

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 10-K

(Mark One)

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

For the Fiscal Year Ended December 31, 2022

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

(State of incorporation)

82-4233771

(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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input checked="" type="checkbox"/>		

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. \$57,424,946.

As of March 23, 2023, there were 41,310,108 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 within 120 days after the end of the fiscal year ended December 31, 2022. Portions of such proxy statement 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;
- the impact of the COVID-19 on our business and local and global economic conditions;
- 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;
- our dependence on the successful commercialization of our proposed solution;
- our dependence on third parties to design, manufacture, market and distribute our proposed 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 United States;
- the impact of healthcare regulations and reform measures;
- the accuracy of our estimates of market size for our planned solution;
- 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.

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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.

The Company’s initial commercial product in development 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 we expect to include resting heart rate, heart rate variability (“HRV”), blood oxygen saturation (“SpO₂”), 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 will provide 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 that could mitigate the risks of chronic disease.

Movano Health is planning to seek FDA clearance for the Evie Ring, which will make it one of the first consumer wearables that is also FDA cleared for medical use. We are on track to file our first FDA submission for the Evie Ring’s heart and SpO₂ data in the second quarter of 2023 following a successful pivotal hypoxia trial during the fourth quarter of 2022. FDA clearance of these metrics would ensure confidence of the Evie Ring’s vital signs monitoring capabilities and could make the device attractive for doctors and in clinical trials for patient monitoring.

In addition to the Evie 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 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.

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 18% of its GDP on healthcare in 2021, and according to the American Heart Association 133 million Americans are living with at least one chronic illness with 170 million expected to be by 2030.

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.

COVID-19

COVID-19 is an infectious disease caused by the SARS-CoV-2 virus, which was declared a public health emergency of international concern by the World Health Organization (“WHO”) in 2020. The virus can spread easily from an infected person’s mouth or nose in small liquid particles when they cough, sneeze, speak, sing or breathe. As of early January 2023, WHO reported that since the beginning of the pandemic there has been more than 669 million cases and nearly 6.74 million deaths caused by COVID-19 worldwide.

While some people infected with the virus experience mild respiratory illness and recover without requiring special treatment, others, especially those with chronic conditions, become seriously ill. Those with underlying medical conditions, such as diabetes or hypertension, are more likely to experience severe illness, ICU admission and face a higher risk of mortality. When people with diabetes become sick, it can dramatically raise blood sugar levels. Having high blood sugar can make it more difficult to fight off illnesses like COVID-19.

However, the risk of getting very sick from COVID-19 is likely to be lower if chronic conditions are well-managed.

The COVID-19 pandemic and the consequent global healthcare crisis have highlighted the need for better monitoring of higher risk populations, such as those living with chronic conditions, to prevent continued deaths and long-term health issues.

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 in development is a smart ring called the Evie Ring.

The Evie Ring combines health and wellness metrics to give a full picture of one’s health, which we expect will include resting heart rate, HRV, SpO₂, 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 SpO₂ 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.



Image: A non-functional rendering of what Movano's Health's Evie Ring currently in development may ultimately look like

Proprietary Technology

The Evie Ring uses a multitude of optical sensors to estimate a variety of analytics, including SpO₂ 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 first planned product is currently in the development stage, and we are testing the wearability and functionality of the device with employees and multiple beta partners, including pharmaceutical and medical device companies, integrated health networks and universities. For testing, we are using a device similar to the one that is depicted in the image above.

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. We are currently preparing for clinical trials using the SoC and our smallest wrist-worn prototype to date.

We have conducted preliminary tests thus far to diversify the data we are collecting, enabling us to better optimize our system. Our preliminary blood pressure testing took place in 2020 over a three-month period during which we collected nearly a hundred hours of data on six internal subjects. Data collections with our prototype were compared to a traditional blood pressure monitor before each test. Our preliminary glucose testing took place in 2020 over a four to five month time period during which we collected several hundreds of hours of data on three internal test subjects. Data collections with our prototype were compared to fingerstick data every five minutes over the course of an hour.

In June 2021, we received approval from an Institutional Review Board (“IRB”) to conduct blood pressure studies on up to 200 participants in our laboratory. In our first study, we used our non-invasive, iPhone-sized prototype device to collect pulse pressure waveform data from 45 external participants. This study marked a significant milestone, confirming our ability to quickly, seamlessly, and efficiently enroll and test subjects and collect meaningful data at the laboratory inside our corporate offices.

In December 2021, we completed our third and largest blood pressure clinical trial, which was conducted on 110 participants in our laboratory. During the study, participants wore our adjustable full finger ring prototype and our wrist-worn wearable prototype along with a hospital-grade FDA-cleared vital signs monitor as the control. Our devices collected pulse pressure waveform data, which will be compared to data from the control device in order to further our signal processing and algorithms.

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 a 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.

In 2021, we completed the tapeout of our single-chip solution with our fabrication partner, Global Foundries. The tapeout of the SoC is a major milestone for us as we were able to shrink our proprietary multi-chip architecture into a singular integrated circuit. With one compact sensor, we have the flexibility to design innovative, small form factors that will be key to developing competitive commercial products in the future. In 2022, we successfully validated the SoC and are currently integrating the SoC into a new prototype system, which will be closer in size and shape to our final product, and enable the Company to conduct longer, more complex blood pressure and glucose studies, which are being planned for 2023.

To date, we have completed two clinical trials with the Evie Ring. Following a successful pilot hypoxia study in July 2022, which compared the accuracy of our heart rate and SpO₂ data to reference devices, we completed a pivotal hypoxia study in October 2022 with the Evie Ring. During the pilot and pivotal studies, our solution achieved a margin of error well below the FDA’s 3.5% requirement for SpO₂, and the ring also estimated heart rate with accuracy commensurate with the FDA’s standards. Based on the positive results of these studies, we plan to file for FDA clearance on these metrics by mid-2023. If clearance is received, the Evie 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.

We expect the direct-to-consumer launch of the Evie Ring to take place in the summer of 2023 prior to any FDA decision regarding medical device clearance. We have hired a world class go-to-market leadership team and have been working with leading app development partners to build on the foundational elements already in place to create a unique and valuable user experience. Further, we have engaged leading marketing, branding, website development and consumer research partners, to ensure the brand is engaging and relevant to the target audience.

To prepare for the consumer launch of the Evie Ring, we are conducting initial beta test programs to evaluate the fit and functionality of the ring with four strategic partners, including Stanford University’s Applied Sports Science Department, Novant Health, a not-for-profit integrated system of medical centers with more than 1,800 physicians providing care through six million annual patient visits at nearly 800 locations across North Carolina, South Carolina and Georgia, a major global pharmaceutical company and a leading patient-focused medical device company.

We are also preparing for a second beta program to evaluate the end to end Evie Ring experience with a new slate of partners, among which are a global athletic apparel company and two additional leading global medical device companies. The beta programs are expected to continue through mid-2023.

Our current primary goals are to successfully conduct beta programs and optimize the ring based on feedback from the programs in order to prepare for the commercialization of our first product. We also plan to begin testing of our single chip solution in more extensive clinical trials and are working with an original equipment manufacturer (“OEM”) to prepare for product manufacturing of the Evie Ring.

We have not launched a first commercial product and do not have a history of revenue or earnings or of product development or manufacturing. As described further below under “Regulation” and “Strategy”, before we can commercialize our planned solution, we will need to determine our commercialization strategy.

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, 2022, we own, jointly own, or have exclusive rights to 16 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, 2022, we own, jointly own, or have exclusive rights to 38 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 expected to be a general wellness device and therefore 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, SpO₂ and respiration rate. 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, 2022, and there are no material expenditures planned for such purposes for the year ended December 31, 2023.

Strategy

We are a newly 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 retail channels and through our website 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 the Company.

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., Nemauro 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, 2022, we had 34 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 on 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 any product.
- We face competition from other technology companies and our operating results will suffer if we fail to compete effectively.
- The outbreak of COVID-19 has and could continue to adversely impact our business.
- 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.
- The ongoing military action by Russia in Ukraine could have negative impact on the global economy, which could materially adversely affect our business, operations, operating results and financial condition.
- 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 proposed solution 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 expect to need FDA clearance or approval for our planned 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 proposed solution 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 proposed solution could suffer.
- We expect our planned solution to be subject to certain Federal Communication Commission ("FCC") regulations.
- Our planned solution may in the future be subject to product recalls that could harm our reputation.
- Healthcare reform measures could hinder or prevent our planned solution's commercial success.
- If we fail to comply with healthcare regulations with respect to our planned solution, we could face substantial penalties and our business, operations and financial condition could be adversely affected.

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 disclosure controls and procedures may not prevent or detect all errors or acts of fraud.
- 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 will designate 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 significant increased costs as a result of becoming 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 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 are a technology company that was formed in January 2018. We have a limited operating history, have no commercial products and have engaged in only 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, 2022, we had an accumulated deficit of approximately \$95.1 million. 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, 2022, we had total assets of approximately \$13.2 million and total liabilities of approximately \$5.3 million. We believe that our cash and cash equivalents as of December 31, 2022 with the addition of the \$6.85 million raised in our February 2023 public offering 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, 2022. Additionally, such cash and cash equivalents and short-term investments are not expected to be sufficient to enable us to complete the development and commercialization of our proposed solution. 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 any product.

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 planned solutions, we 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.

The outbreak of COVID-19 has and could continue to adversely impact our business.

The COVID-19 pandemic, together with related precautionary measures, has materially disrupted our business since February 2020 and may continue to disrupt our business for an unknown period of time. COVID-19 has significantly impacted, and may continue to significantly impact, our work force, supply chain and operating results. The level and nature of the disruption caused by COVID-19, or any future pandemic is unpredictable, may be cyclical and long-lasting, may vary from location to location and may have a material adverse impact on our operations and financial condition and results.

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 in order to fund our operations.

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.

The ongoing military action by Russia in Ukraine could have negative impact on the global economy which could materially adversely affect our business, operations, operating results and financial condition.

On February 24, 2022, Russian forces launched significant military action against Ukraine, and sustained conflict and disruption in the region is possible. The impact to Ukraine as well as actions taken by other countries, including new and stricter sanctions imposed by Canada, the United Kingdom, the European Union, the United States and other countries and companies and organizations against officials, individuals, regions, and industries in Russia and Ukraine, and actions taken by Russia in response to such sanctions, and each country's potential response to such sanctions, tensions, and military actions could adversely affect the global economy and financial markets and thus could affect our business, operations, operating results and financial condition as well as the price of our common stock and our ability to raise additional capital when needed on acceptable terms. The extent and duration of the military action, sanctions and resulting market disruptions, including supply chain disruptions, are impossible to predict, but could be substantial. Any such disruptions caused by Russian military action or resulting sanctions may magnify the impact of other risks described in this Annual Report on Form 10-K.

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. In addition, we could be criticized for the scope of such initiatives or goals or perceived as not acting responsibly in connection with these matters. 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 proposed solution 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 initial solution under development. There is no guarantee that we will be successful in the development of this or any other future product. While we may commercialize our first iteration of the Evie Ring without FDA clearance, subsequent iterations of our proposed solution 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 our proposed solution will receive regulatory clearance or approval or be successfully commercialized. Any failure to obtain regulatory clearance or approval of or to successfully commercialize the proposed solution would have a material adverse effect on our business.

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.

We expect to depend on strategic partners such as third-party OEMs, VARs and other distributors to complete the design, manufacture, market and distribute our product under development or other future products. If these strategic partners fail to successfully complete the design, manufacture, market or distribute our product under development or other 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, 2022, we own, jointly own, or have exclusive rights to 16 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, 2022, we own, jointly own, or have exclusive rights to 38 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 expect to seek FDA clearance or approval for our planned solution, which may be difficult to achieve, and existing laws or regulations or future legislative or regulatory changes may affect our business.

While we may commercialize our first iteration of the Evie Ring without FDA clearance, we expect subsequent iterations of our proposed solution 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 proposed solution 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 proposed solution 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 proposed solution, 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 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. 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 planned solution may in the future 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 planned solution 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 planned solution's 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 device 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 planned solution, 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.

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 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;
- 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, 2022. 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 \$4.11 and a low of \$1.27 in the twelve-month period ended December 31, 2022. 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 listed on Nasdaq Capital Market. If we fail to satisfy the continued listing requirements of Nasdaq, such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to delist our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair our shareholders' ability to sell or purchase our common stock. In the event of a delisting, we would take actions to restore our compliance with Nasdaq's listing requirements, but we can provide no assurance that any such action taken by us would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with Nasdaq's listing requirements.

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 8.1% 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, Leabman Holdings LLC and certain trusts established by Emily Fairbairn beneficially own approximately 9.1% and 8.8%, 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” for up to five years, 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 increased costs as a result of becoming 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 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 13 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 March 23, 2023, there were 36 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.

The Company's initial commercial product in development 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, including resting heart rate, heart rate variability ("HRV"), SpO₂, 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 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 a development stage company with a limited operating history. To date, we have invested substantially all of our efforts and financial resources into the research and development of the products we are developing, including conducting clinical studies and related sales, general and administrative costs. 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 net losses were \$30.3 million and \$21.8 million for the years ended December 31, 2022 and 2021, 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, 2022, we had \$10.8 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 13 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.

Critical Accounting Policies and Estimates

Our consolidated financial statements are prepared in accordance with U.S. generally accepted accounting principles, or GAAP, which requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses. These estimates require the use of judgment as future events, and the effect of these events cannot be predicted with certainty.

Liquidity

In accordance with Accounting Standard Codification (“ASC”) 205-40, “Presentation of Financial Statements - Going Concern”, the Company continually evaluates whether there are conditions or events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within one year after the date that the consolidated financial statements are issued. We have incurred operating losses and negative cash flows from operating activities in each year since its inception.

We believe that our cash and cash equivalents as of December 31, 2022 with the addition of the \$6.85 million raised in our February 2023 public offering will not be sufficient to fund our projected operating requirements for at least the next 12 months from the filing date of this annual report.

Redeemable Convertible Preferred Stock

We recorded all shares of redeemable convertible preferred stock at their respective issuance price less issuance costs on the dates of issuance. Under certain circumstances, we would have been required to redeem the Series A and Series B redeemable convertible preferred stock unless an Initial Public Offering (“IPO”) had been consummated prior to April 1, 2021, or an extension or waiver was obtained upon approval of a majority of the holders of such preferred stock. As the preferred stock became redeemable due to the passage of time, we considered the preferred stock to be redeemable as of April 1, 2021. We record the accretion of the Series A and B preferred stock balances to their respective redemption amounts using the effective interest method. Upon the IPO, the redeemable convertible preferred stock converted in to 11,436,956 shares of common stock.

Paycheck Protection Program Loan

We accounted for funds received from the Paycheck Protection Program as a financial liability with interest accrued and expensed over the term of the loan under the effective interest method. The loan remained recorded as a liability until the Company was legally released from the liability. The amount that was ultimately forgiven by the lender was recognized in the consolidated statement of operations and comprehensive loss as a gain extinguishment.

Convertible Financial Instruments

We bifurcate embedded redemption and conversion options from their host instruments and account for them as freestanding derivative financial instruments at fair value, if certain criteria are met. The criteria include circumstances in which (a) the economic characteristics and risks of the embedded derivative instrument are not clearly and closely related to the economic characteristics and risks of the host contract, (b) the hybrid instrument that embodies both the embedded derivative instrument and the host contract is not re-measured at fair value under otherwise applicable GAAP with changes in fair value reported in earnings as they occur and (c) a separate instrument with the same terms as the embedded derivative instrument would be considered a derivative instrument. Debt discounts under these arrangements are amortized to interest expense using the interest method over the earlier of the term of the related debt or their earliest date of redemption.

We may retain a third-party appraiser to estimate the fair value of the derivative financial instruments. These fair value estimates are subjective in nature and require careful consideration and judgement. Management reviews the third-party reports for reasonableness of the assigned values. We believe that the appraised values represent the fair value of the freestanding derivative financial instruments, and we have not had to modify the assumptions.

From time to time, we issue convertible financial instruments to nonemployees in payment for services that are provided. Until the services are completely rendered, we will expense the principal and any interest earned prior to the service completion to the representative expense account for the services performed and will record a noncurrent liability for the expected amount of the principal balance. Upon completion of the services, we will reclassify the noncurrent liability balance to the balance of an outstanding convertible financial instrument and assess the embedded redemption and conversion options that are applicable at that time.

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 the Black-Scholes option pricing model which contains 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 the Company's 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.

Fair Value of Common Stock

Prior to our IPO in March 2021, the fair values of the shares of our common stock underlying our share-based awards and warrant grants were estimated on each grant date by our board of directors. In order to determine the fair value of our common stock, our board of directors considered, among other things, valuations of our common stock prepared by an independent third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants Practice Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*.

The fair value of our common stock was estimated using a two-step process. First, our enterprise value was established using generally accepted valuation methodologies, such as comparable public company and market adjusted option pricing analysis as well as consideration of company financing transactions. Second, the enterprise value was allocated among the securities that comprise our capital structure using the option-pricing method. The option-pricing method treats all levels of the capital structure as call options on the enterprise's value, with exercise price based on the "breakpoints" between each of the different claims on the securities. The inputs necessary for the option-pricing model include the current equity value (the enterprise value as previously calculated), breakpoints (the various characteristics for each class of equity, including liquidation preferences and priority distributions, in accordance with our certificate of incorporation, as amended and restated), term, risk-free rate, and volatility.

Given the absence of a public trading market for our common stock, our board of directors exercised their judgment and considered a number of objective and subjective factors to determine the best estimate of the fair value of our common stock, including valuations performed by an independent third party, developments in our operations, sales of preferred stock, the prices, rights, preferences and privileges of our preferred stock relative to the common stock, actual operating results and financial performance and capital resources, the conditions in the our industry and the economy and capital markets in general, the stock price performance and volatility of comparable public companies, the likelihood of achieving a liquidity event for shares of our common stock underlying these stock options, such as an initial public offering or sale of our company, and the lack of liquidity of our common stock, among other factors.

The assumptions underlying these valuations were highly complex and subjective and represented management's best estimates, which involved inherent uncertainties and the application of management's judgment. As a result, if we had used significantly different assumptions or estimates, the fair value of our common stock and our stock-based compensation expense could be materially different.

The fair value of the underlying common stock was determined by the board of directors until the IPO when our common stock started trading on The Nasdaq Capital Market under the ticker symbol MOVE on March 23, 2021. Consequently, after our IPO the fair value of the shares of common stock underlying the stock options is the closing market price on the option grant date.

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, 2022 and 2021

Our consolidated statements of operations for the years ended December 31, 2022 and 2021 as discussed herein are presented below.

	Year Ended December 31,		Change	
	2022	2021	\$	%
	(in thousands)			
OPERATING EXPENSES:				
Research and development	\$ 18,994	\$ 13,427	\$ 5,567	41%
Sales, general and administrative	11,468	6,376	5,092	80%
Total operating expenses	<u>30,462</u>	<u>19,803</u>	<u>10,659</u>	<u>54%</u>
Loss from operations	<u>(30,462)</u>	<u>(19,803)</u>	<u>(10,659)</u>	<u>(54)%</u>
Other income (expense), net:				
Interest expense	—	(883)	883	100%
Change in fair value of warrant liability	—	(1,581)	1,581	100%
Change in fair value of derivative liability	—	121	(121)	(100)%
Forgiveness of Paycheck Protection Program Loan	—	351	(351)	(100)%
Interest and other income, net	133	22	111	505%
Other income (expense), net	<u>133</u>	<u>(1,970)</u>	<u>2,103</u>	<u>107%</u>
Net loss	<u>\$ (30,329)</u>	<u>\$ (21,773)</u>	<u>\$ (8,556)</u>	<u>(39)%</u>

Research and Development

Research and development expenses totaled \$19.0 million and \$13.4 million for the years ended December 31, 2022 and 2021, respectively. This increase of \$5.6 million was due primarily to the growth of the Company and its activities. 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. Research and development expenses for the year ended December 31, 2021 included expenses related to employee compensation of \$6.0 million, tools and equipment expenses of \$1.0 million, other professional fees of \$5.9 million, rent of \$0.1 million, depreciation and amortization of \$0.1 million, and other expenses of \$0.3 million.

Sales, General and Administrative

Sales, general and administrative expenses totaled \$11.5 million and \$6.4 million for the years ended December 31, 2022 and 2021, respectively. This increase of \$5.1 million was due primarily to the growth of the Company and its activities. 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. Sales, general and administrative expenses for the year ended December 31, 2021 included expenses related to employee and board of director compensation of \$3.2 million, professional and consulting fees of \$1.7 million, and other expenses of \$1.5 million.

Loss from Operations

Loss from operations was \$30.5 million for the year ended December 31, 2022, as compared to \$19.8 million for the year ended December 31, 2021.

Other Income (Expense), Net

Other income (expense), net for the year ended December 31, 2022 was a net other income of \$0.1 million as compared to a net other expense of \$2.0 million for the year ended December 31, 2021. Other income (expense), net for the year ended December 31, 2022 reflected the net interest income on short-term investments. Other income (expense), net for the year ended December 31, 2021 included interest expense of \$0.9 million related to the accrual of interest and amortization of debt discounts on the convertible promissory notes and \$1.6 million related to the change in the fair value of warrant liability, which were partially offset by \$0.1 million related to the change in fair value of the derivative liability and forgiveness of the Paycheck Protection Program Loan of \$0.4 million.

Net Loss

As a result of the foregoing, net loss was \$30.3 million for the year ended December 31, 2022, as compared to \$21.8 million for the year ended December 31, 2021.

Liquidity and Capital Resources

At December 31, 2022, we had cash, cash equivalents \$10.8 million. During the year ended December 31, 2022, the Company used \$24.9 million of cash in our operating activities. Our cash and short-term investments are not expected to be sufficient to enable us to complete the development and commercialization of our first proposed commercial product, the Evie Ring. 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 year ended December 31, 2022, the Company sold an aggregate of 810,400 shares of common stock through the ATM program for proceeds of approximately \$2.2 million, net of commissions paid. Approximately \$47.7 million remains available on the ATM equity offering program at December 31, 2022. 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 development of the Evie Ring and other potential products;
- prepare applications required for marketing approval of the Evie Ring in the United States;
- develop 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, planned commercialization efforts and our operation as a public company.

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,	
	2022	2021
Net cash used in operating activities	\$ (24,902)	\$ (16,183)
Net cash provided by/(used in) investing activities	15,724	(16,699)
Net cash used in financing activities	2,262	44,847
Net increase/(decrease) in cash and cash equivalents	<u>\$ (6,916)</u>	<u>\$ 11,965</u>

Operating Activities

During the year ended December 31, 2022, the Company used cash of \$24.9 million in operating activities, as compared to \$16.2 million used in operating activities during the year ended December 31, 2021.

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.

The \$16.2 million used in operating activities during the year ended December 31, 2021 was primarily attributable to our net loss of \$21.8 million during the year and changes in our operating assets and liabilities totaling \$1.3 million. These items were offset by non-cash items, including depreciation and amortization of \$0.1 million, stock-based compensation of \$1.9 million, accretion of the debt discount on our convertible promissory notes of \$0.8 million, the forgiveness of our PPP loan of \$0.4 million, accrued interest on our convertible promissory notes of \$0.1 million, accretion of discount on short-term investments of \$0.2 million, compensation of nonemployee services upon the issuance of common stock of \$0.1 million, the change in the fair value of the derivative liability of \$0.1 million and the change in the fair value of the warrant liability of \$1.6 million.

Investing Activities

During the year ended December 31, 2022 the Company was 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.

During the year ended December 31, 2021 the Company used cash of \$16.7 million in investing activities, consisting of \$23.6 million in purchases of marketable securities and \$0.6 million for the purchase of office and laboratory equipment, offset by maturities of short-term investments of \$7.5 million.

Financing Activities

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

During the year ended December 31, 2021, the Company was provided cash of \$44.8 million from financing activities, comprised of \$44.7 million from the net proceeds of our initial public offering and \$0.1 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 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 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 magnitude and extent to which the COVID-19 pandemic impacts our business operations and operating results, as described in “Risk Factors – Risks Related to Our Business.”

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. See Note 13 to the consolidated financial statements for amounts outstanding for operating leases on December 31, 2022.

Off-Balance Sheet Transactions

At December 31, 2022, the Company did not have any transactions, obligations or relationships that could be considered off-balance sheet arrangements.

Non-cancelable Obligations

The Company also had approximately \$0.4 million of non-cancelable contractual commitments as of December 31, 2022, primarily related to its vendor arrangements. These commitments are generally due within one to ten months.

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

Not applicable.

Item 8. Financial Statements and Supplementary Data.

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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, 2022 and 2021, the related consolidated statements of operations and comprehensive loss, redeemable convertible preferred stock and stockholders’ equity (deficit), 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, 2022 and 2021, 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
March 30, 2023

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,	
	2022	2021
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 10,759	\$ 17,675
Short-term investments	—	15,921
Payroll tax credit, current portion	379	166
Prepaid expenses and other current assets	508	1,296
Total current assets	11,646	35,058
Property and equipment, net	443	529
Payroll tax credit, noncurrent portion	667	630
Other assets	487	48
Total assets	\$ 13,243	\$ 36,265
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 557	\$ 311
Other current liabilities	4,421	2,907
Total current liabilities	4,978	3,218
Noncurrent liabilities:		
Early exercised stock option liability	136	281
Other noncurrent liabilities	214	36
Total noncurrent liabilities	350	317
Total liabilities	5,328	3,535
Commitments and contingencies (Note 13)		
Stockholders' equity:		
Preferred stock, \$0.0001 par value, 5,000,000 shares authorized at December 31, 2022 and 2021; no shares issued and outstanding at December 31, 2022 and 2021	—	—
Common stock, \$0.0001 par value, 75,000,000 shares authorized at December 31, 2022 and 2021; 33,659,460 and 32,772,060 shares issued and outstanding at December 31, 2022 and 2021, respectively	3	3
Additional paid-in capital	103,009	97,506
Accumulated other comprehensive loss	—	(11)
Accumulated deficit	(95,097)	(64,768)
Total stockholders' equity	7,915	32,730
Total liabilities and stockholders' equity	\$ 13,243	\$ 36,265

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,	
	2022	2021
OPERATING EXPENSES:		
Research and development	\$ 18,994	\$ 13,427
Sales, general and administrative	11,468	6,376
Total operating expenses	<u>30,462</u>	<u>19,803</u>
Loss from operations	<u>(30,462)</u>	<u>(19,803)</u>
Other income (expense), net:		
Interest expense	—	(883)
Change in fair value of warrant liability	—	(1,581)
Change in fair value of derivative liability	—	121
Forgiveness of Paycheck Protection Program Loan	—	351
Interest and other income, net	133	22
Other income (expense), net	<u>133</u>	<u>(1,970)</u>
Net loss	(30,329)	(21,773)
Accretion and dividends on redeemable convertible preferred stock	—	(2,489)
Net loss attributable to common stockholders	<u>\$ (30,329)</u>	<u>\$ (24,262)</u>
Net loss	\$ (30,329)	\$ (21,773)
Other comprehensive loss:		
Change in unrealized loss on available-for-sale securities	—	(11)
Total comprehensive loss	<u>\$ (30,329)</u>	<u>\$ (21,784)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.92)</u>	<u>\$ (0.92)</u>
Weighted average shares used in computing net loss per share attributable to common stockholders, basic and diluted	<u>33,025,721</u>	<u>26,298,032</u>

See accompanying notes to consolidated financial statements.

Movano Inc.
Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
(in thousands, except share data)

	Redeemable Convertible Preferred Stock				Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Series A		Series B		Shares	Amount				
	Shares	Amount	Shares	Amount						
Balance at December 31, 2020	2,692,253	\$ 13,856	4,942,319	\$ 18,962	6,393,069	\$ 1	\$ —	\$ —	\$ (40,881)	\$ (40,880)
Stock-based compensation	—	—	—	—	—	—	1,854	—	—	1,854
Accretion of Series A and Series B redeemable convertible preferred stock	—	686	—	1,803	—	—	(2,489)	—	—	(2,489)
Issuance of common stock upon exercise of options	—	—	—	—	134,541	—	49	—	—	49
Vesting of early exercised stock options	—	—	—	—	—	—	163	—	—	163
Reclassification of negative additional paid-in capital	—	—	—	—	—	—	2,114	—	(2,114)	—
Conversion of preferred stock to common stock upon initial public offering	(2,692,253)	(14,542)	(4,942,319)	(20,765)	11,436,956	1	35,306	—	—	35,307
Issuance of common stock upon initial public offering, net of issuance costs	—	—	—	—	9,775,000	1	41,924	—	—	41,925
Issuance of underwriter warrants upon initial public offering	—	—	—	—	—	—	2,349	—	—	2,349
Reclassification of liability-classified warrants upon initial public offering	—	—	—	—	—	—	3,130	—	—	3,130
Conversion of convertible promissory notes and accrued interest upon initial public offering	—	—	—	—	5,015,494	—	12,550	—	—	12,550
Issuance of common stock for nonemployee services	—	—	—	—	17,000	—	85	—	—	85
Beneficial conversion feature upon issuance of convertible promissory note	—	—	—	—	—	—	471	—	—	471
Other comprehensive loss	—	—	—	—	—	—	—	(11)	—	(11)
Net loss	—	—	—	—	—	—	—	—	(21,773)	(21,773)
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	—	—	—	—	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 income	—	—	—	—	—	—	—	11	—	11
Net loss	—	—	—	—	—	—	—	—	(30,329)	(30,329)
Balance at December 31, 2022	—	\$ —	—	\$ —	33,659,460	\$ 3	\$ 103,009	\$ —	\$ (95,097)	\$ 7,915

See accompanying notes to consolidated financial statements.

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

	Year Ended December 31,	
	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (30,329)	\$ (21,773)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	147	74
Forgiveness of Paycheck Protection Program loan	—	(351)
Stock-based compensation	3,096	1,854
Noncash lease expense	(13)	—
Accretion of debt discount on convertible promissory notes	—	772
Accrued interest on convertible promissory notes	—	115
Accretion of discount on short-term investments	103	202
Non-employee services under convertible promissory notes	—	50
Compensation of non-employee services upon issuance of common stock	—	74
Change in fair value of derivative liability	—	(121)
Change in fair value of warrant liability	—	1,581
Loss on disposal of property and equipment	44	—
Changes in operating assets and liabilities:		
Payroll tax credit	(250)	(162)
Prepaid expenses and other current assets	788	(802)
Other assets	(50)	(38)
Accounts payable	246	65
Other current and noncurrent liabilities	1,316	2,277
Net cash used in operating activities	<u>(24,902)</u>	<u>(16,183)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(105)	(565)
Purchases of short-term investments	—	(23,633)
Maturities of short-term investments	15,829	7,499
Net cash provided by/(used in) investing activities	<u>15,724</u>	<u>(16,699)</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Issuance of common stock - net of issuance costs	2,231	76
Issuance of common stock upon exercise of stock options	31	—
Proceeds from issuance of shares upon Initial Public Offering - net of issuance costs	—	44,771
Net cash provided by financing activities	<u>2,262</u>	<u>44,847</u>
Net increase/(decrease) in cash and cash equivalents	(6,916)	11,965
Cash and cash equivalents at beginning of period	17,675	5,710
Cash and cash equivalents at end of period	<u>\$ 10,759</u>	<u>\$ 17,675</u>
NONCASH INVESTING AND FINANCING ACTIVITIES:		
Accretion of Series A redeemable convertible preferred stock	\$ —	\$ 686
Accretion of Series B redeemable convertible preferred stock	\$ —	\$ 1,803
Conversion of preferred stock to common stock upon initial public offering	\$ —	\$ 35,307
Reclassification of liability-classified warrants upon initial public offering	\$ —	\$ 3,130
Issuance of underwriter warrants upon initial public offering	\$ —	\$ 2,349
Issuance of convertible promissory notes for completion of non-employee services	\$ —	\$ 500
Beneficial conversion feature upon issuance of convertible promissory note	\$ —	\$ 471
Conversion of convertible promissory notes upon initial public offering	\$ —	\$ 12,550
Vesting of common stock issued upon early exercise	\$ 145	\$ 136
Issuance of common stock for non-employee services	\$ —	\$ 11
Reclassification of deferred offering costs upon initial public offering	\$ —	\$ 497
Property and equipment purchases in other current liabilities	\$ 19	\$ —

See accompanying notes to consolidated financial statements.

Movano Inc.
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, HRV, sleep, respiration rate, temperature, SpO₂, steps, 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, 2022 and 2021, respectively.

Since inception, the Company has engaged in only limited research and development of product candidates and underlying technology. As of December 31, 2022, the Company had not yet completed the development of its product and had not yet recorded any revenues.

In December 2019, a novel coronavirus and the resulting disease (“COVID-19”) was reported, and in January 2020, the World Health Organization (“WHO”) declared it a Public Health Emergency of International Concern. In February 2020, the WHO raised its assessment of the COVID-19 threat from high to very high at a global level due to the continued increase in the number of cases and affected countries, and in March 2020, the WHO characterized COVID-19 as a pandemic. The Company continues to evaluate the impact of the COVID-19 pandemic and has concluded that while it is reasonably possible that the virus could have a negative effect on the Company’s consolidated financial position or consolidated results of operations, the specific impact is not readily determinable as of the date of these consolidated financial statements. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

The Company’s Registration Statement on Form S-1, as amended (Reg. No. 333-252671), was declared effective by the U.S. Securities and Exchange Commission (the “SEC”) on March 23, 2021. The registration statement registered the securities offered in the Company’s initial public offering (“IPO”). In the IPO, the Company sold 9,775,000 shares of common stock at a price to the public of \$5.00 per share, including the full exercise of the underwriters’ option to purchase additional shares. The IPO closed on March 25, 2021 and the underwriters exercised their overallotment option as of March 25, 2021, as a result of which the Company raised net proceeds of \$44.3 million after deducting \$3.3 million in underwriting discounts, commissions, and expenses and \$1.3 million in offering expenses paid by the Company. National Securities Corporation (“NSC”) was the underwriter for the IPO, and also received a warrant related to the IPO, which is discussed in Note 11. No portion of the net proceeds from the IPO were used for payments made by the Company to its directors or officers or persons owning ten percent or more of its common stock or to their associates, or to the Company’s affiliates, other than payments in the ordinary course of business to officers for salaries and to nonemployee directors as compensation for board or board committee service.

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 \$6.85 million (See Note 16).

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, 2022, the Company has relied primarily on the proceeds from equity offerings to finance its operations. Through December 31, 2022, the Company has received proceeds of approximately \$2.2 million from an at-the-market issuance program, and an aggregate offering price amount of approximately \$47.7 million remains available to be issued. (See Note 10.) 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 \$95.1 million as of December 31, 2022. 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, but are not limited to, the accrual of research and development expenses, the valuation of common stock, stock options and warrants, the valuation of the embedded redemption derivative liability 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. The Company classifies all marketable securities for use in current operations, even if the security matures beyond 12 months, and presents them as short-term investments in the consolidated balance sheets.

The Company determines the appropriate classification of marketable securities at the time of purchase and reevaluates such designation at each balance sheet date. The Company has classified and accounted for the purchased marketable securities as available-for-sale. After considering the Company's capital preservation objectives, as well as its liquidity requirements, the Company may sell securities prior to their stated maturities. The Company carries its available-for-sale short-term investments at fair value. The Company reports the unrealized gains and losses, net of taxes, as a component of stockholders' equity, except for unrealized losses determined to be credit-related, which are recorded as other income (expense), net in the consolidated statements of operations and comprehensive loss and reports an allowance for credit losses in short-term investments on the balance sheet, if any. The Company determines any realized gains or losses on the sale of short-term investments on a specific identification method and records such gains and losses as a component of other income (expense), net. Interest earned on cash, cash equivalents, and short-term investments is recorded in interest and other income, net in the accompanying consolidated statements of operations and comprehensive loss and was \$277,000 and insignificant during the years ended December 31, 2022 and 2021.

The Company's investment policy only allows purchases of high credit quality instruments and provides guidelines on concentrations and credit quality to ensure minimum risk of loss. The Company evaluates whether the unrealized loss on available-for-sale short-term investments is the result of the credit worthiness of the securities it held, or other non-credit-related factors such as liquidity by reviewing a number of factors such as the implied yield of the corporate note based on the market price, the nature of the invested entity's business or industry, market capitalization relative to debt, changes in credit ratings, and the market prices of the instruments subsequent to the period end.

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. 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, 2022 at one financial institution that totaled approximately \$2.3 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 comprised of prepaid expenses, other current receivables, and deferred offering costs, which consist of legal, accounting, filing and other fees related to the IPO that were capitalized prior to the IPO. The deferred offering costs were offset against proceeds from the IPO within additional paid-in capital upon the effective date of the IPO.

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, 2022 and 2021, 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.

Paycheck Protection Program Loan

The Company accounted for funds received from the Paycheck Protection Program as a financial liability with interest accrued and expensed over the term of the loan under the effective interest method. The loan remained recorded as a liability until the Company was legally released from the liability. The amount that was ultimately forgiven by the lender was recognized in the consolidated statement of operations and comprehensive loss as a gain on extinguishment.

Convertible Financial Instruments

The Company bifurcates embedded redemption and conversion options from their host instruments and accounts for them as freestanding derivative financial instruments at fair value if certain criteria are met. The criteria include circumstances in which (a) the economic characteristics and risks of the embedded derivative instrument are not clearly and closely related to the economic characteristics and risks of the host contract, (b) the hybrid instrument that embodies both the embedded derivative instrument and the host contract is not re-measured at fair value under otherwise applicable GAAP with changes in fair value reported in earnings as they occur and (c) a separate instrument with the same terms as the embedded derivative instrument would be considered a derivative instrument. Debt discounts under these arrangements are amortized to interest expense using the interest method over the earlier of the term of the related debt or their earliest date of redemption.

From time to time, the Company issues convertible financial instruments to nonemployees in payment for services that are provided. Until the services are completely rendered, the Company will expense the principal and any interest earned prior to the service completion to the representative expense account for the services performed and will record a noncurrent liability for the expected amount of the principal balance. Upon completion of the services, the Company will reclassify the noncurrent liability balance to the balance of an outstanding convertible financial instrument and assess the embedded redemption and conversion options that are applicable at that time.

Beneficial Conversion Feature

If the conversion feature of conventional convertible promissory notes provides for a rate of conversion that is below fair value, this feature is characterized as a beneficial conversion feature ("BCF"). A BCF is recorded by the Company as a debt discount and as additional paid-in capital on the consolidated balance sheet. In those circumstances, the convertible debt is recorded net of the discount related to the BCF and the Company amortizes the discount to interest expense over the life of the debt using the effective interest method.

Redeemable Convertible Preferred Stock

The Company records all shares of redeemable convertible preferred stock at their respective issuance price less issuance costs on the dates of issuance. Under certain circumstances the Company would have been required to redeem the Series A and Series B redeemable convertible preferred stock unless an IPO had been consummated prior to April 1, 2021, or an extension or waiver was obtained upon approval of a majority of the holders of such preferred stock. As the preferred stock became redeemable due to the passage of time, the Company considered the preferred stock to be redeemable as of April 1, 2021. The Company recorded the accretion of the Series A and B preferred stock balances to their respective redemption amounts using the effective interest method. The redeemable convertible preferred stock is presented outside of stockholders' deficit on the consolidated balance sheet as of December 31, 2020. Upon the IPO, the redeemable convertible preferred stock converted into 11,436,956 shares of common stock.

Comprehensive Loss

Comprehensive loss is the change in stockholders' equity (deficit) from transactions and other events and circumstances other than those resulting from investments by stockholders and distributions to stockholders. The Company's other comprehensive loss is comprised of unrealized gains and losses on investments in available-for-sale securities.

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.

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.

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 year ended December 31, 2022 and 2021.

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 Attributable to Common Stockholders

Basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding during the period, without consideration for common stock equivalents. The net loss attributable to common stockholders is calculated by adjusting the net loss of the Company for the accretion on the Series A and B redeemable convertible preferred stock and cumulative dividends on Series A and B redeemable convertible preferred stock. Diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders, since the effects of potentially dilutive securities are antidilutive.

Recently Adopted Accounting Pronouncements

The Company adopted FASB's ASU No. 2016-02, *Leases* ("ASC 842"), as of January 1, 2022, using the modified retrospective approach which provides a method for recording existing leases at the beginning of the period of adoption.

In addition, the Company elected the package of practical expedients and other expedients permitted under the transition guidance within the new standard, which among other things, allowed the Company to carry forward the historical lease classification and not to restate the comparative periods prior to the adoption and to combine lease and non-lease components for all asset classes. The Company made an accounting policy election not to recognize right of use assets and lease liabilities for leases with a lease term of 12 months or less, including renewal options that are reasonably certain to be exercised, that also do not include an option to purchase the underlying asset that is reasonably certain of exercise. Instead, lease payments for these leases are recognized as lease expense on a straight-line basis over the lease term. The disclosures required under ASC 842 are not presented for periods before the date of adoption. For the comparative periods prior to adoption, the Company presented the disclosures which were required under the previous accounting guidance. The adoption of the new standard did not have a material impact on the Company's results of operations or cash flows.

Operating lease right of use ("ROU") assets represent the right to use the leased asset for the lease term and operating lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. Adoption of the new standard resulted in the recording of operating lease liabilities of \$429,000 and ROU assets of \$380,000 as of January 1, 2022. The difference between the ROU assets and lease liabilities represents the net book value of deferred rent recognized as of December 31, 2021, which was adjusted against the ROU asset upon adoption. The ROU asset is included in other assets on the Company's consolidated balance sheet. At adoption, operating lease liabilities of \$166,000 and \$263,000, respectively, were included in other current liabilities and other noncurrent liabilities on the Company's consolidated balance sheet.

As most leases do not provide an implicit rate, the Company uses an incremental borrowing rate based on the information available at the adoption date in determining the present value of future payments. Lease expense for minimum lease payments is amortized on a straight-line basis over the lease term and is included in research and development expenses and sales, general and administrative expenses in the consolidated statements of operations and comprehensive loss. Variable lease payments for common area maintenance, property taxes and other operating expenses are recognized as expense in the period when the changes in facts and circumstances on which the variable lease payments are based occur.

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 Company measures its cash equivalents, short-term investments and derivative financial instruments at fair value. The Company classifies its cash equivalents and short-term investments within Level 1 or Level 2 because the Company values these investments using quoted market prices or alternative pricing sources and models utilizing market observable inputs. The fair value of the Company's Level 1 financial assets is based on quoted market prices of the identical underlying security. The fair value of the Company's Level 2 financial assets is based on inputs that are directly or indirectly observable in the market, including the readily-available pricing sources for the identical underlying security that may not be actively traded.

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.

Changes in fair value measurements categorized within Level 3 of the fair value hierarchy are analyzed each period based on changes in estimates or assumptions and recorded as appropriate.

The carrying amounts of prepaid expenses, payroll tax credit, accounts payable and accrued 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, 2022 and 2021 (in thousands).

	December 31, 2022			
	Fair Value	Level 1	Level 2	Level 3
Cash equivalents:				
Money market funds	\$ 8,171	\$ 8,171	\$ —	\$ —
Total cash equivalents	<u>\$ 8,171</u>	<u>\$ 8,171</u>	<u>\$ —</u>	<u>\$ —</u>
	December 31, 2021			
	Fair Value	Level 1	Level 2	Level 3
Cash equivalents:				
Money market funds	\$ 16,830	\$ 16,830	\$ —	\$ —
Total cash equivalents	<u>\$ 16,830</u>	<u>\$ 16,830</u>	<u>\$ —</u>	<u>\$ —</u>
Short-term investments:				
Certificates of deposit	\$ 250	\$ —	\$ 250	\$ —
Commercial paper	2,210	—	2,210	—
Corporate notes	12,024	—	12,024	—
Municipal bonds	1,437	—	1,437	—
Total short-term investments	<u>\$ 15,921</u>	<u>\$ —</u>	<u>\$ 15,921</u>	<u>\$ —</u>

NOTE 4 – CASH, CASH EQUIVALENTS AND SHORT-TERM INVESTMENTS

Cash, cash equivalents and short-term investments consist of the following (in thousands):

	December 31,	
	2022	2021
Cash and cash equivalents:		
Cash	\$ 2,588	\$ 845
Money market funds	8,171	16,830
Total cash and cash equivalents	<u>\$ 10,759</u>	<u>\$ 17,675</u>
Short-term investments:		
Certificates of deposit	\$ —	\$ 250
Commercial paper	—	2,210
Corporate notes	—	12,024
Municipal bonds	—	1,437
Total short-term investments	<u>\$ —</u>	<u>\$ 15,921</u>

The following table summarizes the unrealized gains and losses related to short-term investments classified as available-for-sale on the Company's consolidated balance sheet at December 31, 2021 (in thousands):

	December 31, 2021			Aggregate Estimated Fair Value
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	
Short-term investments:				
Certificates of deposit	\$ 250	\$ —	\$ —	\$ 250
Commercial paper	2,210	—	—	2,210
Corporate notes	12,035	—	(11)	12,024
Municipal bonds	1,437	—	—	1,437
Total short-term investments	\$ 15,932	\$ —	\$ (11)	\$ 15,921

As of December 31, 2022, the Company does not have any remaining available-for-sale short-term investments.

No sales of available-for-sale short-term investments occurred during the years ended December 31, 2022 and 2021, respectively.

NOTE 5 – PROPERTY AND EQUIPMENT

Property and equipment, net, as of December 31, 2022 and 2021, consisted of the following (in thousands):

	December 31,	
	2022	2021
Office equipment and furniture	\$ 263	\$ 237
Software	131	115
Test equipment	277	278
Total property and equipment	671	630
Less: accumulated depreciation	(228)	(101)
Total property and equipment, net	\$ 443	\$ 529

Total depreciation and amortization expense related to property and equipment for the years ended December 31, 2022 and 2021 was approximately \$147,000 and \$74,000, respectively.

NOTE 6 – OTHER CURRENT LIABILITIES

Other current liabilities as of December 31, 2022 and 2021 consisted of the following (in thousands):

	December 31,	
	2022	2021
Accrued compensation	\$ 2,708	\$ 2,211
Accrued severance payment	517	—
Accrued research and development	536	289
Accrued vacation	243	276
Lease liabilities, current portion	212	—
Other	205	131
Total other current liabilities	<u>\$ 4,421</u>	<u>\$ 2,907</u>

NOTE 7 – PAYCHECK PROTECTION PROGRAM LOAN

The Paycheck Protection Program (“PPP”) was established under the Coronavirus Aid, Relief, and Economic Security Act (the “CARES Act”) and is administered by the U.S. Small Business Administration (“SBA”). On April 23, 2020, the Company entered into a promissory note with Silicon Valley Bank evidencing an unsecured loan in the aggregate amount of approximately \$351,000 under the PPP (the “PPP Loan”). The interest rate on the PPP Loan was 1.00% and the term was two years, with a deferral of payments for ten months from the date of origination. On May 7, 2020, the Company elected to repay the PPP loan in full until further guidance was provided by the SBA on the loan origination and eligibility requirements. On May 27, 2020, the Company entered into a promissory note with Silicon Valley Bank evidencing an unsecured loan in the aggregate amount of approximately \$351,000, with all other terms the same as the prior loan. Beginning eleven months from the date of the PPP Loan, the Company was required to make monthly payments of principal and interest. The promissory note evidencing the PPP Loan contained customary events of default relating to, among other things, payment defaults or breaching the terms of the PPP Loan documents. The occurrence of an event of default may result in the repayment of all amounts outstanding, collection of all amounts owing from the Company, or filing suit and obtaining judgment against the Company. The PPP Loan was repayable at any time by the Company without prepayment penalties.

Funds from the PPP Loan could be used for payroll costs, costs used to continue group health care benefits, mortgage payments, rent, utilities, and interest on other debt obligations, if those debt obligations were incurred before February 15, 2020. The Company used the entire PPP Loan amount for qualifying expenses.

Under the terms of the CARES Act, PPP loan recipients can apply for and be granted forgiveness for all or a portion of the loan granted under the PPP. Such forgiveness will be determined, subject to limitations, based on the use of loan proceeds for qualifying expenses. On May 28, 2021, the Company received full loan forgiveness for obligations related to the PPP loan. The Company accounted for the PPP loan as debt, and the loan forgiveness was accounted for as a debt extinguishment. The amount of loan and interest forgiven is recognized as a gain upon debt extinguishment and is reported in the accompanying consolidated statement of operations and comprehensive loss for the year ended December 31, 2021.

NOTE 8 – CONVERTIBLE PROMISSORY NOTES

On various dates between February 2020 and December 2020, the Company received total proceeds of approximately \$11.8 million from the issuance of subordinated convertible promissory notes (“Convertible Notes”) to investors. The Convertible Notes accrued interest at 4% per year and the principal balance of the Convertible Notes, plus all accrued interest would have been due on February 28, 2022 (the “Maturity Date”).

The Convertible Notes were convertible upon the occurrence of certain events, including upon a change in control or a next equity financing. The conversion features are described as follows:

Conversion Event	Description	Conversion Price
Automatic Conversion – Next Qualified Equity Financing	Upon the closing of a Next Qualified Equity Financing (defined as greater than \$5,000,000), the Convertible Notes are converted into shares issued equal to the outstanding balance divided by the Conversion Price.	An amount equal to the lower of (i) 80% of the lowest per-share selling price of such stock sold by the Company at the Next Qualified Equity Financing or (ii) the implied per share price determined by dividing \$60,000,000 by the total number of Common Stock Equivalents (defined as fully diluted common shares for all outstanding securities, excluding common shares reserved for issuance or exercise of options or grants in the future) immediately prior to Next Qualified Equity Financing closing.
Automatic Conversion – Change of Control (defined as consolidation or merger of the Company or transfer of a majority of share ownership or disposition of substantially all assets of the Company)	If at any time before payment or conversion of the balance, the Company effects a Change of Control, all of the balance outstanding immediately prior to such Change of Control will automatically convert into the most senior series of Preferred Stock outstanding immediately prior to such Change of Control at the Conversion Price.	An amount equal to the implied per share price determined by dividing \$60,000,000 by the total number of Common Stock Equivalents immediately prior to such Change of Control.
Automatic Conversion – Maturity Date	If the Company has not paid or otherwise converted the entire balance before the Maturity Date, then on the Maturity Date, all of the balance then outstanding will automatically convert into the most senior series of Preferred Stock outstanding as of the Maturity Date at the Conversion Price then in effect.	An amount equal to the implied per share price determined by dividing \$60,000,000 by the total number of Common Stock Equivalents as of the Maturity Date.
Automatic Conversion – IPO	If at any time before payment or conversion of the balance, the Company consummates an IPO, all of the balance outstanding immediately prior to the IPO will automatically convert into Common Stock at the Conversion Price.	An amount equal to the lower of (i) 80% of the lowest per-share selling price of the Common Stock sold by the Company in an IPO or (ii) the implied per share price determined by dividing \$60,000,000 by the total number of Common Stock Equivalents immediately prior to closing of an IPO.

Conversion Event	Description	Conversion Price
Optional Conversion	If at any time while the Convertible Notes are still outstanding the Company sells stock in a single transaction or in a series of related transactions that does not constitute a Next Qualified Equity Financing (and thus is defined as a Non-qualified Financing), then, at the closing of the Nonqualified Financing, the balance then outstanding may be converted, at the option of the holder, into that number of shares of Non-qualified Preferred Stock (preferred stock sold in the Non-qualified Financing) determined by dividing (i) the balance by (ii) the Conversion Price then in effect.	An amount equal to the lowest per share selling price of Nonqualified Preferred Stock sold by the Company for new cash investment in the Non-qualified Financing.

As part of the Convertible Note financing, the Company agreed to issue subordinated convertible promissory notes to nonemployees in exchange for services totaling \$747,000.

As of December 31, 2020, Convertible Notes totaling approximately \$247,000 were issued to nonemployees in exchange for services. As of December 31, 2020, future services of \$500,000 of the original \$747,000 had not been fully completed. A portion of those services that had been completed were recorded as a component of other noncurrent liabilities of \$150,000 at December 31, 2020.

During the three months ended March 31, 2021, additional nonemployee services of \$50,000 were completed, which were recorded as a component of other noncurrent liabilities. In connection with the IPO, a Convertible Note for \$500,000 was issued for nonemployee services and the \$300,000 of the nonemployee services that remained to be completed was recorded in prepaid assets and other current expenses on the consolidated balance sheet. The Company calculated a BCF of approximately \$500,000 upon the issuance of this Convertible Note.

In connection with the Convertible Notes, the Company issued 10,000 and 204,500 warrants to purchase common stock, to a noteholder and its brokers, respectively. The warrants have a five-year life and are initially exercisable into common stock at \$2.97 per share. (See Note 11 – Common Stock Warrants for fair value computation and discussion of the change in the exercise price). During March 2021, 42,220 of these warrants to purchase common stock were cancelled.

Issuance costs and commissions to brokers to obtain the Convertible Notes were recorded as a debt discount in the amount of approximately \$83,000 and \$612,000, respectively.

The Company determined that the terms that would result in Convertible Notes automatically converting at (i) 80% of the lowest per-share selling price of the stock sold by the Company in the Next Qualified Equity Financing or (ii) 80% of the lowest per-share selling price of the Conversion Stock sold by the Company in an IPO are deemed a redemption feature. The Company also concluded that those redemption features require bifurcation from the Convertible Notes and subsequent accounting in the same manner as a freestanding derivative. Accordingly, subsequent changes in the fair value of these redemption features are measured at each reporting period and recognized in the consolidated statement of operations and comprehensive loss.

The sum of the fair value of the warrants, the fair value of the embedded redemption derivative liability, issuance costs, BCF and commission payments for the Convertible Notes were recorded as debt discounts to be amortized to interest expense over the respective term using the effective interest method. During the year ended December 31, 2021, the Company recognized interest expense of \$0.8 million from the accretion of those debt discounts, respectively.

The Convertible Notes automatically converted upon the closing of the IPO at the implied per share price determined by dividing \$60,000,000 by the total number of Common Stock Equivalents immediately prior to the closing of the IPO. The outstanding principal (\$12.5 million) and interest due (\$0.4 million) under the Convertible Notes, in an aggregate amount of \$12.9 million, was converted into 5,015,494 shares of the Company's common stock at the implied per share conversion of \$2.5736. The carrying value of the Convertible Notes was credited to common stock and additional paid-in capital on the consolidated balance sheet. The remaining unamortized discount of \$0.4 million was recorded to additional paid-in capital and no gain or loss was recognized on the conversion. The remaining unamortized discount related to the BCF of \$0.5 million was recognized immediately as interest expense in the consolidated statement of operations and comprehensive loss.

Derivative Liability

As described above, the redemption provisions embedded in the Convertible Notes required bifurcation and measurement at fair value as a derivative. The fair value of the Convertible Note embedded redemption derivative liability was calculated by determining the value of the debt component of the Convertible Notes at various conversion or maturity dates using a Probability Weighted Expected Return valuation method. The fair value calculation placed greater probability on the occurrence of the conversion or the maturity date scenario, with little or no weight given to other scenarios. The fair value of the embedded redemption derivative liability is significantly influenced by the discount rate, the remaining term to maturity and the Company's assumptions related to the probability of a qualified financing or no financing prior to maturity. The Financing Date is the estimated date of an automatic conversion as the result of a Next Qualified Equity Financing or an IPO.

The embedded redemption derivative liability no longer had significant value as of the date of the Company's IPO since the conversion of the Convertible Notes occurred via a redemption feature that was not bifurcated as a derivative. Upon the conversion of the Convertible Notes at the IPO, the Company recorded a final change in the fair value of the derivative liability of \$0.1 million in the consolidated statement of operations and comprehensive loss, and the derivative liability was extinguished.

The changes in the fair value of the derivative liability for the year ended December 31, 2021 is presented as follows (in thousands):

Warrant Issuance	December 31, 2020	Fair Value at issuance date	Change in fair value	December 31, 2021
Derivative liability	\$ 121	—	(121)	\$ —

NOTE 9 – REDEEMABLE CONVERTIBLE PREFERRED STOCK

The Series B preferred stock was measured and recorded at the transaction price net of issuance costs, resulting in an initial value of \$9.3 million. The accretion to the carrying value of the Series B preferred stock was recorded as a charge to additional paid in capital. The accumulated accretion as of the IPO date was \$11.5 million, which resulted in an adjusted Series B preferred stock carrying value of \$20.8 million.

The accretion to the carrying value of the Series A preferred stock was recorded as a charge to additional paid-in capital. The accumulated accretion as of the IPO date was \$8.2 million, which resulted in an adjusted Series A preferred stock carrying value of \$14.5 million.

Upon the IPO, the redeemable convertible preferred stock converted in to 11,436,956 shares of common stock and no shares of redeemable convertible preferred stock remain outstanding as of December 31, 2021.

On March 24, 2021, the Company's Third Amended and Restated Certificate of Incorporation was filed with the Delaware Secretary of State which (i) eliminated the Company's Series A and Series B preferred stock, (ii) increased the authorized number of shares of common stock to 75,000,000 and (iii) authorized 5,000,000 shares of preferred stock at par value of \$0.0001 per share. The significant rights and preferences of the preferred stock will be established by the Company's Board of Directors (the "Board") upon issuance of any such series of preferred stock in the future.

NOTE 10 – COMMON STOCK

As of December 31, 2022 and 2021, the Company was authorized to issue 75,000,000 shares of common stock with a par value of \$0.0001 per share, and 33,659,460 and 32,772,060 shares were issued and outstanding, respectively.

Conversion of Redeemable Convertible Preferred Stock

In connection with the closing of the IPO, on March 25, 2021, the outstanding shares of the Company's Series A and Series B redeemable convertible preferred stock were converted into 11,436,956 shares of the Company's common stock.

Conversion of Convertible Notes

In connection with the funding of the IPO, on March 25, 2021, the principal and interest due under the Company's Convertible Notes, in an aggregate amount of \$12.9 million, was converted into 5,015,494 shares of the Company's common stock.

Third Amended and Restated Certificate of Incorporation

In connection with the IPO, the Third Amended and Restated Certificate of Incorporation became effective and authorized 75,000,000 shares of common stock at par value of \$0.0001 per share. Dividends may be declared and paid on the common stock when and if determined by the Board of Directors. Upon liquidation, each common stockholder is entitled to receive an equal portion of the distribution. Each holder of common stock will have one vote in respect of each share of common stock held. The rights and privileges listed above will be subject to preferential rights of any then outstanding shares of preferred stock.

At the IPO date, the Company issued 17,000 shares of common stock for nonemployee services valued at \$85,000.

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, 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, 2022, an aggregate offering price amount of approximately \$47.7 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, 2022 is summarized as follows:

	December 31, 2022
Warrants to purchase common stock	1,938,143
Stock options outstanding	6,919,894
Stock options available for future grants	6,711,065
Total	<u>15,569,102</u>

Restricted Stock Purchase Agreements

In 2018, 400,000 shares of common stock were issued to the Company's founder at inception pursuant to a Restricted Stock Purchase Agreement. The Restricted Stock Purchase Agreement stipulates that in the event of the voluntary or involuntary termination of the Company's founder's continuous service status for any reason (including death or disability), with or without cause, the Company or its assignees(s) shall have an option ("Repurchase Option") to repurchase all or any portion of the shares held by the Purchaser as of the termination date which have not yet been released from the Company's Repurchase Option at the original purchase price of \$0.0125 per share. Shares are to be released from the Repurchase Option over four years. The initial 12/48ths of the shares were released on January 30, 2019, and an additional 1/48th of the shares are being released monthly thereafter. As of December 31, 2022 and 2021, no and 8,333 of the shares issued to the Company's founder remain subject to the Repurchase Option, respectively. These shares were originally purchased by the Company's founder at \$0.0125 per share.

In 2018, 3,640,000 shares of common stock were also issued pursuant to a Restricted Stock Purchase Agreement. The holders of these shares are considered related parties of the Company because the holders are directly related either to the founder or to the former legal counsel of the Company. The same terms described above apply to these issuances. As of December 31, 2022 and 2021, no and 75,833 of the shares issued to these holders remain subject to the Repurchase Option, respectively. These shares were originally purchased by the holders at \$0.0125 per share.

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, 2022 and 2021, no and 50,000 shares of common stock were issued upon the early exercise of common stock options.

As of December 31, 2022 and 2021, the Company has recorded a repurchase liability for approximately \$136,000 and \$281,000 for 266,147 and 567,397 shares that remain unvested, respectively. The weighted average remaining vesting period at December 31, 2022 is approximately 1.09 years.

NOTE 11 – COMMON STOCK WARRANTS

Preferred A Placement Warrants

On February 22, 2018, the Company entered into an agreement with NSC, pursuant to which the Company engaged NSC as the Company's exclusive financial advisor and placement agent in connection with an offering or series of offerings of Company securities. Specifically, NSC was the placement agent in connection with the sale of its Series A preferred stock.

In connection with the closing of the Series A preferred stock offering, the Company issued warrants ("Preferred A Placement Warrants") to purchase a total of 133,648 shares of its common stock to NSC on March 14, 2018 and April 23, 2018. The Preferred A Placement Warrants included an adjustment provision pursuant to which upon completion of the IPO, and the conversion of the Series A preferred stock in connection therewith, the number of shares issuable upon exercise of the warrants was adjusted to be equal to 10% of the aggregate number of common stock shares issued by the Company upon conversion of 1,336,485 shares of Series A preferred stock (the "Preferred A Adjustment Provision"). In August 2019, the Preferred A Placement Warrants were amended and reissued and the total number of warrant shares increased to 242,847.

The Second Amended and Restated Certificate of Incorporation that was approved on March 28, 2019 amended and fixed the conversion price of the Series A preferred stock at \$1.40. As a result, on August 28, 2019, the Company elected to amend and reissue the Preferred A Placement Warrants, thereby reducing the exercise price to \$1.40 and increasing the number of warrant shares by 109,200 to a total of 242,847 warrant shares.

In connection with the IPO, pursuant to the Preferred A Adjustment Provision variable settlement provision, the number of shares of common stock subject to the Preferred A Placement Warrants settled, resulting in an additional 50,195 shares of common stock.

Preferred A Lead Investor Warrants

During February 2021, a total of 52,500 warrants for common stock were issued to advisors to the Company at a weighted average exercise price of \$0.0125 per share. The resulting fair value of the warrants for common stock is not significant.

Preferred B Placement Warrants

On April 16, 2019, in connection with the Series B preferred stock offering, the Company issued warrants ("Preferred B Placement Warrants") to purchase 414,270 shares of its common stock to NSC, Newbridge Securities Corporation, and five individuals at LVP. The Preferred B Placement Warrants have a term of five years and their exercise price is equal to \$2.10, the conversion price of Series B preferred stock. The Preferred B Placement Warrants included an adjustment provision pursuant to which upon completion of the IPO, and the conversion of the Series B preferred stock in connection therewith, the number of shares issuable upon exercise of the warrants was adjusted to be equal to 10% of the aggregate number of common stock shares issued by the Company upon conversion of 4,142,270 shares of Series B preferred stock (the "Preferred B Adjustment Provision").

In connection with the IPO, pursuant to the Preferred B Adjustment Provision variable settlement provision, the number of shares of common stock subject to the Preferred B Placement Warrants settled, resulting in an additional 49,528 shares of common stock.

Convertible Note Placement Warrants

In connection with the Convertible Notes, the Company issued 10,000 and 204,050 warrants to purchase common stock, to a noteholder and its brokers, respectively. The warrants have a five-year life and were initially exercisable into common stock at \$2.97 per share with the warrants ultimately being exercisable into common stock at the final Conversion Price of the Convertible Notes. When the Convertible Notes converted at the IPO date as described in Note 8, the exercise price of the warrants was adjusted to equal the Conversion Price, which is \$2.57. During March 2021, 42,220 of these warrants to purchase common stock were cancelled.

Underwriter Warrants

In connection with the IPO, the Company issued the underwriter a warrant to purchase shares of common stock equal to 9.79% of the shares of common stock sold in the IPO or 956,973 shares. The warrant is exercisable at \$6.00 per share and has a 5-year term.

The following is a summary of the Company's warrant activity for the years ended December 31, 2022 and 2021:

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
			<u>1,938,143</u>	<u>—</u>	<u>—</u>	<u>—</u>	<u>—</u>	<u>1,938,143</u>	

Warrant Issuance	Issuance	Exercise Price	Outstanding, December 31, 2020	Granted	Exercised	Canceled/Expired	Variable Settlement Provision Adjustment	Outstanding, December 31, 2021	Expiration
Preferred A Placement Warrants	March and April 2018 and August 2019	\$ 1.40	242,847	—	—	—	50,195	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	414,270	—	—	—	49,528	463,798	April 2024
Convertible Notes Placement Warrants	August 2020	\$ 2.57	214,050	—	—	(42,220)	—	171,830	August 2025
Underwriter Warrants	March 2021	\$ 6.00	—	956,973	—	—	—	956,973	March 2026
			<u>871,167</u>	<u>1,009,473</u>	<u>—</u>	<u>(42,220)</u>	<u>99,723</u>	<u>1,938,143</u>	

Warrants Classified as Liabilities

Preferred A Placement Warrants and Preferred B Placement Warrants

The Preferred A Placement Warrants and Preferred B Placement Warrants were initially classified as a derivative liability because their variable terms did not qualify these as being indexed to the Company's own common stock and were initially measured at fair value on a recurring basis.

As a result of the conversion of the Preferred Stock into common stock in connection with the IPO, and the related impact of the Preferred A Adjustment Provision and the Preferred B Adjustment Provision, the number of warrant shares that are convertible is no longer variable. Accordingly, the Preferred A Placement Warrants and Preferred B Placement Warrants were determined to be indexed to the Company's own common stock and will no longer be measured at fair value on a recurring basis. Thus, the Preferred A Placement Warrants and the Preferred B Placement Warrants were determined to be equity instruments, and the liability was recorded at fair value with the change in fair value recorded in the consolidated statement of operations and comprehensive loss and reclassified to additional paid-in capital at their estimated fair value at the IPO date.

Convertible Notes Placement Warrants

The Convertible Notes Placement Warrants were classified as a derivative liability because the exercise price was variable, thus these did not qualify as being indexed to the Company's own common stock and were measured at fair value on a recurring basis.

As a result of the conversion of the Convertible Notes into common stock in connection with the IPO, the exercise price is no longer variable. Accordingly, the Convertible Notes Placement Warrants were determined to be indexed to the Company's own common stock and will no longer be measured at fair value on a recurring basis. Thus, the Convertible Notes Placement Warrants were determined to be equity instruments, and the liability was recorded at fair value with the change in fair value recorded in the consolidated statement of operations and comprehensive loss and reclassified to additional paid-in capital at their estimated fair value at the IPO date.

Estimated Fair Value of Outstanding Warrants Classified as Liabilities

The estimated fair value of outstanding warrants classified as liabilities is determined at each consolidated balance sheet date. Any decrease or increase in the estimated fair value of the warrant liability since the most recent consolidated balance sheet date is recorded in the consolidated statements of operations and comprehensive loss as a change in fair value of warrant liability.

There were no warrants classified as liabilities outstanding as of December 31, 2022 and 2021.

The changes in fair value of the outstanding warrants classified as liabilities for the year ended December 31, 2021 were as follows (in thousands):

Warrant Issuance	Warrant liability, December 31, 2020	Fair value of warrants granted	Fair value of warrants exercised	Change in fair value of warrants	Reclassified to additional paid-in capital	Warrant liability, December 31, 2021
Preferred A Placement Warrants	\$ 518	\$ —	\$ —	\$ 575	\$ (1,093)	\$ —
Preferred B Placement Warrants	708	—	—	800	(1,508)	—
Convertible Notes Placement Warrants	323	—	—	206	(529)	—
	<u>\$ 1,549</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 1,581</u>	<u>\$ (3,130)</u>	<u>\$ —</u>

The fair values of the outstanding warrants accounted for as liabilities at the IPO date are calculated using the Black-Scholes option pricing model with the following assumptions:

Black-Scholes Fair Value Assumptions at IPO Date				
Warrant Issuance	Dividend Yield	Expected Volatility	Risk-Free Interest Rate	Expected Life
Preferred A Placement Warrants	—%	59.21%	0.14%	2.0 years
Preferred B Placement Warrants	—%	58.51%	0.30%	3.0 years
Convertible Note Placement Warrants	—%	52.28%	0.82%	4.4 years

Upon the conversion of the redeemable convertible preferred stock and the Convertible Notes into common stock at the IPO date, the estimated fair value of the outstanding warrants accounted for as liabilities of \$3.1 million was reclassified to additional paid-in capital.

Warrants Classified as Equity

Certain 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 fair value as determined at the issuance date is recorded as an issuance cost of the related stock. Those warrants and the assumptions used to calculate the fair value at issuance are as follows for the warrants issued during the year ended December 31, 2021. There were no warrants issued during the year ended December 31, 2022.

Black-Scholes Fair Value Assumptions						
Warrant Issuance	Issuance Date	Fair Value	Dividend Yield	Expected Volatility	Risk-Free Interest Rate	Expected Life
Underwriter Warrants	March 2021	\$ 2,349	—%	52.58%	0.82%	5.0 years

NOTE 12 – 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.

In connection with the closing of the IPO, effective 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, 2022, the Company had 5,424,815 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, 2022, the Company had 1,286,250 shares available for future grant under the Inducement Plan.

Stock Options

Stock option activity for the years ended December 31, 2022 and 2021 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, 2020	3,188,011	\$ 0.66	9.0 years	\$ 8,155
Granted	2,684,500	\$ 4.05		
Exercised	(134,541)	\$ 0.56		
Cancelled	(145,833)	\$ 0.59		
Outstanding at December 31, 2021	<u>5,592,137</u>	\$ 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	<u>6,919,894</u>	\$ 2.34	8.2 years	\$ 2,034
Exercisable as of December 31, 2022	<u>3,762,779</u>	\$ 1.74	7.7 years	\$ 1,826
Vested and expected to vest as of December 31, 2022	<u>6,769,694</u>	\$ 2.32	8.2 years	\$ 1,988

The weighted-average grant date fair value of options granted during the years ended December 31, 2022, and 2021 was \$1.48 and \$2.54 per share, respectively. During the years ended December 31, 2022 and 2021, 77,000 and 134,531 options were exercised for proceeds of \$31,000 and \$0.1 million, respectively. The fair value of the 1,707,794 and 839,380 options that vested during the years ended December 31, 2022 and 2021 was approximately \$3.2 million and \$0.7 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 will vest in full upon the shipment of 20,000 product units on or before June 30, 2023. If the shipments have not occurred by June 30, 2023, the options will be cancelled and forfeited. For year ended December 31, 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.

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, 2022 and 2021.

	Year Ended December 31,	
	2022	2021
Dividend yield	—%	—%
Expected volatility	61.97%	66.38%
Risk-free interest rate	2.78%	0.93%
Expected life	6.07 years	6.05 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, 2022 and 2021 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,	
	2022	2021
Research and development	\$ 1,169	\$ 716
Sales, general and administrative	1,927	1,138
	<u>\$ 3,096</u>	<u>\$ 1,854</u>

As of December 31, 2022, unamortized compensation expense related to unvested stock options was approximately \$6.6 million, which is expected to be recognized over a weighted average period of 2.6 years.

NOTE 13 – COMMITMENTS AND CONTINGENCIES

Operating Leases

As of December 31, 2022, 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.

On January 1, 2022, the Company adopted ASC 842. Under this new guidance, lessees are required to recognize assets and liabilities on the balance sheet for the rights and obligations created by all leases. Upon adoption, the Company recognized ROU assets of \$380,000 and corresponding lease liabilities of \$429,000 for the one operating lease of the Company at the adoption date.

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

	As of December 31, 2022
Operating leases	
Right-of-use assets	\$ 389
Operating lease liabilities - Short-term	\$ 212
Operating lease liabilities - Long-term	\$ 214
	Year Ended December 31, 2022
Lease Cost:	
Operating lease cost	\$ 226
Other Information:	
Cash paid for amounts included in the measurement of lease liabilities for the year ended	\$ 209
Weighted average remaining lease term - operating leases (in years)	1.97
Average discount rate - operating lease	10.00%

Future minimum lease payments for this new corporate office space lease are as follows as of December 31, 2022 (in thousands):

2023	\$	242
2024		203
2025		27
Total lease payments		<u>472</u>
Less: Interest		<u>(46)</u>
Total operating lease liability	\$	<u><u>426</u></u>

Rent expense for the years ended December 31, 2022 and 2021 was \$226,000 and \$154,000, respectively.

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, 2022.

Non-cancelable Obligations

The Company also had \$0.4 million of non-cancelable contractual commitments as of December 31, 2022, primarily related to its vendor arrangements. These commitments are generally due within one to ten months.

NOTE 14 – INCOME TAXES

For the years ended December 31, 2022 and 2021, no U.S. provision or benefit for income taxes was recorded and an insignificant amount of Ireland provision for income taxes for the year ended December 31, 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,	
	2022	2021
US federal provision (benefit)		
At statutory rate	21%	21%
Valuation allowance	(22)%	(18)%
Changes in stock-based compensation, fair value of warrants and derivative liability and interest expense for convertible promissory notes	(1)%	(3)%
Other	1%	1%
Effective tax rate	—	—

Significant components of the Company's deferred tax assets and liabilities as of December 31, 2022 and 2021 are as follows (in thousands):

	2022	2021
Gross deferred tax assets:		
Net operating loss carryforwards	\$ 10,040	\$ 7,765
Research and development credit carryforward	1,434	712
Capitalized research and development	3,444	—
Accrued bonus	464	403
Stock-based compensation	590	72
Lease liabilities	90	—
Other	53	76
Total gross deferred tax assets	16,115	9,029
Less valuation allowance	(16,024)	(9,022)
Total net deferred tax assets	91	7
Deferred tax liabilities:		
Property and equipment	(9)	(7)
Right-of-use assets	(82)	—
Total deferred tax liabilities	(91)	(7)
Net deferred tax assets	\$ —	\$ —

During 2022 and 2021, 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 \$7,002,000 and \$4,034,000 during the years ended December 31, 2022 and 2021, respectively.

As of December 31, 2022 and 2021, the Company has federal net operating loss carryforwards of approximately \$48.5 million and \$37.4 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, 2022 and 2021, the Company has federal research and development (“R&D”) credit carryforwards of approximately \$1,179,000 and \$565,000, respectively. The federal R&D credits begin to expire in 2039.

As of December 31, 2022 and 2021, the Company has California R&D credit carryforwards of approximately \$1,066,000 and \$640,000, 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 California. For jurisdictions in which tax filings have been filed, all tax years remain open for examination by the federal and California 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, 2022 and 2021 were approximately \$811,000 and \$487,000, respectively, related to Federal and California R&D credits. As of December 31, 2022 and 2021, 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 and comprehensive loss. The Company had no accrued interest and penalties related to unrecognized tax benefits as of December 31, 2022.

The following is a rollforward of the total gross unrecognized tax benefits for the years ended December 31, 2022 and 2021 (in thousands):

	Year Ended December 31,	
	2022	2021
Beginning Balance	\$ 487	\$ 289
Gross Increases - Tax Position in Prior Periods	1	—
Gross Increases - Tax Position in Current Period	323	198
Ending Balance	<u>\$ 811</u>	<u>\$ 487</u>

All tax years remain subject to examination by the U.S. federal and state taxing authorities due to the Company’s net operating losses and R&D credit carryforwards.

NOTE 15 – 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, 2022 and 2021 is as follows (in thousands, except share and per share data):

	Year Ended December 31,	
	2022	2021
Numerator:		
Net loss	\$ (30,329)	\$ (21,773)
Accretion and dividends on redeemable convertible preferred stock	—	(2,489)
Net loss attributable to common stockholders	<u>\$ (30,329)</u>	<u>\$ (24,262)</u>
Denominator:		
Weighted-average common shares outstanding	<u>33,025,721</u>	<u>26,298,032</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.92)</u>	<u>\$ (0.92)</u>

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, 2022 and 2021 because including them would have been antidilutive are as follows:

	Year Ended December 31,	
	2022	2021
Non-vested shares under restricted stock grants	-	84,167
Shares subject to options to purchase common stock	6,769,694	5,541,937
Shares subject to warrants to purchase common stock	<u>1,938,143</u>	<u>1,938,143</u>
Total	<u>8,707,837</u>	<u>7,564,247</u>

For the years ended December 31, 2022 and 2021, performance based option awards for 150,200 and 50,200 shares of common stock, respectively, are not included 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 16 – SUBSEQUENT EVENTS

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 and expire five years after the date of issuance. Beginning on the one-year anniversary of the close of the offering, all outstanding warrants may be redeemed at the option of the Company, in whole or in part on a pro-rata basis, at the redemption price of \$0.025 per warrant, provided that (i) the closing price of the Company's common stock has equaled or exceeded \$4.87 per share for ten consecutive trading days and (ii) the daily trading volume of the common stock on the Company's primary trading market exceeded 100,000 shares on each of such ten trading days. The public offering price per share, before the underwriters' discount and commissions, for each share of common stock and accompanying warrant was \$1.40. All of the securities in the underwritten public offering were sold by the Company. The warrants will not be listed on any securities exchange or other nationally recognized trading system. The net proceeds from the offering were approximately \$6.85 million.

During February 2023, the Company granted common stock option awards to non-executive employees, covering a total of 60,000 shares of common stock, at an exercise price of \$1.37 per share.

During February 2023, the Board approved the amendment of 293,042 Preferred A Placement Warrants to extend the maturity date by six months for each warrant and to remove the cashless exercise provision in the warrant agreements. The amended maturity dates for 234,197 and 58,845 Preferred A Placement Warrants will be in September 2023 and October 2023, respectively.

During January and February 2023, the Company issued common stock upon the exercise of 245,855 common stock option awards at a weighted average exercise price of \$0.44 and proceeds of \$0.1 million.

During March 2023, the Company granted common stock option awards to executive employees, covering a total of 562,875 shares of common stock and to non-executive employees for a total of 662,500 shares of common stock. The exercise price is \$1.29 per share.

During March 2023, the Company sold 2,070,616 shares of common stock under the ATM equity offering program at a weighted average price of \$1.36 per share for gross proceeds of approximately \$2.8 million.

During March 2023, the Preferred A Lead Investor Warrants for 52,500 shares of common stock expired.

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, 2022, our disclosure controls and procedures were ineffective.

As of December 31, 2022, 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, 2022: 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, 2022: 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, 2022.

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, 2022, 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 to our Proxy Statement on Schedule 14A relating to our 2023 annual meeting of stockholders.

Item 11. Executive Compensation

The information required by this Item is incorporated by reference to our Proxy Statement on Schedule 14A relating to our 2023 annual meeting of stockholders.

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

The information required by this Item is incorporated by reference to our Proxy Statement on Schedule 14A relating to our 2023 annual meeting of stockholders.

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

The information required by this Item is incorporated by reference to our Proxy Statement on Schedule 14A relating to our 2023 annual meeting of stockholders.

Item 14. Principal Accountant Fees and Services

The information required by this Item is incorporated by reference to our Proxy Statement on Schedule 14A relating to our 2023 annual meeting of stockholders.

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).

Exhibit Number	Exhibit Description	Incorporated by Reference			SEC File/Registration Number	
		Filed Herewith	Form	Exhibit		Filing Date
3.1	Third Amended and Restated Certificate of Incorporation of the Registrant		8-K	3.1	March 25, 2021	001-40254
3.2	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				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: March 30, 2023

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.

<u>Signatures</u>	<u>Title</u>	<u>Date</u>
<u>/s/ John Mastrototaro</u> John Mastrototaro	Chief Executive Officer and Director (Principal Executive Officer)	March 30, 2023
<u>/s/ J. Cogan</u> J. Cogan	Chief Financial Officer (Principal Financial and Accounting Officer)	March 30, 2023
<u>/s/ Emily Wang Fairbairn</u> Emily Wang Fairbairn	Director	March 30, 2023
<u>/s/ Brian Cullinan</u> Brian Cullinan	Director	March 30, 2023
<u>/s/ Rubén Caballero</u> Rubén Caballero	Director	March 30, 2023
<u>/s/ Michael Leabman</u> Michael Leabman	Director	March 30, 2023
<u>/s/ Nan Kirsten Forte</u> Nan Kirsten Forte	Director	March 30, 2023

