-party OEMs are required to comply with FDA's Quality System Regulations and other regulatory bodies' equivalent regulations, which cover the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of our planned non-invasive solution. They may also be subject to similar state requirements and licenses and engage in extensive recordkeeping and reporting and make available their manufacturing facilities and records for periodic unannounced inspections by governmental agencies, including FDA, state authorities and comparable agencies in other countries. If any OEM fails such an inspection, our operations could be disrupted and our manufacturing interrupted. Failure to take adequate corrective action in response to an adverse inspection could result in, among other things, a shut-down of our manufacturing operations, significant fines, suspension of marketing clearances and approvals, seizures or recalls of our products, operating restrictions and criminal prosecutions, any of which would cause our business to suffer. Furthermore, these OEMs may be engaged with other companies to supply and/or manufacture materials or products for such companies, which would expose our OEMs to regulatory risks for the production of such materials and products. As a result, failure to meet the regulatory requirements for the production of those materials and products may also affect the regulatory clearance of a third-party manufacturer's facility. If FDA determines that any of the facilities that manufacture our proposed solution are not in compliance with applicable requirements, we may need to find alternative manufacturing facilities, which would impede or delay our ability to develop, obtain regulatory clearance or approval for, or market our products, if developed and approved. Additionally, our key component suppliers may not currently be or may not continue to be in compliance with applicable regulatory requirements, which may result in manufacturing delays for our product and cause our results of operations to suffer.

We expect our planned solution to be subject to certain Federal Communication Commission ("FCC") regulations.

Our RF-based technology involves the transmission of RF energy, and as such, will be subject to regulation by the FCC, including the FCC's equipment authorization regulations and its regulations governing human exposure to RF energy. In particular, we expect the planned solution to be regulated under Part 18 of the FCC's rules governing industrial, scientific, and medical (ISM) equipment, and to be classified as consumer ISM equipment under that rule part. Based on the expected frequency and power of operation, we expect that the product will comply with the Part 18 technical specifications for these types of devices, which we will be required to verify under FCC equipment authorization procedures. We also expect, based on the device's frequency and power of operation, that the product will comply with the FCC's requirements governing human exposure to RF energy. There is the risk that the product, as we expect it to be developed, may not comply with these requirements, which could significantly affect our development costs and delay commercialization of the product. There is also the risk that we will be unable to cost effectively develop and produce a solution using RF technology that complies with these FCC requirements.

Our current or future products may be subject to product recalls that could harm our reputation.

Regulatory agencies have the authority to require the recall of commercialized products in the event of material regulatory deficiencies or defects in design or manufacture. A government-mandated or voluntary recall by us could occur as a result of component failures, manufacturing errors or design or labeling defects. Recalls of our current or future products would divert management's attention, be expensive, harm our reputation with customers and harm our financial condition and results of operations. A recall announcement would also negatively affect the price of our securities.

Healthcare reform measures could hinder or prevent our commercial success.

There have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system in ways that could harm our future revenues and profitability and the future revenues and profitability of our potential customers. Federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. For example, one of the most significant healthcare reform measures in decades, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (the "Affordable Care Act"), was enacted in 2010. The Affordable Care Act contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse measures, all of which may impact existing government healthcare programs and result in the development of new programs. The Affordable Care Act imposed a 2.3 percent excise tax on sales of medical devices. The excise tax was suspended by statute twice before being repealed in December 2019. While this tax has been repealed, Congress could enact future legislation or further change the law related to the medical devise excise tax in a manner that could negatively impact our operating results. The financial impact such future taxes could have on our business is unclear.

Other significant measures contained in the Affordable Care Act include research on the comparative clinical effectiveness of different technologies and procedures, initiatives to revise Medicare payment methodologies, such as bundling of payments across the continuum of care by providers and physicians, and initiatives to promote quality indicators in payment methodologies. The Affordable Care Act also includes significant new fraud and abuse measures, including required disclosures of financial payments to and arrangements with physician customers, lower thresholds for violations and increasing potential penalties for such violations.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act. It remains unclear whether changes will be made to the Affordable Care Act, or whether it will be repealed or materially modified. There likely will continue to be legislative and regulatory proposals at the federal and state levels directed at containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future or their full impact. The continuing efforts of the government, insurance companies, managed care organizations and other payers of healthcare services to contain or reduce costs of healthcare may harm our ability to set a price that we believe is fair for our products, our ability to generate revenues and achieve or maintain profitability and the availability of capital.

If we fail to comply with healthcare regulations with respect to our current or future products, we could face substantial penalties and our business, operations and financial condition could be adversely affected.

Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third party payers, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights will be applicable to our business. We could be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. The regulations that will affect how we operate include:

- the federal healthcare program Anti-Kickback Statute, which prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs;

- the federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government;

- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- the federal Physician Payment Sunshine Act, created under the Affordable Care Act, and its implementing regulations, which require manufacturers of drugs, medical devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the U.S. Department of Health and Human Services information related to payments or other transfers of value made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;

- the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payer, including commercial insurers.

The Affordable Care Act, among other things, amends the intent requirement of the Federal Anti-Kickback Statute and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the Affordable Care Act provides that 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 False Claims Act.

Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal and similar foreign healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations, any of which could harm our ability to operate our business and our results of operations.

Failure to comply with privacy and security laws and regulations could result in fines, penalties and damage to our reputation and have a material adverse effect on our business.

We are or may become subject to a number of federal and state laws and regulations protecting the use, disclosure, and confidentiality of certain patient health and personal information and restricting the use and disclosure of that protected information, including state breach notification laws, the Health Insurance Portability and Accountability Act, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and the California Consumer Privacy Act, among others.

HIPAA extensively regulates the use and disclosure of individually identifiable health information, known as "protected health information," and require covered entities to implement administrative, physical and technical safeguards to protect the security of such information. Covered entities must report breaches of unsecured protected health information to affected individuals without unreasonable delay and notification must also be made to the U.S. Department of Health & Human Services, Office for Civil Rights (the "OCR") and, in certain situations involving large breaches, to the media. Various U.S. state laws and regulations may also require us to notify affected individuals and state agencies in the event of a data breach involving individually identifiable information.

Compliance with HIPAA privacy regulations and security regulations is costly, and violations of the HIPAA privacy and security regulations may result in criminal and civil penalties. The OCR enforces the regulations and performs compliance audits. In addition to enforcement by OCR, state attorneys general are authorized to bring civil actions seeking either injunction or damages in response to violations that threaten the privacy of state residents. We also are or may become subject to state privacy-related laws, such as the CCPA, that are more restrictive than the privacy regulations issued under HIPAA. These laws vary and could impose additional penalties.

Risks Related to Owning Our Securities and Our Financial Results

Our quarterly and annual results may fluctuate significantly, may not fully reflect the underlying performance of our business and may result in decreases in the price of our securities.

Our financial condition and operating results may fluctuate significantly from quarter-to-quarter and year-to-year due to a variety of factors, some of which are beyond our control. Our operating results will be affected by numerous factors such as:

- variations in the level of expenses related to our proposed products;
- status of our product development efforts;
- execution of collaborative, licensing or other arrangements, and the timing of payments received or made under those arrangements;
- intellectual property prosecution and any infringement lawsuits to which we may become a party;
- regulatory developments affecting our products or those of our competitors;
- our ability to obtain and maintain FCC clearance and/or FDA approval for our products, which have not yet been approved for marketing;
- our ability to successfully commercialize our products;
- market acceptance of our products;
- the timing and success of new products and feature introductions by us or our competitors or any other change in the competitive dynamics of our industry, including consolidation among competitors, customers or strategic partners;
- the amount and timing of costs and expenses related to the maintenance and expansion of our business and operations;
- general economic, industry and market conditions;
- the hiring, training and retention of key employees, including our ability to develop a sales team;
- litigation or other claims against us;
- our ability to obtain additional financing;
- the failure of our common stock to meet the minimum requirements for continued listing on the Nasdaq Capital Market;
- business interruptions caused by events such as pandemics and natural disasters; and
- advances and trends in new technologies and industry standards.

Any or all of these factors could adversely affect our cash position requiring us to raise additional capital, which may be on unfavorable terms and result in substantial dilution.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act, and are required to maintain disclosure controls and procedures that are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified by the rules and forms of the SEC, and that such information is accumulated and communicated to management to allow timely decisions regarding required disclosure.

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in those internal controls. Such internal controls are designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of a company's annual or interim financial statements will not be prevented or detected on a timely basis. We have identified a material weakness in our internal control over financial reporting at December 31, 2023. The material weakness relates to the ineffective design and operation of our financial close and reporting controls. Although we are making efforts to remediate this issue, these efforts may not be sufficient to avoid similar material weaknesses in the future. Designing and implementing internal controls over financial reporting may be time consuming, costly and complicated as we are a small organization with limited management resources.

If the material weakness in our internal controls is not fully remediated or if additional material weaknesses are identified, those material weaknesses could cause us to fail to meet our future reporting obligations, reduce the market's confidence in our consolidated financial statements, harm our stock price and subject us to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. In addition, our common stock may not be able to remain listed on Nasdaq or any other securities exchange.

For as long as we are an "emerging growth company," as defined in the JOBS Act, or a non-accelerated filer, as defined in Rule 12b-2 under the Exchange Act, our auditors will not be required to attest as to our internal control over financial reporting. If we continue to identify material weaknesses in our internal control over financial reporting, are unable to comply with the requirements of Section 404 in a timely manner, are unable to assert that our internal control over financial reporting is effective or, once required, our independent registered public accounting firm is unable to attest that our internal control over financial reporting is effective, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could decrease. We could also become subject to stockholder or other third-party litigation as well as investigations by the securities exchange on which our securities are listed, the SEC or other regulatory authorities, which could require additional financial and management resources and could result in fines, trading suspensions or other remedies.

Any control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

The issuance of additional stock in connection with financings, acquisitions, our equity incentive plan, upon exercise of outstanding warrants or otherwise will dilute our existing stockholders.

If we issue additional equity securities, our existing stockholders' percentage ownership will be reduced and these stockholders may experience substantial dilution. We may also issue equity securities that provide for rights, preferences, and privileges senior to those of our common stock. Subject to compliance with applicable rules and regulations, we may issue our shares of common stock in connection with a financing, acquisition, our equity incentive plan, upon exercise of outstanding warrants or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and cause the trading price of our common stock to decline.

Our stock price has fluctuated widely and is likely to continue to be volatile.

The market price for our common stock varied between a high of $2.10 and a low of $0.58 in the twelve-month period ended December 31, 2023. Our stock price is likely to continue to be volatile and subject to significant price and volume fluctuations in response to market and other factors, including those listed in this "Item 1A. Risk Factors" section and other, unknown factors. Among numerous other factors, our stock price also may be affected by:

- actual or anticipated fluctuations in our quarterly or annual operating results;
- changes in financial or operational estimates or projections;
- conditions in markets generally;
- changes in the economic performance or market valuations of companies similar to ours; and
- general economic or political conditions in the United States or elsewhere.

In particular, the market prices of technology companies like ours have been highly volatile due to factors, including, but not limited to:

- any delay or failure to commercialize products acceptable to the market;
- developments or disputes concerning our product's intellectual property rights;

- our or our competitors' technological innovations;
- changes in market valuations of similar companies;
- announcements by us or our competitors of significant contracts, acquisitions, strategic partnerships, joint ventures, capital commitments, new technologies, or patents; and
- failure to complete significant transactions or collaborate with vendors in manufacturing our product.

Any of these factors may result in large and sudden changes in the volume and trading price of our common stock. The stock market, generally, has from time to time experienced significant price and volume fluctuations that are not related to the operating performance of particular companies. These market fluctuations may also materially and adversely affect the market price of shares of our common stock.

The daily trading volume of our common stock has historically been relatively low. If we are unable to develop and maintain a liquid market for our common stock, our shareholders may not be able to sell common stock at prices they consider to be fair or at times that are convenient, or at all. This situation may be attributable to a number of factors, including but not limited to the fact that we are a development-stage company that is relatively unknown to stock analysts, stock brokers, institutional investors, and others in the investor community. In addition, investors may be risk averse to investments in development-stage companies. The low trading volume is outside of our control and may not increase or, if it increases, may not be maintained. In addition, following periods of volatility in the market price of a company's securities, litigation has often been brought against that company and we may become the target of litigation as a result of price volatility. Litigation could result in substantial costs and divert our management's attention and resources from our business. This could have a material adverse effect on our business, results of operations and financial condition.

Our failure to meet the continued listing requirements of Nasdaq could result in a de-listing of our common stock.

Our common stock is currently traded on the Nasdaq Stock Market ("Nasdaq"). On November 14, 2023, we were notified by Nasdaq that because the closing bid price for the Company's common stock listed on Nasdaq was below $1.00 for 30 consecutive trading days, the Company no longer meets the minimum bid price requirement for continued listing on The Nasdaq Capital Market under Nasdaq Marketplace Rule 5550(a)(2), requiring a minimum bid price of $1.00 per share (the "Minimum Bid Price Requirement"). In accordance with Nasdaq Marketplace Rule 5810(c)(3)(A), (1) we will have a period of 180 calendar days from November 14, 2023, or until May 13, 2024, to regain compliance with the Minimum Bid Price Requirement, (2) if at any time prior to May 13, 2024, the bid price of the Company's common stock closes at or above $1.00 per share for a minimum of 10 consecutive business days, Nasdaq will provide written notification that the Company has achieved compliance with the Minimum Bid Price Requirement and (3) in the event the Company does not regain compliance with the Minimum Bid Price Requirement by May 13, 2024, the Company will be eligible for an additional 180-day period to regain compliance with the Minimum Bid Price Requirement as long as it meets all other continued listing requirements, with the exception of the Minimum Bid Price Requirement. However, there can be no assurance that we will be afforded additional time to regain compliance with the minimum bid price requirement following the initial 180-day period or that we will regain compliance with the Minimum Bid Price Requirement. If we are unable to regain compliance with Nasdaq Marketplace Rule 5550(a)(2) in a timely manner, Nasdaq will commence suspension and delisting procedures. If Nasdaq delists our common stock from trading on its exchange, among other things, it could lead to a number of negative implications, including reduced liquidity in our common stock, the loss of federal preemption of state securities laws, fewer business development opportunities and greater difficulty in obtaining financing.

Our Certificate of Incorporation designates specific courts as the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us.

Our Third Amended and Restated Certificate of Incorporation specifies that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for most legal actions involving claims brought against us by stockholders; provided that, the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Securities Act, the Exchange Act, the rules and regulations thereunder or any other claim for which the federal courts have exclusive jurisdiction; and provided further that, if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in the State of Delaware. Our Certificate of Incorporation further provides that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall, to the fullest extent permitted by law, be the sole and exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our Certificate of Incorporation described above.

We believe these provisions benefit us by providing increased consistency in the application of Delaware law by chancellors particularly experienced in resolving corporate disputes and in the application of the Securities Act by federal judges, as applicable, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, the provisions may have the effect of discouraging lawsuits against our directors, officers, employees and agents as it may limit any stockholder's ability to bring a claim in a judicial forum that such stockholder finds favorable for disputes with us or our directors, officers, employees or agents. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with any applicable action brought against us, a court could find the choice of forum provisions contained in our Certificate of Incorporation to be inapplicable or unenforceable in such action. If a court were to find the choice of forum provisions contained in our Certificate of Incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business, financial condition or results of operations.

We have not paid dividends in the past and have no immediate plans to pay dividends.

We plan to reinvest all of our earnings, to the extent we have earnings, in order to further develop our technology and potential products and to cover operating costs. We do not plan to pay any cash dividends with respect to our securities in the foreseeable future. We may never generate sufficient surplus cash that would be available for distribution to the holders of our common stock as a dividend. Therefore, our shareholders should not expect to receive cash dividends on the common stock.

Concentration of ownership among our existing executive officers, directors and significant stockholders may prevent new investors from influencing significant corporate decisions.

All decisions with respect to the management of the Company will be made by our board of directors and our officers, who beneficially own approximately 10.5% of our common stock, as calculated in accordance with Rule 13d-3 promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). In addition, Peter Appel, Leabman Holdings LLC and Emily Fairbairn beneficially own approximately 9.9%, 7.5% and 6.1%, respectively, as calculated in accordance with Rule 13d-3 promulgated under the Exchange Act. As a result, these stockholders will be able to exercise a significant level of control over all matters requiring stockholder approval, including the election of directors, amendment of our Certificate of Incorporation and approval of significant corporate transactions. This control could have the effect of delaying or preventing a change of control of the Company or changes in management, in each case, which other stockholders might find favorable, and will make the approval of certain transactions difficult or impossible without the support of these significant stockholders.

We are an "emerging growth company" under the JOBS Act and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and we expect to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including, but not limited to, (i) being required to present only two years of audited financial statements and related financial disclosure, (ii) not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, (iii) extended transition periods for complying with new or revised accounting standards, (iv) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and (v) 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. We cannot predict if investors will find our common stock less attractive because we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and the price of our common stock may be more volatile.

We will remain an "emerging growth company" through December 31, 2026, although we will lose that status sooner if our annual revenues exceed $1.07 billion, if we issue more than $1 billion in non-convertible debt in a three-year period, or if the market value of our common stock that is held by non-affiliates exceeds $700 million as of any June 30.

We are incurring significant costs as a public company that reports to the SEC and our management is required to devote substantial time to meet compliance obligations.

As a public company listed in the United States, we incur significant legal, accounting and other expenses that we did not incur as a private company. We are subject to reporting requirements of the Exchange Act and the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC and Nasdaq that impose significant requirements on public companies, including requiring the establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. In addition, the Dodd-Frank Wall Street Reform and Protection Act includes significant corporate governance and executive compensation-related provisions that have and will continue to increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and may also place undue strain on our personnel, systems and resources. Our management and other personnel must devote a substantial amount of time to these compliance initiatives. In addition, these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, our board committees or as executive officers.

If securities or industry analysts do not publish research reports about our business, or if they issue an adverse opinion about our business, the price of our common stock and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. We do not currently have and may never obtain research coverage by securities and industry analysts. If no or few analysts commence research coverage of us, or one or more of the analysts who cover us issues an adverse opinion about our company, the price of our common stock would likely decline. If one or more of these analysts ceases research coverage of us or fails to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause the price of our common stock or trading volume to decline.

Our charter documents and Delaware law may inhibit a takeover that stockholders consider favorable.

Our Certificate of Incorporation and bylaws and applicable provisions of Delaware law may delay or discourage transactions involving an actual or potential change in control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares, or transactions that our stockholders might otherwise deem to be in their best interests. The provisions in our Certificate of Incorporation and bylaws:

- authorize our board of directors to issue preferred stock without stockholder approval and to designate the rights, preferences and privileges of each class; if issued, such preferred stock would increase the number of outstanding shares of our common stock and could include terms that may deter an acquisition of us;
- classifies our board of directors into three classes, with members of each class serving staggered three-year terms;
- limit who may call stockholder meetings;
- do not provide for cumulative voting rights;
- provide that all vacancies may be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- provide that stockholders must comply with advance notice procedures with respect to stockholder proposals and the nomination of candidates for director;
- provide that stockholders may only amend our Certificate of Incorporation and Bylaws upon a supermajority vote of stockholders; and
- provide that the Court of Chancery of the State of Delaware will be the exclusive forum for certain legal claims.

In addition, section 203 of the Delaware General Corporation Law may limit our ability to engage in any business combination with a person who beneficially owns 15% or more of our outstanding voting stock unless certain conditions are satisfied. This restriction lasts for a period of three years following the share acquisition. These provisions may have the effect of entrenching our management team and may deprive our shareholders of the opportunity to sell shares to potential acquirers at a premium over prevailing prices. This potential inability to obtain a control premium could reduce the price of our common stock.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 1C. Cybersecurity

Risk Management and Strategy

We operate in the technology and general wellness, continuous glucose and blood pressure monitoring sectors, which are subject to various cybersecurity risks that could adversely affect our business, financial condition, and results of operations, including intellectual property theft; fraud; extortion; harm to employees or customers; violation of privacy laws and other litigation and legal risk; and reputational risk. We have implemented a risk-based approach to identify and assess the cybersecurity threats that could affect our business and information systems. Our processes also include assessing cybersecurity threat risks associated with our use of third-party services providers in normal course of business use. Third-party risks are included within our cybersecurity risk management processes discussed above. In addition, we assess cybersecurity considerations in the selection and oversight of our third-party services providers, including due diligence on the third parties that have access to our systems and facilities that house systems and data.

Our business depends on the availability, reliability, and security of our information systems, networks, data, and intellectual property. Any disruption, compromise, or breach of our systems or data due to a cybersecurity threat or incident could adversely affect our operations, customer service, product development, and competitive position. They may also result in a breach of our contractual obligations or legal duties to protect the privacy and confidentiality of our stakeholders. Such a breach could expose us to business interruption, lost revenue, ransom payments, remediation costs, liabilities to affected parties, cybersecurity protection costs, lost assets, litigation, regulatory scrutiny and actions, reputational harm, customer dissatisfaction, or harm to our vendor relationships.

Cybersecurity Governance and Oversight

Our board of directors addresses our cybersecurity risk management as part of its general oversight function. We maintain security controls that are continuously reviewed to protect against emerging cyber threats. Our IT Department monitors these security controls and risks and regularly reports to senior management and the board of directors on material developments.

To manage our material risks from cybersecurity threats and to protect against, detect, and prepare to respond to cybersecurity incidents, we undertake the below listed activities:

- Monitor emerging data protection laws in conjunction with our advisors and implement changes to our processes to comply;
- Maintain firewall and virus protection software; and
- Maintain a cybersecurity insurance policy.

Our cybersecurity incident response processes are designed to escalate certain cybersecurity incidents to designated employees and other members of management depending on the circumstances, including in some cases to our executive team. The board of directors receives regular reports from management concerning our cybersecurity risk management program. The board also receives various summaries and/or presentations related to cybersecurity threats, risks and mitigation.

As of the date of this Annual Report on Form 10-K, we are not aware of any cybersecurity threats that have materially affected, or are reasonably likely to materially affect, our business strategy, results of operations or financial position.

Item 2. Properties

Our principal office is located at 6800 Koll Center Parkway, Pleasanton, California, and is comprised of office and laboratory space that we occupy pursuant to a lease. See Note 10 Commitments and Contingencies of our consolidated financial statements for further discussion of this lease facility.

Item 3. Legal Proceedings

We are not currently a party to any pending legal proceedings that we believe will have a material adverse effect on our business or financial conditions. We may, however, be subject to various claims and legal actions arising in the ordinary course of business from time to time.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our shares of common stock have been listed on the Nasdaq Capital Market under the symbol "MOVE" since March 23, 2021. Prior to that date, there was no public trading market for our common stock.

As of April 10, 2024, there were 215 holders of record of our common stock.

Dividend Policy

We have never paid cash dividends on our securities, and we do not anticipate paying any cash dividends on our shares of common stock in the foreseeable future. We intend to retain any future earnings for reinvestment in our business. Any future determination to pay cash dividends will be at the discretion of our board of directors, and will be dependent upon our financial condition, results of operations, capital requirements and such other factors as our board of directors deems relevant.

Recent Sales of Unregistered Securities

Not applicable.

Item 6. Reserved

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion of our financial condition and results of operations should be read in conjunction with the financial statements and the related notes thereto included elsewhere in this Annual Report. This discussion and analysis contains forward-looking statements that are based on our management's current beliefs and assumptions, which statements are subject to substantial risks and uncertainties. Our actual results may differ materially from those expressed or implied by these forward-looking statements as a result of many factors, including those discussed in "Risk Factors" in Item 1A of this Annual Report. Please also see "Cautionary Note Regarding Forward-Looking Statements" at the beginning of this Annual Report.

Overview

Movano Inc., dba Movano Health, a Delaware corporation, is developing a platform to deliver purpose-driven healthcare solutions to bring medical-grade, high-quality data to the forefront of consumer health devices.

Our initial commercial product in development is the Evie Ring, a wearable designed specifically for women that was launched in November 2023. The Evie Ring combines health and wellness metrics to give a full picture of one's health, which include resting heart rate, HRV, SpO_2, respiration rate, skin temperature variability, period and ovulation tracking, menstrual symptom tracking, activity profile, including steps, active minutes and calories burned, sleep stages and duration, and mood tracking.

In addition to the Evie Ring, we are developing one of the smallest patented and proprietary SoC designed specifically for blood pressure or CGM systems. Movano Health built the integrated sensor from the ground up with multiple antennas and a variety of frequencies to achieve an unprecedented level of precision in health monitoring. We are currently conducting clinical trials with the SoC and developing algorithms that, if successful, will enable us to develop wearables that can monitor glucose non-invasively and blood pressure without a cuff. Our end goal is to bring a Class II FDA-cleared device to the market that includes CGM and cuffless blood pressure monitoring capabilities. Over time, our technology could also enable the measurement and continuous monitoring of other health data.

On April 28, 2021, the Company established Movano Ireland Limited, organized under the laws of Ireland, as a wholly owned subsidiary of the Company.

Financial Operations Overview

We are an early-stage technology company with a limited operating history. To date, we have invested substantially all of our efforts and financial resources into (i) the research and development of the products we are developing, including conducting clinical studies and related sales, general and administrative costs, and (ii) the commercialization of our first commercial product, the Evie Ring. To date, we have funded our operations primarily from the sale of our equity securities.

We have incurred net losses in each year since inception. Our losses were $29.3 million and $30.3 million for the years ended December 31, 2023 and 2022, respectively. Substantially all our net losses have resulted from costs incurred in connection with our research and development programs and from sales, general and administrative costs associated with our operations.

As of December 31, 2023, we had $6.1 million in available cash and cash equivalents.

Adoption of New Accounting Pronouncement - Leases

In February 2016, the FASB issued ASU 2016-02, *Leases* (ASC 842) which requires lessees to recognize leases on the balance sheet by recording a right-of-use asset and lease liability. We adopted this new guidance as of January 1, 2022 and applied the modified retrospective approach, whereby prior comparative periods will not be retrospectively presented in the consolidated financial statements. We elected the package of practical expedients not to reassess prior conclusions related to contracts containing leases and lease classification and the lessee practical expedient to combine lease and non-lease components for all asset classes. We made a policy election to not recognize right-of-use assets and lease liabilities for short-term leases for all asset classes. See Note 10 Commitments and Contingencies of our consolidated financial statements for further details.

Upon adoption on January 1, 2022, we recognized right-of-use assets and lease liabilities for operating leases of $380,000 and $429,000, respectively. The difference between the right-of-use asset and lease liability primarily represents the net book value of deferred rent recognized as of December 31, 2021, which was adjusted against the right-of-use asset upon adoption.

Adoption of New Accounting Pronouncement - Debt

In August 2020, the FASB issued Accounting Standards Update 2020-06, *Debt - Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging - Contracts in Entity's Own Equity (Subtopic 815-40) - Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*. The amendments in this update reduce the number of accounting models for convertible debt instruments and convertible preferred stock, resulting in fewer embedded conversion features being recognized separately from their host contracts. The pronouncement also revises the derivatives scope exception for contracts in an entity's own equity and improves the consistency of earnings per share calculations as that relates to convertible instruments. We early-adopted this pronouncement as of January 1, 2023 using the modified retrospective method of transition. The adoption did not have any impact on our consolidated financials.

Adoption of New Accounting Pronouncement – Income Taxes

On December 14, 2023, the FASB issued ASU 2023-09, *Improvements to Income Tax Disclosures*, which amends the guidance in ASC 740, *Income Taxes*. The ASU is intended to improve the transparency of income tax disclosures by requiring (1) consistent categories and greater disaggregation of information in the rate reconciliation and (2) income taxes paid disaggregated by jurisdiction. It also includes certain other amendments to improve the effectiveness of income tax disclosures. The ASU's amendments are effective for public business entities for annual periods beginning after December 15, 2024. Entities are permitted to early adopt the standard "for annual financial statements that have not yet been issued or made available for issuance." Adoption is either prospectively or retrospectively, we will adopt this ASU on a prospective basis. We are currently evaluating the impact of the ASU but do not expect any material impacts upon adoption.

Critical Accounting Estimates

The discussion and analysis of our consolidated financial condition and results of operations are based on our consolidated financial statements, which we have prepared in accordance with U.S. GAAP. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements as well as the reported expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in Note 2 "Significant Accounting Policies" to the consolidated financial statements in Part II, Item 8 of this Annual Report on Form 10-K, we believe that the following accounting estimates are most critical to a full understanding and evaluation of our consolidated reported financial results.

Common Stock Warrants

During the normal course of business, from time to time, we issue warrants to purchase common stock as part of a debt or equity financing or to vendors as consideration to perform services. We assess each warrant to determine if it meets the characteristics of a liability or a derivative, and if the warrant does meet the characteristics of a liability or a derivative, we classify the warrant as a liability measured at fair value. The derivative liabilities are remeasured at each period end, on a recurring basis, to the estimated fair value with the changes in fair value reflected as current period income or loss until the warrant is exercised, extinguished, or expires. If the warrant does not meet the characteristics of a liability or a derivative, we classify the warrant as equity, and record the warrant at its fair value on the date of issuance. The fair value of our warrants is estimated using appropriate pricing models based on the nature and characteristics of the underlying warrants and such models contain estimates and assumptions that require careful consideration and judgment. To date, we have not experienced changes in these estimates and have not had to modify our assumptions.

Stock-Based Compensation

We measure equity classified stock-based awards granted to employees, directors, and nonemployees based on the estimated fair value on the date of grant and recognizes compensation expense of those awards on a straight-line basis over the requisite service period, which is generally the vesting period of the respective award. The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option pricing model. This valuation model for stock-based compensation expense requires us to make assumptions and judgments about the variables used in the calculation including the expected term, the volatility of our common stock, and an assumed risk-free interest rate. As a result, if we revise our assumptions and estimates, our stock-based compensation expense could change. These assumptions include:

Dividend Rate — The expected dividend rate was assumed to be zero, as we have not previously paid dividends on common stock and have no current plans to do so.

Expected Volatility — The expected volatility was derived from the historical stock volatilities of several public companies within our industry that we consider to be comparable to our business over a period equivalent to the expected term of the stock option grants.

Risk-Free Interest Rate — The risk-free interest rate is based on the interest yield in effect at the date of grant for zero coupon U.S. Treasury notes with maturities approximately equal to the option's expected term.

Expected Term — The expected term represents the period that our stock options are expected to be outstanding. The expected term of option grants that are considered to be "plain vanilla" are determined using the simplified method. The simplified method deems the term to be the average of the time-to-vesting and the contractual life of the options. For other option grants not considered to be "plain vanilla," we determined the expected term to be the contractual life of the options.

Forfeitures — We made the one-time policy election to recognize forfeitures when they occur.

Income Taxes

We account for income taxes using the asset and liability method. Under this method, deferred tax assets and liabilities are determined based on differences between the financial statement and tax basis of assets and liabilities and net operating loss and credit carryforwards using enacted tax rates in effect for the year in which the differences are expected to reverse. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

We account for unrecognized tax benefits using a more-likely-than-not threshold for financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. We establish a liability for tax-related uncertainties based on estimates of whether, and the extent to which, additional taxes will be due. We record an income tax liability, if any, for the difference between the benefit recognized and measured and the tax position taken or expected to be taken on our tax returns. To the extent that the assessment of such tax positions changes, the change in estimate is recorded in the period in which the determination is made. The liability is adjusted considering changing facts and circumstances, such as the outcome of a tax audit. The provision for income taxes includes the impact of liability provisions and changes to the liability that are considered appropriate. Changes in recognition or measurement are reflected in the period in which the change in judgment occurs.

Results of Operations

Years Ended December 31, 2023 and 2022

Our consolidated statements of operations for the years ended December 31, 2023 and 2022 as discussed herein are presented below.

	Year Ended December 31,		Change	
	2023	2022	$	%
	(in thousands, except share and per share data)			
OPERATING EXPENSES:				
Research and development	$ 16,893	$ 18,994	$ (2,101)	-11%
Sales, general and administrative	12,797	11,468	1,329	12%
Total operating expenses	29,690	30,462	(772)	-3%
Loss from operations	(29,690)	(30,462)	772	3%
Other income (expense), net:				
Interest and other income, net	407	133	274	206%
Other income (expense), net	407	133	274	206%
Net loss	$ (29,283)	$ (30,329)	$ 1,046	3%

Research and Development

Research and development expenses totaled $16.9 million and $19.0 million for the years ended December 31, 2023 and 2022, respectively. This decrease of $2.1 million was due primarily to a reduction in design costs and activity. Research and development expenses for the year ended December 31, 2023 included expenses related to employee compensation of $5.6 million, other professional fees of $5.7 million, tools and equipment expenses of $4.4 million, rent of $0.2 million, depreciation and amortization of $0.1 million, and other expenses of $0.9 million. Research and development expenses for the year ended December 31, 2022 included expenses related to employee compensation of $9.4 million, other professional fees of $6.7 million, tools and equipment expenses of $2.0 million, rent of $0.2 million, depreciation and amortization of $0.1 million, and other expenses of $0.6 million.

Sales, General and Administrative

Sales, general and administrative expenses totaled $12.8 million and $11.5 million for the years ended December 31, 2023 and 2022, respectively. This increase of $1.3 million was due primarily to the growth of the Company and in preparation for the Evie Ring product launch. Sales, general and administrative expenses for the year ended December 31, 2023 included expenses related to employee and board of director compensation of $5.9 million, professional and consulting fees of $2.6 million, rent of $0.1 million, insurance of $0.8 million, and other expenses of $3.4 million. Sales, general and administrative expenses for the year ended December 31, 2022 included expenses related to employee and board of director compensation of $6.1 million, professional and consulting fees of $2.5 million, rent of $0.1 million, insurance of $1.3 million, and other expenses of $1.5 million.

Loss from Operations

Loss from operations was $29.7 million for the year ended December 31, 2023, as compared to $30.5 million for the year ended December 31, 2022.

Other Income (Expense), Net

Other income (expense), net for the year ended December 31, 2023 was a net other income of $0.4 million as compared to a net other income of $0.1 million for the year ended December 31, 2022. The increase of $0.3 million was primarily attributable to additional interest income on cash and cash equivalent due to higher prevailing interest rates.

Net Loss

As a result of the foregoing, net loss was $29.3 million for the year ended December 31, 2023, as compared to $30.3 million for the year ended December 31, 2022.

Liquidity and Capital Resources

At December 31, 2023, we had cash and cash equivalents of $6.1 million. During the year ended December 31, 2023, we used $26.2 million of cash in our operating activities. Our cash and cash equivalents are not expected to be sufficient to fund our operations for the next twelve months after the date these consolidated financial statements are issued.

In August 2022, we entered into an at-the-market issuance ("ATM") agreement with B. Riley Securities Inc., or B. Riley, to sell shares of our common stock for aggregate gross proceeds of up to $50.0 million, from time to time, through an ATM equity offering program under which B. Riley acts as sales agent. During the years ended December 31, 2023 and 2022, the Company sold an aggregate of 2,531,757 and 810,400 shares of common stock, respectively, through the ATM program for proceeds of approximately $3.2 million and $2.2 million, net of commissions paid, respectively. Approximately $44.4 million remains available on the ATM equity offering program at December 31, 2023. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We anticipate that our expenses will increase substantially as we:

- advance the engineering design and further development of the Evie Ring and other potential products;
- prepare applications required for marketing approval of the Evie Ring in the United States;
- continue to expand our plans for manufacturing, distributing and marketing the Evie Ring and other potential products; and
- add operational, financial and management information systems and personnel, including personnel to support our product development, commercialization efforts and our operation as a public company.

On April 2, 2024, the Company entered into a securities purchase agreement for the private placement of an aggregate of 45,252,517 units with each unit consisting of (1) one share of the Company's common stock or at the election of the purchaser a pre-funded warrant, and (2) one warrant to purchase one share of common stock. The purchase price paid for each unit was $0.533. Certain directors and officers participated and purchased 287,500 units at an offering price of $0.565 per share.

Each pre-funded warrant has an exercise price of $0.001 per share, was immediately exercisable on the date of issuance and does not expire. Each warrant has an exercise price equal to $0.4071 per share, was exercisable immediately and expires on the fifth anniversary of the initial exercise date of the warrant. The warrants being issued to the Company's officers and directors have an exercise price equal to $0.44.

The gross proceeds were approximately $24.1 million, before deducting offering fees and expenses of approximately $1.4 million. The offering closed on April 5, 2024.

Until we can generate a sufficient amount of revenue from our products, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings or corporate collaborations and licensing arrangements. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs or our commercialization efforts or it may become impossible for us to remain in operation. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience additional dilution, and debt financing, if available, may involve restrictive covenants. To the extent that we raise additional funds through collaborations and licensing arrangements, it may be necessary to relinquish some rights to our technologies or applications or grant licenses on terms that may not be favorable to us. We may seek to access the public or private capital markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time.

These circumstances raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the consolidated financial statements are issued. Our consolidated financial statements do not include adjustments to the amounts and classification of assets and liabilities that may be necessary should we be unable to continue as a going concern. Our ability to continue as a going concern depends on our ability to raise additional capital through the sale of equity or debt securities to support our future operations.

The following table summarizes our cash flows for the periods indicated (in thousands):

	Year Ended December 31,	
	2023	2022
Net cash used in operating activities	$ (26,177)	$ (24,902)
Net cash provided by / (used in) investing activities	(64)	15,724
Net cash provided by financing activities	21,600	2,262
Net decrease in cash and cash equivalents	$ (4,641)	$ (6,916)

Operating Activities

During the year ended December 31, 2023, we used cash of $26.2 million in operating activities, as compared to $24.9 million used in operating activities during the year ended December 31, 2022.

The $26.2 million used in operating activities during the year ended December 31, 2023 was primarily attributable to our net loss of $29.3 million and changes in our operating assets and liabilities totaling $0.3 million. These items were offset by non-cash items, including stock-based compensation of $3.0 million, non-cash lease expense of $0.2 million, and depreciation and amortization of $0.2 million.

The $24.9 million used in operating activities during the year ended December 31, 2022 was primarily attributable to our net loss of $30.3 million and changes in our operating assets and liabilities totaling $2.1 million. These items were offset by non-cash items, including stock-based compensation of $3.1 million, depreciation of $0.1 million and accretion of discount on short-term investments of $0.1 million.

Investing Activities

During the year ended December 31, 2023 we used cash of $64,000 in investing activities, consisting of purchases of property and equipment.

During the year ended December 31, 2022 we were provided cash of $15.7 million in investing activities, consisting of $15.8 million in maturities of short-term investments and offset by $0.1 million for the purchase of office and laboratory equipment.

Financing Activities

During the year ended December 31, 2023, we were provided cash of $21.6 million which included net proceeds of $6.7 million, $8.1 million and $3.6 million from the issuance of equity securities in public offerings in February 2023, June 2023 and November 2023, respectively, net proceeds of $3.2 million from the issuance of common stock through the ATM equity offering program.

During the year ended December 31, 2022, we were provided cash of $2.3 million from financing activities, comprised of $2.3 million from the issuance of common stock.

Funding Requirements

We anticipate that, excluding non-recurring items, we will continue to generate annual losses for the foreseeable future as we continue the commercialization and further development of our Evie Ring and other products in development. We will require additional capital to fund our operations, to complete our ongoing and planned clinical studies, to commercialize our products, to continue investing in and to further develop our general infrastructure, and such funding may not be available to us on acceptable terms or at all.

If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may be required to delay, limit, reduce the scope of, or terminate one or more of our clinical studies, research and development programs, or our future commercialization efforts.

Our future funding requirements will depend on many factors, including the following:

- the success of our commercialization of the Evie Ring;
- the scope, rate of progress, results and cost of our product development and clinical testing;
- the cost of manufacturing our products in development and any products that we may develop in the future;
- the number and characteristics of the potential products that we pursue;
- the cost, timing, and outcomes of regulatory approvals; and
- the potential that our common stock will be delisted by Nasdaq in the event we fail to regain compliance in a timely manner with the minimum bid price requirement.

We expect to satisfy future cash needs through existing capital balances, through some combination of public or private equity offerings, debt financings, licensing arrangements, and other marketing and distribution arrangements. Please see “Risk Factors—Risks Related to Our Business.”

Contractual Obligations

Material contractual obligations arising in the normal course of business primarily consist of operating leases and financing leases. See Note 10 to the consolidated financial statements for amounts outstanding for operating leases and financing leases on December 31, 2023.

Off-Balance Sheet Transactions

At December 31, 2023, We did not have any transactions, obligations or relationships that could be considered off-balance sheet arrangements.

Non-cancelable Obligations

We did not have any non-cancelable contractual commitments as of December 31, 2023.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Not applicable.

Item 8. Financial Statements and Supplementary Data.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of
Movano Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Movano Inc. (the "Company") as of December 31, 2023 and 2022, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2023 and 2022, and the consolidated results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses from operations and has a net capital deficiency that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

/s/ Moss Adams LLP

San Francisco, California
April 16, 2024

We have served as the Company's auditor since 2019.

Movano Inc.
Consolidated Balance Sheets
(in thousands, except share and per share data)

	Year Ended December 31,	
	2023	**2022**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 6,118	$ 10,759
Payroll tax credit, current portion	450	379
Vendor deposits	399	103
Inventory	1,114	—
Prepaid expenses and other current assets	442	405
Total current assets	8,523	11,646
Property and equipment, net	342	443
Payroll tax credit, noncurrent portion	169	667
Other assets	387	487
Total assets	$ 9,421	$ 13,243
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,118	$ 557
Deferred revenue	1,252	—
Other current liabilities	1,529	4,421
Total current liabilities	5,899	4,978
Noncurrent liabilities:		
Early exercised stock option liability	23	136
Other noncurrent liabilities	50	214
Total noncurrent liabilities	73	350
Total liabilities	5,972	5,328
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock, $0.0001 par value, 5,000,000 shares authorized at December 31, 2023 and 2022; no shares issued and outstanding at December 31, 2023 and 2022	—	—
Common stock, $0.0001 par value, 150,000,000 shares authorized at December 31, 2023 and 75,000,000 at December 31, 2022; 55,848,272 and 33,659,460 shares issued and outstanding at December 31, 2023 and 2022, respectively	6	3
Additional paid-in capital	127,823	103,009
Accumulated deficit	(124,380)	(95,097)
Total stockholders' equity	3,449	7,915
Total liabilities and stockholders' equity	$ 9,421	$ 13,243

See accompanying notes to consolidated financial statements.

Movano Inc.
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)

	Year Ended December 31,	
	2023	**2022**
OPERATING EXPENSES:		
Research and development	$ 16,893	$ 18,994
Sales, general and administrative	12,797	11,468
Total operating expenses	29,690	30,462
Loss from operations	(29,690)	(30,462)
Other income (expense), net:		
Interest and other income, net	407	133
Other income (expense), net	407	133
Net loss and comprehensive loss	$ (29,283)	$ (30,329)
Net loss per share, basic and diluted	$ (0.63)	$ (0.92)
Weighted average shares used in computing net loss per share, basic and diluted	46,195,403	33,025,721

See accompanying notes to consolidated financial statements.

Movano Inc.
Consolidated Statements of Stockholders' Equity
(In thousands, except share data)

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Loss	Deficit	Equity
Balance at December 31, 2021	32,772,060	$ 3	$ 97,506	$ (11)	$ (64,768)	$ 32,730
Stock-based compensation	—	—	3,096	—	—	3,096
Issuance of common stock, net of issuance costs	810,400	—	2,231	—	—	2,231
Issuance of common stock upon exercise of options	77,000	—	31	—	—	31
Vesting of early exercised stock options	—	—	145	—	—	145
Other comprehensive loss	—	—	—	11	—	11
Net loss	—	—	—	—	(30,329)	(30,329)
Balance at December 31, 2022	33,659,460	$ 3	$ 103,009	$ —	$ (95,097)	$ 7,915
Stock-based compensation	—	—	2,980	—	—	2,980
Issuance of common stock upon February 2023 public offering, net of issuance costs	5,340,600	1	5,179	—	—	5,180
Issuance of warrants upon February 2023 public offering	—	—	1,473	—	—	1,473
Issuance of common stock upon June 2023 public offering, net of issuance costs	9,200,000	1	8,065	—	—	8,066
Issuance of common stock upon November 2023 public offering, net of issuance costs	4,870,600	1	3,568	—	—	3,569
Issuance of common stock	2,531,757	—	3,203	—	—	3,203
Issuance of common stock upon exercise of options	245,855	—	109	—	—	109
Issuance of common stock warrant	—	—	124	—	—	124
Vesting of early exercised stock options	—	—	113	—	—	113
Net loss	—	—	—	—	(29,283)	(29,283)
Balance at December 31, 2023	55,848,272	$ 6	$ 127,823	$ —	$ (124,380)	$ 3,449

See accompanying notes to consolidated financial statements.

Movano Inc.
Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2023	**2022**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (29,283)	$ (30,329)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	158	147
Stock-based compensation	2,980	3,096
Noncash lease expense	224	(13)
Accretion of discount on short-term investments	—	103
Loss on disposal of property and equipment	13	44
Changes in operating assets and liabilities:		
Payroll tax credit	427	(250)
Inventory	(1,114)	—
Prepaid expenses, vendor deposits and other current assets	(209)	788
Other assets	(41)	(50)
Accounts payable	2,555	246
Deferred revenue	1,252	—
Other current and noncurrent liabilities	(3,139)	1,316
Net cash used in operating activities	(26,177)	(24,902)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(64)	(105)
Maturities of short-term investments	—	15,829
Net cash provided by (used in) investing activities	(64)	15,724
CASH FLOWS FROM FINANCING ACTIVITIES:		
Issuance of common stock and warrants upon February 2023 public offering, net of issuance costs	6,653	—
Issuance of common stock upon June 2023 public offering, net of issuance costs	8,066	—
Issuance of common stock upon November 2023 public offering, net of issuance costs	3,569	—
Issuance of common stock, net of issuance costs	3,203	2,231
Issuance of common stock upon exercise of stock options	109	31
Net cash provided by financing activities	21,600	2,262
Net decrease in cash and cash equivalents	(4,641)	(6,916)
Cash and cash equivalents at beginning of period	10,759	17,675
Cash and cash equivalents at end of period	$ 6,118	$ 10,759
NONCASH INVESTING AND FINANCING ACTIVITIES:		
Vesting of common stock issued upon early exercise	$ 113	$ 145
Warrants issued upon February 2023 public offering	$ 1,473	$ —
Issuance of common stock warrant	$ 124	$ —
Property and equipment purchases in other current liabilities	$ —	$ 19
Right of use asset recorded for equipment finance lease	$ 50	$ —

See accompanying notes to consolidated financial statements.

NOTE 1 – BUSINESS ORGANIZATION, NATURE OF OPERATIONS

Movano Inc., dba Movano Health (the "Company", "Movano", "Movano Health", "we", "us" or "our"), was incorporated in Delaware on January 30, 2018 as Maestro Sensors Inc. and changed its name to Movano Inc. on August 3, 2018. The Company is in the development-stage and is developing a platform to deliver purpose-driven healthcare solutions at the intersection of medical and consumer devices. Movano is on a mission to make medical grade data more accessible and actionable for all.

The Company's solutions are being developed to provide vital health information, including heart rate, heart rate variability ("HRV"), sleep, respiration rate, temperature, SpO_2, steps, and calories as well as glucose and blood pressure data, in a variety of form factors to meet individual style needs and give users actionable feedback to improve their quality of life.

On April 28, 2021, the Company established Movano Ireland Limited, organized under the laws of Ireland, as a wholly owned subsidiary of the Company. Operations and activity at the wholly owned subsidiary were not significant for the years ended December 31, 2023 and 2022, respectively.

Since inception, the Company has engaged in only limited research and development of product candidates and underlying technology and the commercialization of the Company's first proposed commercial product, the Evie Ring. As of December 31, 2023, the Company had not yet completed the development of its product and had not yet recorded any revenues.

On February 6, 2023, the Company completed a $7.5 million underwritten public offering of 5,340,600 shares of its common stock and warrants to purchase up to 2,670,300 shares of common stock, including the full exercise of the underwriter's overallotment option. The warrants were offered at the rate of one warrant for every two shares of purchased common stock and are exercisable at a price per share of $1.57. The public offering price per share, before the underwriters' discount and commissions, for each share of common stock and accompanying warrant was $1.40. The net proceeds from the offering were approximately $6.7 million (See Note 7).

On June 15, 2023, the Company completed a $9.2 million underwritten public offering of 9,200,000 shares of its common stock, including the full exercise of the underwriter's overallotment option. The public offering price per share, before the underwriters' discount and commissions, for each share of common stock was $1.00. The net proceeds from the offering were approximately $8.1 million (See Note 7).

On November 17, 2023, the Company completed a $4.1 million underwritten public offering of 4,870,600 shares of its common stock, including the full exercise of the underwriter's overallotment option. The public offering price per share, before the underwriters' discount and commissions, for each share of common stock was $0.85. The net proceeds from the offering were approximately $3.6 million. (See Note 7).

The Company has incurred losses from operations and has generated negative cash flows from operating activities since inception. The Company expects to continue to incur net losses for the foreseeable future as it continues the development of its technology. The Company's ultimate success depends on the outcome of its research and development and commercialization activities, for which it expects to incur additional losses in the future. Through December 31, 2023, the Company has relied primarily on the proceeds from equity offerings to finance its operations. Through December 31, 2023, the Company has received gross proceeds of approximately $5.6 million from an at-the-market issuance program, and an aggregate offering price amount of approximately $44.4 million remains available to be issued. (See Note 7.) The Company expects to require additional financing to fund its future planned operations, including research and development and commercialization of its products. The Company will likely raise additional capital through the issuance of equity, borrowings, or strategic alliances with partner companies. However, if such financing is not available at adequate levels, the Company would need to reevaluate its operating plans.

Liquidity and Going Concern

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has incurred significant losses and has an accumulated deficit of $124.4 million as of December 31, 2023. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales. The Company's existence is dependent upon management's ability to obtain additional funding sources. These circumstances raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued.

Adequate additional financing may not be available to the Company on acceptable terms, or at all. If the Company is unable to raise additional capital and/or enter into strategic alliances when needed or on attractive terms, it would be forced to delay, reduce, or eliminate its product or any commercialization efforts. There can be no assurance that the Company's efforts will result in the resolution of the Company's liquidity needs. The accompanying consolidated financial statements do not include any adjustments that might result should the Company be unable to continue as a going concern.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The Company has prepared the accompanying consolidated financial statements in accordance with GAAP.

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of expenses during the reporting periods.

Significant estimates and assumptions reflected in these consolidated financial statements include the fair value of stock options and warrants and income taxes. Estimates are periodically reviewed considering changes in circumstances, facts, and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ from those estimates or assumptions.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one segment. The Company's chief operating decision maker is the Chief Executive Officer.

Cash, Cash Equivalents and Short-term Investments

The Company invests its excess cash primarily in money market funds, commercial paper and short-term debt securities. The Company considers all highly liquid investments with an original maturity of three months or less to be cash equivalents. As of December 31, 2023 and 2022, the Company did not hold any short-term investments.

Concentrations of Credit Risk and Off-Balance Sheet Risk

Cash and cash equivalents are financial instruments that are potentially subject to concentrations of credit risk. Substantially all cash and cash equivalents are held in United States financial institutions. Cash equivalents consist of interest-bearing money market accounts and institutional money market funds. The amounts deposited in the money market accounts exceed federally insured limits. Further, the Company has amounts in excess of federally insured limits as of December 31, 2023 at one financial institution that totaled approximately $2.5 million. The Company has not experienced any losses related to this account and believes the associated credit risk to be minimal due to the financial condition of the depository institutions in which those deposits are held.

The Company is dependent on third-party manufacturers to supply products for research and development activities. These programs could be adversely affected by a significant interruption in the supply of such materials.

The Company has no financial instruments with off-balance sheet risk of loss.

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets were primarily comprised of prepaid expenses and other current receivables.

Inventory

Inventory, which consists of raw materials, is stated at the lower of cost or net realizable value. Cost comprises purchase price and incidental expenses incurred in bringing the inventory to its present location and condition. Cost is computed using the weighted-average cost method.

The Company writes down its inventory for estimated obsolescence or unmarketable inventory equal to the difference between the cost of inventory and the estimate net realized value based upon assumptions about future demand and market conditions. If actual market conditions are less favorable than those projected by management, additional inventory write-downs may be required.

Software Development Costs

Costs related to software development are included in research and development expense until the point that technological feasibility is reached, which, for the Company's product, will be shortly before the product is released to manufacturing. Once technological feasibility is reached, such costs are capitalized and amortized to cost of revenue over the estimated lives of the product. During the years ended December 31, 2023 and 2022, no development costs were capitalized.

Impairment of Long-Lived Assets

The Company reviews the impairment of long-lived assets whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. An impairment loss would be recognized when estimated future cash flows expected to result from the use of the asset and its eventual disposition is less than its carrying amount.

Revenue

The Company generates revenue from the sale of Evie Rings, portable chargers and charging cables, ring sizers, and mobile applications. As part of the purchase, customers also receive customer support and future unspecified software updates. These items are collectively referred to as the Evie Ring Elements. During the year ended December 31, 2023 the Company began taking pre-orders for the Evie Ring Elements but did not deliver any Evie Rings as of December 31, 2023. The Company recognizes revenue when control is transferred to the customer in an amount that reflects the net consideration to which the Company expects to be entitled.

In determining how revenue should be recognized, a five-step process is used which includes identifying the contract, identifying the distinct performance obligations, determining the transaction price, allocating the transaction price to each distinct performance obligation, and determining the timing of revenue recognition for each distinct performance obligation.

For each contract, the Company considers the obligation to transfer the Evie Ring Elements, each of which are distinct, to be separate performance obligations.

Transaction price for the Evie Ring Elements reflects the net consideration to which the Company expects to be entitled. Transaction price is based on the sales price. The Company includes an estimate of variable consideration in the calculation of the transaction price at the time of sale. Variable consideration primarily includes product return provisions. The Company classifies the product return provisions as liabilities in the consolidated balance sheet.

The adequacy of the estimates for the variable consideration is reviewed at each reporting date. If the actual amount of consideration differs from the estimates, the Company would adjust the estimates, impacting revenue in the period that such variances become known. If any of the judgments were to change, this change could cause a material increase or decrease in the amount of revenue reported in a particular period.

The Company allocates the transaction price to each performance obligation using the relative standalone selling price ("SSP") for each distinct good or service in the contract.

The Company offers limited rights of return for a 30-day right of return, whereby customers may return the Evie Ring Elements.

The Company records revenue from the sales of the Evie Ring Elements upon transfer of control of the distinct Evie Ring Elements to the customer. The Company typically determines transfer of control for the Evie Ring Elements based on when the product is delivered, or when our customer has obtained the significant risks and reward of ownership. The future unspecified software updates and customer support that the Company offers are separate performance obligations, and revenue is recognized over time on a ratable basis.

The sales of the Evie Ring Elements include an assurance warranty.

Contract balances represent amounts presented in the consolidated balance sheets when the Company has transferred goods or services to the customer, or the customer has paid consideration to the Company under the contract. Payment is made by the customer upon the purchase of the Evie Ring Elements, and the Company has no accounts receivable at December 31, 2023, 2022, or 2021, respectively. The Company records deferred revenue when cash payments from customers are received prior to the transfer of control or satisfaction of the related performance obligations. A contract asset is recorded when inventory has shipped but control has not yet transferred to the customer. Deferred revenue at December 31, 2023 was $1.3 million and is included in current liabilities on the consolidated balance sheets. There was no deferred revenue at December 31, 2022 or 2021, respectively. There were no contract assets at December 31, 2023, 2022, or 2021, respectively.

The Company collects sales taxes at the point of sale and remits the taxes to the proper state authorities. Sales tax is excluded from the measurement of the transaction price.

Shipping and handling costs are incurred as part of fulfillment activities with customers and are included as a component of cost of revenue.

Advertising Costs

The Company expenses advertising costs as they are incurred. Advertising expenses were $1.35 million for the year ending December 31, 2023 and were not significant for the year ended December 31, 2022. These costs are included in “Sales, general and administrative expenses” in the accompanying consolidated statements of operations and comprehensive loss.

Research and Development

Research and development costs are expensed as incurred and consist of salaries and benefits, stock-based compensation expense, lab supplies and facility costs, as well as fees paid to other nonemployees and entities that conduct certain research and development activities on the Company’s behalf.

Stock-Based Compensation

The Company measures equity classified stock-based awards granted to employees, directors, and nonemployees based on the estimated fair value on the date of grant and recognizes compensation expense of those awards on a straight-line basis over the requisite service period, which is generally the vesting period of the respective award. The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option pricing model. This valuation model for stock-based compensation expense requires the Company to make assumptions and judgments about the variables used in the calculation including the expected term, the volatility of the Company’s common stock, and an assumed risk-free interest rate. The Company accounts for forfeitures as they occur.

Common Stock Warrants

The Company assesses each warrant to determine if it meets the characteristics of a liability or a derivative, and if the warrant does meet the characteristics of a liability or a derivative, the warrant is measured at fair value. The derivative liabilities are remeasured at each period end, on a recurring basis, to the estimated fair value with the changes in fair value reflected as current period income or loss until the warrant is exercised, extinguished, or expires. If the warrant does not meet the characteristics of a liability or a derivative, the warrant is classified as equity and recorded at its fair value on the date of issuance. The fair value of warrants is estimated using appropriate pricing models based on the nature and characteristics of the underlying warrants.

Early Exercised Stock Option Liability

Upon the early exercise of stock options by employees, the Company records as a liability the purchase price of unvested common stock that the Company has a right to repurchase if and when the employment of the stockholder terminates before the end of the requisite service period. The proceeds originally recorded as a liability are reclassified to additional paid-in capital as the Company's repurchase right lapses.

Leases

The Company determines if an arrangement is a lease or implicitly contains a lease at inception based on the lease definition, and if the lease is classified as an operating lease or finance lease in accordance with Accounting Standards Codification 842, *Leases* ("ASC 842"). Operating and finance leases are included in right-of-use ("ROU") assets and lease liabilities in the Company's consolidated balance sheets. ROU assets represent the Company's right to use an underlying asset for the lease term. Lease liabilities represent the Company's obligation to make lease payments arising from the lease. ROU assets and lease liabilities are recognized at commencement date for existing leases based on the present value of lease payments over the lease term using an estimated discount rate.

For leases which do not provide an implicit rate, the Company uses an incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments over a similar term. In determining the estimated incremental borrowing rate, the Company considers relevant banking rates and the Company's costs incurred for underwriting discounts and financing costs in its previous equity financings. The ROU assets also include any lease payments made and exclude lease incentives. For operating leases, lease expense is recognized on a straight-line basis over the lease term. Lease and non-lease components within a contract are generally accounted for separately. Short-term leases of twelve months or less, if any. are expensed as incurred which approximates the straight-line basis due to the short-term nature of the leases.

Income Taxes

The Company accounts for income taxes using the asset and liability method. Under this method, deferred tax assets and liabilities are determined based on differences between the financial statement and tax basis of assets and liabilities and net operating loss and credit carryforwards using enacted tax rates in effect for the year in which the differences are expected to reverse. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized. As the Company maintained a full valuation allowance against its deferred tax assets, the changes resulted in no provision or benefit from income taxes during the years ended December 31, 2023 and 2022.

The Company accounts for unrecognized tax benefits using a more-likely-than-not threshold for financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. The Company establishes a liability for tax-related uncertainties based on estimates of whether, and the extent to which, additional taxes will be due. The Company records an income tax liability, if any, for the difference between the benefit recognized and measured and the tax position taken or expected to be taken on the Company's tax returns. To the extent that the assessment of such tax positions changes, the change in estimate is recorded in the period in which the determination is made. The liability is adjusted considering changing facts and circumstances, such as the outcome of a tax audit. The provision for income taxes includes the impact of liability provisions and changes to the liability that are considered appropriate. Changes in recognition or measurement are reflected in the period in which the change in judgment occurs.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted average number of shares of common stock outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is the same as basic net loss per share since the effects of potentially dilutive securities are antidilutive.

Recently Adopted Accounting Pronouncements

In August 2020, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update 2020-06, *Debt — Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging — Contracts in Entity's Own Equity (Subtopic 815-40) — Accounting for Convertible Instruments and Contracts in an Entity's Own Equity.* The amendments in this update reduce the number of accounting models for convertible debt instruments and convertible preferred stock, resulting in fewer embedded conversion features being recognized separately from their host contracts. The pronouncement also revises the derivatives scope exception for contracts in an entity's own equity and improves the consistency of earnings per share calculations as that relates to convertible instruments. The Company has early-adopted this pronouncement as of January 1, 2023 using the modified retrospective method of transition. The adoption did not have any impact on the Company's consolidated financials.

Recently Issued Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09, *Improvements to Income Tax Disclosures*, which amends the guidance in ASC 740, *Income Taxes*. The ASU is intended to improve the transparency of income tax disclosures by requiring (1) consistent categories and greater disaggregation of information in the rate reconciliation and (2) income taxes paid disaggregated by jurisdiction. It also includes certain other amendments to improve the effectiveness of income tax disclosures. The ASU's amendments are effective for public business entities for annual periods beginning after December 15, 2024. Adoption of the provisions should be on a prospective basis. The Company is currently evaluating the impact of the ASU but does not expect any material impacts upon adoption.

NOTE 3 – FAIR VALUE MEASUREMENTS

Financial assets and liabilities are recorded at fair value. The Company uses a three-level hierarchy, which prioritizes, within the measurement of fair value, the use of market-based information over entity-specific information for fair value measurements based on the nature of inputs used in the valuation of an asset or liability as of the measurement date. Fair value focuses on an exit price and is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The inputs or methodology used for valuing financial instruments are not necessarily an indication of the risk associated with investing in those financial instruments.

A three-tier fair value hierarchy is used to prioritize the inputs in measuring fair value as follows:

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

Level 2 – Quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable, either directly or indirectly.

Level 3 – Significant unobservable inputs that cannot be corroborated by market data.

The asset's or liability's fair value measurement level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. The Company's Level 1 financial assets are money market funds whose fair values are based on quoted market prices. The carrying amounts of prepaid expenses and other current assets, payroll tax credit, vendor deposits, inventory, accounts payable, deferred revenue, and other current liabilities approximate fair value due to the short-term nature of these instruments.

The following tables provide a summary of the assets and liabilities that are measured at fair value on a recurring basis as of December 31, 2023 and 2022 (in thousands).

	December 31, 2023			
	Fair Value	Level 1	Level 2	Level 3
Cash equivalents:				
Money market funds	$ 4,393	$ 4,393	$ —	$ —
Total cash equivalents	$ 4,393	$ 4,393	$ —	$ —

	December 31, 2022			
	Fair Value	Level 1	Level 2	Level 3
Cash equivalents:				
Money market funds	$ 8,171	$ 8,171	$ —	$ —
Total cash equivalents	$ 8,171	$ 8,171	$ —	$ —

NOTE 4 – CASH AND CASH EQUIVALENTS

Cash and cash equivalents consist of the following (in thousands):

	December 31,	
	2023	2022
Cash and cash equivalents:		
Cash	$ 1,725	$ 2,588
Money market funds	4,393	8,171
Total cash and cash equivalents	$ 6,118	$ 10,759

NOTE 5 – PROPERTY AND EQUIPMENT

Property and equipment, net, as of December 31, 2023 and 2022, consisted of the following (in thousands):

	December 31,	
	2023	2022
Office equipment and furniture	$ 266	$ 263
Software	144	131
Test equipment	310	277
Total property and equipment	720	671
Less: accumulated depreciation	(378)	(228)
Total property and equipment, net	$ 342	$ 443

Total depreciation and amortization expense related to property and equipment for the years ended December 31, 2023 and 2022 was approximately $158,000 and $147,000, respectively.

NOTE 6 – OTHER CURRENT LIABILITIES

Other current liabilities as of December 31, 2023 and 2022 consisted of the following (in thousands):

	December 31,	
	2023	2022
Accrued compensation	$ 299	$ 2,708
Accrued research and development	461	536
Accrued vacation	246	243
Accrued severance payment	5	517
Lease liabilities, current portion	217	212
Other	301	205
Total other current liabilities	$ 1,529	$ 4,421

NOTE 7 – COMMON STOCK

As of December 31, 2023 and 2022, the Company was authorized to issue 150,000,000 and 75,000,000 shares of common stock, respectively, with a par value of $0.0001 per share. As of December 31, 2023 and 2022, 55,848,272 and 33,659,460 shares were outstanding, respectively.

January and February 2023 Issuance of Common Stock

On February 6, 2023, the Company completed a $7.5 million underwritten public offering of 5,340,600 shares of its common stock and warrants to purchase up to 2,670,300 shares of common stock, including the full exercise of the underwriter's overallotment option. The warrants were offered at the rate of one warrant for every two shares of purchased common stock and are exercisable at a price per share of $1.57 (See Note 8). The public offering price per share, before the underwriters' discount and commissions, for each share of common stock and accompanying warrant was $1.40. The Company used the relative fair value method to allocate the gross proceeds of approximately $7.5 million between the common stock and the warrants. The net proceeds from the offering were approximately $6.7 million after the deduction of underwriting discounts, commissions and other offering expenses that were approximately $0.8 million. The Company recorded the fair value of the warrants of $1.5 million as additional costs of issuance, thus reducing the net proceeds of $6.7 million to $5.2 million as presented in the accompanying consolidated statements of stockholders' equity.

June 2023 Issuance of Common Stock

On June 15, 2023, the Company completed a $9.2 million underwritten public offering of 9,200,000 shares of its common stock, including the full exercise of the underwriter's overallotment option. The public offering price per share, before the underwriters' discount and commissions, for each share of common stock was $1.00. The net proceeds from the offering were approximately $8.1 million after the deduction of underwriting discounts, commissions and other offering expenses that were approximately $1.1 million.

November 2023 Issuance of Common Stock

On November 17, 2023, the Company completed a $4.1 million underwritten public offering of 4,870,600 shares of its common stock, including the full exercise of the underwriter's overallotment option. The public offering price per share, before the underwriters' discount and commissions, for each share of common stock was $0.85. The net proceeds from the offering were approximately $3.6 million after the deduction of underwriting discounts, commissions and other offering expenses that were approximately $0.5 million.

At-the-Market Issuance of Common Stock

On August 15, 2022, the Company entered into an At-the-Market Issuance Agreement (the "Issuance Agreement") with B. Riley Securities, Inc. (the "Sales Agent"). Pursuant to the terms of the Issuance Agreement, the Company may sell from time to time through the Sales Agent shares of the Company's common stock having an aggregate offering price of up to $50,000,000 (the "Shares"). Sales of Shares, if any, may be made by means of transactions that are deemed to be "at the market" offerings as defined in Rule 415 under the Securities Act, including block trades, ordinary brokers' transactions on the Nasdaq Capital Market or otherwise at market prices prevailing at the time of sale, at prices related to prevailing market prices or at negotiated prices or by any other method permitted by law.

Under the terms of the Issuance Agreement, the Company may also sell Shares to the Sales Agent as principal for its own accounts at a price to be agreed upon at the time of sale. Any sale of Shares to the Sales Agent as principal would be pursuant to the terms of a separate terms agreement between the Company and the Sales Agent.

The Company has no obligation to sell any of the Shares under the Issuance Agreement and may at any time suspend solicitation and offers under the Issuance Agreement.

During the year ended December 31, 2023, the Company issued and sold an aggregate of 2,531,757 shares of common stock through the Issuance Agreement at a weighted-average public offering price of $1.31 per share and received net proceeds of $3.2 million. During the year ended December 31, 2022, the Company issued and sold an aggregate of 810,400 shares of common stock through the Issuance Agreement at a weighted-average public offering price of $2.84 per share and received net proceeds of $2.2 million. As of December 31, 2023, an aggregate offering price amount of approximately $44.4 million remains available to be issued and sold under the Issuance Agreement.

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance at December 31, 2023 is summarized as follows:

	December 31, 2023
Warrants to purchase common stock	4,757,256
Stock options outstanding	7,448,412
Stock options available for future grants	5,936,692
Total	18,142,360

Early Exercised Stock Option Liability

The Exercise Notice (Early Exercise) Agreement states that the Company has the option to repurchase all or a portion of the unvested shares in the event of the separation of the holder from service to the Company. The shares continue to vest in accordance with the original vesting schedules of the former option agreements. During the years ended December 31, 2023 and 2022, no shares of common stock were issued upon the early exercise of common stock options.

As of December 31, 2023 and 2022, the Company has recorded a repurchase liability for approximately $23,000 and $136,000 for 43,751 and 266,147 shares that remain unvested, respectively. The weighted average remaining vesting period at December 31, 2023 is less than one year.

NOTE 8 – COMMON STOCK WARRANTS

Preferred A Placement Warrants

During February 2023, September 2023 and November 2023, the Board approved the amendment of 293,042 Preferred A Placement Warrants to extend the maturity to April 2024. The Company assessed the accounting treatment of the warrant amendments and determined that the amendments are modifications for accounting purposes. The Company determined the modifications had an insignificant impact on the consolidated financial statements.

January and February 2023 Warrants

In connection with the sale of common stock during January and February 2023, the Company issued warrants to purchase shares of common stock to common stockholders and to the underwriter for 2,322,000 and 348,300 shares, respectively. The warrants are exercisable upon issuance at $1.57 per share and have a 5-year term.

Beginning with the one-year anniversary of the issuance dates, the Company may redeem the outstanding warrants in whole or in part at $0.25 per warrant at any time after the date on which (i) the closing price of the Company's common stock has equaled or exceeded $4.87 for ten consecutive trading days and (ii) the daily trading volume of the Company's common stock has exceeded 100,000 shares on each of ten trading days. A minimum of thirty days prior written notice of redemption is required.

August 2023 Warrants

In August 2023, the Company issued warrants to purchase 201,613 shares of common stock to a third-party professional services firm.

The following is a summary of the Company's warrant activity for the years ended December 31, 2023 and 2022:

Warrant Issuance	Issuance	Exercise Price	Outstanding, December 31, 2022	Granted	Exercised	Canceled/ Expired	Variable Settlement Provision Adjustment	Outstanding, December 31, 2023	Expiration
Preferred A Placement Warrants	March and April 2018 and August 2019	$ 1.40	293,042	—	—	—	—	293,042	April 2024
Preferred A Lead Investor Warrants	February 2021	$ 0.0125	52,500	—	—	(52,500)	—	—	March 2023
Preferred B Placement Warrants	April 2019	$ 2.10	463,798	—	—	—	—	463,798	April 2024
Convertible Notes Placement Warrants	August 2020	$ 2.57	171,830	—	—	—	—	171,830	August 2025
Underwriter Warrants	March 2021	$ 6.00	956,973	—	—	—	—	956,973	March 2026
January 2023 warrants	January 2023	$ 1.57	—	2,322,000	—	—	—	2,322,000	January 2028
February 2023 warrants	February 2023	$ 1.57	—	348,000	—	—	—	348,000	February 2028
August 2023 warrants	August 2023	$ 1.24	—	201,613	—	—	—	201,613	August 2028
			1,938,143	2,871,613	—	(52,500)	—	4,757,256	

Warrant Issuance	Issuance	Exercise Price	Outstanding, December 31, 2021	Granted	Exercised	Canceled/ Expired	Variable Settlement Provision Adjustment	Outstanding, December 31, 2022	Expiration
Preferred A Placement Warrants	March and April 2018 and August 2019	$ 1.40	293,042	—	—	—	—	293,042	March and April 2023
Preferred A Lead Investor Warrants	February 2021	$ 0.0125	52,500	—	—	—	—	52,500	March 2023
Preferred B Placement Warrants	April 2019	$ 2.10	463,798	—	—	—	—	463,798	April 2024
Convertible Notes Placement Warrants	August 2020	$ 2.57	171,830	—	—	—	—	171,830	August 2025
Underwriter Warrants	March 2021	$ 6.00	956,973	—	—	—	—	956,973	March 2026
			1,938,143	—	—	—	—	1,938,143	

Warrants Classified as Equity

All of the Company's outstanding warrants are classified as equity instruments since they do not meet the characteristics of a liability or a derivative and are recorded at fair value on the date of issuance.

January and February 2023 Warrants

The warrants are classified as an equity instrument because they are both indexed to the Company's own stock and classified in stockholders' equity. The fair value of the warrants was estimated using a Monte Carlo simulation approach. Subsequent changes in fair value are not recognized as long as the warrants continue to be classified in equity. The fair value at the issuance date was calculated utilizing the Monte Carlo univariate pricing model, which simulates a distribution of stock prices for Movano throughout the remaining performance period, based on certain assumptions of stock price behavior.

The following major assumptions were used: (1) the stock price of the Company follows a geometric Brownian motion; (2) the daily stock price for the Company is simulated until the termination date using a volatility estimate based on term-match daily stock price returns of peer companies; and (3) the valuation is done under a risk-neutral framework using the term-matched zero-coupon risk-free interest rate.

The major inputs were:

	Issuance Date
Dividend yield	—%
Expected volatility	60.83%
Risk-free interest rate	3.54%
Expected life	5.0 years
Valuation date common stock price	$ 1.39

The fair value of the January and February 2023 warrants at the issuance date is approximately $1.5 million.

August 2023 Warrants

The warrants are classified as equity instruments since they do not meet the characteristics of a liability or a derivative and are recorded at fair value on the date of issuance using the Black-Scholes option pricing model with the following assumptions. The amount of the fair value was insignificant.

NOTE 9 – STOCK-BASED COMPENSATION

2019 Equity Incentive Plan

Effective as of November 18, 2019, the Company adopted the 2019 Omnibus Incentive Plan ("2019 Plan") administered by the Board. The 2019 Plan provides for the issuance of incentive stock options, non-statutory stock options, and restricted stock awards, for the purchase of up to a total of 4,000,000 shares of the Company's common stock to employees, directors, and consultants and replaces the previous plan. The Board or a committee of the Board has the authority to determine the amount, type, and terms of each award. The options granted under the 2019 Plan generally have a contractual term of ten years and a vesting term of four years with a one-year cliff. The exercise price for options granted under the 2019 Plan must generally be at least equal to 100% of the fair value of the Company's common stock at the date of grant, as determined by the Board. The incentive stock options granted under the 2019 Plan to 10% or greater stockholders must have an exercise price at least equal to 110% of the fair value of the Company's common stock at the date of grant, as determined by the Board, and have a contractual term of ten years.

As of March 25, 2021, the 2019 Plan was amended and restated as a result of which the aggregate number of shares of common stock that may be issued pursuant to the 2019 Plan was increased from 6,000,000 to 7,400,000.

On April 15, 2022, the Board approved, subject to stockholder approval, an increase in the aggregate number of shares of common stock that may be issued pursuant to the 2019 Plan from 7,400,000 to 13,400,000. On June 21, 2022, the stockholders approved this increase.

As of December 31, 2023, the Company had 4,455,442 shares available for future grant under the 2019 Plan.

2021 Employment Inducement Plan

On September 15, 2021 the Company's Board adopted the Movano, Inc. 2021 Inducement Award Plan (the "Inducement Plan") without stockholder approval pursuant to Rule 5635(c)(4) of the Nasdaq Stock Market LLC listing rules ("Rule 5635(c)(4)"). In accordance with Rule 5635(c)(4), awards under the Inducement Plan may only be made to a newly hired employee who has not previously been a member of the Company's Board, or an employee who is being rehired following a bona fide period of non-employment by the Company or a subsidiary, as a material inducement to the employee's entering into employment with the Company or its subsidiary. An aggregate of 2,000,000 shares of the Company's common stock have been reserved for issuance under the Inducement Plan.

As of December 31, 2023, the Company had 1,481,250 shares available for future grant under the Inducement Plan.

Stock Options

Stock option activity for the years ended December 31, 2023 and 2022 was as follows (in thousands, except share, per share, and remaining life data):

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Life	Intrinsic Value
Outstanding at December 31, 2021	5,592,137	$ 2.29	8.6 years	$ 9,912
Granted	2,525,000	$ 2.77		
Exercised	(77,000)	$ 0.40		
Cancelled	(1,120,243)	$ 3.15		
Outstanding at December 31, 2022	6,919,894	$ 2.34	8.2 years	$ 2,034
Granted	1,610,375	$ 1.23		
Exercised	(245,855)	$ 0.44		
Cancelled	(836,002)	$ 2.66		
Outstanding at December 31, 2023	7,448,412	$ 2.13	7.1 years	$ 726
Exercisable as of December 31, 2023	4,760,030	$ 2.02	6.5 years	$ 712
Vested and expected to vest as of December 31, 2023	7,448,412	$ 2.13	7.1 years	$ 726

The weighted-average grant date fair value of options granted during the years ended December 31, 2023, and 2022 was $0.74 and $1.48 per share, respectively. During the years ended December 31, 2023 and 2022, 245,855 and 77,000 options were exercised for proceeds of $109,000 and $31,000, respectively. The fair value of the 2,008,712 and 1,707,794 options that vested during the years ended December 31, 2023 and 2022 was approximately $3.1 million and $3.2 million, respectively.

On June 21, 2022, the Company granted an award of 100,000 options to the Company's founder at an exercise price of $5.00 per share. The options were to vest in full upon the shipment of 20,000 product units on or before June 30, 2023. For the years ended December 31, 2023 and 2022, the Company has not recognized stock compensation expense of approximately $0.1 million related to this award as the successful achievement of the performance conditions is not yet probable, and the award has been cancelled.

The Company estimated the fair value of stock options using the Black-Scholes option pricing model. The fair value of the stock options was estimated using the following weighted average assumptions for the years ended December 31, 2023 and 2022.

	Year Ended December 31,	
	2023	2022
Dividend yield	—%	—%
Expected volatility	61.55%	61.97%
Risk-free interest rate	3.77%	2.78%
Expected life	5.98 years	6.07 years

Dividend Rate — The expected dividend rate was assumed to be zero, as the Company had not previously paid dividends on common stock and has no current plans to do so.

Expected Volatility — The expected volatility was derived from the historical stock volatilities of several public companies within the Company's industry that the Company considers to be comparable to the business over a period equivalent to the expected term of the stock option grants.

Risk-Free Interest Rate — The risk-free interest rate is based on the interest yield in effect at the date of grant for zero coupon U.S. Treasury notes with maturities approximately equal to the option's expected term.

Expected Term — The expected term represents the period that the Company's stock options are expected to be outstanding. The expected term of option grants that are considered to be "plain vanilla" are determined using the simplified method. The simplified method deems the term to be the average of the time-to-vesting and the contractual life of the options. For other option grants not considered to be "plain vanilla," the Company determined the expected term to be the contractual life of the options.

Forfeiture Rate — The Company recognizes forfeitures when they occur.

The Company has recorded stock-based compensation expense for the years ended December 31, 2023 and 2022 related to the issuance of stock option awards to employees and nonemployees in the consolidated statement of operations and comprehensive loss as follows:

	Year Ended December 31,	
	2023	2022
Research and development	$ 940	$ 1,169
Sales, general and administrative	2,040	1,927
	$ 2,980	$ 3,096

As of December 31, 2023, unamortized compensation expense related to unvested stock options was approximately $4.0 million, which is expected to be recognized over a weighted average period of 2.0 years.

NOTE 10 – COMMITMENTS AND CONTINGENCIES

Operating Leases

As of December 31, 2023, the Company had one office lease for the Corporate headquarters and laboratory space.

On April 15, 2021, the Company executed a lease agreement for corporate office space. The lease commenced on May 14, 2021 when the improvements were completed by the landlord and the Company had access to the facility. The lease term is 40 months, and the base rent is approximately $14,000 per month for the first twelve months, with subsequent escalation provisions for future months. The Company paid a security deposit of approximately $47,000.

On April 22, 2022, the Company executed an amendment to its corporate office lease agreement for additional corporate office space. The lease term for the additional space is 36 months from the expansion commencement date of June 23, 2022. The base rent is approximately $5,100 per month for the first twelve months, with subsequent escalation provisions for future months. The Company paid an additional security deposit of approximately $5,500.

Finance Lease

On November 22, 2023, the Company executed a lease agreement for equipment. The lease term is 36 months, and the monthly payment is approximately $1,700. The lease agreement has a bargain purchase option at the end of the lease term.

The balances of the lease related accounts as of December 31, 2023 and 2022 are as follows (in thousands):

	As of December 31,	
Operating and Finance leases	**2023**	**2022**
Right-of-use assets	$ 247	$ 389
Operating lease liabilities - Short-term	$ 203	$ 212
Operating lease liabilities - Long-term	$ 15	$ 214
Finance lease liabilities - Short-term	$ 14	$ —
Finance lease liabilities - Long-term	$ 35	$ —

Right-of-use assets are included in other assets on the consolidated balance sheets. The short-term lease liabilities and the long-term lease liabilities are included in other current liabilities and other noncurrent liabilities, respectively, on the consolidated balance sheets.

The components of lease expense and supplemental cash flow information as of and for the years ended December 31, 2023 and 2022 are as follows (in thousands):

	Year Ended December 31,	
	2023	**2022**
Lease Cost:		
Operating lease cost	$ 261	$ 226
Other Information:		
Cash paid for amounts included in the measurement of lease liabilities for the year ended	$ 243	$ 209
Weighted average remaining lease term - operating leases (in years)	0.90	1.97
Average discount rate - operating leases	10.00%	10.00%
Weighted average remaining lease term - financing leases (in years)	3.00	—
Average discount rate - financing leases	15.08%	—

Future minimum lease payments are as follows as of December 31, 2023 (in thousands):

2024	224
2025	48
2026	18
Total lease payments	290
Less: Interest	(23)
Total lease liabilities	$ 267

Litigation

From time to time, the Company may become involved in various litigation and administrative proceedings relating to claims arising from its operations in the normal course of business. Management is not currently aware of any matters that may have a material adverse impact on the Company's business, financial position, results of operations or cash flows.

Indemnification

The Company enters into standard indemnification agreements in the ordinary course of business. Pursuant to these arrangements, the Company indemnifies, holds harmless and agrees to reimburse the indemnified parties for losses suffered or incurred by the indemnified party, in connection with any trade secret, copyright, patent or other intellectual property infringement claim by any third party with respect to its technology. The term of these indemnification agreements is generally perpetual after the execution of the agreement. The maximum potential amount of future payments the Company could be required to make under these agreements is not determinable because it involves claims that may be made against the Company in the future, but have not yet been made. The Company has not incurred costs to defend lawsuits or settle claims related to these indemnification agreements.

The Company has entered into indemnification agreements with its directors and officers that may require the Company to indemnify its directors and officers against liabilities that may arise by reason of their status or service as directors or officers, other than liabilities arising from willful misconduct of the individual.

No amounts associated with such indemnifications have been recorded as of December 31, 2023.

Non-cancelable Obligations

The Company did not have any non-cancelable contractual commitments as of December 31, 2023.

NOTE 11 – INCOME TAXES

For the years ended December 31, 2023 and 2022, no U.S. provision or benefit for income taxes was recorded and an insignificant amount of Ireland provision for income taxes for the years ended December 31, 2023 and 2022 was offset by credits.

The effective tax rate of the Company's provision (benefit) for income taxes differs from the federal rate as follows:

	Year Ended December 31,	
	2023	2022
U.S. federal provision (benefit):		
At statutory rate	21%	21%
Valuation allowance	(23)%	(22)%
Changes in stock-based compensation	(1)%	(1)%
Other	3%	1%
Effective tax rate	—	—

Significant components of the Company's deferred tax assets and liabilities as of December 31, 2023 and 2022 are as follows (in thousands):

	2023	2022
Gross deferred tax assets:		
Net operating loss carryforwards	$ 13,396	$ 10,040
Research and development credit carryforward	2,703	1,434
Capitalized research and development	5,964	3,444
Accrued bonus	41	464
Stock-based compensation	999	590
Lease liabilities	56	90
Other	12	53
Total gross deferred tax assets	23,171	16,115
Less valuation allowance	(23,101)	(16,024)
Total net deferred tax assets	70	91
Deferred tax liabilities:		
Property and equipment	(18)	(9)
Right-of-use assets	(52)	(82)
Total deferred tax liabilities	70	(91)
Net deferred tax assets	$ —	$ —

During 2023 and 2022, the Company has maintained a valuation allowance against the net deferred tax assets due to the uncertainty surrounding the realization of those assets. The Company periodically evaluates the recoverability of the deferred tax assets and, when it is determined to be more-likely-than-not that the deferred tax assets are realizable, the valuation allowance is reduced. The valuation allowance increased by approximately $7.1 million and $7.0 million during the years ended December 31, 2023 and 2022, respectively.

As of December 31, 2023 and 2022, the Company has federal net operating loss carryforwards of approximately $64.8 million and $48.5 million, respectively, all of which do not expire. The net operating loss carryforwards may be available to offset future taxable income for income tax purposes.

As of December 31, 2023 and 2022, the Company has federal research and development ("R&D") credit carryforwards of approximately $2.4 million and $1.2 million, respectively. The federal R&D credits begin to expire in 2039.

As of December 31, 2023 and 2022, the Company has California R&D credit carryforwards of approximately $1.5 million and $1.1 million, respectively. The California R&D credits do not expire.

In accordance with the 2017 Tax Act, research and experimental, or R&E, expenses under IRC Section 174 are required to be capitalized beginning in 2022. R&E expenses are required to be amortized over a period of five years for domestic expenses and 15 years for foreign expenses.

The Internal Revenue Code imposes limitations on a corporation's ability to utilize net operating loss ("NOL") and credit carryovers if it experiences an ownership change as defined in Section 382. In general terms, an ownership change may result from transactions increasing the ownership of certain stockholders in the stock of a corporation by more than 50% over a three-year period. If an ownership change has occurred, or were to occur, utilization of the Company's NOLs and credit carryovers could be restricted.

The Company accounts for uncertainty in income taxes pursuant to the relevant authoritative guidance. The guidance clarified the recognition of tax positions taken, or expected to be taken, on a tax return. The impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more likely than not to be sustained upon audit by the relevant taxing authority. An uncertain tax position will not be recognized if it has a less than 50% likelihood of being sustained. No liability related to uncertain tax positions is recorded in the financial statements.

The Company files income tax returns in the U.S. federal jurisdiction and in various states. For jurisdictions in which tax filings have been filed, all tax years remain open for examination by the federal and various state authorities for three and four years, respectively, from the date of utilization of any net operating losses or credits.

Total gross unrecognized tax benefit liabilities as of December 31, 2023 and 2022 were approximately $1.2 million and $0.8 million, respectively, related to Federal and California R&D credits. As of December 31, 2023 and 2022, the Company had no unrecognized tax benefits, which, if recognized would affect the Company's effective tax rate due to the full valuation allowance. The Company's policy is to classify interest and penalties related to unrecognized tax benefits as part of the income tax provision (benefit) in the statements of operations. The Company had no accrued interest and penalties related to unrecognized tax benefits as of December 31, 2023.

The following is a rollforward of the total gross unrecognized tax benefits for the years ended December 31, 2023 and 2022 (in thousands):

	Year Ended December 31,	
	2023	2022
Beginning Balance	$ 811	$ 487
Gross Increases - Tax Position in Prior Periods	—	1
Gross Increases - Tax Position in Current Period	423	323
Ending Balance	$ 1,234	$ 811

NOTE 12 – NET LOSS PER SHARE ATTRIBUTABLE TO COMMON STOCKHOLDERS

The following table computes the computation of the basic and diluted net loss per share attributable to common stockholders during the years ended December 31, 2023 and 2022 is as follows (in thousands, except share and per share data):

	Year Ended December 31,	
	2023	2022
Numerator:		
Net loss	$ (29,283)	$ (30,329)
Denominator:		
Weighted average shares used in computing net loss per share, basic and diluted	46,195,403	33,025,721
Net loss per share, basic and diluted	$ (0.63)	$ (0.92)

The potential shares of common stock that were excluded from the computation of diluted net loss per share attributable to common stockholders for the years ended December 31, 2023 and 2022 because including them would have been antidilutive are as follows:

	Year Ended December 31,	
	2023	2022
Shares subject to options to purchase common stock	7,448,412	6,769,694
Shares subject to warrants to purchase common stock	4,757,256	1,938,143
Total	12,205,668	8,707,837

For the year ended December 31, 2022, performance based option awards for 150,200 shares of common stock, respectively, are not included in in the table above or considered in the calculation of diluted earnings per share until the performance conditions of the option award are considered probable by the Company.

NOTE 13 – SUBSEQUENT EVENTS

On April 2, 2024, the Company entered into a securities purchase agreement for the private placement of an aggregate of 45,252,517 units with each unit consisting of (1) one share of the Company's common stock or at the election of the purchaser a pre-funded warrant, and (2) one warrant to purchase one share of common stock. The purchase price paid for each Unit was $0.533. Certain directors and officers participated and purchased 287,500 of the units at an offering price of $0.565 per share.

Pre-funded warrants totaling 3,149,028 shares were issued. Each pre-funded warrant has an exercise price equal to $0.001 per share or calculated pursuant to the cashless exercise provision. The warrants were immediately exercisable on the date of issuance and do not expire.

Warrants totaling 45,252,517 shares were issued. Each warrant that was issued to holders other than the Company's officers and directors has an exercise price equal to $0.4071 per share or calculated pursuant to the cashless exercise provision. The warrants issued to the Company's officers and directors have an exercise price equal to $0.44 or calculated pursuant to the cashless exercise provision. The warrants were exercisable immediately and expire on the fifth anniversary of the initial exercise date of the warrant. After April 4, 2025, the warrants may be redeemed in whole or in part at the option of the Company with at least thirty days' notice to the holder of the warrant, which notice may not be given before, but may be given at any time after the date on which (i) the closing price of the Company's common stock has equaled or exceeded $5.00 for ten consecutive trading days and (ii) the daily trading volume of the common stock has exceeded 100,000 shares on each of such ten trading days. The redemption price is $0.025 per share.

The gross proceeds were approximately $24.1 million, before deducting offering fees and expenses of approximately $1.4 million. The offering closed on April 5, 2024. Common stock shares of 42,103,489 were issued.

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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

As of the end of the period covered by this report, management performed, with the participation of our principal executive and principal financial officers, an evaluation of the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosures. Based on the evaluation, our principal executive and principal financial officers concluded that, as of December 31, 2023, our disclosure controls and procedures were ineffective.

As of December 31, 2023, we had a material weakness in our internal control over financial reporting, as described below. A "material weakness" is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim consolidated financial statements will not be prevented or detected on a timely basis.

Management has identified the following material weakness at December 31, 2023: ineffective design and operation of our financial close and reporting controls. Specifically, we did not design and maintain effective controls over certain account reviews and analyses and certain information technology general controls. The material weakness did not result in any identified misstatements to the consolidated financial statements and there were no changes in previously released financial results.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining effective internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act. Internal control over financial reporting is a process designed to provide reasonable assurance to the Company's management and board of directors regarding the reliability of our financial reporting for external purposes in accordance with accounting principles generally accepted in the United States of America.

Because of its inherent limitations, internal control over financial reporting is not intended to provide absolute assurance that a misstatement of our consolidated financial statements would be prevented or detected. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Therefore, even those systems determined to be effective can only provide reasonable assurance with respect to financial statement preparation and presentation.

Management conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. Management identified the following material weakness as of December 31, 2023: ineffective design and operation of our financial close and reporting controls. Specifically, we did not design and maintain effective controls over certain account reviews and analyses and certain information technology general controls. The material weakness did not result in any identified misstatements to the consolidated financial statements and there were no changes in previously released financial results. Because of this material weakness, management concluded that the Company's internal control over financial reporting was not effective as of December 31, 2023.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm on our internal control over financial reporting due to an exemption established by the JOBS Act for "emerging growth companies."

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) under the Exchange Act during the year ended December 31, 2023, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

Not applicable.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item is incorporated by reference from our definitive Proxy Statement to be filed with the SEC in connection with our 2024 Annual Meeting of Stockholders or an amendment to this Form 10-K within 120 days after the end of the fiscal year ended December 31, 2023.

Item 11. Executive Compensation

The information required by this item is incorporated by reference from our definitive Proxy Statement to be filed with the SEC in connection with our 2024 Annual Meeting of Stockholders or an amendment to this Form 10-K within 120 days after the end of the fiscal year ended December 31, 2023.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholders Matters.

The information required by this item is incorporated by reference from our definitive Proxy Statement to be filed with the SEC in connection with our 2024 Annual Meeting of Stockholders or an amendment to this Form 10-K within 120 days after the end of the fiscal year ended December 31, 2023.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this item is incorporated by reference from our definitive Proxy Statement to be filed with the SEC in connection with our 2024 Annual Meeting of Stockholders or an amendment to this Form 10-K within 120 days after the end of the fiscal year ended December 31, 2023.

Item 14. Principal Accountant Fees and Services

The information required by this item is incorporated by reference from our definitive Proxy Statement to be filed with the SEC in connection with our 2024 Annual Meeting of Stockholders or an amendment to this Form 10-K within 120 days after the end of the fiscal year ended December 31, 2023.

PART IV

Item 15. Exhibits, Financial Statements and Schedules

(a) List of documents filed as part of this report:

1. Financial Statements (see "Financial Statements and Supplementary Data" at Item 8 and incorporated herein by reference).

2. Financial Statement Schedules (Schedules to the Financial Statements have been omitted because the information required to be set forth therein is not applicable or is shown in the accompanying Financial Statements or notes thereto)

3. Exhibit Index (The exhibits required to be filed as a part of this Report are listed in the Exhibit Index).

			Incorporated by Reference			
Exhibit Number	**Exhibit Description**	**Filed Herewith**	**Form**	**Exhibit**	**Filing Date**	**SEC File/ Registration Number**
3.1	Third Amended and Restated Certificate of Incorporation of the Registrant		8-K	3.1	March 25, 2021	001-40254
3.2	Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation of the Registrant		8-K	3.1	June 21, 2023	001-40254
3.3	Amended and Restated Bylaws of the Registrant		8-K	3.2	March 25, 2021	001-40254
4.1	Specimen Certificate representing shares of common stock of the Registrant		S-1/A	4.1	March 10, 2021	333-252671
4.2	Form of Underwriter Warrant		S-1/A	4.2	March 10, 2021	333-252671
4.3	Form of Amended and Restated Warrant to Purchase Common Stock issued to the placement agent in the Registrant's 2018 private placement offering		S-1	4.3	February 2, 2021	333-252671
4.4	Form of Amended and Restated Warrant to Purchase Common Stock issued to the placement agent in the Registrant's 2019 private placement offering		S-1	4.4	February 2, 2021	333-252671
4.5	Form of Warrant to Purchase Common Stock issued in 2020		S-1	4.6	February 2, 2021	333-252671
4.6	Description of Common Stock of the Registrant Registered Pursuant to Section 12 of the Securities Exchange Act of 1934		10-K	4.6	March 30, 2022	001-40254
4.7	Form of Warrant to Purchase Common Stock		8-K	4.1	January 31, 2023	001-40254
4.8	Warrant Agent Agreement, dated January 31, 2023, by and between the Company and Pacific Stock Transfer Company		8-K	4.2	January 31, 2023	001-40254
10.1	Movano Inc. Amended and Restated 2019 Omnibus Incentive Plan †		S-1/A	10.1	March 10, 2021	333-252671
10.2	Form of Stock Option Award Agreement under 2019 Omnibus Incentive Plan †		S-1	10.2	February 2, 2021	333-252671
10.3	Non-Employee Director Compensation Policy †		10-K	10.3	March 30, 2022	001-40254
10.4	Form of Indemnification Agreement by and between the Registrant and each of its directors and executive officers †		S-1	10.4	February 2, 2021	333-252671
10.5	Offer Letter, dated November 29, 2019, by and between the Registrant and Michael Leabman †		S-1	10.5	February 2, 2021	333-252671
10.6	Offer Letter, dated November 29, 2019, by and between the Registrant and J. Cogan †		S-1	10.7	February 2, 2021	333-252671

10.7	Form of 2020 Note Purchase Agreement		S-1	10.16	February 2, 2021	333-252671
10.8	Amended and Restated Lead Investor Agreement, dated August 27, 2020, between the Registrant and Maestro Venture Partners, LLC		S-1	10.17	February 2, 2021	333-252671
10.9	Offer Letter, dated February 8, 2021, by and between the Registrant and John Mastrototaro †		S-1/A	10.17	March 10, 2021	333-252671
10.10	First Amendment to Employment Letter Agreement, dated February 10, 2021, by and between the Registrant and Michael Leabman †		S-1/A	10.18	March 10, 2021	333-252671
10.11	First Amendment to Employment Letter Agreement, dated February 10, 2021, by and between the Registrant and J. Cogan †		S-1/A	10.20	March 10, 2021	333-252671
10.12	Amendment No. 1 to Movano Inc. Amended and Restated Omnibus Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 22, 2022) †		8-K	10.1	June 22, 2022	001-40254
10.13	At the Market Issuance Agreement, dated August 15, 2022 by and between the Company, as issuer, and B. Riley Securities, Inc. as sale agent		10-Q	1.1	August 15, 2022	001-40254
21.1	Subsidiaries of the Company	x				
23.1	Consent of Moss Adams, LLP	x				
24.1	Power of Attorney (included on signature page)	x				
31.1	Rule 13(a)-14(a)/15(d)-14(a) Certification of Principal Executive Officer	x				
31.2	Rule 13(a)-14(a)/15(d)-14(a) Certification of Principal Financial and Accounting Officer	x				
32.1	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith)	x				
97.1	Incentive-Based Compensation Recovery Policy	x				
101.INS	Inline XBRL Instance Document					
101.SCH	Inline XBRL Taxonomy Extension Schema Document.					
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.					
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.					
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.					
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.					
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).					

† Management contract or compensatory plan or arrangement

Item 16. Form 10-K Summary

Not applicable.

SIGNATURES

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

Movano, Inc.

Dated: April 16, 2024

By: /s/ John Mastrototaro
John Mastrototaro
Chief Executive Officer
(Principal Executive Officer)

POWER OF ATTORNEY AND SIGNATURES

We, the undersigned officers and directors of Movano, Inc., hereby severally constitute and appoint John Mastrototaro our true and lawful attorney, with full power to him to sign for us and in our names in the capacities indicated below, any amendments to this Annual Report on Form 10-K, and generally to do all things in our names and on our behalf in such capacities to enable Movano, Inc. to comply with the provisions of the Securities Exchange Act of 1934, as amended, and all the requirements of the Securities Exchange Commission.

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

Signatures	Title	Date
/s/ John Mastrototaro John Mastrototaro	Chief Executive Officer and Director (Principal Executive Officer)	April 16, 2024
/s/ J. Cogan J. Cogan	Chief Financial Officer (Principal Financial and Accounting Officer)	April 16, 2024
/s/ Emily Wang Fairbairn Emily Wang Fairbairn	Director	April 16, 2024
/s/ Brian Cullinan Brian Cullinan	Director	April 16, 2024
/s/ Rubén Caballero Rubén Caballero	Director	April 16, 2024
/s/ Michael Leabman Michael Leabman	Director	April 16, 2024
/s/ Nan Kirsten Forte Nan Kirsten Forte	Director	April 16, 2024

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