UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K

X ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2022

or

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from_____ to _____

Commission file number: 001-41052

Tivic Health Systems, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**81-4016391**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
25821 Industrial Blvd., Suite 100 **Hayward, CA 94545**	**(888) 276-6888**
(Address of principal executive offices including zip code)	(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	**TIVC**	**The Nasdaq Stock Market LLC**

SECURITIES REGISTERED PURSUANT TO SECTION 12(G) OF THE ACT: **None**

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

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

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

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

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

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

If an emerging growth company, indicate by check mark if the registrant has 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 ☒

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant as of June 30, 2022, the last business day of the registrant's most recently completed second fiscal quarter, based upon the closing price of the common stock as reported by The Nasdaq Capital Market on such date, was approximately $13.0 million. This calculation does not reflect a determination that persons are affiliates for any other purposes.

As of March 24, 2023, 29,677,734 shares of the registrant's common stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (this "Report") contains forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995, which represent our expectations or beliefs statements concerning, without limitation, our operations, economic performance, financial condition, growth and acquisition strategies, investments, and future operational plans. For this purpose, any statements contained herein that are not statements of historical fact may be deemed to be forward-looking statements. Without limiting the generality of the foregoing, words such as "may," "will," "expect," "believe," "anticipate," "intent," "could," "estimate," "might," "plan," "predict" or "continue" or the negative or other variations thereof or comparable terminology are intended to identify forward-looking statements. These statements, by their nature, involve substantial risks and uncertainties, certain of which are beyond our control, and actual results may differ materially depending on a variety of important factors, including uncertainty related to acquisitions, governmental regulation, managing and maintaining growth, the operations of the Company, volatility of stock price, commercial viability of our product candidates and any other factors discussed in this and other registrant filings with the Securities and Exchange Commission (the "Commission").

These risks and uncertainties and other factors include, but are not limited to those set forth under "Risk Factors" of this Report. Given these risks and uncertainties, readers are cautioned not to place undue reliance on our forward-looking statements. All subsequent written and oral forward-looking statements attributable to us or to persons acting on our behalf are expressly qualified in their entirety by these cautionary statements. Except as otherwise required by applicable law, we undertake no obligation to publicly update or revise any forward-looking statements or the risk factors described in this Report or in the documents and/or information that we incorporate by reference, whether as a result of new information, future events, changed circumstances or any other reason after the date of this Report.

This Report contains forward-looking statements, including statements regarding, among other things:

- our ability to continue as a going concern;
- our anticipated needs for working capital, and our ability to secure additional financing on favorable terms, if at all;
- the availability of electronic parts and other components for our products, as well as our ability to source such parts and components at favorable prices;
- the demand for our products;
- our sales, marketing, and distribution prospects;
- our financial performance;
- the level of expenses related to our product development and operations;
- our efforts to expand our products and our business;
- the implementation of our business model and strategic plans for our business and technology;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- our expectations regarding the effects of a potential recession, market volatility and macroeconomic factors on our business, our suppliers and our customers; and
- developments and projections relating to our competitors and our industry.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and you are cautioned not to unduly rely upon these statements.

Actual events or results may differ materially from those discussed in forward-looking statements as a result of various factors, including, without limitation, the risks outlined under “Risk Factors” and matters described in this Report generally. In light of these risks and uncertainties, there can be no assurance that the forward-looking statements contained in this Report will in fact occur. We caution you not to place undue reliance on these forward-looking statements. In addition to the information expressly required to be included in this Report, we will provide such further material information, if any, as may be necessary to make the required statements, in light of the circumstances under which they are made, not misleading.

You should read this Report and the documents that we reference in this Report and have filed as exhibits to this Report, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in this Report by these cautionary statements.

PART I

Item 1 – Business

As used in this Report, unless the context otherwise requires, references to "we," "us," "our," "Company," and "Tivic Health" refer to Tivic Health Systems, Inc.

Business Overview

We are a health technology company focused on developing and commercializing non-invasive bioelectronic medicine. Our platform-based technology activates the body's own healing mechanisms and can be programmed to treat various disease conditions. Our products provide a natural alternative to the standard synthetic chemical methods used by the pharmaceutical industry.

Bioelectronic medicine treats disease and conditions by modulating the electrical signals carried along various nerve pathways. The field grew out of the neuromodulation industry and relied, historically, on implantable devices (e.g., pacemakers, spinal implants, deep brain stimulators). IDTechEx has identified several fast-growing areas in the bioelectronic medicine field, including peripheral nerve stimulation, which it has indicated is forecasted to grow at a 35% CAGR from 2019 through 2029.

First Commercial Product

ClearUP® Sinus Relief, our first commercial product, has received multiple innovation awards and high customer ratings across multiple sales platforms. It is based on a non-invasive peripheral nerve stimulation platform that combines proprietary algorithms, programmable stimulation parameters, and a patented monopolar delivery. ClearUP has U.S. FDA approval for the treatment of sinus pain and congestion, and is the first FDA-approved bioelectronic treatment of such indications. Additionally, ClearUP has E.U. CE Mark approval for the treatment of sinus pain, pressure and congestion, which provides us commercial access in the U.S., European Union Member states and certain other countries. It is currently available to consumers in the United States without prescription with expanded end-user labeling including sinus pressure which occurs with sinus pain.

The patented handled device uses ultra-low current electrical waves to relieve sinus pain and congestion symptoms that are prevalent in nasal allergies, sinus infections, chronic sinusitis, cold and flu and other disease conditions. The global treatment markets for each of these disease areas are in the billions, currently dominated by pharmaceuticals, and are projected to grow. According to the Mintel Group Ltd.'s 2020 report, the U.S. market size for cough, cold, flu and allergy in 2022 was expected to be approximately $11.1 billion. We also conducted a market research study (via an online survey) of 600 individuals with ongoing sinus conditions and noted 90% of the participants reported interest in treatments that reduce the use of medications.

We conducted two published clinical studies with leading research institutions. The first clinical study was a randomized controlled double-blind trial conducted by the Stanford University Sinus Center consisting of 71 subjects suffering from sinus pain and congestion, each of whom used either ClearUP or a sham device. The second clinical study was a 30-person study on the use of ClearUP over a period of four weeks conducted by the Allergy and Asthma Associates of Santa Clara Valley Research Center. These studies have substantially demonstrated that ClearUP is highly effective at treating sinus pain from allergic rhinitis and moderate to severe congestion with no sustantive side effects.

Potential for Platform Technology Expansion

We intend to leverage our platform-based technology and our deep experience with non-invasive bioelectronic medicine to develop or acquire a suite of FDA-approved commercial products for the treatment of various disease conditions.

Our non-invasive bioelectronic platform-based technology enables effective therapeutic solutions with high safety profile and broad application. We are currently conducting a sham-controlled clinical trial in concert with the Icahn School of Medicine at Mount Sinai, designed to reduce pain resulting from functional endoscopic sinus surgery. If successful, a product based on this research would require new regulatory clearances for a novel indication. Additionally, we have completed a market and technology assessment of a potential migraine indication and are developing a clinical protocol related thereto. We have also developed a novel non-invasive approach to targeted vagus nerve stimulation and have conducted proof of principle experiments demonstrating effects on the autonomic nervous system, and have initiated a clinical research program with the Feinstein Institute to further characterize the autonomic effects of the device intervention.

Given our deep expertise and relationships in the field of bioelectronic medicine, we are continuously monitoring and evaluating options to add complementary product lines into our product portfolio.

Market Opportunity

In December 2021, Precedence Research noted that the burden of various chronic diseases and infections is growing and so have people's healthcare expenditures. Consumers are increasing spending on their healthcare. The shift to an increased focus on improving lifestyle, growing geriatric population, rising disposable income, rising penetration of healthcare insurance, and improved access to healthcare facilities are major factors that drive growth of the medical electronics market. In 2018, the per capita healthcare expenditure in the U.S. was over $10,500. This number is expected to increase.

Grand View Research projects that the non-invasive electroceutical devices segment will witness the highest growth through 2030. This is due to technological advancements and rising investments in research and development by companies for innovative product development. Moreover, increasing healthcare awareness and popularity of electroceuticals in developing countries such as India, China, South Africa, and Argentina are expected to propel market growth. Factors such as industrialization, climate change, and changing lifestyles are increasing the prevalence of allergic rhinitis, making this a large and growing segment.

The FDA initially provided clearance to our ClearUP product under a 510(k) as an allergy treatment in January 2019. As a treatment for allergy-related sinus pain, we believe that the available market for ClearUP is approximately 45 million U.S. adults.

The FDA granted ClearUP a subsequent De Novo clearance in March 2021, which expanded ClearUP's label, enabling marketing of ClearUP for allergies, sinusitis, cold, flu, and any inflammatory condition involving congestion. With this De Novo clearance, we believe that the available market for ClearUP expands to over 200 million U.S. adults. Based upon our market research (conducted by a national sampling company in 2019, which electronically surveyed 600 individuals reporting ongoing sinus conditions) indicating that 27% of consumers are willing to pay more than $150.00 for ClearUP, and assuming an available market of 200 million U.S. adults, we estimate an available U.S. market of approximately $8 billion. Our market research indicates that, among our target consumers, 74% would expect to purchase ClearUp on Amazon and 65% from the manufacturer's website.

According to Mintel Group Ltd., over-the-counter allergy, cough, cold and flu treatments were projected to be an $11.1 billion market in 2022 in the U.S. alone. According to our research, among recurring sufferers (those who reported having an ongoing chronic sinus condition), 90% are interested in treatments that reduce use of medications, 66% are concerned about the side effects of pharmaceutical choices, and over 43% are concerned about addiction. We commissioned this research, and it was conducted by a national sampling company, which electronically surveyed 600 individuals reporting ongoing sinus conditions. Only subjects who reported having an ongoing chronic sinus condition were eligible to participate in the study.

In clinical research studies pertaining to ClearUP:

- 82% of participants indicated that they prefer it to their current treatments;[1] and
- 77% of participants indicated that they would recommend ClearUP.[2]

[1] Data from a 71-person randomized controlled study conducted by a third-party academic research center.

[2] Data from a 30-person open label trial conducted by a third-party clinical research organization.

Additionally, we have received a CE Mark for international marketing. The CE Mark for ClearUP covers an equally broad set of conditions related to sinonasal inflammation with the symptoms pain, pressure and congestion. The CE Mark allows sales in European Union Member states and certain other countries that recognize the CE Mark for regulatory governance. We believe that there are international opportunities for the sale of ClearUP.

Customers

We sell our products direct-to-consumer through our own website and major online stores, including Amazon and Walmart, and also sell to major U.S. online retailers, such as BestBuy and FSAStore.

Sales and Marketing

Purchase Motivation

ClearUP's main consumer benefits as supported by our clinical studies, include the following:

- Efficacious drug-free alternative with no significant adverse side effects.
- Efficacy for 74% of trial subjects within ten minutes of first treatment.
- Efficacy for 88% of trial subjects with use over four-weeks.
- Continued reduction of sinus pain and congestion with regular use.
- Portable, go anywhere, use anytime solution with no recommendation to discontinue use after a specified period of time or limit the number of times per day used.
- Average product useful life of approximately 3.5 years.
- More environmentally friendly than synthetic chemical treatments.

Sales Channels

ClearUP is sold directly to consumers through our own website, Amazon, and Walmart. We also sell to major online retailers, such as BestBuy and FSAStore.

Expansion of our ClearUP sales channels has been gradual and measured to maintain pricing integrity, cultivate consumer acceptance and establish strong channel relationships. With this foundation in place, we believe we are poised to accelerate sales through the expansion of our advertising and marketing efforts.

Current sales represent a very small percentile of the available market. We project that there is a significant growth opportunity for ClearUP with expanded advertising and product variants to reach new customers and medical professionals.

Marketing and Advertising Strategies

We utilize omnichannel marketing to raise consumer awareness of ClearUP and convert consumers to purchasers. We participate in press and media to raise general awareness of both ClearUP and the bioelectronic medicine more generally. Since our IPO in November 2021, we have seen a steady increase in direct-to-consumer sales volume as we continue to expand and optimize marketing and advertising tactics.

Core Technology

Our technology provides a natural alternative to the standard synthetic chemical methods dominated by the pharmaceutical industry. Our market research study indicates consumers are interested in non-pharmaceutical treatment alternatives. We combine proprietary algorithms, programmable stimulation parameters, and a patented monopolar delivery mechanism to modulate the nerve signals. We are researching the clinical utility of this stimulation approach for other clinical conditions. This platform has the potential to accelerate new product development by: (i) extending the existing device platform to other clinical areas, thereby reducing research and development time, and (ii) continuing to benefit from low-risk non-invasive device designations and regulatory pathways by the FDA, which typically result in shorter time to approval when compared with invasive devices or new drugs. Although it is our intention to bring new products to market, medical device development is inherently uncertain and there is no guarantee that our research and development efforts will lead to approved products for other clinical indications.

Key elements of our platform include:

- a proprietary algorithmic means of detecting areas of dense nerve innervation and blood vessels, which help guide a user to the optimal treatment locations;
- a proprietary algorithmic means of adapting treatment currents and detection to the unique physiological attributes of the technology's user at the time of use;
- a proprietary algorithmic means of dynamically adjusting treatment levels to maintain both efficacy and comfort;
- programmability of the stimulation protocols via firmware to deliver varied stimulation protocols for different physical and disease targets, providing accelerated opportunities for new product applications; and
- a unique monopolar design that enables ultra-low currents to pass through skin and tissue while maintaining nearly imperceptible current levels.

This combination creates a platform for *non-invasively* influencing peripheral activity with an *ultra-low current* level.

Numerous inflammatory conditions are associated with trigeminal and peripheral nerve activity of the face, including:

- chronic quality-of-life conditions such as migraines (39 million U.S.), temporomandibular joint disorder (31 million U.S.), and tinnitus (50 million U.S.);
- severe, life-altering conditions such as trigeminal neuralgia (150,000 U.S., severe condition); and
- acute conditions such as ear infections (50% of children) and pain and swelling from facial and sinus surgeries (600,000 functional endoscopic surgeries annually, U.S.).

Each of these applications would involve regulation of pain and inflammation-related mediators like those seen in sinus and nasal inflammation.

Competitive Landscape

Pharmaceutical Treatments

Sinus pain, pressure and congestion can be caused by allergic rhinitis (allergies), rhinosinusitis, sinus infections, cold and flu and are most often treated with over-the-counter products targeted symptomatically.

- Sinus pain/pressure is usually managed with analgesic medications (e.g., ibuprofen/Advil, acetaminophen/Tylenol, naproxen sodium/Aleve). Analgesic medications provide short periods of relief and are often associated with side effects including stomach pain, bleeding, ulcers, constipation, diarrhea, gas, bloating, heartburn, nausea, vomiting, dizziness, headache, nervousness, and rash.

- Congestion is treated with a variety of approaches:

  - **Antihistamine medications** are often a first-line therapy for allergy-related symptoms and research indicates that they are effective for treating allergy symptoms such as itchiness, but are less effective for congestion. Antihistamine medications (e.g., loratadine/Claritin) are generally well-tolerated, but may have side-effects including headache, sleepiness, fatigue, dry mouth, and sore throat.

  - **Oral decongestants** (e.g., phenylephrine/Sudafed) used to treat congestion have been demonstrated to exert poor to moderate efficacy, and are associated with nervousness, restlessness, insomnia, dizziness, tachycardia, heart palpitations, syncope, headache, sweating, nausea or vomiting, trembling, paleness, and weakness.

  - **Intranasal decongestants** (e.g., oxymetazoline/Afrin) are more effective than oral decongestants. However, they have reduced effectiveness and rebound effects after three days of use and can lead to the development of a serious condition, rhinitis medicamentosa. Additionally, intranasal decongestants cause side effects including nose irritation or burning, sneezing, dizziness, increased blood pressure, tachycardia, heart palpitations, restlessness and insomnia.

  - **Intranasal glucocorticoids** (e.g., fluticasone propionate/Flonase) have been shown to have the most significant benefits, with some studies showing a 34% reduction in congestion severity after one week of use. Intranasal glucocorticoids have several side effects including epistaxis, dryness, stinging, burning in nose, headache, nausea, vomiting, diarrhea, dizziness, sore throat, and cough.

Examples of companies developing drugs for pain and congestion include GlaxoSmithKline, Bayer, and Johnson & Johnson.

Limitations on Use of Pharmaceutical Treatments

Due to the side effect profiles of pharmaceuticals, many of the above-mentioned treatments carry warnings to discontinue use after two weeks or less according to the U.S. National Library of Medicine. Additionally, some carry warnings regarding use with certain medications or diseases such as high blood pressure.

Non-pharmaceutical Treatments

According to Mintel Group Ltd., consumers are increasingly seeking natural, non-pharmaceutical treatment options. Alternative options currently include, without limitation:

- **Nasal irrigation with saline**, rinsing the nasal passages with saline solution, is the most common non-pharmaceutical treatment, representing approximately $706 million in sales (based on sales of both nasal irrigation products and related accessories) in the U.S. in 2020. Example products include NeilMed Sinus Rinse, Navage Nasal Care and Vicks Sinex Severe. Nasal irrigation is understudied, but there is some evidence of improved quality of life and clearance of mucus. However, saline can irritate an already inflamed sinonasal tissue and nasal irrigation using tap water has been found to carry risk of parasite-driven encephalitis.

•**Bioelectronic devices.** ClearUP is the first device globally to have been cleared by the FDA under a de novo classification for the intended use for temporary relief of moderate to severe congestion. The Company also received FDA clearance for the intended use in treatment of sinus pain associated with allergic rhinitis.

Examples of companies developing non-drug products for sinus pain and congestion include NeilMed, Rhinosystems Inc., and Vapore LLC.

Principal Competitors

Over the counter pharmaceuticals have historically had the greatest market share for sinus pain and congestion treatments; however, according to Mintel Group Ltd.'s 2020 report on Cough, Cold, Flu, and Allergy Remedies, and our own online survey, there is increasing interest among consumers to reduce reliance on drugs and to find non-drug solutions. For this reason, other companies selling non-pharmaceutical treatments, specifically nasal irrigation products, represent our closest competitors.

ClearUP is a novel product offering in the non-drug category, an emerging bioelectronic medicine segment, and currently has small market share compared to the existing establishments, most of which offer pharmaceutical options. Currently, ClearUP is the only FDA approved bioelectronic medicine for the treatment of sinus pain and congestion. It is also a CE-Marked medical device for the treatment of sinus pain, pressure and congestion.

Clinical Research on ClearUP

Allergic rhinitis is an inflammatory disease driven by IgE-mediated reactions to inhaled indoor or seasonal outdoor allergens. The resulting sinus and nasal inflammation may cause symptoms including sinus pain and pressure, nasal congestion, runny nose, sneezing, and nasal itching. Allergic rhinitis affects a significant number of U.S. adults, of which a vast majority experience sinus pain, pressure and congestion as a result of inflammation of the nasal and sinus mucosa.

Key Technical Features

•***Treatment Point Detection.*** ClearUP employs an advanced treatment point detection algorithm that dynamically personalizes to each user. Haptic vibration indicates to the user to hold the device over these points to facilitate stimulation in areas that maximize therapeutic benefit. We have innovated by integrating dynamic measurement with neuromodulation technology to create this novel therapy. (Issued patents: US10625076, US11160978, and US10537738)

•***Monopolar Circuit.*** ClearUP delivers microcurrent stimulation via a monopolar circuit in which the rounded tip of the device is the active electrode and the conductive housing of the device serves as the return electrode. The monopolar design of ClearUP is a significant improvement over typical bipolar approaches to neuromodulation engineering and facilitates deeper delivery of current and sensitive treatment point detection. (Issued patents: US10625076, US11160978, and US10596374)

•***Proprietary Waveform Delivery.*** ClearUP delivers a specific frequency, waveform shape, and amplitude of microcurrent that was empirically determined to have fast-acting therapeutic effects on users with common sinonasal symptoms like pain and congestion. Additionally, we have developed an adaptive algorithm that ensures consistent and comfortable delivery of microcurrent treatment on different parts of the face that can have varying electrical properties. (Issued patents: US10625076, US11160978, and US10537738**)**

•***Ergonomic Design and Ease of Use.*** ClearUP's design ensures the product is comfortable to hold and that the hand will always be in contact with the conductive housing of the monopolar circuit. The device shape has also been refined so that the user can navigate the treatment path with ease. Additionally, the single-button control and intuitive indicators make ClearUP Sinus Relief simple to use. Greater than 95% of users report that applying ClearUP Sinus Relief treatment is easy. (Issued patents: US10596374, US10576280)

Two separate clinical trials have demonstrated the safety and efficacy of ClearUP Sinus Relief in treating sinus pain from allergic rhinitis and moderate to severe congestion.

Pivotal Study: randomized, placebo-controlled, double-blinded clinical trial

In July 2018, the Stanford University Sinus Center conducted a double-blind randomized controlled clinical trial using the ClearUP bioelectronic device. 71 subjects suffering from sinus pain and congestion used either ClearUP or a sham device. The sham device was identical to ClearUP in every way except that it used a continuous DC output instead of the pulsed AC stimulation used by ClearUP.

Each subject used the real or sham device for a single five-minute treatment. Before and ten minutes after treatment, subjects completed questionnaires to quantify their symptoms. Subjects treated with ClearUP reported a rapid and clinically meaningful reduction in sinus pain (-29.6%) and congestion (-35%) at ten minutes after treatment.

This magnitude of change was significantly greater than that observed in sham device-treated subjects.

PUBLICATION: Maul, X. A., Borchard, N. A., Hwang, P. H., & Nayak, J. V. (2019, April). Microcurrent technology for rapid relief of sinus pain: a randomized, placebo-controlled, double-blinded clinical trial. In International forum of allergy & rhinology (Vol. 9, No. 4, pp. 352-356).

Open-label Prospective Trial

The Allergy and Asthma Associates of Santa Clara Valley Research Center conducted a 30-person study on the use of ClearUP over four weeks. Subjects with sinus pain and congestion used the ClearUP device for five minutes during the study visit and then took the device home with them with instructions to use the device one to four times daily for five minutes per treatment as needed for four weeks. Subjects rated their symptoms weekly using a questionnaire. After the first five-minute treatment with ClearUP, subjects reported reduced sinus pain that remained six hours later, the longest time interval tested in the study. Additionally, subjects reported that after four weeks of use, they experienced an average of 43% reduction in sinus pain and 44% reduction in congestion. This magnitude of change was equivalent to efficacy seen in studies of fluticasone propionate after two-weeks of use.

PUBLICATION: Goldsobel, A. B., Prabhakar, N., & Gurfein, B. T. (2019). Prospective trial examining safety and efficacy of microcurrent stimulation for the treatment of sinus pain and congestion. Bioelectronic medicine, 5(1), 1-9.

Safety

In the clinical studies and post-market surveillance, there have been no reports of any significant side effects and very few reports of minor side effects. Minor side effects have included reddening of skin (0.02%), eyelid twitch (0.01%), and headache (0.01%), all of which resolved without intervention.

New Product Introductions

We are currently preparing improvements and extensions to our ClearUP product line. Covered by the same patents, our new product offerings under the ClearUP design architecture are expected to decrease the cost of products by decreasing manufacturing, fulfillment and shipping costs.

Based on our analysis of regulatory guidance issued by the FDA and approval by our designated EU Notified Body (an organization designated by an EU member state to assess the conformity of certain products prior to their release in the EU market), we expect the expansion of our ClearUP product offerings to be covered by existing regulatory clearances applicable to ClearUP.

Research Initiatives: New Product Candidates

We combine proprietary algorithms, programmable stimulation parameters, and a patented monopolar delivery mechanism to modulate the nerve signals that control inflammation-driven symptoms like pain and congestion. This design has proven effective in treating sinus and nasal inflammatory conditions and we are researching the clinical utility of this stimulation approach for other clinical conditions. This platform has the potential to accelerate new product development by: (i) extending the existing device platform to other clinical areas, thereby reducing research and development time, and (ii) continuing to benefit from low-risk, non-invasive device designations and regulatory pathways by the FDA, which typically result in shorter time to approval when compared with invasive devices or new drugs.

Numerous inflammatory conditions are associated with peripheral nerve activity of the face, including:

- chronic quality-of-life conditions such as migraines (39 million U.S.), temporomandibular joint disorder (31 million U.S.), and tinnitus (50 million U.S.);
- severe, life-altering conditions such as trigeminal neuralgia (150,000 U.S., severe condition); and
- acute conditions such as ear infections (50% of children) and pain and swelling from facial and sinus surgeries (600,000 functional endoscopic surgeries annually, U.S.).

Each of these applications would involve regulation of pain and inflammation-related mediators like those seen in sinus and nasal inflammation. Firmware programming of ClearUP allows various stimulation protocols to be used for different disease and neural targets, providing accelerated opportunities for new product candidates at varying price points.

Activities are ongoing for two product candidates: (i) npdPP, an at home-use device for treating postoperative pain after sinus surgery, and (ii) npdMI, an at home-use device for treating migraine headaches. These product candidates are still in early stages of research and development and will require additional studies and regulatory clearances prior to bringing them to market.

npdPP: We completed a ten-person pilot study with the U.S. Institute for Advanced Sinus Care and Research (Cleveland, OH) to evaluate a new device for the treatment of postoperative pain after functional endoscopic sinus surgery ("FESS"). The pilot study was conducted to establish clinical feasibility and we subsequently began a double-blind randomized controlled trial with the Icahn School of Medicine at Mt. Sinai to further test this application. Enrollment in this study is continuing.

npdMI: We are in the process of investigating the area of migraine headaches, which impacts approximately 1 billion people worldwide and 39 million people in the U.S. As part of our research and development activities for migraine, we have been in communication with the FDA to determine the next steps and an appropriate regulatory pathway for expanding our indications. We have completed a market and technology assessment of a potential migraine indication and are developing a clinical protocol related thereto.

We believe our commitment to non-invasive bioelectronic medicine simplifies clinical trial approaches, improves the safety profile important in regulatory matters, and lowers barriers to adoption once in the market. These factors could afford us a unique opportunity for a rapid pace of innovation relative to other therapeutic companies. While it is our intention to bring new products to market, therapeutic development is inherently uncertain and there is no guarantee that our research and development efforts will lead to approved products for other clinical indications.

Component Sourcing and Manufacturing

The ClearUP device is comprised of conventional, off-the-shelf electronic components.

Certain of our electronic components are sourced primarily from China. To increase predictability in sourcing and pricing of electronic components used in our products, we maintain an agreement with Future Electronics, Inc., one of the largest global electronic components distributors. The contract has an initial term of 12 months that automatically renews for additional 12-month periods, subject to annual review, and provides for extended payment terms. Future Electronics may terminate the agreement upon 30 days prior written notice if it determines, in its sole discretion, that we are not meeting our minimum purchase requirement or we are otherwise not performing our obligations under the agreement.

Packaging production is divided between North America and China. The plastic enclosure components and sub-assemblies are produced in China. Materials for both packaging and plastics are commonly available and can be sourced from multiple vendors. Lead times may vary due to supply shortages, customs and port management issues.

We encountered disruptions in our supply of various materials and components, and electronic components in particular, due to well-documented shortages and constraints in the global supply chain during 2022. Although we currently do not anticipate a supply shortage will continue to pose a material risk for the Company in the near term, we are continuously evaluating alternative and secondary source suppliers in order to ensure that we are able to source sufficient components and materials to manufacture our products. In the event that we are unable to source sufficient components and materials from our current suppliers, or to develop relationships with additional suppliers, to manufacture enough of our products to satisfy demand, we may have to cease or slow down production and our business operations and financial condition may be materially harmed.

Electronic components are assembled onto printed circuit boards in North America. ClearUP is assembled, tested, warehoused at, and distributed from the San Francisco Bay Area.

We continue investing in development of the expansion of our ClearUP product line, which is expected to lower product, fulfillment and shipping costs and increase flexibility for line extensions.

The Company has ISO 13485 certification (70488) required to validate the internal processes being compliant with the FDA 21 CFR Part 820 and good manufacturing practices ("GMP"). The Company was re-certified, and the certificates extended until the fourth quarter of 2026.

Intellectual Property / Barriers to Entry

Intellectual Property

Our success depends in part on our ability to obtain and maintain proprietary protection for our product candidates and other discoveries, inventions, trade secrets and know-how that are critical to our business operations. Our success also depends in part on our ability to operate without infringing the proprietary rights of others, and in part, on our ability to prevent others from infringing our proprietary rights. A comprehensive discussion on risks relating to intellectual property is provided under the section of this Report titled “Risk Factors—Risks Related to Our Intellectual Property.”

We rely primarily on a combination of patent, copyright, trademark, and trade secret laws, as well as contractual provisions with employees and third parties, to establish and protect our intellectual property rights. Our patent strategy is to pursue broad protection for key technologies, supplemented by additional patent filings covering conceptual methods, specific aspects of current and proposed products, and forward-looking applications and technological developments. We also engage in strategic analysis of our owned patent assets, and pursue additional patent claims from our existing portfolio that may provide us with market advantages. We do not rely heavily on trade secret protection, but do maintain a certain amount of in-house know-how that is not disclosed publicly.

Our intellectual property portfolio currently consists of:

- 5 issued U.S. patents.
- 21 patents pending in the U.S. and abroad.

- 7 trademarks granted in the U.S. and China.

- 2 trademark applications have been filed in the U.S.

Our intellectual property portfolio includes a large number of disclosures that cover enhanced cost and manufacturability, performance, ergonomics, comfort, ease of use, system expansion, and treatments performed. Identity is protected by way of trademarks. Various aspects of design and function that cannot be readily reverse engineered are held as trade secrets.

In most jurisdictions in which we file, the patent term is 20 years from the earliest date of filing of a non-provisional patent application. However, the term of U.S. patents may be extended for delays incurred due to compliance with FDA requirements or by delays encountered during prosecution that are caused by the United States Patent and Trademark Office ("USPTO"). We intend to seek patent term extensions in any jurisdiction where these are available and where we also have a patent that may be eligible; however, there is no guarantee that the applicable authorities will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions.

Other Barriers to Entry

We have published high-quality clinical research in high-impact peer reviewed journals, establishing Tivic Health as an evidence-based company. Our first-to-market position has secured a high volume and proportion of positive reviews on our websites and other ecommerce channels. We believe that each of these assets, in addition to our intellectual property and regulatory clearances, will create barriers to entry for competitors.

Government Regulation

ClearUP is a U.S. FDA Class II and EU Class IIa medical device that has received three regulatory clearances: (US FDA 510(k) number K182025, US FDA De Novo number DEN200006 and EU CE Mark Certificate number CE (704687). Our EU CE Mark Certificate expires in June 2024 and we are in the process of applying for a new EU CE Mark Certificate under the new EU Medical Device Regulations (MDR) 2017/745. We expect to be compliant with the new regulations prior to the EU CE Mark Certificate expiry date.

Regulation by the FDA

In the United States, the Federal Food, Drug, and Cosmetic Act ("FD&C Act"), as well as FDA regulations and other federal and state statutes and regulations, govern medical device design and development, preclinical and clinical testing, device safety, premarket clearance, grant, and approval, establishment registration and device listing, manufacturing, labeling, storage, record-keeping, advertising and promotion, sales and distribution, export and import, recalls and field safety corrective actions, and post-market surveillance, including complaint handling and medical device reporting of adverse events.

The FDA classifies medical devices into three classes (Class I, II or III) based on the degree of risk associated with a device and the level of regulatory control deemed necessary to ensure its safety and effectiveness. Class I devices are those for which safety and effectiveness can be assured by adherence to the FDA's general controls for medical devices. Class II devices are subject to the FDA's general controls and any other special controls the FDA deems necessary to ensure the safety and effectiveness of the device. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury.

De Novo classification is a risk-based classification process. The De Novo process provides a pathway to classify novel medical devices for which general controls alone, or general and special controls, provide reasonable assurance of safety and effectiveness for the intended use, but for which there is no legally marketed predicate device. De Novo classified devices fall either into Class I or Class II and may be marketed and used as predicates for future premarket notification 510(k) submissions.

In 2019, the FDA issued guidance stating that it does not intend to examine low risk general wellness products to determine whether they are devices within the meaning of the FD&C Act or, if they are devices, whether they comply with the premarket review and post-market regulatory requirements for devices under the FD&C Act and implementing regulations. For purposes of its guidance, the FDA defined general wellness products as "products that meet the following two factors: (1) are intended for only general wellness use, as defined in this guidance, and (2) present a low risk to the safety of users and other persons." Although the FDA classifies our peripheral nerve stimulation platform as a Transcutaneous Electrical Nerve Stimulator ("TENS") regulated as a Class II medical device, we also intend to pursue development and marketing of general wellness claims and assess if our products fall within the general wellness FDA guidelines.

ClearUP Sinus Relief was cleared under 510(k) number K182025 based on clinical data supporting its safety and efficacy for the temporary relief of sinus pain associated with allergic rhinitis. We were subsequently granted the rights to market ClearUP for the temporary relief of moderate to severe congestion under De Novo number DEN200006.

Labeling

All medical devices commercially distributed in the U.S. must comply with specific FDA labeling requirements. These requirements address the labeling (e.g., device label, Instruction for Use, package label, etc.) that must be affixed to the device or packaging and, in the case of devices used by the consumer, provided to all users of the device. Our ClearUP labeling has been reviewed by the FDA as part of our regulatory clearances and our quality management system provides for control of documents to prevent changes that might invalidate FDA's review.

Quality System Regulation

The devices that we commercially distribute in the U.S. are subject to pervasive and continuing regulation by the FDA and certain state agencies. This includes product listing and establishment registration requirements, which facilitate FDA inspections and other regulatory actions. We adhere to applicable current good manufacturing practice, or cGMP, requirements, as set forth in the 21 CFR 820 QSR, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all phases of the design and manufacturing process. We are also required to verify that our suppliers maintain facilities, procedures and operations that comply with applicable quality and regulatory requirements. The FDA enforces the QSR through periodic announced or unannounced inspections of medical device manufacturing facilities, which may include the facilities of contractors. FDA regulations also require investigation and correction of any deviations from the QSR and impose reporting and documentation requirements upon us and our third-party manufacturers.

Post-market surveillance

We must also comply with post-market surveillance regulations, including medical device reporting ("MDR"), requirements which require that we review and report to the FDA any incident in which our products may have caused or contributed to a death or serious injury, and any incident in which our device has malfunctioned if that malfunction would likely cause or contribute to a death or serious injury if it were to recur. We must also comply with medical device correction and removal reporting regulations, which require manufacturers to report to the FDA corrections and removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FD&C Act that may present a risk to health. Although we may undertake recall actions voluntarily, we must submit detailed information on any recall action to the FDA, and the FDA can order a medical device recall in certain circumstances. To date, we have not been made aware of any reportable incidents that would require us to submit a medical device report to the FDA or any competent authority globally.

In addition to post-market quality and safety actions, labeling and promotional activities are subject to scrutiny by the FDA and, in certain circumstances, by the FTC. Medical devices approved, cleared, or granted by the FDA may not be promoted for outside their respective Indication for Use, otherwise known as "off-label" promotion.

Other healthcare laws and regulations

The healthcare industry is also subject to federal and state fraud and abuse laws, including anti-kickback, self-referral, false claims and physician payment transparency laws, as well as patient data privacy and security and consumer protection and unfair competition laws and regulations. Our operations are also subject to certain state and local laws, including manufacturing license, sales and marketing practices, interactions with consumers, consumer incentive and other promotional programs, and state corporate practice and fee-splitting prohibitions.

Currently, ClearUP is not reimbursed by any government or private healthcare program, limiting our exposure under certain laws such as the Sunshine Act.

CE Mark – European Union and other jurisdictions that recognize the CE Mark

In 2020 we secured the CE Mark CE 704687 allowing sales and marketing of ClearUP in the European Union and in any country that recognizes CE Mark certificate for relief of sinus pain, pressure and congestion, without regard to the cause of pain, pressure and congestion. Sales in such jurisdictions will expose our operations to additional regulations.

To the extent that any of our products are sold in a foreign country, we may become subject to foreign laws, which may include, for example, applicable post-marketing requirements, including post-market clinical follow up, safety surveillance, anti-fraud and abuse laws and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals. We must operate our business within the requirements of these laws.

Coverage and reimbursement

Our current product is purchased on a cash-pay basis and is not covered by government healthcare programs and/or other third-party payors. However, we monitor federal and state legislations and regulatory changes that could affect our results of operations.

Privacy and security

The Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and their implementing regulations, imposes privacy, security and breach reporting obligations with respect to individually identifiable health information upon "covered entities" (health care providers, health plans and health care clearinghouses), and their respective business associates, individuals or entities that create, received, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity.

Even when HIPAA does not apply, according to the FTC, failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards.

In addition, certain states and non-U.S. laws, such as the GDPR, govern the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. For example, California recently enacted the California Consumer Privacy Act, or CCPA, which took effect on January 1, 2020 and was amended and expanded by the California Privacy Rights Act, or CPRA, which took effect on January 1, 2023. The CCPA, as amended by the CPRA, among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information and the right to access information about how their data is being used.

Environmental Matters

Our operations, properties and products are subject to a variety of U.S. and foreign environmental laws and regulations governing, among other things, use of manufacturing components containing substances below established threshold, air emissions, wastewater discharges, management and disposal of hazardous and non-hazardous materials and waste and remediation of releases of hazardous materials. We believe, based on current information that we are in material compliance with environmental laws and regulations applicable to us and rely heavily on our outsourced design and manufacturing partners to assist in maintaining compliance.

Facilities

Our principal executive office is located at 25821 Industrial Blvd., Suite 100, Hayward, California 94545. On November 17, 2021, we entered into a sublease agreement for approximately 9,091 square feet of office and warehouse space. The term of the sublease will expire on October 31, 2025. Monthly rent for the premises is currently $12,609 per month (which will be subject to 3% escalations annually), plus the Company's pro rata share of operating expenses, which are currently approximately $4,500 per month.

Human Capital Resources

As of December 31, 2022, we had 16 full-time employees and four contractors. None of our employees are represented by a labor union, and we consider our employee relations to be good. Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards and cash-based performance bonus awards.

Legal Proceedings

We are not currently a party to any material legal proceedings. We may, however, in the ordinary course of business face various claims brought by third parties, and we may, from time to time, make claims or take legal actions to assert our rights, including intellectual property rights as well as claims relating to employment matters and the safety or efficacy of our products. Any of these claims could subject us to costly litigation. If this were to happen, the payment of any such awards could have a material adverse effect on our business, financial condition and results of operations. Additionally, any such claims, whether or not successful, could damage our reputation and business.

Corporate Information

The Company was incorporated in California in September 2016 and reincorporated as a Delaware corporation in June 2021. Our principal executive offices are located at 25821 Industrial Blvd., Suite 100, Hayward, California 94545. Our telephone number is (888) 276-6888. Our website address is www.tivichealth.com. Information contained on, or that can be accessible through, our website is not a part of this Report and the inclusion of our website address in this Report is an inactive textual reference only.

Item 1A – Risk Factors

You should carefully consider the risks described below, as well as the other information in this Report, including our financial statements and the related notes and the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations," before investing in our publicly traded securities. The occurrence of any of the events or developments described below could harm our business, financial condition, operating results, and/or growth prospects. The risks described below are not the only ones facing us. Our business is also subject to the risks that affect many other companies, such as competition, labor relations, general economic conditions, geopolitical changes, and international operations. We operate in a rapidly changing environment that involves a number of risks, some of which are beyond our control. Additional risks not currently known to us or that we currently believe are immaterial also may impair our business operations and our liquidity. The risks described below could cause our actual results to differ materially from those contained in the forward-looking statements we have made in this Report, the information incorporated herein by reference, and those forward-looking statements we may make from time to time. You should understand that it is not possible to predict or identify all such factors. Consequently, you should not consider the following to be a complete discussion of all potential risks or uncertainties.

Risk Factor Summary

Below is a summary of the principal factors that make an investment in our securities speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below and should be carefully considered, together with other information included in this Report.

- We have a relatively limited operating history and may not be able to execute on our business strategy.
- Our cash and financial resources may be insufficient to meet our anticipated needs for the next twelve months, which raises substantial doubt about our ability to continue as a going concern.
- Our operating results may be volatile and may not be a reliable indicator of our future performance.
- If we fail to manage our growth effectively, including with respect to potential acquisitions of other companies, our business could be materially and adversely affected.
- We have a history of net losses, and we may not achieve or maintain profitability in the future.
- We have identified a material weakness in our internal control over financial reporting associated with staffing levels, which is common for the stage and size of the Company.
- We expect that we will need additional capital, which, if obtainable, could dilute the ownership interest of investors.
- Our business plan depends heavily on product revenues from our core technology, the clinical and consumer acceptance of which is at this time unproven.
- Economic uncertainty and capital markets disruption, which has been significantly impacted by geopolitical instability, could harm our financial condition and results of operations.
- Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or non-performance by financial institutions or transactional counterparties, could adversely affect our current and projected business operations and our financial condition and results of operations.
- We rely on third parties to supply and manufacture our devices, and we expect to continue to rely on third parties to manufacture and supply our devices. We encountered disruptions in our supply of various materials and components during 2022 due to the well-documented shortages and constraints in the global supply chain. If we experience similar constraints in the future, the supply or manufacture of our devices could be stopped, delayed or made less profitable if any of these third parties fail to provide us with sufficient quantities at acceptable quality levels or prices, or fail to maintain or achieve satisfactory regulatory compliance.
- We may be adversely affected by the effects of inflation.
- We depend on our senior management team, and the loss of one or more key personnel or an inability to attract and retain highly skilled personnel may impair our ability to grow our business.
- The guarantees and warranties we provide on our products could have a material adverse effect on our business, financial condition and results of operations.
- Our markets are undergoing continuous change, and our future success will depend on our ability to meet the changing needs of our customers.
- Developing medical technology entails significant technical, regulatory and business risks.

•We may face risks associated with expanding to international markets, including trade disputes that could materially impact our business and currency risks.

•The size and expected growth of our available market has not been established with precision and may be smaller than we estimate.

•Our insurance may not adequately cover our operating risk.

•Our business could be disrupted by catastrophic occurrences and similar events.

•Changes in the regulatory landscape for our products could render our business model contrary to applicable regulatory requirements, and we may be required to seek additional clearance or approval for our products. Additionally, we have relied on guidance documents from FDA and our EU Notified Body to make determinations about the regulatory pathway for future products, which may be interpreted to a different effect by the governing regulatory bodies.

•We are subject to consumer protection laws that regulate our marketing practices and prohibit unfair or deceptive acts or practices. Our actual or perceived failure to comply with such obligations could harm our business, and changes in such regulations or laws could require us to modify our products or marketing or advertising efforts.

•Our reliance on vendors in foreign countries, including China, subjects us to risks and uncertainties relating to foreign laws and regulations and changes in relations between the United States and such foreign countries.

•We are highly dependent on our intellectual property ("IP") and our methods of protecting our IP may not be adequate or could be costly. In addition, we may face risks of claims for IP infringement. We may be unable to enforce our intellectual property rights throughout the world.

•If our stock price continues to remain below $1.00, our common stock may be subject to delisting from Nasdaq, which would materially reduce the liquidity of our common stock and have an adverse effect on our market price.

•If we elect to implement a reverse stock split to regain compliance with the Nasdaq continued listing requirements, such reverse stock split could have a materially adverse effect on our business.

•Our stock price has fluctuated significantly since our IPO, and may continue to fluctuate significantly, and investors may not be able to resell the securities that they purchase at or above the price at which they purchased them. An active trading market for our common stock may never develop or be sustained.

•We do not expect to pay any cash dividends for the foreseeable future.

•Future issuances of stock or other securities could dilute the holdings of our stockholders and could materially affect the price of our common stock.

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

•If we are unable to implement and maintain effective internal control over financial reporting in the future, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock may decline.

•If our operating and financial performance in any given period does not meet any guidance that we provide to the public, the market price of our common stock may decline.

•Actual or perceived failures to comply with applicable data privacy and security laws, regulations, policies, standards, contractual obligations and other requirements related to data privacy and security and changes to such laws, regulations, standards, policies and contractual obligations could adversely affect our business, financial condition and results of operations.

Risks Related to Our Financial Condition and Business Model

We have a relatively limited operating history and may not be able to execute on our business strategy.

We were originally incorporated in 2016 and began selling our first product in 2019. Accordingly, we have a limited operating history, which makes an evaluation of our future prospects and execution ability difficult. Our revenue and income-producing potential is unproven, and our business model and strategy may continue to evolve. Future revenues are contingent upon several factors, including, without limitation, our ability to successfully develop and scale-up sales of the ClearUP line and future products, our ability to develop relationships with channel partners and customers, as well as the clinical and market acceptance of our technology. We may need to make business decisions that could adversely affect our operating results, such as modifications to our pricing strategy, business structure or operations.

Our operating results will likely be volatile and may not be a reliable indicator of our future performance.

Our future expenses, revenues and operating results may vary significantly from quarter to quarter due to a number of factors, including, without limitation:

•receptiveness of the market to a fundamentally new way of treating target conditions;

•intrinsic variability in spending patterns associated with the conduct of clinical trials;

•disruptions to the global supply chain and inflationary pressures;

•fluctuations in demand for our technology, including seasonal variations; and

•delays in introducing new technology to market, including product design, manufacturing, marketing cycles, sales and distribution related delays.

We expect that our revenues may be volatile as we develop new technology and obtain new customers in the future. The volume and timing of commercial outcomes are difficult to estimate, as the adoption of bioelectronic treatments is immature, and the sales cycle may vary substantially from forecasts.

If we fail to manage our growth effectively, our business could be materially and adversely affected.

We will not be successful unless we are able to generate additional revenues and grow our business, which will likely require us to hire additional employees and expand our technology, product, development and sales and marketing divisions in order to achieve our business plan. Our management systems are emergent. The continued growth of our business may place demands on our management, financial, operational, technological and other resources, and we expect that our growth will require us to continue developing and improving our operational, financial and other internal controls. We may not be able to address these challenges in a cost-effective manner, or at all. If we do not effectively manage our growth, we may not be able to execute on our business plan, respond to competitive pressures, take advantage of market opportunities, satisfy customer requirements or maintain high-quality product offerings, which could have a material adverse effect on our business, financial condition and results of operations.

We have a history of net losses and we may not achieve or maintain profitability in the future.

We have incurred net losses since inception. For the years ended December 31, 2022 and 2021, we incurred net losses of $10.1 million and $8.5 million, respectively, and at December 31, 2022, we had working capital of $3.4 million and an accumulated deficit of $29.6 million. During the years ended December 31, 2022 and 2021, we used $8.9 million and $5.6 million of cash, respectively, for operating activities. The net losses we incur may fluctuate significantly from quarter to quarter and may increase as a result of macroeconomic factors. Additionally, future costs relating to product development and operating activities may be significantly higher than our historical costs.

Management expects to incur substantial additional operating losses for at least the next two years to expand our markets, complete development of new products, obtain regulatory approvals, launch and commercialize our products and continue research and development programs.

Our future capital requirements will depend upon many factors, including, without limitation, progress with developing, manufacturing and marketing our technologies; the time and costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other proprietary rights; our ability to successfully execute our acquisition strategy, including the closing of potential acquisitions and integrating new business into our own; our ability to establish collaborative arrangements; marketing activities; and competing technological and market developments. Our ability to generate revenue and achieve profitability requires us to successfully market and secure purchase orders for our products and services from customers currently identified in our sales pipeline as well as new customers. We will also be required to efficiently manufacture and deliver equipment on those purchase orders. These activities, including our planned research and development efforts, will require significant uses of working capital. There can be no assurance that we will generate revenue and cash as expected in our current business plan. We expect that we will need to raise additional capital to continue operating our business and fund our planned operations, including to execute on our acquisition strategy, research and development, clinical trials and, if regulatory approval is obtained, commercialization of future product candidates. We may seek additional funds through equity or debt offerings and/or borrowings under notes payable, lines of credit or other sources. We do not know whether additional financing will be available on commercially acceptable terms, or at all, when needed. If adequate funds are not available or are not available on commercially acceptable terms, our ability to fund our operations, support the growth of our business or otherwise respond to competitive pressures could be significantly delayed or limited, which could materially and adversely affect our business, financial conditions, or results of operations.

Our long-term success is dependent upon our ability to successfully develop, commercialize and market our products, earn revenue, obtain additional capital when needed and, ultimately, to achieve profitable operations. We will need to generate significant additional revenue to achieve profitability. Future products may require substantially higher levels of investment than initial products, including investments in research, development, regulatory and/or marketing and sales. It is possible that we will not achieve profitability or that, even if we do achieve profitability, we may not maintain or increase profitability in the future. Our failure to achieve or maintain profitability could negatively impact the value of our common stock.

There is substantial doubt about our ability to continue as a going concern.

Because we have incurred operating losses since inception, and based on our current cash levels and burn rate, amongst other things, we believe our cash and financial resources may be insufficient to meet our anticipated needs for the twelve months, which raises substantial doubt about our ability to continue as a going concern within one year from the issuance date of the financial statements included elsewhere in this prospectus. These losses are expected to continue for at least a period of time. The financial statements included elsewhere in this Report 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 financial statements do not include any adjustments relating to the recoverability and classification of asset amounts or the classification of liabilities that might be necessary should we be unable to continue as a going concern within one year after the date the financial statements are issued.

Our ability to obtain additional financing will depend on a number of factors, including, among others, the condition of the capital markets and the other risks described in these risk factors. If any one of these factors is unfavorable, we may not be able to obtain additional funding, in which case, our business could be jeopardized and we may not be able to continue our operations or pursue our strategic plans. If we are forced to scale down, limit or cease operations, our shareholders could lose all or part of their investment in our Company.

We have identified a material weakness in our internal control over financial reporting.

Prior to our initial public offering, we were a private company and had limited accounting and financial reporting personnel and other resources with which to address our internal controls and related procedures. In connection with the audit of our financial statements for the years ended December 31, 2022 and 2021, we identified a material weakness in our internal control over financial reporting. 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. The material weakness identified in 2021 arose from an accumulation of significant deficiencies, which amounted to a material weakness in internal controls. Such significant deficiencies identified included insufficient accounting and financial reporting personnel, inadequate segregation of duties, and inadequate application of inventory cost accounting procedures. In 2022, we remediated the deficiencies related to the segregation of duties and inventory cost accounting procedures. In addition, we have completed our internal control design and formalized various internal control processes and procedures as of December 31, 2022. However, due to the small size of our accounting and financial reporting team and the fact that we have only recently implemented new processes and procedures to mitigate the risk of a material misstatement, we believe that there is still a reasonable possibility that a material misstatement of our annual or interim financial statements may not be prevented or detected on a timely basis. If we are unable to remedy our material weakness, or if we generally fail to establish and maintain effective internal controls appropriate for a public company, we may be unable to produce timely and accurate financial statements, and we may continue to conclude that our internal control over financial reporting is not effective, which could adversely impact our investors' confidence and our stock price.

We expect that we will need additional capital, which, if obtainable, could dilute the ownership interest of investors.

We anticipate we will need additional capital to market our products, develop additional products and fund our operations, which we may raise through the sale and issuance of equity, equity-related or convertible debt, or other securities. Our future capital requirements depend on many factors including our need to market our products, acquire or develop additional products and fund our operations. We cannot be certain that additional financing will be available to us on acceptable terms when required, or at all.

If we issue additional equity securities or securities convertible into equity securities, our existing stockholders will be subject to dilution. Additionally, sales of substantial amounts of our equity securities could have an adverse effect on the value of our equity and our ability to raise additional capital through future capital increases.

Our business plan depends heavily on revenues from our initial products, the clinical and consumer acceptance of which is unproven at this time.

Our future growth depends on the commercial success of our technology and initial products. It is not certain that our target customers will choose our technology for technical, cost, support or commercial reasons. If our target customers do not widely adopt and purchase our technology, our future growth will be limited. Further, our resources and investments may not be adequate to achieve the targeted level of manufacturing and sales set out in our business plan.

We are currently operating in a period of economic uncertainty and capital markets disruption, which has been significantly impacted by geopolitical instability due to the ongoing military conflict between Russia and Ukraine. Our business, financial condition and results of operations could be materially adversely affected by any negative impact on the global economy and capital markets resulting from the conflict in Ukraine or any other geopolitical tensions.

U.S. and global markets are experiencing volatility and disruption following the escalation of geopolitical tensions and the start of the military conflict between Russia and Ukraine. On February 24, 2022, a full-scale military invasion of Ukraine by Russian troops was reported. Although the length and impact of the ongoing military conflict is highly unpredictable, the conflict in Ukraine could lead to market disruptions, including significant volatility in commodity prices, credit and capital markets, as well as supply chain interruptions. We are continuing to monitor the situation in Ukraine and globally and assessing its potential impact on our business.

Additionally, the recent military conflict in Ukraine has led to sanctions and other penalties being levied by the United States, European Union and other countries against Russia. Additional potential sanctions and penalties have also been proposed and/or threatened. Russian military actions and the resulting sanctions could adversely affect the global economy and financial markets and lead to instability and lack of liquidity in capital markets, potentially making it more difficult for us to obtain additional funds.

Although our business has not been materially impacted by the ongoing military conflict between Russian and Ukraine to date, it is impossible to predict the extent to which our operations, or those of our suppliers and manufacturers, will be impacted in the short and long term, or the ways in which the conflict may impact our business. The extent and duration of the military action, sanctions and resulting market disruptions are impossible to predict, but could be substantial. Any such disruptions may also magnify the impact of other risks described in this Report.

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or non-performance by financial institutions or transactional counterparties, could adversely affect our current and projected business operations and our financial condition and results of operations.

Actual events involving reduced or limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds, have in the past and may in the future lead to market-wide liquidity problems. For example, in March 2023, Silicon Valley Bank and Signature Bank were closed and taken over by the Federal Deposit Insurance Corporation ("FDIC") as receiver. Although we did not have any cash or cash equivalent balances on deposit with Silicon Valley Bank or Signature Bank, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, or result in breaches of our financial and/or contractual obligations. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and/or projected business operations and financial condition and results of operations.

We rely on third parties to supply and manufacture our devices which could cause supply shortages, and we expect to continue to rely on third parties to manufacture and supply our devices.

We encountered disruptions in our supply of various materials and components, and electronic components during 2022 due to the well-documented shortages and constraints in the global supply chain. This was exacerbated by the resurgence of the COVID-19 pandemic in certain parts of China, which resulted in the temporary closure of manufacturing facilities, including those that make electronic parts like those that we included in our products, in certain parts of China. If we experience similar constraints in the future, the supply or manufacture of our devices could be stopped, delayed or made less profitable if any of these third parties fail to provide us with sufficient quantities at acceptable quality levels or prices, or fail to maintain or achieve satisfactory regulatory compliance.

We rely on, and expect to continue to rely on, third-party providers for the supply and manufacturing of our devices, including components and electronic parts. Lead times for ordered components may vary significantly, and some components used to manufacture our products are provided by a limited number of sources.

We are continuously evaluating alternative and secondary source suppliers in order to ensure that we are able to source sufficient components and materials to manufacture our products. In the event that we are unable source sufficient components and materials from our current suppliers, or to develop relationships with additional suppliers, to manufacture enough of our products to satisfy demand, we may have to cease or slow down production of our products. To the extent our current manufacturers or suppliers, or any manufacturers and suppliers that we engage in the future, are unable to meet our requirements in a timely and cost-effective manner, we may not be able to obtain an adequate supply of electronic parts or components for our products. Any shortage of materials caused by any disruption or unavailability of supply or an increase in the demand for our products, could harm our ability to satisfy customer demand, delay deliveries of our products to customers, lead to customer cancellations and returns, delay the development and launch of new products, or increase our costs and decrease our revenue. Any such impacts or delays could adversely affect our sales, customer satisfaction, profitability, cash flows and financial condition. and our business may be adversely affected. Our efforts to mitigate supply chain weaknesses may not be successful or may have unfavorable effects.

We do not control the operational processes of the contract manufacturing organizations with whom we contract and are dependent on these third parties for the production of our devices in accordance with relevant regulations, which include, among other things, quality control, quality assurance and the maintenance of records and documentation.

We may be adversely affected by the effects of inflation.

Inflation has the potential to adversely affect our liquidity, business, financial condition and results of operations by increasing our overall cost structure, particularly if we are unable to achieve commensurate increases in the prices we charge our customers. The existence of inflation in the economy has resulted in, and may continue to result in, higher interest rates and capital costs, shipping costs, supply shortages, increased costs of labor, weakening exchange rates and other similar effects. As a result of inflation, we have experienced and may continue to experience, cost increases. Although we may take measures to mitigate the impact of this inflation, if these measures are not effective our business, financial condition, results of operations and liquidity could be materially adversely affected. Even if such measures are effective, there could be a difference between the timing of when these beneficial actions impact our results of operations and when the cost inflation is incurred.

We depend on our senior management team and the loss of one or more key personnel or an inability to attract and retain highly skilled personnel may impair our ability to grow our business.

Our future success depends heavily upon the continued services of our executive officers and key personnel. The Company is headquartered in California, which is an at will employment state. Accordingly, the employment agreements that we have entered into with our executive officers and other key personnel do not require them to continue to work for us for any specified period and, therefore, they may terminate employment with us at any time, for any reason and with no advance notice. The replacement of members of our senior management team or other key personnel would likely involve significant time and costs, and the loss of these employees may significantly delay or prevent the achievement of our business objectives.

In addition, our ability to recruit and retain talent in all areas of the business, including but not limited to skilled hires in marketing, product development, regulatory, clinical, quality, logistics, and finance, faces significant competition. We may not be able to hire or retain the type and number of managerial, sales and technical personnel necessary for future success. We will need to devote considerable resources to ensure that we retain our employees in the face of a highly competitive market for talented personnel. If we fail to attract and retain the skilled employees required, this could harm our business and hamper future expansion of our business operations.

We rely on third parties for sales, marketing, manufacturing, distribution, and other business operations.

For us to be successful, third parties providing us with sales, marketing, manufacturing, distribution and other business operations services must be able to provide us with such services in compliance with regulatory requirements, in accordance with agreed upon specifications, at acceptable costs, and on a timely basis. While our service providers have generally met our expectations in the past, their ability and willingness to continue to do so going forward, and the ability and willingness of any new service provider to meet our expectations in the future, may be limited for several reasons, including our relative importance as a customer. Additionally, we rely on third-party online retailers such as Amazon, BestBuy, Walmart, FSAStore and other specialty online retailers, to sell our products. We do not have long-term agreements in place with certain of these third parties and there is no guarantee that such third parties will continue to allow us to sell our products through their platforms. Accordingly, we may be exposed to disruptions or reduced qualify of services, including access to distribution channels, due to factors beyond our direct control, which may impact our ability to operate successfully.

We may not be able to successfully identify, consummate or integrate acquisitions or to successfully manage the impacts of such transactions on our operations.

Part of our business strategy includes investigating growth through acquisitions. We may expand our business by making strategic acquisitions and seeking suitable acquisition targets to enhance our growth. Material acquisitions, dispositions and other strategic transactions involve a number of risks, including: (i) the potential disruption of our ongoing business; (ii) the distraction of management away from the ongoing oversight of our existing business activities; (iii) incurring additional indebtedness; (iv) the anticipated benefits and cost savings of those transactions not being realized fully, or at all, or taking longer to realize than anticipated; (v) an increase in the scope and complexity of our operations; (vi) exposure to unknown liabilities, and (vii) the loss or reduction of control over certain of our assets.

The pursuit of acquisitions may pose certain risks to us. We may not be able to identify acquisition candidates that fit our criteria for growth and profitability. Even if we are able to identify such candidates, we may not be able to acquire them on terms or financing satisfactory to us. We may incur expenses and dedicate attention and resources associated with the review of acquisition opportunities, whether or not we consummate such acquisitions, which may divert management's attention from our day-to-day business.

Additionally, even if we are able to acquire suitable targets on agreeable terms, we may not be able to successfully integrate their operations with ours. Achieving the anticipated benefits of any acquisition will depend in significant part upon whether we integrate such acquired businesses in an efficient and effective manner. We may not be able to achieve the anticipated operating and cost synergies or long-term strategic benefits of our acquisitions within the anticipated timing, or at all. The benefits from any acquisition will be offset by the costs incurred in integrating the businesses and operations. We may also assume liabilities in connection with acquisitions to which we would not otherwise be exposed. An inability to realize any or all of the anticipated synergies or other benefits of an acquisition as well as any delays that may be encountered in the integration process, which may delay the timing of such synergies or other benefits, could have an adverse effect on our business, results of operations and financial condition.

The guarantees and warranties we provide on our products could have a material adverse effect on our business, financial condition and results of operations.

We provide product guarantees to our customers, pursuant to which we allow for the return of products from customers within 60 days after the original sale. We also provide a one-year warranty for any defective product. Existing and future product guarantees and warranties place us at the risk of incurring future returns and repair and/or replacement costs. While we engage in product quality programs and processes, including monitoring and evaluating the quality of our components sourced from our suppliers, our guaranty and warranty obligation is affected by actual product defect rates, parts and equipment costs and service labor costs incurred in correcting a product defect. During the years ended December 31, 2022 and 2021, we accrued return reserves equal to approximately 10% and 9%, respectively, of gross revenues. We believe our reserve as of December 31, 2022 is adequate. However, our reserves set aside to cover warranty returns and customer returns may be inadequate due to an unanticipated number of customer returns, undetected product defects, unanticipated component failures or changes in estimates for material, labor and other costs we may incur to replace projected product defects. As a result, if actual customer returns, product defect rates, parts and equipment costs or service labor costs exceed our estimates, it could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Our Business and Markets

Our ability to compete in the sinus, cold and allergy market is unproven.

We currently compete in the sinus, cold and allergy market segment, a segment with large, entrenched players. We expect to experience competition from current and potential new competitors, some of which may be better established and have significantly greater financial, technical, marketing and distribution resources. We encounter competition from larger, well-established and well-financed entities that may continue to acquire, invest in, or form joint ventures with producers of alternate sinus care technologies.

Our competitors may be able to respond more quickly to new or emerging technologies and changes in customer requirements than we can. Our market position could erode rapidly as a result of the development of new, superior products and technology by competitors. In addition, current and potential competitors may have greater name recognition, broader physician reach and more extensive customer bases. Increased competition could result in price reductions, lower volume sales, and reduced gross margins. There can be no assurance that we will be able to compete successfully against our current or future competitors or that competitive pressures will not have a material adverse effect on our business, financial condition and results of operations.

Our markets are undergoing continuous change, and our future success will depend on our ability to meet the changing needs of our customers.

For our business to survive and grow, we must continue to enhance and improve our products and technology to address a broader range of customers' needs. If customer behavior or new industry standards or practices emerge, our existing technology may become obsolete. Our future success will depend upon, among other things, our ability to:

- develop and license new technologies that address the increasingly sophisticated and varied needs of prospective customers;
- stay ahead of technological advances and emerging industry standards and practices on a cost-effective and timely basis; and
- monitor and stay ahead of shifts in the competitive landscape.

Developing medical technology entails significant technical, regulatory and business risks.

We may fail to adapt our technology to user requirements or emerging treatment standards. Microcurrent and other neuromodulation therapies are not currently considered standard of care for inflammation and may not ever be considered standard of care. Treatment standards may not evolve to incorporate our product. New industry standards for the development, manufacture and marketing of medical devices may evolve and we may not be able to conform to the changes, meet new standards in a timely fashion or maintain a competitive position in the market. In particular, regulatory standards for bioelectronic treatments of medical conditions are evolving. If we face material delays in introducing our products and new technology, we may fail to attract new customers.

Customer or third-party complaints or negative reviews or publicity about our company or our products could harm our reputation and brand.

We are heavily dependent on customers who use our ClearUP device to provide good reviews and word-of-mouth recommendations to contribute to our growth. Customers who are dissatisfied with their experiences with our products or services may post negative reviews. We may also be the subject of blog, forum or other media postings that include inaccurate statements and/or create negative publicity. In addition, any negative news regarding bioelectronic medicine may adversely impact our business. Any negative reviews or publicity, whether real or perceived, disseminated by word-of-mouth, by the general media, by electronic or social networking means or by other methods, could harm our reputation and brand and could severely diminish consumer confidence in our products.

We may face risks associated with expanding to international markets.

We intend to pursue marketing and selling our products internationally, primarily through e-commerce accelerators, distribution arrangements and regional licensing. We have limited experience operating outside the United States, and we will likely need to rely heavily on distributors and licensees. Expansion into international markets may expose us to, among other things, the following additional risks:

- strain on our managerial resources;
- pricing pressure that we may experience internationally;
- a shortage of high-quality e-commerce accelerators, distributors, and licensees;
- competitive disadvantage to competition with established business and customer relationships;
- foreign currency exchange rate fluctuations;
- the imposition of additional U.S. and foreign governmental controls or regulations;
- economic instability;
- changes in duties and tariffs, license obligations and other non-tariff barriers to trade;
- the imposition of restrictions on the activities of foreign agents, representatives and distributors;
- scrutiny of foreign tax authorities which could result in significant fines, penalties and additional taxes being imposed on us;
- laws and business practices favoring local companies;
- difficulties in maintaining consistency with our internal guidelines;
- difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;
- the imposition of costly and lengthy new export licensing requirements;

•the imposition of U.S. or international sanctions against a country, company, person or entity with whom we do business that would restrict or prohibit continued business with the sanctioned country, company, person or entity; and

•the imposition of new trade restrictions.

The size and expected growth of our available market has not been established with precision and may be smaller than we estimate.

Our data on the available market for our current products and future products is based on a number of internal and third-party research reports, estimates and assumptions. While we believe that such research, our assumptions and the data underlying our estimates are reasonable, these assumptions and estimates may not be correct. In addition, the statements in this Report relating to, among other things, the expected growth in the market for our ClearUP device are based on a number of internal and third-party data, estimates and assumptions, and may prove to be inaccurate. If the actual number of consumers who would benefit from our products, the price at which we can sell future products or the available market for our products is smaller than we estimate, it could have a material adverse effect on our business, financial condition and results of operations.

Our insurance may not adequately cover our operating risk or litigation exposure.

We have insurance to protect our assets, operations and employees. While we believe our insurance coverage addresses the material risks to which we are exposed and is adequate and customary in our current state of operations, such insurance is subject to coverage limits and exclusions and may not be available for the risks and hazards to which we are exposed. Also, our insurance may be insufficient to cover the costs of any securities-related or other lawsuits or litigation, regardless of the merits of any such lawsuits or litigation. In addition, no assurance can be given that such insurance will be adequate to cover our liabilities or will be generally available in the future or, if available, that premiums will be commercially justifiable or affordable. If we were to incur substantial liability and such damages were not covered by insurance or were in excess of policy limits, or if we were to incur such liability at a time when we are not able to obtain liability insurance, our business, results of operations and financial condition could be materially adversely affected.

Our business could be disrupted by catastrophic occurrences and similar events.

Our headquarters are located in the San Francisco Bay Area, and we are vulnerable to interruption from catastrophic occurrences, such as earthquakes, floods, fires, power loss, telecommunication failures, terrorist attacks, criminal acts, sabotage, other intentional acts of vandalism and misconduct, geopolitical events, disease, such as the COVID-19 pandemic, and similar events. The San Francisco Bay Area is a region known for seismic activity. Despite any precautions we may take, the occurrence of a natural disaster or other unanticipated problems at our facilities or the facilities of our suppliers and vendors could result in disruptions and other performance and quality problems. If we are unable to develop adequate plans to ensure that our business functions continue to operate during and after a disaster and/or to execute successfully on those plans in the event of a disaster or emergency, our business would be seriously harmed.

Risks Related to Legal and Regulatory Matters

Changes in the regulatory landscape for our products could render our business model contrary to applicable regulatory requirements, and we may be required to seek additional clearance or approval for our products.

Our ClearUP device is a US FDA Class II device with FDA clearance for over-the-counter purchase. We continue to expand our product offerings within the ClearUP brand based on the architecture used in the ClearUP product line. Such expansions may include design modifications of the ClearUP device. Given that current improvements to the ClearUP product line are a line extension of the ClearUP device, and based on the approval by our designated EU Notified Body and our assessment of relevant FDA guidance (Guidance for Industry and Food and Drug Administration Staff "Deciding When to Submit a 510(k) for a Change to and Existing Device" October 25, 2017), we have determined that such current expansions of the ClearUP product line are covered under the same regulatory clearances as ClearUP. If the FDA were to determine that our products or product candidates do not properly satisfy the conditions for FDA clearance as Class II devices, or that our ClearUP product line expansion is not covered by the same regulatory clearances as our existing ClearUP device, we could be required to cease distribution of our products until we obtain regulatory clearance or approval, abandon new product launch plans, and/or we could be subject to additional enforcement action by the FDA. All existing FDA clearances, including those covering our ClearUP device, could be subject to change based on subsequent FDA review or changes in FDA regulations. In addition, many states have laws regarding the provision of medical devices, and if we are found to be in violation of the laws of any state in which our devices are sold, we could be subject to further sanctions at the state level.

The laws and regulations applicable to the industries in which we operate are continuously evolving. Changes in our regulatory and legal landscape could substantially increase the costs of compliance, increase the time and resources required to bring new products to market, or otherwise negatively impact our business. There can be no assurance that new legislation or regulations will not impose significant additional costs or burdens on our business or subject us to additional liabilities. We may be or become subject to claims that our operations violate these laws or regulations.

Our business is subject to risks arising from epidemic diseases, such as the recent COVID-19 pandemic.

The occurrence of regional epidemics or a global pandemic such as COVID-19 may adversely affect our operations, financial condition, and results of operations. The COVID-19 pandemic has had widespread, rapidly evolving, and unpredictable impacts on global society, economies, financial markets, and business practices over the last two and a half years, and may continue to have impacts in the future. The extent to which global pandemics, including COVID-19, impact our business going forward will depend on various factors such as the duration and scope of the pandemic; governmental, business, and individuals' actions in response to the pandemic; and the impact on economic activity including the possibility of recession or financial market instability.

Measures taken by the governments of countries affected by COVID-19 and/or future pandemics could adversely impact our business, financial condition, or results of operations. Potential disruptions may include, without limitations, delays in processing registrations or approvals by applicable state or federal regulatory bodies, delays in product development efforts, and additional government requirements or other incremental mitigation efforts that may further impact our capacity to manufacture, sell and support the use of our ClearUP device or other products.

We are subject to consumer protection laws that regulate our marketing practices and prohibit unfair or deceptive acts or practices. Our actual or perceived failure to comply with such obligations could harm our business, and changes in such regulations or laws could require us to modify our products or marketing or advertising efforts.

In connection with the marketing or advertisement of our products, we could be the target of claims relating to false, misleading, deceptive or otherwise noncompliant advertising or marketing practices, including under the auspices of the FTC and state consumer protection statutes. If we rely on third parties to provide any marketing and advertising of our products, we could be liable for, or face reputational harm as a result of, their marketing practices if, for example, they fail to comply with applicable statutory and regulatory requirements.

If we are found to have breached any consumer protection, advertising, unfair competition or other laws or regulations, we may be subject to enforcement actions that require us to change our marketing and business practices in a manner that may negatively impact us. This could also result in litigation, fines, penalties and adverse publicity that could cause reputational harm and loss of customer trust, which could have a material adverse effect on our business, financial condition and results of operations.

Our reliance on vendors in foreign countries, including China, subjects us to risks and uncertainties relating to foreign laws and regulations and changes in relations between the United States and such foreign countries.

Electronic components for our ClearUP devices are sourced primarily from China, and we may in the future source components from vendors located in other foreign countries. Under its current leadership, the government of China has been pursuing economic reform policies, including by encouraging foreign trade and investment. However, there is no assurance that the Chinese government will continue to pursue such policies, that such policies will be successfully implemented, that such policies will not be significantly altered, or that such policies will be beneficial to our partnerships in China. China's system of laws, as well as the laws of other foreign countries where we may source components, can be unpredictable, especially with respect to foreign investment and foreign trade. The United States government has called for substantial changes to foreign trade policy with China and has raised tariffs on several Chinese goods. China has retaliated with increased tariffs on United States goods. Any further changes in United States trade policy could trigger retaliatory actions by affected countries, including China, resulting in trade wars. Changes to Chinese regulations affecting the manufacture of electronic components may also be unpredictable. In addition, throughout the duration of the pandemic, there have been resurgences of COVID-19 in certain parts of China, which have resulted in manufacturing plants being temporarily closed in some areas; if a similar resurgence and lockdown occurs again, it could further impact our ability to source the electronic components necessary for our products at favorable prices, if at all. Changes to regulations in any other country where we may source components in the future may also be unpredictable and could affect the manufacture of electronic components in such countries and our ability to purchase components on a cost-effective basis. Any regulatory changes and changes in United States and China relations, or changes in relations with the United States any other country where we may source components in the future, may have a material adverse effect on our vendors in China and other such countries which could materially harm our business and financial condition.

International trade disputes could result in tariffs and other protectionist measures that could have a material adverse effect on our business, financial condition and results of operations.

Tariffs could increase the cost of our products and raw materials that go into making them. These increased costs could adversely impact the gross margin that we earn on our products. Tariffs could also make our products more expensive for customers, which could make our products less competitive and reduce consumer demand. Countries may also adopt other protectionist measures that could limit our ability to offer our products. Political uncertainty surrounding international trade disputes and protectionist measures could also have a negative effect on consumer confidence and spending, which could have a material adverse effect on our business, financial condition and results of operations.

We may in the future become subject to the requirements of the Sunshine Act.

We are not currently subject to the Physician Payment Sunshine Act ("Sunshine Act"), which was enacted as part of the Affordable Care Act. However, if we begin selling our products directly to governmental entities or our products become reimbursable by Medicare or Medicaid, then we may become subject to the Sunshine Act, which will require us to report annually to the Secretary of Health and Human Services: (i) payments or other transfers of value made by us, or by a third-party as directed by us, to physicians and teaching hospitals or to third parties on behalf of physicians or teaching hospitals; and (ii) physician ownership and investment interests in our company. The payments required to be reported include the cost of meals provided to a physician, travel reimbursements and other transfers of value, including those provided as part of contracted services such as speaker programs, advisory boards, consultation services and clinical trial services. Failure to comply with the reporting requirements can result in significant civil monetary penalties ranging from $1,000 to $10,000 for each payment or other transfer of value that is not reported (up to a maximum per annual report of $150,000) and from $10,000 to $100,000 for each knowing failure to report (up to a maximum per annual report of $1.0 million). Additionally, becoming subject to the Sunshine Act and the information we disclose could lead to greater scrutiny, which could result in modifications to established practices and additional costs. Additionally, similar reporting requirements have also been enacted on the state level domestically, and an increasing number of countries worldwide have either adopted or are considering adopting similar laws requiring transparency of interactions with healthcare professionals.

Risks Related to Our Intellectual Property

We are highly dependent on intellectual property ("IP"), and our methods of protecting our IP may not be adequate or could be costly.

We rely on a combination of patent and trademark laws, trade secrets, confidentiality procedures and contractual provisions to protect our IP rights. We are building our IP portfolio, and may not be able to secure sufficient protection to prevent competition from entering the market or from creating competing products.

We cannot be certain that we will be able to obtain patent protection on the key components of our technology or that we will be able to obtain patents in key jurisdictions, such as the United States, Europe and Asia. We cannot give assurances that we will develop new products or technologies that are patentable or (to the extent applicable) that any new products will be covered by existing patents, that any issued patent will provide us with any competitive advantages or will not be challenged by third parties, or that the patents of others will not impair our ability to do business.

We cannot guarantee that the applicable governmental authorities will approve any of our future trademark applications. Even if the applications are approved, third parties may seek to oppose or challenge these registrations. A failure to obtain trademark registrations in key jurisdictions could limit our ability to use our trademarks and impede our marketing efforts in those jurisdictions.

Despite our efforts to protect our IP, unauthorized parties may attempt to copy or obtain and use our technology. Policing the unauthorized use of our technology on a global basis is difficult, and there can be no assurance that the steps taken by us will prevent misappropriation of our technology.

We cannot give assurances that our measures for preserving the secrecy of our trade secrets and confidential information will be sufficient to prevent others from obtaining our trade secrets.

We generally require our employees, consultants and corporate partners to sign confidentiality and non-disclosure agreements prohibiting them from disclosing any of our trade secrets. Our employment agreements and consulting agreements also contain confidentiality undertakings, as well as non-compete provisions, which prohibit employees, advisors and consultants from acting contrary to our interests during the period of their relationship with us.

Despite our efforts to preserve the secrecy of our trade secrets and confidential information, we may not have adequate remedies to preserve our trade secrets or to compensate us fully for our loss if employees, consultants or corporate partners breach confidentiality agreements with us. We cannot give assurances that our trade secrets will provide any competitive advantage, as they may become known to, or be independently developed by, competitors, regardless of the success of any measures we may take to try to preserve their confidentiality.

Any failure or inability to protect any of our IP or confidential information, or to enforce our rights against any infringement or misappropriation of our IP or confidential information, could have a material adverse effect on our business, financial condition and results of operations. Additionally, we may be forced to litigate to enforce or defend our IP, to protect our trade secrets or to determine the validity and scope of other parties' proprietary rights. Any such litigation could be very costly and could distract our management from focusing on operating our business. The existence and/or outcome of any such litigation could harm our business.

We may face risks of claims for IP infringement.

Our competitors or other persons may have already obtained or may in the future obtain patents or other rights relating to one or more aspects of our technology. Because we have not conducted a formal freedom to operate analysis for patents related to our technology, we may not be aware of issued patents that a third party might assert are infringed by our current or any future technology, which could materially impair our ability to commercialize our current or any future technology. Even if we diligently search third-party patents for potential infringement by our current or any future technology, we may not successfully find patents that our current or any future technology may infringe. If we are unable to secure and maintain freedom to operate, others could preclude us from commercializing our current or future technology. We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our current and any future technology, whether or not we are actually infringing, misappropriating or otherwise violating the rights of third parties. If we are sued for patent or other intellectual property right infringement, we may be forced to incur substantial costs in defending our self.

If litigation were to result in a judgment that we infringed a valid and enforceable patent or other intellectual property right, a court may order us to pay substantial damages to the owner of the patent or other intellectual property right and to stop using any infringing technology or products. This could cause a significant disruption in our business and force us to incur substantial costs to develop and implement alternative, non-infringing technology or products, or to obtain a license from the patent or other intellectual property right owner.

We cannot give assurance that we would be able to develop non-infringing alternatives at a reasonable cost that would be commercially acceptable, or that we would be able to obtain a license from any patent or other intellectual property right owner on commercially reasonable terms, if at all.

We may be unable to enforce our intellectual property rights throughout the world.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. The area of bioelectronic medicine, specifically, is a nascent and emerging industry. To the extent we demonstrate novel means to manage physiological functions, the nature and degree of intellectual property protection we can obtain throughout the world may vary. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. This could make it difficult for us to stop infringement of our foreign patents, if obtained, or the misappropriation of our other intellectual property rights. For example, some foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, some countries limit the enforceability of patents against certain third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries.

Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of our intellectual property.

Risks Related to Our Common Stock

If our stock price continues to remain below $1.00, our common stock may be subject to delisting from the Nasdaq Capital Market, which would materially reduce the liquidity of our common stock and have an adverse effect on our market price.

On January 26, 2023, we received Notice from Nasdaq that the Company is not in compliance with Nasdaq Listing Rule 5550(a)(2), as the minimum bid price of our common stock has been below $1.00 per share for 30 consecutive business days. The Notice has no immediate effect on the listing of our common stock, which will continue to trade at this time on the Nasdaq Capital Market under the symbol "TIVC."

In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have a period of 180 calendar days, or until July 25, 2023, to regain compliance with the minimum bid price requirement. To regain compliance, the closing bid price of our common stock must meet or exceed $1.00 per share for at least ten consecutive business days during this 180 calendar day period. In the event we do not regain compliance by July 25, 2023, we may be eligible for an additional 180 calendar day grace period if the Company meets the continued listing requirement for market value of publicly held shares ($1 million) and all other initial listing standards for the Nasdaq Capital Market, with the exception of the minimum bid price, and we provide written notice to Nasdaq of our intention to cure the deficiency during the second compliance period by effecting a reverse stock split, if necessary. If we do not regain compliance within the allotted compliance period(s), Nasdaq will provide notice that our common stock will be subject to delisting from the Nasdaq Capital Market. Additionally, if the closing bid price of our common stock is $0.10 or less for ten consecutive trading days, Nasdaq will provide notice that our common stock will be subject to delisting from the Nasdaq Capital Market. In the event we recieve a delisting notice, we may appeal such delisting determination to a hearings panel.

We are currently evaluating our alternatives to resolve the listing deficiency, but expect that we will effect a reverse stock split of our common stock. To the extent that we are unable to resolve the listing deficiency, there is a risk that our common stock may be delisted from Nasdaq, which would adversely impact liquidity of our common stock, potentially result in even lower bid prices for our common stock, and make it more difficult for us to obtain financing through the sale of our common stock.

If we elect to implement a reverse stock split to regain compliance with the Nasdaq continued listing requirements, such reverse stock split could have a materially adverse effect on our business.

As noted above, we expect that we will implement a reverse stock split in order to regain compliance with Nasdaq Listing Rule 5550(a)(2). There are a number of risks associated with implementing a reverse stock split, including, without limitation:

- The market price per share of our common stock post-reverse stock split may not remain in excess of the $1.00 minimum bid price per share, as required by Nasdaq, or we may fail to meet the other requirements for continued listing on Nasdaq, including the minimum value of listed securities, resulting in the delisting of our common stock from the Nasdaq Capital Market;

- the reverse stock split may not result in a price per share that will successfully attract certain types of investors, and such resulting share price may not satisfy the investing guidelines of institutional investors or investment funds;

- the trading liquidity of the shares of our common stock may not improve, or may decline, as a result of the reverse stock split and there can be no assurance that the reverse stock split, if completed, would result in the intended benefits;

- a reverse stock split could be viewed negatively by the market and other factors, which may adversely affect the market price of our common stock.

There can be no assurances that implementation of a reverse stock split would allow us to prevent the delisting of our common stock from the Nasdaq Capital Market, and it could have a materially adverse effect on our business.

We expect that our stock price may fluctuate significantly, and investors may not be able to resell their shares at or above the price at which they purchased them. An active trading market for our common stock may never develop.

Prior to our initial public offering, you could not buy or sell our common stock publicly. Even though our common stock is now listed on the Nasdaq Capital Market, an active trading market for our shares may not develop or be sustained following our initial public offering. If an active market for our common stock does not develop or is not maintained, it may be difficult for you to sell your shares depressing the market price for the shares, or at all. An inactive trading market may also impair our ability to raise capital to continue to fund operations by selling additional shares of our common stock and may impair our ability to acquire other companies or technologies by using shares of our common stock as consideration.

The market price of shares of our common stock could be subject to wide fluctuations in response to many risk factors listed in this section, and others beyond our control, including:

- the effect of macroeconomic factors on our business and operations and on market conditions generally;
- the success of our products and of competitive products or technologies;
- regulatory or legal developments in the United States and other countries;
- the level of expenses related to our products or development programs;
- announcements by us, our partners or our competitors of new products or therapies, significant contracts, strategic partnerships, joint ventures, collaborations, commercial relationships, or capital commitments;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- issuance of new or updated research or reports by securities analysts or recommendations for our stock;
- disputes or other developments related to proprietary rights (including patents), litigation matters, and our ability to obtain patent protection for our technologies;
- commencement of, or our involvement in, litigation;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- manufacturing disputes or delays;
- any future sales of our common stock or other securities;
- any change to the composition of the board of directors or key personnel;
- general economic conditions and slow or negative growth of our markets;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcement or expectation of additional debt or equity financing efforts; and
- other factors described in this section of the Report.

These and other market and industry factors may cause the market price and demand for our common stock to fluctuate substantially, regardless of our actual operating performance. In addition, the stock market in general, and medical device companies in particular, have experienced price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In the past, when the market price of a stock has been volatile, holders of that stock have on occasion instituted securities class action litigation against the company that issued the stock. If any of our stockholders were to bring a lawsuit against us, the defense and disposition of the lawsuit could be costly and divert the time and attention of our management and harm our operating results.

We do not expect to pay any cash dividends for the foreseeable future.

We do not expect to pay dividends to our stockholders at any time in the foreseeable future. Anyone considering investing in our stock should not rely on such investment to provide dividend income. Instead, we plan to retain any earnings to establish, maintain and expand our operations and product offerings. In addition, any future debt financing arrangement may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our stock. Accordingly, investors must rely on sales of their shares after price appreciation, which may never occur, as the only way to realize any return on their investment.

Future issuances of stock or other securities could dilute the holdings of stockholders and could materially affect the price of the shares of our common stock.

We anticipate that we will issue shares of capital stock in conjunction with future funding requirements. Any issuance of new shares of our common stock, or securities exercisable for or convertible into shares of our common stock, for the purpose of securing capital will result in the dilution of the ownership interests of our existing stockholders.

We have used and intend to continue to use equity incentives for employees, advisors, directors, key consultants and select affiliates. Any issuance of stock upon the conversion of options and/or incentive rights will result in the dilution of the ownership interests of our existing stockholders.

In addition, we may in the future decide to offer additional stock or other securities in order to finance new capital-intensive projects, in connection with unanticipated liabilities or expenses or for any other purposes. There is no assurance that we will not decide to conduct offerings of securities in the future. Depending on the structure of any future offering, certain existing stockholders may not have the ability to purchase additional equity securities. If we raise additional funds by issuing additional equity securities, the holdings and voting interests of existing stockholders could be diluted.

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

We qualify as an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 ("JOBS Act"). For so long as we remain an emerging growth company, we are permitted and plan to rely on exemptions from certain disclosure requirements that are applicable to public companies that are not emerging growth companies. These provisions include, but are not limited to: being permitted to have only two years of audited financial statements and only two years of management's discussion and analysis of financial condition and results of operations disclosure; an exemption from compliance with the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, as amended ("Sarbanes-Oxley Act"); not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board, or PCAOB, regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements; reduced disclosure obligations regarding executive compensation arrangements in our periodic reports, registration statements and proxy statements; and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. In addition, the JOBS Act permits emerging growth companies to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We intend to take advantage of certain of the exemptions discussed above.

In addition, we are currently a "smaller reporting company," as defined in the Securities Exchange Act of 1934, as amended ("Exchange Act"), and have elected to take advantage of certain of the scaled disclosures available to smaller reporting companies. To the extent that we continue to qualify as a "smaller reporting company" as such term is defined in Rule 12b-2 under the Exchange Act, after we cease to qualify as an emerging growth company, certain of the exemptions available to us as an "emerging growth company" may continue to be available to us as a "smaller reporting company," including exemption from compliance with the auditor attestation requirements pursuant to the Sarbanes-Oxley Act and reduced disclosure about our executive compensation arrangements. We will continue to be a "smaller reporting company" until we have more than $250 million in public float (based on our common stock) measured as of the last business day of our most recently completed second fiscal quarter or, in the event we have no public float (based on our common stock), annual revenues of more than $100 million during the most recently completed fiscal year.

As a result, the information we provide will be different than the information that is available with respect to other public companies. In this Report, we have not included all of the executive compensation-related information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if 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 market price of our common stock may be more volatile.

If we are unable to implement and maintain effective internal control over financial reporting in the future, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock may decline.

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. In addition, beginning with this Report, we are required to furnish a report by management on the effectiveness of our internal control over financial reporting, pursuant to Section 404 of the Sarbanes-Oxley Act. As of December 31, 2022, based on an analysis completed by management, our internal controls were not effective due to the existence of a material weakness. The process of designing, implementing and testing the internal control over financial reporting required to comply with this obligation is time consuming, costly and complicated. If we identify material weaknesses in our internal control over financial reporting (as we have for the period covered by this Report), if we are unable to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to assert 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 decline, and we could also become subject to investigations by the stock exchange on which our common stock is listed, the Commission or other regulatory authorities, which could require additional financial and management resources.

If our operating and financial performance in any given period does not meet any guidance that we provide to the public, the market price of our common stock may decline.

We may, but are not obligated to, provide public guidance on our expected operating and financial results for future periods. Any such guidance will be comprised of forward-looking statements subject to the risks and uncertainties described in this prospectus and in our other public filings and public statements. Our actual results may not always be in line with or exceed any guidance we have provided, especially in times of economic uncertainty. If, in the future, our operating or financial results for a particular period do not meet any guidance we provide or the expectations of investment analysts, or if we reduce our guidance for future periods, the market price of our common stock may decline. Even if we do issue public guidance, there can be no assurance that we will continue to do so in the future.

Anti-takeover provisions in our charter documents, and under Delaware law, could make an acquisition of our company more difficult, limit attempts by our stockholders to replace or remove our current management and limit the market price of our common stock.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws may have the effect of delaying or preventing a change of control or changes in our management. Our amended and restated certificate of incorporation and amended and restated bylaws include provisions that:

- authorize our board of directors to issue, without further action by the stockholders, shares of undesignated preferred stock with terms, rights, and preferences determined by our board of directors that may be senior to our common stock;
- require that any action to be taken by our stockholders be effected at a duly called annual or special meeting and not by written consent;
- specify that special meetings of our stockholders can be called only by our board of directors, the chairperson of our board of directors, our Chief Executive Officer or our President (in the absence of a Chief Executive Officer);
- establish an advance notice procedure for stockholder proposals to be brought before an annual meeting, including proposed nominations of persons for election to our board of directors;
- prohibit cumulative voting in the election of directors;
- establish that our board of directors will be divided into three classes—Class I, Class II, and Class III—with each class serving staggered three-year terms;
- provide that, so long as our board of directors is classified, directors may only be removed for cause;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum; and
- require the approval of our board of directors or the holders of two-thirds of our outstanding shares of voting stock to amend our bylaws and certain provisions of our certificate of incorporation.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which generally, subject to certain exceptions, prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any "interested" stockholder for a period of three years following the date on which the stockholder became an "interested" stockholder. Any of the foregoing provisions could limit the price that investors might be willing to pay in the future for shares of our common stock, and they could deter potential acquirers of our company, thereby reducing the likelihood that you would receive a premium for your shares of our common stock in an acquisition.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that the Court of Chancery of the State of Delaware or the federal district court for the District of Delaware will be the exclusive forum for certain disputes between us and our stockholders, which could result in increased costs for our stockholders to bring a claim and could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that, unless the Company consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, in the event that the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware or other state courts of the State of Delaware) is the exclusive forum for (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of fiduciary duty owed by, or other wrongdoing by, any director, officer, employee or agent of the Company to the Company or our stockholders, creditors or other constituents; (iii) any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws; (iv) any action to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws; or (v) or any action asserting a claim against us that is governed by the internal affairs doctrine; provided that, the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Securities Act, Exchange Act 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, or the Company consents in writing to the selection of an alternative forum, such action may be brought in another state or federal court sitting in the State of Delaware. Our amended and restated certificate of incorporation and amended and restated bylaws also provide that the federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause of action against us or any of our directors, officers, employees or agents and arising under the Securities Act or Exchange Act. Nothing in our amended and restated certificate of incorporation or amended and restated bylaws preclude stockholders that assert claims under the Exchange Act from bringing such claims in state or federal court, subject to applicable law.

We believe these provisions may benefit us by providing increased consistency in the application of Delaware law and federal securities laws by chancellors and judges, as applicable, particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, this choice of forum provision could result in increased costs for our stockholders to bring a claim and could may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims, although our stockholders will not be deemed to have waived our compliance with federal securities laws and the rules and regulations thereunder. Furthermore, 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 a court could find these types of provisions to be inapplicable or unenforceable. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions, and there can be no assurance that such provisions will be enforced by a court in those other jurisdictions. If a court were to find the choice of forum provision that will be contained in our amended and restated certificate of incorporation and amended and restated bylaws 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 and financial condition.

General Risk Factors

If securities or industry analysts do not publish research or publish unfavorable or inaccurate research about our business, the market price and trading volume of our common stock could decline.

The market price and trading volume of our common stock is heavily influenced by the way analysts interpret our financial information and other disclosures. We do not have control over these analysts. If few securities analysts commence coverage of us, or if industry analysts cease coverage of us, our stock price would be negatively affected. If securities or industry analysts do not publish research or reports about our business, downgrade our common stock, or publish negative reports about our business, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our stock price to decline and could decrease the trading volume of our common stock.

We have and will continue to incur increased costs and are subject to heightened regulations and requirements as a result of becoming a public company, which could lower our profits or make it more difficult to run our business.

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company, including costs associated with public company reporting requirements. We also have incurred and will continue to incur costs associated with the Sarbanes-Oxley Act, and related rules implemented by the SEC, and the Nasdaq Capital Market. The expenses generally incurred by public companies for reporting and corporate governance purposes have been increasing. These rules and regulations have increased and will continue to increase our legal and financial compliance costs and to make some activities more time-consuming and costlier, although we are currently unable to estimate these costs with any degree of certainty. These laws and regulations also make it more difficult or costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. These laws and regulations may also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on our board committees or as our executive officers. Furthermore, if we are unable to satisfy our ongoing obligations as a public company, we could be subject to delisting of our common stock, fines, sanctions, other regulatory action and potentially civil litigation.

Actual or perceived failures to comply with applicable data privacy and security laws, regulations, policies, standards, contractual obligations and other requirements related to data privacy and security and changes to such laws, regulations, standards, policies and contractual obligations could adversely affect our business, financial condition and results of operations.

The global data protection landscape is rapidly evolving, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business. We are subject to numerous state, federal and foreign laws, requirements and regulations governing the collection, transmission, use, disclosure, storage, retention and security of personal and personally-identifying information, such as information that we may collect in connection with conducting our business in the United States and abroad. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards or perception of their requirements may have on our business. This evolution may create uncertainty in our business; affect our ability to operate in certain jurisdictions; or to collect, store, transfer use and share personal information; necessitate the acceptance of more onerous obligations in our contracts; result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulation, our internal policies and procedures, or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, fines, imprisonment of company officials and public censure, claims by third parties, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition and results of operations.

Changes in accounting standards and subjective assumptions, estimates and judgments by management related to complex accounting matters could significantly affect our financial results.

U.S. generally accepted accounting principles ("GAAP") and related pronouncements, implementation guidelines and interpretations with regard to a wide variety of matters that are relevant to our business, such as, but not limited to, revenue recognition, stock-based compensation, trade promotions and income taxes are highly complex and involve many subjective assumptions, estimates and judgments by our management. Changes to these rules or their interpretation or changes in underlying assumptions, estimates or judgments by our management could significantly change our reported results.

We are subject to anti-corruption, anti-bribery, anti-money laundering, and similar laws, and non-compliance with such laws could subject us to criminal or civil liability and harm our business, financial condition, and results of operations.

We are subject to the U.S. Foreign Corrupt Practices Act of 1977, as amended ("FCPA"), U.S. domestic bribery laws, the UK Bribery Act 2010, and other anti-corruption and anti-money laundering laws in the countries in which we conduct business. Anti-corruption and anti-bribery laws have been enforced aggressively in recent years and are interpreted broadly to generally prohibit companies, their employees, and their third-party intermediaries from authorizing, offering, or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector. As we increase our international sales and business and sales to the public sector, we may engage with business partners and third-party intermediaries to market our products and to obtain necessary permits, licenses, and other regulatory approvals. In addition, we or our third-party intermediaries may have direct or indirect interactions with officials and employees of government agencies or state-owned or affiliated entities. We can be held liable for the corrupt or other illegal activities of these third-party intermediaries, our employees, representatives, contractors, partners, and agents, even if we do not explicitly authorize such activities. While we have policies and procedures to address compliance with such laws, there is a risk that our employees and agents will take actions in violation of our policies and applicable law, for which we may be ultimately held responsible. As we expand internationally, our risks under these laws may increase.

Detecting, investigating, and resolving actual or alleged violations of anti-corruption laws can require a significant diversion of time, resources, and attention from senior management. In addition, noncompliance with anti-corruption, anti-bribery, or anti-money laundering laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, enforcement actions, fines, damages, other civil or criminal penalties or injunctions, suspension or debarment from contracting with certain persons, reputational harm, adverse media coverage, and other collateral consequences. If any subpoenas or investigations are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal proceeding, our business, financial condition, and results of operations could be harmed.

Item 1B – Unresolved Staff Comments

None.

Item 2 – Properties

Our principal executive office is located at 25821 Industrial Blvd., Suite 100, Hayward, California 94545. On November 17, 2021, we entered into a sublease agreement for approximately 9,091 square feet of office and warehouse space. The term of the sublease will expire on October 31, 2025. Monthly rent for the premises is currently $12,609 per month (which will be subject to 3% escalations annually), plus the Company's pro rata share of operating expenses, which are currently approximately $4,500 per month.

Item 3 – Legal Proceedings

We are not currently a party to any material legal proceedings. We may, however, in the ordinary course of business face various claims brought by third parties, and we may, from time to time, make claims or take legal actions to assert our rights, including intellectual property rights as well as claims relating to employment matters and the safety or efficacy of our products. Any of these claims could subject us to costly litigation. If this were to happen, the payment of any such awards could have a material adverse effect on our business, financial condition and results of operations. Additionally, any such claims, whether or not successful, could damage our reputation and business.

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 common stock is listed on the Nasdaq Capital Market under the ticker symbol "TIVC."

Our common stock, par value $0.0001 per share, has been publicly traded on The Nasdaq Capital Market under the symbol "TIVC" since our initial public offering on November 11, 2021, which was completed at an offering price to the public of $5.00 per share. Prior to our initial public offering, there was no public market for our common stock.

Holders

As of March 24, 2023, there were approximately 112 shareholders of record of our common stock. A substantially greater number of holders of our common stock are "street name" or beneficial holders, whose shares are held by banks, brokers, and other financial institutions.

Dividends

We have never declared or paid cash dividends on our common stock. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any cash dividends on our common stock in the foreseeable future. We may enter into credit agreements or other borrowing arrangements in the future that will restrict our ability to declare or pay cash dividends on our common stock. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant.

Recent Sales of Unregistered Securities; Use of Proceeds from Registered Securities

During the fiscal year ended December 31, 2022, there were no unregistered sales of our securities that were not reported in a Current Report on Form 8-K or our Quarterly Reports on Form 10-Q.

Use of Proceeds

On November 10, 2021, our registration statement on Form S-1 (File No. 333-258411) was declared effective by the Commission for our initial public offering ("IPO"). There has been no material change in the planned use of proceeds from our initial public offering as described in our final prospectus filed with the Commission on November 12, 2021, pursuant to Rule 424(b)(4).

Repurchases

None.

Item 6 – [Reserved]

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

You should read the following discussion and analysis of our financial condition and operating results together with our financial statements and related notes included elsewhere in this Report. This discussion and analysis contains forward-looking statements based upon current beliefs, plans and expectations that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under "Risk Factors" or in other parts of this Report.

Overview

We are a bioelectronic medicine company developing and commercializing drug-free treatments for various diseases and conditions. Bioelectronic medicine, also referred to as electroceuticals or neuromodulation, is the treatment of disease and conditions by preferentially activating electrical functions of the body to modify central or peripheral nerve activity. ClearUP is our first commercial product, and is FDA- approved for the treatment of sinus pain and congestion. It is also a CE-Marked medical device for the treatment of sinus pain, pressure and congestion. ClearUP is currently sold in the U.S. directly to consumers on various platforms and through reseller channels.

Business Developments

Bioelectronic medicine is an emerging, multiple billion-dollar market. Since our formation in September 2016, we have devoted substantially all of our efforts to the development of our proprietary technology platform to provide noninvasive, drug free treatments and treatment candidates for various diseases and conditions. In 2019, we launched ClearUP in the U.S. market. ClearUP is approved by the FDA for sale in the U.S. for the two FDA-approved indications noted above and has a CE Mark, which covers a third indication (sinus pressure) and gives us commercial access to European Union Member states and certain other countries. We currently sell directly to consumers through our own website, Amazon, and Walmart. We also sell to major and specialty online retailers, such as BestBuy and FSAStore.

Recent Developments

Mutual Termination of Proposed Reliefband Acquisition

On October 7, 2022, we entered into an Asset Purchase Agreement (the "Purchase Agreement"), by and among RB Buyer Co, LLC, a Delaware limited liability company ("Buyer") and wholly-owned subsidiary of the Company, Reliefband Technologies, LLC, a Delaware limited liability company ("Reliefband"), certain of Reliefband's beneficial owners (the "Beneficial Owners"), and Shareholder Representative Services LLC, a Colorado limited liability company as representative of Reliefband and its Beneficial Owners.

Pursuant to the Purchase Agreement, Buyer agreed to purchase substantially all of the assets, and certain specified liabilities, of Reliefband that are used in connection with the development, manufacture, distribution, and sale of Reliefband's electronic nerve stimulation devices (the "Reliefband Acquisition") for an aggregate cash purchase price of $33.5 million, subject to working capital adjustments as defined in the Purchase Agreement, less Reliefband transaction expenses and any indebtedness of Reliefband at closing (the "Acquisition Consideration").

After significant diligence, we felt that the Reliefband product line was highly complementary to our ClearUP product line and our existing commercial capabilities. Unfortunately, due to various factors, including without limitation, volatile and unfavorable market conditions and difficulties obtaining sufficient financing to fund the acquisition, we determined that proceeding with the acquisition was not in the Company's or its shareholders' bests interests at that time, and we mutually agreed to terminate the purchase agreement and abandon the Reliefband acquisition.

On December 7, 2022, the parties to the Purchase Agreement entered into an Agreement of Termination and Release (the "Termination Agreement"), pursuant to which the parties mutually agreed to terminate the Purchase Agreement immediately and abandon the proposed Reliefband Acquisition. As a result of the Termination Agreement, the Purchase Agreement is of no further force or effect.

We remain committed to our growth strategy and will continue to evaluate strategic acquisition, licensing, and partnership opportunities. If an acquisition is identified and pursued, a substantial portion of our cash reserves may be required to complete such acquisition. If we identify an attractive acquisition that would require more cash to complete than we are willing or able to use from our cash reserves, we will consider financing options to complete the acquisition, including through equity and/or debt financings.

Microart Agreement

On October 21, 2022, we entered into a Manufacturing Agreement (the "Microart Agreement"), with Microart Services Inc. ("Microart"). Pursuant to the Microart Agreement, Microart manufactures, on a non-exclusive basis, certain components and sub-assemblies (collectively, "Products") of our current and may manufacture our future products. During the term of the Microart Agreement, we shall order Products from Microart by issuing purchase orders, and Microart shall manufacture and supply Products to us in the quantities specified in the applicable purchase orders and in accordance with our specifications. Subject to certain exceptions, Microart will charge us a fixed price for every Product purchased, which fixed price may only be changed by Microart once per each cumulative twelve-month period, and in each case, any increase shall not exceed an amount specified in the Microart Agreement.

The Microart Agreement has a three-year initial term, with automatic annual renewals until terminated by one of the parties in accordance with the terms of the Microart Agreement. The Microart Agreement may be terminated as follows: (i) at any time upon mutual agreement of the parties; (ii) by either party at the end of the initial three year term or any subsequent annual renewal term upon written notice received by the other party not less than 60 calendar days prior to the expiration of the relevant term; (iii) by either party upon 30 calendar days written notice to the other party following a material breach of the agreement if the breaching party fails to cure such breach in a reasonable period of time; or (iv) by either party upon the other party seeking an order for relief under bankruptcy laws, a composition with or assignment for the benefit of creditors, or the dissolution or liquidation.

We expect that this new relationship with Microart will significantly reduce the manufacturing cost of a key component of ClearUP, and potentially future products.

ALOM Agreement

On November 25, 2022, we entered into a Fulfillment Services Agreement (the "ALOM Agreement"), with ALOM Technologies Corporation ("ALOM"). Pursuant to the ALOM Agreement, commencing on November 28, 2022, began providing, on a non-exclusive basis, certain assembly, procurement, storage, returns, and fulfillment services to our end customers and retailers within the United States. During the term of the ALOM Agreement, ALOM shall provide the services in accordance with purchase orders issued by us from time to time. The consideration payable by us to ALOM for services rendered under the ALOM Agreement will be calculated and invoiced based on fixed hourly rates and fixed unit pricing, as applicable, subject to certain exceptions; provided that, commencing April 1, 2023, we will be subject to certain minimum periodic purchase requirements.

The ALOM Agreement has a three-year initial term, with automatic annual renewals until terminated by one of the parties in accordance with the terms of the agreement. The ALOM Agreement may be terminated as follows: (i) for cause upon sixty calendar days' written notice describing with particularity the conduct constituting such breach, if such breach is not cured to the reasonable satisfaction of the aggrieved party within such 60-day period; (ii) for failure to pay any invoices when due, if full payment is not made within twenty calendar days after delivery of a written notice; or (iii) for convenience, upon sixty calendar days' written notice.

We expect this new relationship with ALOM will significantly reduce the cost of assembly and distribution of ClearUP, and potentially future products.

Nasdaq Compliance

On January 26, 2023, we received notice (the "Notice") from the Nasdaq Stock Market LLC ("Nasdaq") that we were not in compliance with Nasdaq Listing Rule 5550(a)(2), as the minimum bid price of our common stock had been below $1.00 per share for 30 consecutive business days. The Notice had no immediate effect on the listing of our common stock, which continues to trade at this time on the Nasdaq Capital Market under the symbol "TIVC."

In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have 180 calendar days, or until July 25, 2023, to regain compliance with the minimum bid price requirement. To regain compliance, the closing bid price of our common stock must meet or exceed $1.00 per share for at least ten consecutive business days during this 180 calendar day period. In the event we do not regain compliance by July 25, 2023, we may be eligible for an additional 180 calendar day grace period if we meet the continued listing requirement for market value of publicly held shares ($1 million) and all other initial listing standards for the Nasdaq Capital Market, with the exception of the minimum bid price, and provide written notice to Nasdaq of our intention to cure the deficiency during the second compliance period by effecting a reverse stock split, if necessary. If we do not regain compliance within the allotted compliance period(s), Nasdaq will provide notice that the Company's common stock will be subject to delisting from the Nasdaq Capital Market. In that event, we may appeal such delisting determination to a hearings panel.

We will continue to monitor the closing bid price of our common stock and are considering options to resolve our noncompliance with the minimum bid price requirement, but expect that we will implement a reverse stock split.

February Public Offering

On February 8, 2023, we entered into an underwriting agreement (the "Underwriting Agreement") with ThinkEquity LLC ("ThinkEquity"), as representative of the underwriters, pursuant to which we agreed to issue and sell to ThinkEquity in a firm commitment underwritten public offering (the "Offering"), 20,000,000 shares of our common stock at a public offering price of $0.25 per share, less underwriting discounts and commissions, resulting in gross proceeds to the Company of $5.0 million. In addition, pursuant to the Underwriting Agreement, we granted ThinkEquity a 45-day option (the "Overallotment Option") to purchase up to an additional 3,000,000 shares of common stock, solely to cover over-allotments.

The Offering closed on February 13, 2023, with the sale of 20,000,000 shares of Company common stock to ThinkEquity. The net proceeds to the Company, after deducting the underwriting discount and commissions and estimated expenses of the Offering payable by the Company, was approximately $3.6 million.

Additionally, pursuant to the Underwriting Agreement, on February 13, 2023, we issued designees of ThinkEquity warrants to purchase an aggregate of 1,000,000 shares of common stock (the "Representative's Warrants," and together with the Shares, the "Securities"), representing 5.0% of the aggregate shares sold in the Offering, as partial consideration for services rendered in connection with the Offering. The Representative's Warrants have an initial exercise price of $0.3125 per share, and will be exercisable for a four-year period commencing 180 days following the commencement of sales in the Offering.

The Securities were registered pursuant to the registration statement on Form S-1 (File No. 333-268010), which was initially filed with the Securities and Exchange Commission (the "Commission") on October 26, 2022, and amended on December 09, 2022, December 20, 2022, January 6, 2023, February 1, 2023, and February 9, 2023, which the Commission declared effective on February 8, 2023 (the "Registration Statement").

In addition, pursuant to the terms of the Underwriting Agreement, the Company and its executive officers, directors and certain of its shareholders have entered into lock-up agreements providing that the Company and each of these persons may not, subject to limited exceptions, offer, sell, transfer or otherwise dispose of the Company's securities for a period of three months following the effective date of the Underwriting Agreement.

Other Operational Updates

Fiscal 2022

In 2022, we also invested in our marketing, product design and e-commerce distribution infrastructure as follows:

- We broadened our advertising mix and increased marketing spend to drive sales growth.
- We optimized our sales channel strategy to increase our profit margin, and terminated less profitable channels.

•We made infrastructure-level improvements to our website and ecommerce functions, including to enhance mobile access to, and use of, our website and adding payment options.

•We were featured in ABC News Report: "New Bioelectronic Technologies Could Signal the Future of Medicine" in January 2022.

•ClearUP was named best sinus pain relief solution of 2021 by Global Health & Pharma Magazine in February 2022.

•Our CEO spoke at high-profile events evangelizing bioelectronic medicine as a first-line therapeutic option for chronic disease, including Fortune Brainstorm Health and Neurotech Leaders' Forum.

•We successfully launched the rebranding of our website and related marketing materials and increased ClearUP sales price from $149.00 to $169.99.

In 2022, we also invested in our product innovation and development programs as follows:

•We advanced the collaboration with Mount Sinai School of Medicine Division of Rhinology and Skull Base Surgery on a sham-controlled clinical trial to evaluate a new bioelectronic approach to treating postoperative pain after sinus surgery. This randomized sham-controlled clinical trial is currently .

•We initiated development work related to a potential product candidate in migraine as follows:

oCompleted market studies to identify needs in the treatment of migraine;

oIdentified multiple internal and external assets for device development;

oIdentified clinical partner: Allergy & Asthma Associates of Santa Clara Valley Research Center; and

oDeveloped a clinical trial protocol.

•We furthered our regulatory compliance through a formal re-certification audit by an external third party, BSI, and were found to be fully conforming to the ISO 13485 certification requirements leading to an extension of our certification.

•We broadened our IP portfolio receiving one new issuance, bringing issued claims to 96. We also filed 4 additional Patent Cooperation Treaty ("PCT") applications covering new indications.

In 2022, we also strengthened our management team with key new hires, and we now have a core team of 16 individuals. We have intentionally maintained a small core team at this stage of the Company. We have relied, and continue to rely, heavily on third-party service providers, including marketing agencies, clinical research organizations and academic research partnerships, finance and accounting support, legal support, and contract manufacturing organizations to carry out our operations. In connection with our IPO in November last year, we upgraded various aspects of the Company to align with public company standards.

First Quarter of Fiscal 2023

In the first quarter of 2023, we invested in our marketing, product design and e-commerce distribution infrastructure as follows:

•We were included on Fast Company's annual list of the world's most innovative companies (2023) in March 2023.

•We were named as the most pioneering bioelectronic medicine company by Global Health & Pharma Magazine.

In the first quarter of 2023, we also invested in our regulatory and quality continuous improvement programs as follows:

- We updated our quality management system to support the new EU medical device regulations 2017/745.

- We completed our process integration with Microart and ALOM, co-developing quality processes to facilitate defect detection early in the process, and forging partnerships in our quality management system as part of our continuous improvement of our product and processes.

- We developed and deployed key quality objectives and commenced monitoring key performance metrics to improve our focus on customer quality and to have the ability for proactive corrective action as required.

- We interfaced with our notified body (BSI) to finalize our plans for future certifications and to optimally stage our certification costs.

Components of Results of Operations

Revenue

Revenue is generated by the sale of our ClearUP and ancillary products, including accessories and accelerated shipping charges, and is net of return reserves. We currently sell directly to consumers through our own website, Amazon and Walmart. We also sell to major and specialty online retailers, such as BestBuy and FSAStore. Noninvasive bioelectronic medicine is an emerging market space that provides consumers with non-drug treatments for various diseases and ClearUP is the first FDA-approved bioelectronic treatment for sinus pain and congestion. We expect our sales to continue to grow as we further our market penetration efforts and implement price increases.

Cost of Sales

Cost of sales consists primarily of the materials and services to manufacture our products, the internal personnel costs to oversee manufacturing and supply chain functions, and the shipment of goods to customers. A significant portion of our cost of sales is currently in fixed and semi-fixed expenses associated with the management of manufacturing and supply chain. Cost of sales is expected to increase on an absolute basis as sales volume increases. Cost of sales is expected to decrease as a proportion of revenue with (i) the optimization of our supply chain, including the new MicroArt and ALOM partnerships, and (ii) the allocation of fixed and semi-fixed expenses over increasing unit sales volume over time.

Gross Margin

Gross margin has been and will continue to be affected by, and is likely to fluctuate on a quarterly basis due to, a variety of factors, including sales volumes, product and channel mix, pricing strategies, costs of finished goods, and product return rates, new product launches and potential new manufacturing partners and suppliers. We expect our gross margin to increase with future price increases, optimization of our product design and supply-chain, and increasing sales volume over which fixed and semi-fixed costs are allocated.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred to conduct research, including the discovery, development and validation of product candidates. Research and development expenses include personnel costs, including stock-based compensation expense, third-party contractor services, including development and testing of prototype devices, and maintenance of limited in-house research facilities. We expense research and development costs as they are incurred. We expect research and development expenses to increase with the discovery and validation of new product candidates.

Sales and Marketing Expenses

Sales and marketing expenses include personnel costs and expenses for advertising and other marketing services. Personnel costs consist of salaries, bonuses, benefits and stock-based compensation expense. We expect sales and marketing expenses to increase as we continue to expand our markets and distribution channels.

General and Administrative Expenses

General and administrative expenses include D&O insurance, personnel costs, expenses for outside professional services and other expenses. Personnel costs consist of salaries, bonuses, benefits and stock-based compensation expense. Outside professional services consist of legal, finance, accounting and audit services, and other consulting fees. We expect general and administrative expenses to increase at a modest rate as we grow our business.

Other Income / Expense, Net

Other income and expense include interest expense, change in fair value of derivative liabilities, loss on extinguishment of debt, and other income.

Results of Operations

Comparison of the Years Ended December 31, 2022 and 2021

The following table summarizes our results of operations (in thousands):

	Year Ended December 31,		
Statement of operations data:	**2022**	**2021**	**Change**
Revenue	$ 1,840	$ 1,257	$ 583
Cost of sales	1,541	1,295	246
Gross profit (loss)	299	(38)	337
Operating expenses:			
Research and development	1,730	878	852
Sales and marketing	2,792	1,787	1,005
General and administrative	5,875	2,930	2,945
Total operating expenses	10,397	5,595	4,802
Loss from operations	(10,098)	(5,633)	(4,465)
Other income (expense):			
Interest income (expense)	2	(1,823)	1,825
Change in fair value of derivative liabilities	—	436	(436)
Loss on extinguishment of debt	—	(1,636)	1,636
Other income	—	162	(162)
Total other income (expense)	2	(2,861)	2,863
Net loss	$ (10,096)	$ (8,494)	$ (1,602)

Revenue

Revenue (net of return reserve) increased $583 thousand (46%) to $1.8 million for the year ended December 31, 2022 from $1.3 million for the year ended December 31, 2021, which increase was primarily attributable to increased unit sales of 22% and a moderate price increase late in the third quarter. Unit sales were approximately 15,400 for the year ended December 31, 2022 and were approximately 12,600 for the year ended December 31, 2021. Ancillary revenues were less than 1.5% of total revenue for both of the years ended December 31, 2022 and 2021.

	Year Ended December 31,		
Statement of operations data (in thousands):	**2022**	**2021**	**Change**
Product Revenue			
Direct-to-consumer	$ 1,635	$ 764	$ 871
Reseller	416	610	(194)
Return Reserves	(211)	(117)	(94)
Revenue	$ 1,840	$ 1,257	$ 583

Direct-to-consumer product revenue increased $871 thousand (114%) to $1.6 million for the year ended December 31, 2022 from $764 thousand for the year ended December 31, 2021, which the increase was primarily attributable to increased unit sales of 104%. Direct-to-consumer unit sales were approximately 11,400 for the year ended December 31, 2022 compared to approximately 5,600 for the year ended December 31, 2021. Additionally, average selling prices in 2022 related to direct-to-consumer sales increased 6% over the prior year.

Reseller channel product revenue decreased $194 thousand (32%) to $416 thousand for the year ended December 31, 2022 from $610 thousand for the year ended December 31, 2021, which decrease was primarily attributable to decreased unit sales of 43%. Reseller channel unit sales were approximately 4,000 for the year ended December 31, 2022 and were approximately 7,000 for the year ended December 31, 2021. Average selling prices attributed to retail sales increased 19% in 2022 compared to 2021. The decrease in unit sales and the increase in average selling price were due to the termination of less profitable reseller channels in 2022.

Return reserves as a percentage of product revenue was approximately 10% for the year ended December 31, 2022, as compared to 9% for the year ended December 31, 2021.

Cost of Sales

Cost of sales for the year ended December 31, 2022 was $1.5 million compared to $1.3 million for the year ended December 31, 2021, an increase of $246 thousand, or 19%. The increase was primarily attributable to the 22% increase in overall unit sales.

Variable cost of goods sold includes product costs, fulfillment, shipping and purchase price variances and other inventory adjustments. Variable cost of goods sold was $1.3 million, or $87.04 per unit, for the year ended December 31, 2022, as compared to $1.0 million, or $82.46 per unit, for the year ended December 31, 2021. The increase in variable costs of goods sold was primarily due to dramatic price increases in several electronic components, during the summer of 2022, due to the global supply chain shortage phenomenon.

Fixed cost of goods sold includes third party product support and logistic fees and allocated overhead costs. Fixed cost of goods sold decreased to $203 thousand for the year ended December 31, 2022, as compared to $256 thousand for the year ended December 31, 2021, primarily due to lower indirect overhead costs as the Company refined its production management process.

Gross profit for the year ended December 31, 2022 was $299 thousand compared to a gross loss of $38 thousand for the year ended December 31, 2021.

Research and Development Expenses

Research and development expenses increased by $852 thousand to $1.7 million for the year ended December 31, 2022 from $878 thousand for the year ended December 31, 2021. The increase was primarily due to $308 thousand (including $108 thousand of noncash stock-based compensation costs) related to increased headcount and $300 thousand of costs related to additional investments in product candidate research and design. The emphasis of research and development activities in 2022 was primarily related to product research and design in the migraine therapeutic area, initiation of a double-blind randomized controlled trial for post-operative pain relief following sinus surgery, and enhancement of our intellectual property protection. Activities in 2021 were primarily focused on seeking FDA approval for a second indication for our ClearUP product line.

We expect to incur additional research and development expenses related to extending the indications for our product(s) in the near term.

Sales and Marketing Expenses

Sales and marketing expenses increased to $2.8 million for the year ended December 31, 2022, compared to $1.8 million for the year ended December 31, 2021. The increase was primarily due to $355 thousand related to the expansion of our marketing team and $639 thousand related sales efforts, including (i) expanding advertising platforms, (ii) growing our social media presence, (iii) upgrading and optimizing ecommerce infrastructure, online/website design, and (iv) other marketing initiatives.

We expect to continue to incur sales and marketing costs to drive adoption and market access in the United States market.

General and Administrative Expenses

General and administrative expenses increased to $5.9 million for the year ended December 31, 2022, compared to $2.9 million for the year ended December 31, 2021, primarily due to $599 thousand of legal and professional fees associated with the attempted acquisition of Reliefband, $663 thousand of increased insurance costs (primarily D&O insurance), $957 thousand of increased employee compensation and recruiting fees (including $231 thousand noncash stock-based compensation), $534 thousand of increased professional services and regulatory filing fees that are required for public companies, and $303 thousand of increased facilities and related expense associated with the relocation of the Company's headquarters.

We expect general and administrative expenses to scale with our operations and operating as a public company, amongst other things.

Other Income (Expense), Net

Other income (expense), net for the year ended December 31, 2021 was primarily related to the loss on the extinguishment of debt upon conversion of the convertible notes payable to common stock of $1.6 million, amortization of debt discount of $1.7 million and interest expense of $76 thousand offset by the income from the forgiveness of the PPP loan and the change in the fair value of the conversion feature derivative liabilities. There were no similar expenses in the year ended December 31, 2022.

Liquidity and Capital Resources

Sources of Liquidity

Since our formation in September 2016, we have devoted substantially all of our efforts to research and development, to regulatory clearance and to early market development and testing for our first product, released September 2019 in the United States. We are not profitable and have incurred net losses and negative cash flows from our operations in each year since our inception. During the years ended December 31, 2022 and 2021, we generated revenue of $1.8 million and $1.3 million, respectively. We incurred net losses of $10.1 million and $8.5 million, respectively, and used $8.9 million and $5.6 million of cash for operations, respectively. As of December 31, 2022, we had cash and cash equivalents of $3.5 million, working capital of $3.4 million and an accumulated deficit of $29.6 million.

We have financed our operations to date primarily through issuances of SAFE instruments, convertible notes and convertible preferred stock and the proceeds from registered offerings of our securities. In 2021, we completed our IPO, generating net proceeds to the Company of approximately $14.9 million, and we borrowed $2.6 million by issuing convertible notes payable, the outstanding balance of all of which converted into shares of our common stock in connection with our IPO. Subsequent to the year ended December 31, 2022, on February 13, 2023, we sold and issued 20,000,000 shares of our common stock to investors in a fully underwritten, registered public offering, resulting in net proceeds to the Company of approximately $3.6 million.

We expect that our operating expenses will increase significantly as we discover, acquire, validate and develop additional product candidates; seek regulatory approval and, if approved, proceed to commercialization of new products; obtain, maintain, protect and enforce our intellectual property portfolio; and hire additional personnel. Furthermore, we have incurred and will continue to incur additional costs associated with operating as a public company that we did not experience as a private company. Management expects to incur substantial additional operating losses for at least the next two years to expand our markets, complete development or acquisition of new product lines, obtain regulatory approvals, launch and commercialize our products and continue research and development programs. Based on the Company's current cash levels and burn rate, amongst other things, the Company believes its cash and financial resources may be insufficient to meet the Company's anticipated needs for the twelve months following the date of issuance of the financial statements for the year ended December 31, 2022, included elsewhere in this Report, which raises substantial doubt about the Company's ability to continue as a going concern within one year from the issuance date of the financial statements.

Plan of Operation and Future Funding Requirements

We use our capital resources primarily to fund marketing and advertising for ClearUP, development of our product candidates, and general operations. We expect that our operating expenses will increase significantly as we discover, acquire, validate and develop additional product candidates; seek regulatory approval and, if approved, proceed to commercialization of new products; obtain, maintain, protect and enforce our intellectual property portfolio; hire additional personnel; and maintain compliance with material government (in addition to environmental) regulations. We plan to increase our research and development investments to identify and develop new product candidates. Furthermore, we have incurred and will continue to incur additional costs associated with operating as a public company that we did not experience as a private company. We expect to continue to incur significant losses for the foreseeable future. At this time, due to the inherently unpredictable nature of research and new product adoption as well as other macroeconomic factors, we cannot reasonably estimate the costs we will incur and the timelines that will be required to complete development, obtain marketing approval and commercialize future product candidates, if at all. For the same reasons, we are also unable to predict how quickly we will generate revenue from ClearUP product sales or whether, or when, if ever, we may achieve profitability from the sales of one or more products. Clinical and preclinical development timelines, the probability of success, and costs can differ materially from expectations. In addition, we cannot forecast which product candidates may be best developed and/or monetized through future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

As previously disclosed, we encountered disruptions in our supply of various materials and components in 2022 due to the well-documented shortages and constraints in the global supply chain. Although we currently do not anticipate a supply shortage will continue to pose a material risk for the Company in the near term, we are continuing to evaluate alternative and secondary source suppliers in order to ensure that we are able to source sufficient components and materials to manufacture our products. Global supply chain shortages (especially when coupled with the increase in inflation and other economic factors) could result in an increase in the cost of the components used in our products, which could result in a decrease of our gross margins or in us having to increase the price at which we sell our products until supply chain constraints are resolved. Additionally, in the event that we are unable to source sufficient components and materials from our current suppliers, or to develop relationships with additional suppliers, to manufacture enough of our products to satisfy demand, we may have to cease or slow down production and our business operations and financial condition may be materially harmed and we may need to alter our plan of operation.

In addition to the foregoing, we may, from time to time, consider opportunities for strategic acquisitions that we believe will align with our growth plan, complement our product offerings and be in the best interest of the Company and our shareholders.

As previously disclosed, in October 2022, we entered into a definitive agreement to acquire substantially all of the assets of Reliefband Technologies, LLC ("Reliefband") that are used in connection with the development, manufacture, distribution, and sale of Reliefband's electronic nerve stimulation devices. After significant diligence, we felt that the Reliefband product line was highly complementary to our ClearUP product line and our existing commercial capabilities. Unfortunately, due to various factors, including without limitation, volatile and unfavorable market conditions and difficulties obtaining sufficient financing to fund the acquisition, we determined that proceeding with the acquisition was not in the Company's or its shareholders' bests interests at that time, and we mutually agreed to terminate the purchase agreement and abandon the Reliefband acquisition.

We remain committed to our growth strategy and will continue to evaluate strategic acquisition, licensing, and partnership opportunities. If an acquisition is identified and pursued, a substantial portion of our cash reserves may be required to complete such acquisition. If we identify an attractive acquisition that would require more cash to complete than we are willing or able to use from our cash reserves, we will consider financing options to complete the acquisition, including through equity and/or debt financings.

We have generated operating losses in each period since inception. We have incurred an accumulated deficit of $29.6 million through December 31, 2022. We expect to incur additional losses in the future as we expand both our marketing and research and development activities. Based on our current cash levels and burn rate, amongst other things, we believe our cash and financial resources may be insufficient to meet our anticipated needs for the next twelve months. As a result, we expect that we will need to raise additional capital to continue operating our business and fund our planned operations, including research and development, clinical trials and, if regulatory approval is obtained, commercialization of future product candidates.

We currently generate sales revenue direct-to-consumer though our own websites, Amazon.com and Walmart.com. We also sell to major and specialty U.S. online retailers such as BestBuy and FSAStore. Our ability to grow sales revenue will depend on successfully executing a comprehensive marketing campaign to drive additional sales through existing and new channels. Long-term growth will be commensurate with our ability to successfully identify, develop, and secure regulatory approval of one or more additional product candidates beyond ClearUP. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through private or public equity or debt financings, collaborative or other arrangements with corporate sources, or through other sources of financing. We do not know whether additional financing will be available on commercially acceptable terms, or at all, when needed. If our common stock is delisted from the Nasdaq Capital Market, it may limit our ability to raise additional funds. See "Nasdaq Deficiency Notice," below. If adequate funds are not available or are not available on commercially acceptable terms, our ability to fund our operations, support the growth of our business or otherwise respond to competitive pressures could be significantly delayed or limited, which could materially adversely affect our business, financial conditions or results of operations, and we may have to significantly delay, scale back or discontinue the development and commercialization of our products and/or future product candidates.

The timing and amount of our operating expenditures will depend largely on:

- our ability to raise additional capital if and when necessary and on terms favorable to the Company;
- the timing and progress of sales initiatives driving top-line revenue;
- the availability of electronic parts and other components for our products, as well as our ability to source such parts and components at favorable prices;
- the timing and adoption rate of ClearUP line extensions at lower cost of goods;
- the payment terms and timing of commercial contracts entered into for manufacturing and sales of our products to and through online third-party retailers;
- the timing and progress of preclinical and clinical development activities;
- the number and scope of preclinical and clinical programs we decide to pursue;
- the timing and amount of milestone payments we may receive under any future collaboration agreements;

•whether we close potential future strategic acquisition opportunities, and if we do, our ability to successfully integrate acquired assets and/or businesses with our own;

•our ability to source new business opportunities through licenses and research and development programs and to establish new collaboration arrangements;

•the costs involved in prosecuting and enforcing patent and other intellectual property claims;

•the cost and timing of additional regulatory approvals beyond those currently held by us;

•our efforts to enhance operational systems and hire additional personnel, including personnel to support finance, sales, marketing, operations and development of our product candidates and satisfy our obligations as a public company; and

•our efforts to maintain compliance with material government (including environmental) regulations.

Until such time, if ever, as we can generate substantial revenue from product sales, we expect to fund our operations and capital funding needs through equity and/or debt financings. We may also consider entering into collaboration arrangements or selectively partnering with third parties for clinical development and commercialization. The sale of additional equity would result in additional dilution to our stockholders. The incurrence of additional debt would result in debt service obligations, and the instruments governing such debt could provide for operating and financing covenants that would restrict our operations or our ability to incur additional indebtedness or pay dividends, among other items. If we raise additional funds through governmental funding, collaborations, strategic partnerships and alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are not able to secure adequate additional funding, we may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, and/or suspend or curtail planned programs. Any of these actions could materially and adversely affect our business, financial condition, results of operations and prospects.

Cash Flows

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

	Year Ended December 31,	
	2022	**2021**
Cash used in operating activities	$ (8,919)	$ (5,612)
Cash used in investing activities	$ (11)	$ —
Cash provided by (used in) financing activities	(528)	17,543
Net increase (decrease) in cash and cash equivalents	$ (9,458)	$ 11,931

Operating Activities

Net cash used in operating activities for the year ended December 31, 2022 was $8.9 million, which consisted primarily of net loss of $10.1 million decreased by non-cash charges of $572 thousand and further decreased by a net change of $605 thousand in our net operating assets and liabilities. The non-cash charges primarily consisted of stock-based compensation of $398 thousand and amortization of right-of-use assets of $164 thousand. The change in our net operating assets and liabilities was primarily due to an increase in accounts payable of $534 thousand and a decrease in prepaids and other current assets of $558 thousand, offset by an increase in inventory of $434 thousand and a decrease in lease liabilities of $178 thousand.

Net cash used in operating activities for the year ended December 31, 2021 was $5.6 million, which consisted primarily of net loss of $8.5 million decreased by non-cash charges of $3.3 million and increased by a net change of $403 thousand in our net operating assets. The non-cash charges primarily consisted of debt discount amortization of $1.7 million, loss on extinguishment of debt from conversion of convertible notes payable to common stock of $1.6 million, stock-based compensation of $57 thousand, accounts receivable allowances of $66 thousand and issuance of warrant for consulting services of $280 thousand offset by the change in fair value remeasurement of derivative liabilities of $436 thousand and the forgiveness of the PPP loan of $157 thousand. The change in our net operating assets and liabilities was primarily due to an increase in inventory and prepaid expenses, offset by an increase in accounts payable.

Investing Activities

Net cash used in investing activities during the year ended December 31, 2022 was related to the purchases of property and equipment. We had no investing activities during the year ended December 31, 2021.

Financing Activities

Our financing activities used $528 thousand of cash during the year ended December 31, 2022, which consisted of $584 thousand of deferred offering costs in connection with the sale of our common stock which closed subsequent to December 31, 2022, offset by $56 thousand of proceeds from the exercise of stock options.

Our financing activities provided $17.5 million of cash during the year ended December 31, 2021, which consisted of the proceeds from the IPO, net of issuance costs, of $14.9 million, convertible notes payable borrowings of $2.6 million and $62 thousand from issuance of common stock from the exercise of stock options, offset by notes payable repayment of $19 thousand.

Nasdaq Deficiency Notice

As discussed elsewhere in this Report, on January 26, 2023, we received Notice from Nasdaq that we were not in compliance with Nasdaq Listing Rule 5550(a)(2), as the minimum bid price of our common stock had been below $1.00 per share for 30 consecutive business days. The Notice had no immediate effect on the listing of our common stock, which continues to trade at this time on the Nasdaq Capital Market under the symbol "TIVC."

In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have 180 calendar days, or until July 25, 2023, to regain compliance with the minimum bid price requirement. To regain compliance, the closing bid price of our common stock must meet or exceed $1.00 per share for at least ten consecutive business days during this 180 calendar day period. In the event we do not regain compliance by July 25, 2023, we may be eligible for an additional 180 calendar day grace period if we meet the continued listing requirement for market value of publicly held shares ($1 million) and all other initial listing standards for the Nasdaq Capital Market, with the exception of the minimum bid price, and provide written notice to Nasdaq of our intention to cure the deficiency during the second compliance period by effecting a reverse stock split, if necessary. If we do not regain compliance within the allotted compliance period(s), Nasdaq will provide notice that the Company's common stock will be subject to delisting from the Nasdaq Capital Market. In that event, we may appeal such delisting determination to a hearings panel.

We will continue to monitor the closing bid price of our common stock and are considering options to resolve our noncompliance with the minimum bid price requirement, but we expect that we will implement a reverse stock split.

Known Trends or Uncertainties

As discussed elsewhere in this Report, the world has been affected by the COVID-19 pandemic, the ongoing conflict between Russia and Ukraine, economic uncertainty in human capital management ("HCM") and certain other macroeconomic factors. Inflation has risen, Federal Reserve interest rates have increased recently, and the general consensus among economists suggests that we should expect a higher recession risk to continue for the near term. Climate change continues to be an intense topic of public discussion and is adding additional challenges and financial burden due to impending preparations and changes in the customer mindset. These factors, amongst other things, could result in further economic uncertainty and volatility in the capital markets in the near term, and could negatively affect our operations. The pandemic and recent economic volatility have negatively impacted our business in various ways over the last two years, including, more recently, as a result of global supply chain constraints at least partially attributable to the pandemic. We will continue to monitor material impacts on our HCM strategies, including potential of employee attrition, amongst other things.

We encountered disruptions in our supply of various materials and components in 2022 due to the well-documented shortages and constraints in the global supply chain. We experienced increased pricing, longer lead-times, unavailability of product and limited supplies, protracted delivery dates, and shortages of certain parts and supplies that were necessary components for our products. As a result, we carried increased inventory balances to ensure availability of necessary products and to secure pricing. Although we currently do not anticipate a supply shortage will continue to pose a material risk for the Company in the near term, we are continuing to evaluate alternative and secondary source suppliers in order to ensure that we are able to source sufficient components and materials to manufacture our products. Global supply chain shortages (especially when coupled with the increase in inflation and other economic factors) could result in an increase in the cost of the components used in our products, which could result in a decrease of our gross margins or in us having to increase the price at which we sell our products until supply chain constraints are resolved. Additionally, in the event that the price of our components increases significantly or we are unable to source sufficient components and materials from our current suppliers, or to develop relationships with additional suppliers, to manufacture enough of our products to satisfy demand, we may have to cease or slow down production and our business operations and financial condition may be materially harmed and we may need to alter our plan of operation.

U.S. and global markets are experiencing volatility and disruption following the escalation of geopolitical tensions and the ongoing military conflict between Russia and Ukraine. Although the length and impact of the ongoing military conflict is highly unpredictable, the conflict in Ukraine could lead to market disruptions, including significant volatility in commodity prices, credit and capital markets, as well as further supply chain interruptions. Additionally, the recent military conflict in Ukraine has led to sanctions and other penalties being levied by the United States, European Union and other countries against Russia. Additional potential sanctions and penalties have also been proposed and/or threatened. Russian military actions and the resulting sanctions could adversely affect the global economy and financial markets and lead to instability and lack of liquidity in capital markets, potentially making it more difficult for us to obtain additional funds.

Although our business has not been materially impacted by the ongoing military conflict between Russian and Ukraine to date, it is impossible to predict the extent to which our operations, or those of our suppliers and manufacturers, will be impacted in the short and long term, or the ways in which the conflict may impact our business. The extent and duration of the military action, sanctions and resulting market disruptions are impossible to predict, but could be substantial. We are continuing to monitor the situation in Ukraine and globally and assessing its potential impact on our business.

Additionally, in March 2023, Silicon Valley Bank and Signature Bank were closed and taken over by the FDIC, which created significant market disruption and uncertainty for those who bank with those institutions, and which raised significant concern regarding the stability of the banking system in the United States, and in particular with respect to regional banks. If other banks and financial institutions enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, our ability to access our cash and cash equivalents may be threatened and such events could have a material adverse effect on our business and financial condition.

As a result of these global issues and other macroeconomic factors, it has been difficult to accurately forecast our revenues or financial results, especially given the near and long term impact of the pandemic, and geopolitical issues, inflation, the Federal Reserve interest rate increases and the potential for a recession. In addition, while the potential impact and duration of these issues on the economy and our business may be difficult to assess or predict, these world events have resulted in, and may continue to result in, significant disruption of global financial markets, and may reduce our ability to access additional capital, which could negatively affect our liquidity in the future. Our results of operations could be materially below our forecasts as well, which could adversely affect our results of operations, disappoint analysts and investors, or cause our stock price to decline. Furthermore, a decrease in orders in a given period could negatively affect our revenues in future periods.

These global issues and events may also have the effect of heightening many risks associated with our customers and supply chain. We may take further actions that alter our operations as may be required by federal, state, or local authorities from time to time, or which we determine are in our best interests. In addition, we may decide to postpone or abandon planned investments in our business in response to changes in our business, which may impact our ability to attract and retain customers and our rate of innovation, either of which could harm our business.

Inflation

Inflation has increased recently and is expected to continue to increase for the near future. Inflationary factors, such as increases in the cost of our products (and components thereof), interest rates, overhead costs and transportation costs may adversely affect our operating results. Although we do not believe that inflation has had a material impact on our financial position or results of operations to date, we may experience some effect in the near future (especially if inflation rates continue to rise) due to supply chain constraints, consequences associated with and the ongoing conflict between Russia and Ukraine, employee availability and wage increases, trade tariffs imposed on certain products from China and increased product pricing due to semiconductor product shortages.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements.

Contractual Obligations and Commitments

Office Lease

The Company executed a noncancelable operating lease for approximately 9,091 square feet of office space in Hayward, California in November 2021 as its headquarters. There lease expires in October 2025 and there is no option to renew for an additional term. The Company is obligated to pay, on a pro-rata basis, real estate taxes and operating costs related to the premises.

Lease costs recorded during the years ended December 31, 2022 and 2021 was $223 thousand and $49 thousand, respectively.

We enter into contracts in the normal course of business with our contract manufacturer and other vendors to assist in the manufacturing of our products and performance of our research and development activities and other services for operating purposes. These contracts generally provide for termination for convenience after expiration of an advance notice period ranging from 0 to 60 days, and therefore are cancelable contracts and not included in the table of contractual obligations and commitments.

Critical Accounting Policies and Significant Judgments and Estimates

The preparation of our financial statements in conformity with accounting principles generally accepted in the United States requires us to make estimates and judgments that affect the amounts reported in those financial statements and accompanying notes. Although we believe that the estimates we use are reasonable, due to the inherent uncertainty involved in making those estimates, actual results reported in future periods could differ from those estimates.

We believe that the accounting policies described below involve a high degree of judgment and complexity. Accordingly, these are the policies we believe are the most critical to aid in fully understanding and evaluating our financial condition and results of our operations.

Revenue Recognition

The Company recognizes revenue from product sales in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 606, Revenue from Contracts with Customers ("Topic 606"). The standard applies to all contracts with customers, except contracts that are within scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments.

Under Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are in within the scope of Topic 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inceptions, once the contract is determined to be within the scope of Topic 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

The Company sells its products direct-to-consumer and third-party online resellers. Revenue is recognized when control of the promised goods is transferred to the customers or retailer, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those goods and services. Revenue associated with products holding rights of return are recognized when the Company concludes there is not a risk of significant revenue reversal in the future periods for the expected consideration in the transaction.

The Company may receive payments at the onset of the contract and before goods have been delivered. In such instances, the Company records a deferred revenue liability. The Company recognizes these contract liabilities as sales after the revenue criteria are met.

The Company relies on third parties to have procedures in place to detect and prevent credit card fraud, as the Company has exposure to losses from fraudulent charges. The Company records the losses related to chargebacks as incurred.

The Company has also elected to exclude from the measurement of the transaction price sales taxes remitted to governmental authorities.

Stock-Based Compensation

We measure all stock options and other stock-based awards granted to our employees, directors, consultants and other non-employee service providers based on the fair value on the date of the grant. Compensation expense related to awards to employees and directors with service-based vesting conditions is recognized on a straight-line basis based on the grant date fair value over the associated service period of the award, which is typically the vesting term. Compensation expense related to awards to employees with performance-based vesting conditions is recognized based on grant date fair value over the requisite service period using the accelerated attribution method to the extent achievement of the performance condition is probable. Non-employee option awards are measured at the earlier of the commitment date for performance by the counterparty or the date when the performance is complete, and compensation expense is recognized in the same manner as if we had paid cash for goods or services.

We classify stock-based compensation expense in our statement of operations in the same way the award recipient's payroll costs are classified or in which the award recipients' service payments are classified.

We use the Black-Scholes option pricing model to estimate the fair value of stock options on the date of grant. Using the Black-Scholes option pricing model requires management to make significant assumptions and judgments. We determined these assumptions for the Black-Scholes option-pricing model as discussed below.

•*Expected Term*—The expected term represents the period that the stock-based awards are expected to be outstanding. As we do not have sufficient historical experience for determining the expected term of the stock option awards granted, we based our expected term for awards issued to employees and non-employees using the simplified method which is presumed to be the midpoint between the vesting date and the end of the contracted term.

•*Risk-Free Interest Rate*—The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the date of grant for zero-coupon U.S. Treasury constant maturity notes with terms approximately equal to the stock-based awards' expected term.

•*Expected Volatility*—Since we do not have a trading history of common stock, the expected volatility was derived from the average historical stock volatilities of the common stock of several public companies within the industry that we consider to be comparable to our business over a period equivalent to the expected term of the stock-based awards.

•*Dividend Rate*—The expected dividend rate is zero as we have not paid and do not anticipate paying any dividends in the foreseeable future.

•*Fair Value of Common Stock*—Prior to our initial public offering ("IPO"), the fair value of the shares of common stock underlying the stock-based awards was determined by our board of directors with input from management. Because there was no public market for our common stock, our board of directors determined the fair value of our common stock at the time of grant of the stock-based award by considering a number of objective and subjective factors, including having valuations of the common stock performed by a third-party valuation specialist, as further described below.

As of December 31, 2022, the total compensation cost related to nonvested service-based awards not yet recognized is $894 thousand. The weighted-average period over which the nonvested awards is expected to be recognized is 2.98 years. The aggregate intrinsic value of stock options outstanding as of December 31, 2022 was $62 thousand, of which $62 thousand related to vested options and none was related to unvested options.

Common Stock Valuations

The fair value of the shares of common stock underlying our stock-based awards prior to our IPO was determined by our board of directors with input from management and contemporaneous third-party valuations. We believe that our board of directors had the relevant experience and expertise to determine the fair value of our common stock prior to our IPO. Given the absence of a public trading market of our common stock, and in accordance with the *American Institute of Certified Public Accountants Practice Aid, Valuation of Privately-Held Company Equity Securities Issued as Compensation*, our board of directors exercised reasonable judgment and considered numerous and subjective factors to determine the best estimate of the fair value of our common stock at each grant date. These factors include:

•contemporaneous valuations of our common stock performed by independent third-party specialists;

•the prices, rights, preferences and privileges of our convertible preferred stock relative to those of our common stock;

•the prices of common or convertible preferred stock sold to third-party investors by us;

•lack of marketability of our common stock;

•our actual operating and financial performance;

•current business conditions and projections;

•hiring of key personnel and the experience of our management;

•the history of the company and notable milestones;

•our stage of development;

•likelihood of achieving a liquidity event, such as an initial public offering or a merger or acquisition of our company given prevailing market conditions;

•the market performance of comparable publicly traded companies; and

•the U.S. and global capital market conditions.

In valuing our common stock, our board of directors determined the equity value of our business using the hybrid method with input from management and contemporaneous third-party valuations. The hybrid method is based upon the probability-weighted value across two scenarios, being (i) successfully consummating an initial public offering and (ii) alternative scenarios in which an initial public offering is not consummated. The hybrid method can be a useful alternative to explicitly modeling all probability-weighted expected return scenarios in situations when the company has transparency into one or more near term exits but is unsure about what will occur if current plans do not materialize. In the first scenario, the potential exit date, the probability exit value and the likelihood of interim financings were considered. In the second scenario, which was assigned the residual probability, the potential exit date, the equity volatility, the assumed interest rate, the dividend yield and equity inflection points at which the allocation of proceeds changes were considered. The valuation method considers the total number of shares authorized and outstanding, as well as recent issuances of both preferred and common stock.

Application of these approaches involves the use of estimates, judgment and assumptions that are highly complex and subjective, such as those regarding the time to the liquidation event and volatility. Changes in these estimates and assumptions or the relationships between these assumptions impact our valuations as of each valuation date and may have a material impact on the valuation of common stock.

Following our IPO, the fair value of each share of underlying common stock will be based on the closing price of our common stock as reported by the Nasdaq Capital Market, or such other national securities exchange that our common stock is listed on, on the date of grant or as otherwise provided in the proposed 2021 Equity Incentive Plan. Future expense amounts for any particular period could be affected by changes in our assumptions or market conditions.

Emerging Growth Company Status

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and may remain an emerging growth company until December 31, 2026. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

•reduced disclosure about our executive compensation arrangements;

•no non-binding stockholder advisory votes on executive compensation or golden parachute arrangements; and

•exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

We have taken advantage of reduced reporting requirements in this Report and may continue to do so until such time that we are no longer an emerging growth company. We will remain an "emerging growth company" until the earliest of (a) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more, (b) December 31, 2026, the last day of the fiscal year following the fifth anniversary of the completion of our IPO, (c) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years or (d) the date on which we are deemed to be a large accelerated filer under the rules of the SEC. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of the extended transition period for complying with new or revised accounting standards. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

In addition, we are also a smaller reporting company as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as (i) our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

Derivative Instruments

The Company issued certain convertible notes in 2018, 2019, 2020 and 2021, which notes contained put options. These embedded put options were not considered clearly and closely related to the debt host and resulted in embedded derivatives that must be bifurcated and accounted for separately from the debt host. Accordingly, the Company recorded these as a derivative financial liability in the year ended December 31, 2021.

Derivative financial liabilities are initially recorded at fair value, with gains and losses arising for changes in fair value recognized in the statement of operations at each period end while such instruments are outstanding. The liability was valued using a probability weighted expected return model. The derivative financial liability related to convertible notes issued in 2020 and 2021 was derecognized upon conversion of the convertible notes into shares of Company common stock in 2021.

Recent Accounting Pronouncements

For a description of recent accounting pronouncements, see Note 2 of the notes to our audited financial statements for the year ended December 31, 2022, included elsewhere in this Report.

Item 7A – Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

Item 8 - Financial Statements and Supplementary Data

See the financial statements included elsewhere in this Report beginning at page F-1, which are incorporated herein by reference.

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

Our Chief Executive Officer and our Chief Financial Officer, after evaluating our "disclosure controls and procedures" (as defined in Securities Exchange Act of 1934 (the "Exchange Act") Rules 13a-15(e) and 15d-15(e) as of the end of the period covered by this Report (the "Evaluation Date"), have concluded that as of the Evaluation Date, our disclosure controls and procedures are effective to ensure that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in Securities and Exchange Commission rules and forms, and to ensure that information required to be disclosed by us in such reports is accumulated and communicated to our management, including our chief executive officer and chief financial officer, where appropriate, to allow timely decisions regarding required disclosure.

Management Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP. Management assessed our internal control over financial reporting as of December 31, 2022, the end of our fiscal year. Management based its assessment on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Management's assessment included evaluation of elements such as the design and operating effectiveness of key financial reporting controls, process documentation, accounting policies, and our overall control environment.

In connection with this assessment, management determined that there was a material weakness in the Company's internal controls over financial reporting due to the small size of our accounting and financial reporting team and the fact that the Company has only recently implemented new processes and procedures to mitigate the risk of a material misstatement. 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. Due to the material weakness, management concluded that as of December 31, 2022, the Company's internal control over financial reporting was not effective. Management reviewed the results of management's assessment with the Audit Committee of our Board of Directors.

In order to address and resolve the weakness, the Company is evaluating the optimal accounting and finance personnel level/resources, to the extent feasible based upon the company's financial position, and continue to enhance its relevant processes and procedures.

As a result of the enactment of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, and the resulting amendment of Section 404 of the Sarbanes-Oxley Act of 2002, as a smaller reporting company, the Company is not required to provide an attestation report by our independent registered public accounting firm regarding internal control over financial reporting for the fiscal year ended December 31, 2022 or thereafter, until such time as we are no longer eligible for the exemption for smaller issuers set forth within the Sarbanes-Oxley Act.

Inherent Limitations on Effectiveness of Controls

Our management, including our Chief Executive Officer and our Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent or detect all errors and all fraud. A 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. The design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Further, 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, if any, have been detected. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Projections of any evaluation of the effectiveness of controls to future periods are subject to risks. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures.

Changes in Internal Control over Financial Reporting

During the fourth quarter of the year ended December 31, 2022, we took various steps to strengthen our internal controls over financial reporting, including, without limitation:

- completed standard segregation of duty templates for each significant accounting and reporting process;
- identified and implemented roles across the entire accounting process cycle to ensure appropriate segregation of duties;
- implemented quarterly inventory count procedures at all inventory sites, which commenced in the second quarter of fiscal 2022; and
- completed our internal control design and formalized various internal control processes and procedures.

As we continue to evaluate and take actions to improve our internal control over financial reporting, we may determine to take additional actions to address control deficiencies or determine to modify certain of the remediation measurements that we are anticipating to make, which may include, without limitation, retaining a third party to assist with the implementation of any such remediations. The retention of third-party service providers for purposes of remediation may involve us incurring material costs in the future.

Item 9B - Other Information

None.

Item 9C – Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10 – Directors, Executive Officers, and Corporate Governance

Directors

The following table sets forth the names, ages, and positions of our directors as of March 24, 2023. There are no arrangements or understandings between any director and any other person pursuant to which any director was or is to be selected as a director.

Name	Age	Position
Jennifer Ernst	54	Chief Executive Officer and Director
Sheryle Bolton	76	Chair of the Board
Karen Drexler	63	Director
Dean Zikria	55	Director

Jennifer Ernst is a co-founder and has served as our Chief Executive Officer and as a director since September 2016; she also served as our Chief Financial Officer from September 2016 to July 2021. Previously, Ms. Ernst served as the Chief Executive Officer of the U.S. subsidiary of Thin Film Electronics ASA from April 2011 to December 2015. Ms. Ernst also served as the Chief Strategy Officer of Thin Film Electronics ASA from January 2014 to December 2015, where she established and guided the strategic planning process across all business functions and four separate product lines. Ms. Ernst also worked for Xerox PARC for over 20 years, where she held multiple go-to-market roles, including as the Director of Business Development. Ms. Ernst previously served as a director of FlexTech Alliance, the U.S. national consortium for flexible and printed electronics, for four years, including one year as the Chair. Ms. Ernst earned her Master of Business Administration degree from Santa Clara University.

Sheryle Bolton has served as a director on our board since July 16, 2019, and as Chair of the board since August 18, 2021. She is an experienced serial technology entrepreneur, public company chief executive officer, corporate executive, speaker, board member, and investor. Ms. Bolton has been a corporate executive in financial services, media, and health care and has served on the boards of private and public corporations, ranging from large groups of mutual funds to technology and finance companies, as well as non-profits, including an NGO, where she served as Chair of the audit committee, focused on financing small businesses in Asia and Sub-Saharan Africa and Berry College, a private college with an internationally known work-study program. Ms. Bolton worked in private equity investing as an investment banker at Merrill Lynch Capital Markets, as Director of Strategy at Home Box Office and in asset management at Rockefeller & Co. In her roles as Chief Executive Officer, she raised significant funding for several start-ups from angels, venture capital, and the public and institutional markets. She previously served as Chief Executive Officer of Scientific Learning Corporation, a health care and educational technology company, where she led the company from pre-product to IPO with venture funding from Warburg Pincus. She also served as Chief Executive Officer and Chair of the public company after completion of their IPO. She has served as a board member for more than forty Scudder-Kemper mutual funds. From 2015 to 2021, Ms. Bolton was an adjunct Professor of Practice at Hult International Business School, where she taught entrepreneurship and finance courses in graduate and undergraduate programs. She has also been an invited speaker on business and entrepreneurship in the U.S., Asia, the Pacific Rim, Latin America, and Europe. Harvard Business School recognized Ms. Bolton as one of its most influential female graduates in Silicon Valley and the San Francisco Bay Area. She was a recipient of the first Springboard All-Women's IPO Class award, formerly served as Chair of Watermark, the largest organization in Silicon Valley for female executives and entrepreneurs, and is a recipient of the "A Woman Who Made Her Mark" award, among many other honors and recognition. Ms. Bolton started her career as a Peace Corps Volunteer in Africa. She holds a Bachelor of Arts. and a Master of Arts in Linguistics from the University of Georgia and a Master of Business Administration from Harvard Business School.

Karen Drexler has served as a director on our board since July 16, 2019. Ms. Drexler is a serial entrepreneur with expertise in the fields of digital health, medical devices and diagnostics. From September 2014 to June 2020 she served as board member of, and from June 2016 until June 2020, she was the Chief Executive Officer of, Sandstone Diagnostics, Inc., a private company developing instruments and consumables for point-of-care medical testing. Ms. Drexler also serves on the boards of ResMed (NYSE: RSMD), OutSet Medical (NASDAQ: OM), EBR Systems (ASX: EBR), VIDA Health, a leading company in AI-powered lung intelligence solutions and analytics, and Huma.ai, a medical intelligence company. From 2011 to 2017, she served as Chair of the board of Hygieia, Inc., a digital insulin therapy company, where she remains involved as an advisor to the chief executive officer. She also acts as a senior strategic advisor for other early-stage companies and spent 11 years on the board of the Keller Center for Innovation in Engineering Education at Princeton University. Ms. Drexler has served on numerous private company boards in the fields of diagnostics, medical devices, and digital health. She is an active mentor and advisor with Astia, a global nonprofit that supports high-potential female founders. She is a founding member of Astia Angels, a network of individual investors who fund such founders, and a lead mentor with StartX, the Stanford University incubator. She is also on the Life Science and Women's Health Councils for Springboard, an accelerator for women-led technology-oriented companies. Through her work with Astia, Springboard, and StartX, she interacts with many promising young medtech companies. Ms. Drexler was a founder, president, and Chief Executive Officer of Amira Medical Inc., a private company focused on minimally invasive glucose monitoring technology, from 1996 until it was sold to Roche Holding AG in 2001. Before joining Amira Medical, she held management roles at LifeScan and played a key role in its sale to Johnson & Johnson (NYSE: JNJ). Ms. Drexler graduated magna cum laude with a Bachelor of Science in Chemical Engineering from Princeton University and earned a Master of Business Administration with honors from the Stanford University Graduate School of Business.

Dean Zikria has served as a director on our board since July 10, 2019. Mr. Zikria brings deep industry experience in allergy and asthma as well as other chronic diseases to the board. Since August 2019, Dean has been the Founder, CEO and Chairman of Mind Machine LLC, a Silicon Valley based marketing/advertising agency - focused on the MedTech industry. From June 1, 2021 until January 2023, he served as the Chief Commercial Officer at Intuity Medical Inc., a Silicon Valley MedTech company launching a highly disruptive glucose meter in the diabetes industry. In addition, he has served as Chairman of DZ Advisors, LLC, a company founded by Mr. Zikria in 2017 that provides consulting and advisory services to the medtech, biotech, digital health and pharmaceutical industries; since inception, where he also served as President from December 2017 until May 31, 2021. Mr. Zikria also sits on the boards of the following privately held companies: AsthmaTek, Inc., a startup digital health company in the asthma space; Paneau Inc., a technology company placing targeted advertising in ride shares; Brev.Dev, Inc., a technology company developing a disruptive platform to aid developers. Dean previously served as Chief Executive Officer of Spirosure Inc., a FeNO detection company for asthma diagnostics, from 2014 to 2017. Additionally, he previously served as head of global marketing for Johnson & Johnson's Animas Corporation within their medical device & diagnostics division. He was head of strategy for Pfizer Pharmaceuticals U.S. Cardiovascular Unit, a division with approximately $7 billion in annual revenues. Mr. Zikria brings experience in strategic planning, scenario planning and analysis, and mergers and acquisitions, including sourcing, transactions and integration.

Board Committees

The Board has three standing committees, the Audit Committee, the Compensation Committee, and the Corporate Governance and Nominating Committee, to assist it with the performance of its responsibilities. The Board designates the members of these committees and the committee chairs based on the recommendation of the Corporate Governance and Nominating Committee. The Board has adopted written charters for each of these committees, all of which can be found on our corporate website at https://tivichealth.com/investor/. The chair of each committee develops the agenda for that committee and determines the frequency and length of committee meetings.

Audit Committee

Our Board has established an Audit Committee which consists of three independent directors, Dean Zikria, Sheryle Bolton and Karen Drexler, with Sheryle Bolton serving as the Chairperson. The Board has determined that each member of the Audit Committee meets the independence requirements of Rule 10A-3 of the Exchange Act, and the applicable rules of Nasdaq, and has sufficient knowledge in financial and auditing matters to serve on the Audit Committee. The committee's primary duties include:

- selecting a firm to serve as the independent registered public accounting firm to audit our financial statements;
- reviewing and discussing with management and our independent auditor our annual and quarterly financial statements and related disclosures, including disclosure under "Management's Discussion and Analysis of Financial Condition and Results of Operations," and the results of the independent auditor's audit or review, as the case may be;
- reviewing our financial reporting processes and internal control over financial reporting systems and the performance, generally, of our internal audit function;
- overseeing the audit and other services of our independent registered public accounting firm and being directly responsible for the appointment, independence, qualifications, compensation and oversight of the independent registered public accounting firm, which reports directly to the Audit Committee;
- providing an open means of communication among our independent registered public accounting firm, management, our internal auditing function and our Board;
- reviewing any disagreements between our management and the independent registered public accounting firm regarding our financial reporting;
- preparing the Audit Committee report for inclusion in our proxy statement for our annual stockholder meetings;
- establishing procedures for complaints received regarding our accounting, internal accounting control and auditing matters; and
- approving all audit and permissible non-audit services conducted by our independent registered public accounting firm.

The Board has determined that Sheryle Bolton is an "audit committee financial expert," as that term is defined in the rules promulgated by the SEC pursuant to the Sarbanes-Oxley Act of 2012. The Board has further determined that each of the members of the Audit Committee is financially literate and that at least one member of the committee has accounting or related financial management expertise, as such terms are interpreted by the Board in its business judgment.

Compensation Committee

Our Board has established a Compensation Committee which consists of three independent directors (as defined under the general independence standards of Nasdaq and our Corporate Governance Guidelines): Dean Zikria, Sheryle Bolton and Karen Drexler are each a "non-employee director" (within the meaning of Rule 16b-3 of the Exchange Act). Karen Drexler serves as Chairperson of the Compensation Committee. The committee's primary duties include:

- reviewing all overall compensation policies and practices;
- approving corporate goals and objectives relevant to executive officer compensation and evaluate executive officer performance in light of those goals and objectives;
- determining and approving executive officer compensation, including base salary and incentive awards;

•reviewing and approving, or making recommendations to the Board regarding, compensation plans; and

•administering our equity incentive plan, subject to Board approval.

Our Compensation Committee determines and approves elements of executive officer compensation, except that compensation of our chief executive officer and chief financial officer will be subject to review and approval by the Board. It also provides recommendations to the Board with respect to non-employee director compensation. The Compensation Committee may not delegate its authority to any other person, other than to a subcommittee.

Corporate Governance and Nominating Committee

Our Board has also established a Corporate Governance and Nominating Committee which consists of Dean Zikria, Sheryle Bolton and Karen Drexler, with Karen Drexler serving as Chairperson. The committee's primary duties include:

•recruiting new directors, consider director nominees recommended by stockholders and others and recommend nominees for election as directors;

•reviewing the size and composition of our Board and committees;

•overseeing the evaluation of the Board;

•recommending actions to increase the Board's effectiveness; and

•developing, recommending and overseeing our corporate governance principles, including our Code of Business Conduct and Ethics and our Corporate Governance Guidelines.

Nomination of Directors

Our Corporate Governance and Nominating Committee is charged with making recommendations to our Board regarding qualified candidates to serve as members of the Board. The Corporate Governance and Nominating Committee's goal is to assemble a board of directors with the skills and characteristics that, taken as a whole, will assure a strong board of directors with experience and expertise in all aspects of corporate governance. Accordingly, the committee believes that candidates for director should have certain minimum qualifications, including personal integrity, strength of character, an inquiring and independent mind, practical wisdom, and mature judgment. In evaluating director nominees, the Corporate Governance and Nominating Committee considers the following factors:

(1) The appropriate size of the Board;

(2) The Company's needs with respect to the particular talents and experience of its directors;

(3) The knowledge, skills, and experience of nominees, including experience in technology, business, finance, administration, and/or public service; and

(4) Relevant Nasdaq, SEC, California, and investor recommendations and requirements.

Other than the foregoing, there are no stated minimum criteria for director nominees, although the Corporate Governance and Nominating Committee may also consider such other factors as it deems to be in the Company's and its stockholders' best interests, including diversity. Although the Company does not have a formal policy with regard to the consideration of diversity in identifying director nominees, the Corporate Governance and Nominating Committee is committed to complying with the diversity requirements recently adopted by Nasdaq and the State of California, as applicable. The Corporate Governance and Nominating Committee does, however, believe it appropriate for at least one member of the Board to meet the criteria for an "audit committee financial expert," as defined by SEC rules, and for a majority of the members of the Board to meet the definition of an "independent director" under Nasdaq listing standards. The Corporate Governance and Nominating Committee also believes it is appropriate for our chief executive officer to serve on our Board.

The Corporate Governance and Nominating Committee identifies nominees by first evaluating the current members of the relevant class of our Board that are willing to continue in service. Current members of our Board with skills and experience that are relevant to our business and who are willing to continue in service are considered for re-nomination, but the committee at all times seeks to balance the value of continuity of service by existing members of the Board with that of obtaining a new perspective. If any member of the relevant class of our Board does not wish to continue in service at the time that their term is scheduled to expire, the Corporate Governance and Nominating Committee's policy is to not re-nominate that member for re-election. The Corporate Governance and Nominating Committee identifies the desired skills and experience of a new nominee, and then uses its network and external resources to solicit and compile a list of eligible candidates.

We do not have a formal policy concerning stockholder recommendations of nominees for director to the Corporate Governance and Nominating Committee as, to-date, we have not received any recommendations from stockholders requesting the Corporate Governance and Nominating Committee to consider a candidate for inclusion among the Company's slate of nominees in our proxy statements. However, the absence of such a policy does not mean that such recommendations will not be considered. Notwithstanding the foregoing, stockholders wishing to recommend a candidate for election must follow the process outlined in Section 2.5 of our amended and restated bylaws and comply with the rules established by the SEC, including Rule 14a-19(b) of the Exchange Act, as applicable.

Executive Officers

The following table sets forth the names, ages, and positions of our executive officers as of March 24, 2023. There are no arrangements or understandings between any executive officer and any other person pursuant to which any executive officer was selected to serve in such role.

Name	Age	Position
Jennifer Ernst	54	Chief Executive Officer and Director
Veronica Cai	47	Chief Financial Officer and Secretary
Blake Gurfein, PhD	39	Chief Scientific Officer
Ryan Sabia	37	Chief Operating Officer

Jennifer Ernst. Please see Ms. Ernst's biography under the section entitled "Directors," above.

Veronica Cai joined the Company on April 1, 2022 with two and a half decades of finance and accounting experience, specializing in scaling finance organizations in early development stage to post commercial, large international corporations and IPOs. She has held various senior financial executive roles in both publicly listed companies and private-equity backed technologies and healthcare businesses, assisting with the navigation through transitions between the different phases of business and fundraising efforts of such businesses. Prior to joining the Company, Ms. Cai served as the Vice President of Accounting & Finance at RefleXion Medical, Inc., a private medical device company located in California, from April 2020 to February 2022. Prior to that, from February 2019 to April 2020, Ms. Cai served as the Principal Accounting Officer and Corporate Controller for Catalyst Biosciences, Inc. (NASDAQ:CBIO), biopharmaceutical company focused on developing protease therapeutics, where she oversaw all accounting functions and assisted their corporate management team with the preparation and filing of all of the Company's SEC regulatory filings. From April 2016 to December 2018, Ms. Cai served as a director and the Assistant Controller of Zogenix, Inc. (previously, NASDAQ:ZGNX), a pharmaceutical company focused on developing and commercializing therapies for certain rare diseases. Additionally, from October 1998 to April 2016, Ms. Cai served in a number of financial and accounting roles advancing her accounting and auditing skills serving on behalf of public and privately-held companies throughout California. Ms. Cai also was an Inspections Specialist at the Public Company Accounting Board (PCAOB) from September 2012 to February 2015. She received Bachelors of Science Degrees in Business Administration and Accounting and Finance from San Francisco State University.

Blake Gurfein, PhD serves as our Chief Scientific Officer, a role that he has held since March 2019, prior to which he served as our Vice President of Research commencing in January 2018. Dr. Gurfein leads our clinical and scientific research. In addition to his full-time role with the Company, he has also served as an Adjunct Assistant Professor of Medicine at the University of California San Francisco since 2012. Dr. Gurfein is an expert in neuromodulation device development and has served as a research executive and consultant for several medical device and pharma companies, including as Chief Scientific Officer of Rio Grande Neurosciences from 2014 to 2017 and as a Medical Writer for EMD Serono/Pfizer in 2012. Dr. Gurfein's prior research in neuroscience and immunology was funded by the National Institutes of Health and philanthropic donors, yielding high-impact journal publications. Dr. Gurfein has a Ph.D. in Neuroscience from the Icahn School of Medicine at Mount Sinai and an Sc.B. in Neuroscience from Brown University.

Ryan Sabia serves as our Chief Operating Officer, a position that he has held since December 2021, and prior to that served as our Vice President of Sales and Operations from March 2021 until his promotion in December. Mr. Sabia has 18 years of experience in global supply chain, systems infrastructure, and sales operations in industries that range from automotive, medical supply, and consumer electronics. From June 2019 to April 2021, Mr. Sabia served as Global Director of Strategic Operations for Wisdom Health, a division of Mars, Inc. From July 2015 to December 2018, he served as General Manager of Operations for Medelita, LLC, a medical apparel design and manufacturing company. Prior to that, he worked as Senior Director of Operations for Pinpoint Resources Group, a software technology consulting and staffing company, from January 2013 to July 2015, and as a Hedge Fund Financial Reporting Analyst for J.P. Morgan from August 2012 to January 2013. Mr. Sabia is seasoned in environments that range from Fortune 500 companies (J.P. Morgan, BestBuy, and Toyota) to bootstrap startups, while specializing in scaling for global omnichannel logistics and e-commerce marketplaces. As a result of his finance and accounting background, Mr. Sabia drives a data-focused approach while leveraging modern technologies for business analytics and resource planning. Mr. Sabia graduated from Suffolk University Sawyer Business School with a Bachelor of Science in Finance.

Family Relationships

There are no family relationships among any of our directors and executive officers.

Legal Proceedings

To our knowledge, (i) no director or executive officer has been a director or executive officer of any business that has filed a bankruptcy petition or had a bankruptcy petition filed against it during the past ten years; (ii) no director or executive officer has been convicted of a criminal offense or is the subject of a pending criminal proceeding during the past ten years; (iii) no director or executive officer has been the subject of any order, judgment or decree of any court permanently or temporarily enjoining, barring, suspending or otherwise limiting his involvement in any type of business, securities or banking activities during the past ten years; and (iv) no director or officer has been found by a court to have violated a federal or state securities or commodities law during the past ten years.

Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics that applies to all of our employees, officers and directors, including those officers responsible for financial reporting. Our Code of Business Conduct and Ethics is available on our corporate website at https://tivichealth.com/investor/. We intend to disclose any amendments to the code, or any waivers of its requirements, on our corporate website or in a Current Report on Form 8-K.

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires the Company's directors and executive officers and persons who beneficially own more than ten percent of a registered class of the Company's equity securities to file with the SEC initial reports of ownership and reports of changes in ownership of Common Stock and other equity securities of the Company. Officers, directors and greater than ten percent beneficial stockholders are required by SEC regulations to furnish us with copies of all Section 16(a) forms they file. To the best of the Company's knowledge based solely on a review of Forms 3, 4, and 5 (and any amendments thereof) received by us during or with respect to the year ended December 31, 2022 and written representations that no other reports were required, Karen Drexler inadvertently failed to timely disclose one transaction, which was reported on a Form 5 filed by Ms. Drexler on February 14, 2023; there were no other late Section 16 filings during the year ended December 31, 2022.

Item 11 – Executive Compensation

Overview

This section discusses the material components of the executive compensation program for our named executive officers who are named in the "Summary Compensation Table," below. For the fiscal year ending December 31, 2022, our "named executive officers" and their positions were as follows:

- Jennifer Ernst, our Chief Executive Officer;
- Veronica Cai, our Chief Financial Officer; and
- Blake Gurfein, our Chief Scientific Officer.

This discussion may contain forward-looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. Actual compensation programs that we adopt in the future may differ materially from the currently planned programs summarized in this discussion.

Summary Compensation Table

The following table sets forth, for the fiscal years ended December 31, 2022 and December 31, 2021, the dollar value of all cash and noncash compensation earned by our named executive officers, as set forth above.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Awards ($)[1]	All Other Compensation ($)[2]	Totals ($)
Jennifer Ernst,	2022	275,000	—	123,320	20,901	419,222
CEO and Director	2021	218,487	—	—	30,965	249,452
Veronica Cai	2022	243,750	—	162,039	1,008	406,797
CFO[3]	2021	—	—	—	—	—
Blake Gurfein, PhD	2022	275,000	50,938	29,038	29,926	384,902
Chief Scientific Officer	2021	227,589	—	183,975	31,356	442,920

[1] Amounts shown in the "Option Awards" column represent the aggregate grant date fair value of stock options. These amounts represent the grant date fair value of stock options granted in fiscal 2022 and 2021 computed in accordance with FASB ASC Topic 718. We do not include any impact of estimated forfeitures related to service-based vesting terms in these calculations.

[2] Includes the cost of health insurance coverage and benefits paid by the Company for each named executive officer that is not reimbursed.

[3] Ms. Cai was appointed as our Chief Financial Officer on April 1, 2022, replacing Ms. Briana Benz, who resigned from her role as our prior Chief Financial Officer as of the same date.

Narrative to the summary compensation table

Employment Agreements/Arrangements

As of the year ended December 31, 2022, we had executive offer letters in place with Jennifer Ernst, our Chief Executive Officer, and Veronica Cai, our Chief Financial Officer. A summary of the terms of Ms. Ernst's and Ms. Cai's executive offer letters is set forth below.

In addition, Blake Gurfein, our Chief Scientific Officer, is currently subject to a standard, at-will offer letter.

Currently, the annual compensation of each of our executive officers is determined by the Board. The named executive officers are also entitled to participate in the Company's benefit plans, which benefits are generally available to all full-time employees.

Executive Offer Letter with Jennifer Ernst

On July 31, 2021, we entered into an executive offer letter with Jennifer Ernst. Pursuant to her executive offer letter, effective July 31, 2021, Ms. Ernst is entitled to a base salary of $275 thousand and, commencing with the 2022 calendar year (payable in the first quarter of 2023), will be eligible to receive, at the sole discretion of the Board, an annual end-of-year incentive bonus in an amount up to 40% of her base salary. The annual end-of-year incentive bonus, if earned, will be determined by the Board, in its sole discretion, and will be dependent upon the achievement of certain Company milestones and profitability, and such other milestones as the Board deems appropriate.

Ms. Ernst's employment is "at will," meaning that either she or the Company are entitled to terminate Ms. Ernst's employment at any time and for any reason, with or without cause. In the event that her employment with the Company is terminated for any reason before December 31 of any given year, she will not be entitled to receive an annual end-of-year bonus. In the event that (i) Ms. Ernst elects to terminate her employment with the Company other than for good reason, (ii) the Company terminates her employment for cause, or (iii) her employment is terminated as a result of her death of complete disability, then Ms. Ernst will not be entitled to receive any separation benefits. In the event that Ms. Ernst terminates her employment for good reason or the Company terminates her employment without cause, Ms. Ernst shall be entitled to receive 1/12 of her base salary for a period of six months after termination.

Executive Offer Letter with Veronica Cai

On April, 1, 2022, in connection with her appointment as Chief Financial Officer, we entered into an executive offer letter with Veronica Cai. Pursuant to her executive offer letter, Ms. Cai is entitled to receive a base salary of $325 thousand per annum (subject to review and adjustment in accordance with the Company's normal performance review practices), and she will be eligible to receive, at the sole discretion of Board, an annual end- of-year incentive bonus in an amount up to 25% of her base salary. Additionally, in connection with her appointment as Chief Financial Officer, on April 1, 2022, we granted Ms. Cai stock options to purchase 117,880 shares of Company common stock under our 2021 Equity Incentive Plan, which options (i) have an exercise price of $1.61 per share, (ii) will expire 10 years from the date of grant, and (iii) shall vest as follows: (a) 25% on April 1, 2023, and (b) the balance will vest in 36 equal monthly installments thereafter, subject to limited exceptions.

Ms. Cai's employment is "at will," meaning that either she or the Company are entitled to terminate Ms. Cai's employment at any time and for any reason, with or without cause. In the event that her employment with the Company is terminated for any reason before December 31 of any given year, she will not be entitled to receive an annual end-of-year bonus. In the event that (i) Ms. Cai elects to terminate her employment with the Company other than for good reason, (ii) the Company terminates her employment for cause, or (iii) her employment is terminated as a result of her death of complete disability, then Ms. Cai will not be entitled to receive any separation benefits. In the event that Ms. Cai terminates her employment for good reason or the Company terminates her employment without cause, then Ms. Cai shall be entitled to receive 1/12 of her base salary for a period of six months after termination and the Company shall pay her COBRA coverage for a period of six months after termination.

Outstanding Equity Awards at Fiscal Year-End 2022

The following table provides information regarding the outstanding equity awards held by our named executive officers as of December 31, 2022. See "Equity Incentive Plan Information," below, for additional information regarding our equity incentive plans.

	Outstanding Equity Awards at Fiscal Year-End								
	Option Awards					Stock Awards			
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)	Option Expiration Date	Number of Shares of Stock That Have Not Vested (#)	Market Value of Shares of Stock That Have Not Vested ($)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested (#)
Jennifer Ernst	57,500	—	—	0.132	4/1/2028	—	—	—	—
	—	200,000 (1)	—	1.830	2/4/2027	—	—	—	—
Veronica Cai	—	117,880 (2)	—	1.610	4/1/2032	—	—	—	—
Blake Gurfein	20,625	61,875 (3)	—	4.590	12/14/2031	—	—	—	—
	7,813	—	—	0.120	4/3/2028	—	—	—	—
	5,209	—	—	0.120	6/27/2028	—	—	—	—
	—	35,000 (4)	—	1.670	2/4/2032	—	—	—	—

(1) The options vest as follows: (i) 25% on February 4, 2023, and (ii) the remaining 75% in equal installments over the next 36 months.

(2) The options vest as follows: (i) 25% on April 1, 2023, and (ii) the remaining 75% in equal installments over the next 36 months.

(3) The options vest as follows: (i) 25% on December 14, 2022, and (ii) the remaining 75% in equal monthly installments over the next 36 months.

(4) The options vest as follows: (i) 25% on February 4, 2022, and (ii) the remaining 75% in equal monthly installments over the next 36 months.

2017 Equity Incentive Plan

The Board adopted the 2017 Plan on April 13, 2017. The principal purpose of the 2017 Plan was to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards and cash-based performance bonus awards. The material terms of the 2017 Plan are summarized below. In August 2021, the Board adopted and our stockholders approved the 2021 Plan, which became effective upon the completion of our IPO. Upon the effectiveness of the 2021 Plan, it replaced the 2017 Plan, except with respect to awards outstanding under the 2017 Plan, and no further awards are available for grant under the 2017 Plan.

Share reserve. Under the 2017 Plan, 981,269 shares of our common stock were reserved for issuance pursuant to a variety of stock-based compensation awards, including stock options, restricted stock awards, and other stock-based awards. With respect to the share reserve under the 2017 Plan:

- to the extent that an award terminated, expired or lapsed for any reason or an award was settled in cash without the delivery of shares prior to the effectiveness of the 2021 Plan, any shares subject to the award at such time would have been available for future grants under the 2017 Plan; and
- prior to the effectiveness of the 2021 Plan, to the extent that shares of our common stock were repurchased by us prior to vesting so that shares were returned to us, such shares would have been available for future grants under the 2017 Plan.

As noted above, upon the effectiveness of the 2021 Plan, it replaced the 2017 Plan, except with respect to awards outstanding under the 2017 Plan, and no further awards are available for grant under the 2017 Plan.

Administration. Following completion of our IPO, the Compensation Committee of the Board began administering the 2017 Plan. Prior to that, the 2017 Plan was administered by the Board.

Subject to the terms and conditions of the 2017 Plan, the administrator has the authority to select the persons to whom awards are to be made, to determine the number of shares to be subject to awards and the terms and conditions of awards, and to make all other determinations and to take all other actions necessary or advisable for the administration of the 2017 Plan. The administrator is also authorized to adopt, amend or rescind rules relating to administration of the 2017 Plan. The Board may at any time remove the Compensation Committee as the administrator and revest in itself the authority to administer the 2017 Plan.

Eligibility. Options, restricted stock and all other stock-based and cash-based awards under the 2017 Plan may be granted to individuals who are then our officers, employees or consultants or are the officers, employees or consultants of certain of our subsidiaries. Such awards also may be granted to our directors. Only employees of our company may be granted incentive stock options ("ISOs").

Awards. The 2017 Plan provides that the administrator may grant or issue stock options, restricted stock, other stock- or cash-based awards and dividend equivalents, or any combination thereof; provided, however, that as noted above, no additional awards may be issued under the 2017 Plan. Each award will be set forth in a separate agreement with the person receiving the award, which will indicate the type, terms and conditions of the award.

- Incentive stock options. ISOs will be designed in a manner intended to comply with the provisions of Section 422 of the Code and will be subject to specified restrictions contained in the Code. Among such restrictions, ISOs must have an exercise price of not less than the fair market value of a share of common stock on the date of grant, may only be granted to employees, and must not be exercisable after a period of ten years measured from the date of grant. In the case of an ISO granted to an individual who owns (or is deemed to own) at least 10% of the total combined voting power of all classes of our capital stock, the 2017 Plan provides that the exercise price must be at least 110% of the fair market value of a share of common stock on the date of grant and the ISO must not be exercisable after a period of five years measured from the date of grant.

- Nonstatutory stock options. Nonstatutory Stock Options, or NSOs, will provide for the right to purchase shares of our common stock at a specified price which may not be less than fair market value on the date of grant, and usually will become exercisable (at the discretion of the administrator) in one or more installments after the grant date, subject to the participant's continued employment or service with us and/ or subject to the satisfaction of corporate performance targets and individual performance targets established by the administrator. NSOs may be granted for any term specified by the administrator that does not exceed ten years.

- Restricted stock. Restricted stock may be granted to any eligible individual and made subject to such restrictions as may be determined by the administrator. Restricted stock, typically, may be forfeited for No consideration or repurchased by us at the original purchase price if the conditions or restrictions on vesting are not met. In general, restricted stock may not be sold or otherwise transferred until restrictions are removed or expire. Purchasers of restricted stock, unlike recipients of options, will have voting rights and will have the right to receive dividends, if any, prior to the time when the restrictions lapse, however, extraordinary dividends will generally be placed in escrow, and will not be released until restrictions are removed or expire.

- Other stock-based awards. Other stock-based awards are awards of fully vested shares of our common stock and other awards valued wholly or partially by referring to, or otherwise based on, shares of our common stock.

Other stock-based awards may be granted to participants and may also be available as a payment form in the settlement of other awards, as standalone payments and as payment in lieu of base salary, bonus, fees or other cash compensation otherwise payable to any individual who is eligible to receive awards. The plan administrator will determine the terms and conditions of other stock-based awards, which may include vesting conditions based on continued service, performance and/or other conditions.

Any award may be granted as a performance award, meaning that the award will be subject to vesting and/or payment based on the attainment of specified performance goals.

Change in control. In the event of a change in control, to the extent that an award (i) is vested, (ii) the terms of an award provide for acceleration of vesting upon a change in control, or (iii) the administrator elects to accelerate the vesting of the award in connection with the change in control, the plan administrator may elect to provide for the purchase or exchange of an award for cash or other property in an amount equal to the difference between (x) the value of cash or other property the optionee would receive in connection with such change in control if the optionee exercised the award, and (y) the aggregate exercise price of the vested portion of the award. If the award is not purchased or exchanged as provided above, then the award will be terminated and cease to be exercisable unless the award is expressly assumed or substituted by the acquirer.

Adjustments of awards. In the event of any stock dividend or other distribution, stock split, reverse stock split, reorganization, combinations or exchange of share, merger, consolidation, split-up, spin off, recapitalization, repurchase or any other corporate event affecting the number of outstanding shares of our common stock or the share price of our common stock that would require adjustments to the 2017 Plan or any awards under the 2017 Plan in order to prevent the dilution or enlargement of the potential benefits intended to be made available thereunder, the administrator will make appropriate, proportionate adjustments to: (i) the aggregate number and type of shares subject to the 2017 Plan; (ii) the number and kind of shares subject to outstanding awards and terms and conditions of outstanding awards (including, without limitation, any applicable performance targets or criteria with respect to such awards); and (iii) the grant or exercise price per share of any outstanding awards under the 2017 Plan. In connection with the 1-for-4 reverse stock split of our issued and outstanding shares of common stock that was effected on August 31, 2021, the terms of certain awards granted under our 2017 Plan were equitably adjusted in accordance with the provisions thereof.

Amendment and termination. The administrator may terminate, amend or modify the 2017 Plan at any time and from time to time. However, we must generally obtain stockholder approval to amend or modify the 2017 Plan to the extent required by applicable law, rule or regulation (including any applicable stock exchange rule). Notwithstanding the foregoing, an option may be amended to reduce the per share exercise price below the per share exercise price of such option on the grant date and options may be granted in exchange for, or in connection with, the cancellation or surrender of options having a higher per share exercise price without receiving additional stockholder approval.

No ISOs may be granted pursuant to the 2017 Plan after the tenth anniversary of the effective date of the 2017 Plan. Any award that is outstanding on the termination date of the 2017 Plan will remain in force according to the terms of the 2017 Plan and the applicable award agreement.

2021 Equity Incentive Plan

In August 2021, the Board adopted and our stockholders approved the 2021 Plan, which became effective upon the completion of our IPO. Upon the effectiveness of the 2021 Plan, it replaced the 2017 Plan, except with respect to awards outstanding under the 2017 Plan, and no further awards may be made under the 2017 Plan. Additionally, any awards that are canceled or expire under the 2017 Plan will not be reissued. The principal purpose of the 2021 Plan is to attract, retain and incentivize the Company's employees and other service providers through the granting of certain stock-based awards, including performance-based awards. The material terms of the 2021 Plan, as it is currently contemplated, are summarized below.

Share reserve. Under the 2021 Plan, 937,500 shares of our common stock were initially reserved for issuance pursuant to a variety of stock-based compensation awards, including stock options, restricted stock awards, restricted stock units, stock bonus awards and performance-based awards as of the date of its adoption by the Company. With respect to the share reserve under the 2021 Plan:

- to the extent that an award terminates, expires or lapses for any reason or an award is settled in cash without the delivery of shares, any shares subject to the award at such time will be available for future grants under the 2021 Plan; and

- to the extent that shares of our common stock are repurchased by us at the original purchase price, such shares will be available for future grants under the 2021 Plan.

In addition, the 2021 Plan provides that additional shares will automatically be added to the shares authorized for issuance under the 2021 Plan on January 1 of each year. The number of shares added each year will be equal to the lesser of: (i) 5.0% of the outstanding on December 31st of the preceding calendar year or (ii) such number of shares determined by the Board, in its discretion. In accordance with this provision, on January 1, 2022, the number of shares of our common stock authorized for issuance under the 2021 Plan automatically increased from 937,500 shares to 1,423,261 shares (an increase equal to 5% of the number of our outstanding shares of common stock as of December 31, 2021). Additionally, on January 1, 2023, the number of shares of our common stock authorized for issuance under the 2021 Plan automatically increased from 1,423,261 shares to 1,907,148 shares (an increase equal to 5% of the number of our outstanding shares of common stock as of December 31, 2022).

Share Counting. For purposes of counting the number of shares available for the grant of stock awards under the 2021 Plan, all shares covered by any stock award shall be counted against shares available under the 2021 Plan on a "one for one" basis. Notwithstanding the foregoing, (i) awards that may be settled only in cash shall not be so counted, and (ii) while any performance-based award is outstanding, the maximum number of shares issuable under such award shall be counted against available shares under the 2021 Plan, and upon final settlement of such performance-based award, any shares not issued to the holder due to failure to achieve any related performance goal(s) shall again be available for grant and issuance under the 2021 Plan.

Administration. The Compensation Committee of the Board is authorized to administer the 2021 Plan unless the Board subsequently assumes authority for administration. The Compensation Committee must consist of at least two members of the Board, each of whom is intended to qualify as a "non-employee director" for purposes of Rule 16b-3 under the Exchange Act and an "independent director" within the meaning of the rules of the applicable stock exchange, or other principal securities market on which shares of our common stock are traded. The term Administrator refers to either the Board or the Compensation Committee, as applicable.

Additionally, the Board or Compensation Committee may delegate certain functions under the 2021 Plan to designate employees who are not Officers to be recipients of awards under the 2021 Plan, and to determine the number of shares subject to awards granted to such employees.

Subject to the terms and conditions of the 2021 Plan, the Administrator has the authority to construe and interpret the 2021 Plan and awards granted under it and to determine the persons to whom and the dates on which awards will be granted, the number of shares of common stock to be subject to each award, the time or times during the term of each award within which all or a portion of such award may be exercised, the exercise price, the type of consideration and other terms of the award. All decisions, determinations and interpretations by the Administrator regarding the 2021 Plan shall be final and binding on all participants or other persons claiming rights under the 2021 Plan or any award.

Awards. The 2021 Plan provides that the Administrator may grant or issue stock options, restricted stock, restricted stock units, other stock-based awards and dividend equivalents, or any combination thereof. Each award will be set forth in a separate agreement with the person receiving the award and will indicate the type, terms and conditions of the award.

Eligibility. Options, restricted stock, restricted stock units and all other stock-based awards under the 2021 Plan may be granted to individuals who are then our officers, employees, directors or consultants or are the officers, employees or consultants of certain of our subsidiaries. Only employees of our company or certain of our subsidiaries may be granted incentive stock options, or ISOs. No ISO may be granted under the 2021 Plan to any person who, at the time of the grant, owns (or is deemed to own) stock possessing more than 10% of the total combined voting power of the Company or any affiliate of the Company, unless the exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant and the term of the option does not exceed five years from the date of grant. In addition, the aggregate fair market value, determined at the time of grant, of the shares of common stock with respect to which ISOs are exercisable for the first time by a participant during any calendar year (under the 2021 Plan and all other such plans of the Company and its affiliates) may not exceed $100,000. ISOs are not transferable except by will or by the laws of descent and distribution, provided that a participant may designate a beneficiary who may exercise an option following the participant's death.

•Stock Options. Options granted under the 2021 Plan may become exercisable in cumulative increments ("vest") as determined by the Administrator. Such increments may be based on continued service to the Company over a certain period of time, the occurrence of certain performance milestones, or other criteria. Options granted under the 2021 Plan may be subject to different vesting terms. Except as to a maximum of five percent (5%) of the number of shares reserved and available for grant and issuance under the 2021 Plan, any options that vest on the basis of the participant's continued service will have a minimum vesting period of one year. In addition, the Administrator may not use discretion to accelerate the vesting of options (subject to a maximum five percent (5%) of shares under the 2021 Plan that may be accelerated) other than in connection with a death, disability or a change in control (where a participant terminates employment in certain situations or equity awards are not assumed or substituted for in the transaction).

To the extent provided by the terms of an option, a participant may satisfy any federal, state or local tax withholding obligation relating to the exercise of such option by a cash payment upon exercise, by authorizing the Company to withhold a portion of the stock otherwise issuable to the participant, or by such other method as may be set forth in the option agreement. The maximum term of options under the 2021 Plan is 10 years, except that in certain cases (see Eligibility) the maximum term of certain incentive stock options is five years. Options under the 2021 Plan generally terminate sixty (60) days after termination of the participant's service unless (i) such termination is due to the participant's disability, in which case the option may, but need not, provide that it may be exercised at any time within 6 months of such termination; (ii) the participant dies before the participant's service has terminated, or within three months after termination of such service, in which case the option may, but need not, provide that it may be exercised within 12 months of the participant's death by the person or persons to whom the rights to such option pass by will or by the laws of descent and distribution; or (iii) the option by its terms specifically provides otherwise. If an optionee's service with the Company, or any affiliate of the Company, ceases with cause, the option will terminate at the time the optionee's service ceases. In no event may an option be exercised after its expiration date.

•Stock Bonuses and Restricted Stock Awards. Stock bonus awards and restricted stock awards are granted through a stock bonus award agreement or restricted stock award agreement. The purchase price for a stock purchase award (if any) may be payable in cash, or any other form of legal consideration approved by the Administrator. Stock bonus awards may be granted in consideration for the recipient's past services for the Company. Common stock issued under a restricted stock or stock bonus award agreement may be subject to a share repurchase option or forfeiture right in our favor, each in accordance with a vesting schedule and subject to the minimum vesting requirement. If a recipient's service relationship with us terminates, we may reacquire or receive via forfeiture all of the shares of our common stock issued to the recipient pursuant to a restricted stock or stock bonus award that have not vested as of the date of termination. Rights under a stock bonus or restricted stock bonus agreement may be transferred only as expressly authorized by the terms of the applicable stock bonus or restricted stock purchase agreement.

•Restricted Stock Units. Restricted stock unit awards are issued pursuant to a restricted stock unit award agreement. The consideration for a stock unit award shall be determined by the Administrator and may be payable in any form acceptable to the Administrator and permitted under applicable law. The Administrator may impose any restrictions or conditions upon the vesting of restricted stock unit awards, or that delay the delivery of the consideration after the vesting of stock unit awards, that it deems appropriate consistent with the minimum vesting requirement. Restricted stock unit awards may be settled in cash or shares of the Company's common stock, as determined by the Administrator. No dividends payments will be made on unvested restricted stock unit awards, but instead any dividends will be deferred until awards become vested. If a restricted stock unit award recipient's service relationship with the Company terminates, any unvested portion of the restricted stock unit award is forfeited upon the recipient's termination of service.

•Performance-Based Award. Any award may be granted as a performance award, meaning that the award will be subject to vesting and/or payment based on the attainment of specified performance goals. Generally, such pre-established performance goals consist of one or more business criteria and a targeted performance level with respect to such criteria as a condition of awards being granted or becoming exercisable, or as a condition to accelerating the timing of such events. Performance may be measured over a period of any length specified by the Administrator.

Certain Corporate Transactions. In the event of a merger, sale of all or substantially all of the assets of the Company or other change of control transaction, unless otherwise determined by the Board, all outstanding awards will be subject to the agreement governing such merger, asset sale or other change of control transaction. Such agreement need not treat all such awards in an identical manner, and it will provide for one or more of the following with respect to each award: (i) the continuation of the award, (ii) the assumption of the award, (iii) the substitution of the award, or (iv) the payment of the excess of the fair market value of the shares subject to the award over the exercise price or purchase price of such shares. In the event the successor corporation refuses to either continue, assume or substitute the shares subject to the award pursuant to the terms of the 2021 Plan, or pay the excess of the fair market value of the shares subject to the award over the exercise price or purchase price of such shares, then outstanding awards shall vest and become exercisable as to 100% of the shares subject thereto contingent upon the consummation of such change of control transaction.

Adjustments Provisions. Transactions not involving receipt of consideration by the Company, such as a merger, consolidation, reorganization, recapitalization, reincorporation, reclassification, stock dividend, dividend in property other than cash, stock split, liquidating dividend, combination of shares, exchange of shares, or a change in corporate structure may change the type(s), class(es) and number of shares of common stock subject to the 2021 Plan and outstanding awards. In that event, the 2021 Plan will be appropriately adjusted as to the type(s), class(es) and the maximum number of shares of common stock subject to the 2021 Plan, and outstanding awards will be adjusted as to the type(s), class(es), number of shares and price per share of common stock subject to such awards.

Amendment and termination. The administrator may terminate, amend or modify the 2021 Plan at any time and from time to time. However, we must generally obtain stockholder approval to amend or modify the 2021 Plan to the extent required by applicable law, rule or regulation (including any applicable stock exchange rule). Notwithstanding the foregoing, an option may be amended to reduce the per share exercise price below the per share exercise price of such option on the grant date and options may be granted in exchange for, or in connection with, the cancellation or surrender of options having a higher per share exercise price without receiving additional stockholder approval.

Director Compensation

The following table sets forth information regarding the compensation awarded to, earned by, or paid to our non-employee directors who served on our Board for the year ended December 31, 2022.

Name	Fees earned or paid in cash ($)[1]	Stock awards ($)	Option awards ($)[2][3]	Non-equity incentive plan compensation ($)	Nonqualified deferred compensation earnings ($)	All other compensation ($)	Total ($)
Sheryle Bolton	63,000	—	59,600	—	—	—	122,600
Karen Drexler	50,000	—	59,600	—	—	—	109,600
Dean Zikria	35,000	—	59,600	—	—	—	94,600

(1) These amounts reflect the cash payments that we made as compensation for Board services during fiscal year 2022.

(2) These amounts represent the grant date fair value of stock options granted in fiscal 2022 computed in accordance with FASB ASC Topic 718. We do not include any impact of estimated forfeitures related to service-based vesting terms in these calculations.

(3) As of December 31, 2022, the number of shares subject to all outstanding option awards and stock awards held by our non-employee directors were as follows:

Director	Number of Shares Subject to Option Awards	Number of Shares Subject to Stock Awards
Sheryle Bolton	64,250	—
Karen Drexler	70,500	—
Dean Zikria	64,250	—

On December 16, 2021, our Board, upon recommendation of the Compensation Committee, approved an annual compensation plan for our Board (the "Board Compensation Plan"). In accordance with the Board Compensation Plan, directors of the Company will be entitled to receive the following annual compensation, which amounts will be paid in equal quarterly installments in accordance with our policies:

- Annual Retainer for all Directors: $35,000
- Chairperson of the Board: $15,000
- Chairperson of the Audit Committee: $13,000
- Chairperson of the Compensation Committee: $9,000
- Chairperson of the Nominating and Governance Committee: $6,000

Prior to approval of the above Board Compensation Plan, we did not have a compensation plan in place for our Board.

Item 12 - Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The following table sets forth certain information regarding the beneficial ownership of our outstanding common stock as of March 24, 2023 by: (i) each of our directors, (ii) each of our named executive officers (as defined by Item 402(a)(3) of Regulation S-K promulgated under the Exchange Act), (iii) all of our directors and named executive officers as a group, and (iv) each person known to us to beneficially own more than 5% of each class of our outstanding common stock. As of March 24, 2023, there were 29,677,734 shares of our common stock issued and outstanding.

Beneficial ownership has been determined in accordance with Rule 13d-3 under the Exchange Act. The percentages in the table have been calculated on the basis of treating as outstanding for a particular person, all shares of our common stock outstanding on that date and all shares of our common stock issuable to that holder in the event of exercise of outstanding options, warrants, rights or conversion privileges owned by that person at that date which are exercisable within 60 days of that date. Except as otherwise indicated, the persons listed below have sole voting and investment power with respect to all shares of our common stock owned by them, except to the extent that power may be shared with a spouse. The Company does not know of any arrangements the operation of which may at a subsequent date result in a change of control of the Company.

Beneficial owner [(1)]	**Amount and Nature of Beneficial Ownership**	**Percent of Class**
Directors and Named Executive Officers		
Jennifer Ernst[(2)]	1,319,876	4.4%
Veronica Cai[(3)]	31,925	*
Blake Gurfein, PhD[(4)]	165,156	*
Dean Zikria[(5)]	23,598	*
Sheryle Bolton[(6)]	23,598	*
Karen Drexler[(7)]	47,924	*
All directors and executive officers as a group (6 persons)	1,612,077	5.4%
5% or Greater Shareholders		
Michael Bigger[(8)]	2,102,988	7.1%

* Less than 1%

(1) Unless otherwise indicated in the footnotes to the table, the address for each beneficial owner listed is c/o Tivic Health Systems, Inc., 25821 Industrial Blvd., Suite 100, Hayward, CA 94545.

(2) Includes 1,199,877 shares of common stock held by Ms. Ernst, and options to purchase 119,999 of common stock that are vested and exercisable (or will be vested and exercisable within 60 days of March 24, 2023).

(3) Includes options to purchase 31,925 shares of common stock that are vested and exercisable (or will be vested and exercisable within 60 days of March 24, 2023).

(4) Includes 111,979 shares of common stock held by Dr. Gurfein, as well as options to purchase 53,177 shares of common stock that are vested and exercisable (or will be vested and exercisable within 60 days of March 24, 2023).

(5) Includes options to purchase 23,598 shares of common stock that are vested and exercisable (or will be vested and exercisable within 60 days of March 24, 2023).

(6) Includes options to purchase 23,598 shares of common stock that are vested and exercisable (or will be vested and exercisable within 60 days of March 24, 2023).

(7) Includes 18,076 shares of common stock held by Ms. Drexler, and options to purchase 29,848 shares of common stock that are vested and exercisable (or will be vested and exercisable within 60 days of March 24, 2023).

(8) Includes 1,102,988 shares of common stock held by Bigger Capital Fund, LP and 1,000,000 shares of Common Stock owned by District 2 Capital Fund LP. Mr. Bigger serves as the managing member of Bigger Capital Fund GP, LLC and the managing member of District 2 Holdings LLC, which may be deemed to beneficially own the (i) 1,102,988 shares of Common Stock beneficially owned by Bigger Capital Fund, LP, and (ii) 1,000,000 shares of Common Stock beneficially owned by District 2 Capital Fund LP. The address for Mr. Bigger is 2250 Red Springs Drive, Las Vegas, NV 89135. The information included is based solely upon information contained in a Schedule 13G filed by Mr. Bigger and certain other persons on February 21, 2023.

Equity Incentive Plan Information

The following table provides information as of December 31, 2022, regarding our equity compensation plans:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans
Equity compensation plans approved by security holders [1]	1,268,850	$ 2.00	456,381
Equity compensation plans not approved by security holders	—	—	—
Total	1,268,850	$ 2.00	456,381

(1) Represents outstanding stock options granted to our current or former employees, directors and consultants pursuant to the 2017 Equity Incentive Plan (the "2017 Plan") and 2021 Equity Incentive Plan (the "2021 Plan").

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

Below, we describe the transactions and series of similar transactions, since January 1, 2021, to which we were a party or will be a party, in which:

- the amounts involved exceeded or will exceed the lesser of $120 thousand or one percent of the average of our total assets for the last two fiscal years; and

- any of our directors, executive officers, holders of more than 5% of our capital stock or any member of their immediate family had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements with directors and executive officers, which are described where required under the sections above entitled "Executive Compensation" and "Director Compensation."

In June 2021, we issued a convertible note payable to Jennifer Ernst, our Chief Executive Officer, for total proceeds of $100 thousand. The note was unsecured, had a term of two years, and accrued interest at a rate of 3% per annum. The note converted into 26,986 shares of our common stock upon consummation of our IPO.

In December 2021, the Company entered into an agreement with a significant shareholder for certain product development consultation services. During the year ended December 31, 2021, the Company incurred $3 thousand of expenses in connection with the agreement and the amount remained unpaid as of December 31, 2021. During the year ended December 31, 2022, the Company incurred $18 thousand of expenses in connection with the agreement. As of December 31, 2022, there were no amounts owed to the shareholder.

Policies and Procedures Regarding Related Party Transactions

Our Board has adopted a written related person transaction policy setting forth the policies and procedures for the review and approval or ratification of related person transactions. This policy covers, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships in which we were or are to be a participant, where the amount involved exceeds $120 thousand and a related person had or will have a direct or indirect material interest, including, without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. In reviewing and approving any such transactions, our Audit Committee is tasked to consider all relevant facts and circumstances, including, but not limited to, whether the transaction is on terms comparable to those that could be obtained in an arm's length transaction and the extent of the related person's interest in the transaction. The related person transactions disclosed in this Proxy Statement were each approved by the full Board or Audit Committee, as applicable.

Director Independence

The Nasdaq rules require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominations committees be independent, or, if a listed company has no nominations committee, that director nominees be selected or recommended for the board's selection by independent directors constituting a majority of the board's independent directors. The Nasdaq rules further require that audit committee members satisfy independence criteria set forth in Rule 10A-3 under the Exchange Act and that compensation committee members satisfy the independence criteria set forth in Rule 10C-1 under the Exchange Act.

Our Board has undertaken a review of the independence of our directors and considered whether any director has a material relationship with us that could compromise that director's ability to exercise independent judgment in carrying out that director's responsibilities. Our Board has affirmatively determined that each of Dean Zikria, Sheryle Bolton and Karen Drexler qualify as an independent director, as defined under the applicable corporate governance standards of Nasdaq. These rules require that our Audit Committee be composed of at least three directors, all of whom must be independent members.

Item 14 – Principal Accounting Fees and Services

Independent Registered Public Accounting Firm Fee Information

The following table sets forth the aggregate fees billed by Rosenberg Rich Baker Berman, P.A. ("RRBB"), independent registered public accounting firm, for the services indicated for each of the years ended December 31, 2022 and 2021:

	December 31, 2022	December 31, 2021
Audit fees [(1)]	$ 114,825	$ 114,085
Audit related fees	—	—
Tax fees	—	—
All other fees	—	—
Total	$ 114,825	$ 114,085

(1) Includes fees for (i) the audit of our annual financial statements for the fiscal years ended December 31, 2022 and 2021 included in this Report; the S-1 Registration Statement, as amended, filed with the SEC in 2021 in connection with our initial public offering; and, to the extent fees were paid in fiscal 2022, the S-1 Registration Statement, as amended, filed with the SEC in 2022 in connection with our public offering that closed in February 2023; (ii) the review of our interim period financial statements for fiscal years 2022 and 2021, and (iii) related services that are normally provided in connection with regulatory filings or engagements.

Audit Committee Pre-Approval Policies and Procedures

Our Audit Committee pre-approves all auditing services and the terms of non-audit services provided by our independent registered public accounting firm, but only to the extent that the non-audit services are not prohibited under applicable law and the committee determines that the non-audit services do not impair the independence of the independent registered public accounting firm. Under our Audit Committees pre-approval policies and procedures, the Audit Committee generally preapproves specified services in defined categories up to specified amounts. Pre-approval may also be given as part of the Audit Committee's approval of the scope of the engagement of the independent registered public accounting firm or on a case-by-case basis for specific tasks before engagement. Our Audit Committee has considered and determined that the provision of the non-audit services described is compatible with maintaining the independence of our registered public accounting firm.

PART IV

Item 15 – Exhibits, Financial Statement Schedules

(a)

(1)Financial Statements. The financial statements are included in this Annual Report on Form 10-K beginning on page F-1.

(2)Financial Statement Schedules. All financial statement schedules have been omitted since the information is either not applicable or required or was included in the financial statements or notes included in this Annual Report on Form 10-K.

(3)List of Exhibits required by Item 601 of Regulation S-K. See part (b) below.

(b)Exhibits. The following exhibits are filed or furnished with this report.

EXHIBIT INDEX

Exhibit number	Exhibit description	Incorporated by Reference (Form Type)	Filing Date	Filed herewith
3.1	Certificate of Incorporation, dated June 3, 2021.	S-1	8/3/2021	
3.2	Certificate of Amendment of Certificate of Incorporation, dated August 31, 2021.	S-1A	9/9/2021	
3.3	Amended and Restated Certificate of Incorporation, dated November 12, 2021.	8-K	11/15/21	
3.4	Bylaws, dated June 7, 2021.	S-1	8/3/2021	
3.5	Amended and Restated Bylaws, dated November 12, 2021.	8-K	11/15/21	
4.1	Specimen Stock Certificate.	S-1A	9/9/2021	
4.2	Form of Representative's Warrant (IPO).	S-1A	9/9/2021	
4.3	Warrant to Purchase Common Stock issued to Hannover International, Inc., dated July 1, 2021.	S-1A	10/29/2021	
4.4	Description of Securities.	10-K	3/31/2022	
4.5	Form of Representative's Warrant (February 2023 offering).	8-K	2/13/2023	
10.1	Series Seed-1, Seed-2, Seed-3 and Seed-4 Preferred Stock Investment Agreement, dated July 16, 2019.	S-1	8/3/2021	
10.2	First Amendment to Series Seed-1, Seed-2, Seed-3 and Seed-4 Preferred Stock Investment Agreement, dated July 18, 2019.	S-1	8/3/2021	
10.3(a)#	2017 Equity Incentive Plan, as amended, dated April 13, 2017.	S-1	8/3/2021	
10.3(b)#	Form Agreements under 2017 Equity Incentive Plan.	S-1	8/3/2021	
10.4(a)#	2021 Equity Incentive Plan, dated August 7, 2021.	S-1A	9/9/2021	
10.4(b)#	Form Agreements under 2021 Equity Incentive Plan.	S-1A	9/9/2021	
10.5#	Form of Restricted Stock Purchase Agreement.	S-1A	9/9/2021	

10.6#	Form of Indemnification Agreement for directors and officers.	S-1A	9/9/2021	
10.7	Form of Note Purchase Agreement, dated June 17, 2020, and Unsecured Convertible Promissory Note.	S-1	8/3/2021	
10.8	Form of Unsecured Convertible Promissory Note.	S-1	8/3/2021	
10.9	Form of Note Amendment Agreement, dated October 14, 2020	S-1	8/3/2021	
10.10†	Letter Agreement, between Tivic Health Systems, Inc. and Future Electronics Corp., dated April 6, 2020.	S-1A	9/9/2021	
10.11†	Form of United States Special Product Agreement for Bonded Inventory, between Tivic Health Systems, Inc. and Future Electronics Corp.	S-1A	9/9/2021	
10.12	Form of Note Purchase Agreement, dated June 17, 2021, and Unsecured Convertible Promissory Note.	S-1	8/3/2021	
10.13	Form of Unsecured Convertible Promissory Note.	S-1	8/3/2021	
10.14	Form of (OID) Unsecured Convertible Promissory Note.	S-1	8/3/2021	
10.15#	Executive Offer Letter, between Tivic Health Systems, Inc. and Briana Benz, dated July 29, 2021.	S-1A	9/9/2021	
10.16#	Restricted Stock Purchase Agreement, between Tivic Health Systems, Inc. and Briana Benz, dated July 30, 2021.	S-1A	9/9/2021	
10.17#	Executive Offer Letter, between Tivic Health Systems, Inc. and Jennifer Ernst, dated July 31, 2021.	S-1A	9/9/2021	
10.18	Form of Note Amendment Agreement.	S-1A	9/9/2021	
10.19	Revolving Line of Credit Note, between the Company and Tethered LLC, dated October 28, 2021.	S-1A	10/29/2021	
10.20	Sublease Agreement, between the Company and Czarnowski Display Services, Inc., dated November 17, 2021.	10-K	3/31/2022	
10.21#	Executive Offer Letter, between Tivic Health Systems, Inc. and Veronica Cai, dated April 1, 2022.	8-K	4/5/2022	
10.22#	Executive Offer Letter, between Tivic Health Systems, Inc. and Ryan Sabia, dated April 1, 2022.	8-K	4/5/2022	
10.23†	Manufacturing Agreement, between Tivic Health Systems, Inc. and MicroArt Services, Inc., dated October 21, 2022.	8-K	10/25/2022	
10.24†	Fulfillment Services Agreement, between Tivic Health Systems, Inc. and ALOM Technologies Corporation, dated November 25, 2022.	8-K	12/1/2022	
23.1	Consent of Rosenberg Rich Baker Berman, P.A.			X
31.1	Certification of Chief Executive Officer pursuant to Securities Exchange Act Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002			X

31.2	Certification of Chief Financial Officer pursuant to Securities Exchange Act Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X

# Indicates management contract or compensatory plan.

† Portions of the exhibit, marked by brackets, have been omitted because the omitted information (i) is not material and (ii) would likely cause competitive harm if publicly disclosed.

Item 16. Form 10-K Summary

None.

SIGNATURES

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

March 31, 2023

TIVIC HEALTH SYSTEMS, INC.

By: /s/ Jennifer Ernst
Jennifer Ernst
Chief Executive Officer

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

NAME	TITLE	DATE
/s/ Jennifer Ernst Jennifer Ernst	Chief Executive Officer *(Principal Executive)*	March 31, 2023
/s/ Veronica Cai Veronica Cai	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 31, 2023
/s/ Sheryle Bolton Sheryle Bolton	*Chair of the Board of Directors*	March 31, 2023
/s/ Karen Drexler Karen Drexler	*Director*	March 31, 2023
/s/ Dean Zikria Dean Zikria	*Director*	March 31, 2023

TIVIC HEALTH SYSTEMS, INC.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and
Stockholders of Tivic Health Systems, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Tivic Health Systems, Inc. (the Company) as of December 31, 2022 and 2021, and the related statements of operations, stockholders' equity (deficit), and cash flows for each of the years in the two-year period ended December 31, 2022, and the related notes (collectively referred to as the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2022, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has incurred recurring losses and negative cash flows from operations and is dependent on additional financing to fund operations. These conditions raise substantial doubt about its ability to continue as a going concern. Management's plans regarding these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

/s/ Rosenberg Rich Baker Berman, P.A.

We have served as Tivic Health Systems, Inc. auditor since 2020

Somerset, New Jersey
March 31, 2023

Tivic Health Systems, Inc.
Balance Sheets
December 31, 2022 and 2021
(in thousands, except share and per share data)

	December 31, 2022	December 31, 2021
ASSETS		
Current assets		
Cash and cash equivalents	$ 3,517	$ 12,975
Accounts receivable, net	88	92
Inventory, net	863	429
Deferred offering costs	584	—
Prepaid expenses and other current assets	235	793
Total current assets	5,287	14,289
Property and equipment, net	12	11
Right-of-use assets, operating lease	523	687
Other assets	34	49
Total assets	$ 5,856	$ 15,036
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 1,323	$ 789
Other accrued expenses	373	267
Operating lease liability, current	163	163
Total current liabilities	1,859	1,219
Operating lease liability	367	545
Total liabilities	2,226	1,764
Commitments and contingencies (Note 6)		
Stockholders' equity		
Preferred stock, $0.0001 par value, 10,000,000 shares authorized, no shares issued and outstanding at December 31, 2022 and 2021, respectively	—	—
Common stock, $0.0001 par value, 200,000,000 shares authorized; 9,677,734 and 9,715,234 shares issued and outstanding at December 31, 2022 and 2021, respectively	1	1
Additional paid in capital	33,271	32,817
Accumulated deficit	(29,642)	(19,546)
Total stockholders' equity	3,630	13,272
Total liabilities and stockholders' equity	$ 5,856	$ 15,036

The accompanying notes are an integral part of these financial statements.

Tivic Health Systems, Inc.
Statements of Operations
Years Ended December 31, 2022 and 2021
(in thousands, except share and per share data)

	Years Ended December 31,	
	2022	**2021**
Revenue	$ 1,840	$ 1,257
Cost of sales	1,541	1,295
Gross profit (loss)	299	(38)
Operating expenses:		
Research and development	1,730	878
Sales and marketing	2,792	1,787
General and administrative	5,875	2,930
Total operating expenses	10,397	5,595
Loss from operations	(10,098)	(5,633)
Other income (expense):		
Interest income (expense)	2	(1,823)
Change in fair value of derivative liabilities	—	436
Loss on extinguishment of debt	—	(1,636)
Other income (expense)	—	162
Total other income (expense)	2	(2,861)
Net loss	$ (10,096)	$ (8,494)
Net loss per share - basic and diluted	$ (1.04)	$ (2.43)
Weighted-average number of shares - basic and diluted	9,672,957	3,493,267

The accompanying notes are an integral part of these financial statements.

Tivic Health Systems, Inc.
Statements of Stockholders' Equity (Deficit)
Years Ended December 31, 2022 and 2021
(in thousands except share and per share data)

	Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Capital	Deficit	(Deficit)
Balances at January 1, 2021	8,908,600	$ 1	2,324,479	$ —	$ 9,874	$ (11,052)	$ (1,177)
Conversion of convertible preferred stock to common stock	(8,908,600)	(1)	2,227,116	—	1	—	—
Conversion of convertible notes payable to common stock			1,204,160	—	7,656	—	7,656
Issuance of common stock, net of issuance costs			3,562,500	1	14,559	—	14,560
Exercise of stock options	—	—	396,979	—	62	—	62
Issuance of warrants	—	—	—	—	608	—	608
Stock-based compensation expense	—	—	—	—	57	—	57
Net loss	—	—	—	—	—	(8,494)	(8,494)
Balances at December 31, 2021	—	$ —	9,715,234	$ 1	$ 32,817	$ (19,546)	$ 13,272
Repurchase of restricted common stock	—	—	(93,750)	—	—	—	—
Exercise of stock options	—	—	56,250	—	56	—	56
Stock-based compensation expense	—	—	—	—	398	—	398
Net loss	—	—	—	—	—	(10,096)	(10,096)
Balances at December 31, 2022	—	$ —	9,677,734	$ 1	$ 33,271	$ (29,642)	$ 3,630

The accompanying notes are an integral part of these financial statements.

Tivic Health Systems, Inc.
Statements of Cash Flows
Years Ended December 31, 2022 and 2021
(in thousands)

	Years Ended December 31,	
	2022	**2021**
Cash flows from operating activities		
Net loss	$ (10,096)	$ (8,494)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock based compensation	398	57
Depreciation	10	8
Change in fair value of derivative liabilities	—	(436)
Amortization of debt discount	—	1,747
Loss on extinguishment of debt	—	1,636
Amortization of right-of-use asset	164	16
Noncash interest	—	76
Forgiveness of PPP loan	—	(157)
Issuance of common stock warrant	—	280
Accounts receivable allowances	—	66
Reserve for inventory obsolescence	—	(8)
Changes in operating assets and liabilities:		
Accounts receivable	4	(66)
Inventory	(434)	(181)
Prepaid expenses and other current assets	558	(707)
Accounts payable	534	419
Accrued expenses	106	128
Lease liabilities	(178)	4
Other assets	15	—
Net cash used in operating activities	(8,919)	(5,612)
Cash flows from investing activities		
Acquisition of property and equipment	(11)	—
Net cash used in investing activities	(11)	—
Cash flows from financing activities		
Repayment of notes payable borrowings	—	(19)
Proceeds from convertible notes payable borrowings	—	2,513
Proceeds from convertible notes payable borrowings – related party	—	100
Proceeds from exercise of stock options	56	62
Proceeds from issuance of common stock, net of issuance costs	—	14,887
Offering costs in advance of sale of common stock	(584)	—
Net cash provided by (used in) financing activities	(528)	17,543
Net increase (decrease) in cash and cash equivalents	(9,458)	11,931
Cash and cash equivalents		
Beginning of period	12,975	1,044
End of period	$ 3,517	$ 12,975
Supplemental disclosure on noncash financing activities		
Issuance of conversion feature derivative liability	$ —	$ 1,355
Conversion of convertible notes payable and accrued interest to common stock	$ —	$ 4,384
Conversion of convertible preferred stock to common stock	$ —	$ 1
Reclassify conversion feature derivative liability to additional paid in capital	$ —	$ 1,636
Issuance of common stock warrant	$ —	$ 328
Recognition of right-of-use asset and operating lease liability	$ —	$ 704

The accompanying notes are an integral part of these financial statements.

1.Formation and Business of the Company

Tivic Health Systems, Inc. (the "Company"), was incorporated in the state of California on September 22, 2016 for the purpose of developing and commercializing non-invasive bioelectronic medicine. In June 2021, the Company was reincorporated as a Delaware corporation. The Company's first commercial product, ClearUP, is an FDA approved medical device for the treatment of sinus and nasal congestion pains. The Company is headquartered in Hayward, California.

The Company has experienced losses and negative cash flows from operations. During the year ended December 31, 2022, the Company incurred a net loss of $10.1 million and used $8.9 million of cash for operations. At December 31, 2022, the Company had an accumulated deficit of $29.6 million. Cash and cash equivalents at December 31, 2022 were $3.5 million. Management expects to incur substantial additional operating losses for the foreseeable future to expand its ClearUP markets, continue its research and development programs and potentially launch new commercial products. Based on the Company's current cash levels and burn rate, amongst other things, the Company believes its cash and financial resources may be insufficient to meet the Company's anticipated needs for the twelve months following the date of issuance of these financial statements.

Our future capital requirements will depend upon many factors, including, without limitation, progress with developing, manufacturing and marketing our technologies, the time and costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other proprietary rights, our ability to establish collaborative arrangements, marketing activities and competing technological and market developments, including regulatory changes and overall economic conditions in our target markets. Our ability to generate revenue and achieve profitability requires us to successfully market and secure purchase orders for our products and services from customers currently identified in our sales pipeline as well as new customers. We also will be required to efficiently manufacture and deliver equipment on those purchase orders. These activities, including our planned research and development efforts, will require significant uses of working capital. There can be no assurance that we will generate revenue and cash as expected in our current business plan.

The Company recognizes it will need to raise additional capital to continue operating its business and fund its planned operations, including research and development, clinical trials and, if regulatory approval is obtained, commercialization of future product candidates. We may seek additional funds through equity or debt offerings and/or borrowings under notes payable, lines of credit or other sources. We do not know whether additional financing will be available on commercially acceptable terms, or at all, when needed. If adequate funds are not available or are not available on commercially acceptable terms, our ability to fund our operations, support the growth of our business or otherwise respond to competitive pressures could be significantly delayed or limited, which could materially adversely affect our business, financial conditions, or results of operations.

2.Summary of Significant Accounting Policies

Basis of Presentation

The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP"). The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The accompanying financial statements do not include any adjustment that might be necessary if the Company is unable to continue as a going concern. Certain reclassification have been made to the prior year's balance sheet, statement of operations and statement of cash flows to confirm to the current year presentation.

Going Concern Uncertainty

The accompanying financial statements have been prepared as if the Company will continue as a going concern. As noted above, the Company has experienced losses and negative cash flows from operations; incurred a net loss of $10.1 million during the year ended December 31, 2022; had cash and cash equivalents of $3.5 million as of December 31, 2022; and had an accumulated deficit of $29.6 million as of December 31, 2022. The Company's working capital as of December 31, 2022 was approximately $3.4 million. The aforementioned factors raise substantial doubt about the Company's ability to continue as a going concern within one year from the issuance date of the financial statements. The accompanying 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 financial statements do not include any adjustments relating to the recoverability and classification of asset amounts or the classification of liabilities that might be necessary should the Company be unable to continue as a going concern within one year after the date the financial statements are issued.

Reverse Stock Split

In August 2021, the Company's Board of Directors and stockholders approved an amendment to the Company's certificate of incorporation to effect a 1-for-4 reverse stock split of the issued and outstanding shares of the Company's common stock which was effected on August 31, 2021. The par value of the common stock was not adjusted as a result of the reverse stock split. Accordingly, all common stock, convertible preferred stock conversion ratios, stock options and related per share amounts in these audited annual financial statements have been retroactively adjusted for all periods presented to give effect to the reverse stock split.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of expenses during the reporting period. Actual results could differ materially from those estimates. The Company evaluates its estimates and assumptions on an ongoing basis using historical experience and other factors and adjusts those estimates and assumptions when facts and circumstances dictate.

Fair Value of Financial Instruments

The Company discloses and recognizes the fair value of its assets and liabilities using a hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The hierarchy gives the highest priority to valuations based upon unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to valuations based upon unobservable inputs that are significant to the valuation (Level 3 measurements). The guidance establishes three levels of the fair value hierarchy as follows:

Level 1 Inputs that reflect unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date;

Level 2 Inputs other than quoted prices that are observable for the asset or liability either directly or indirectly, including inputs in markets that are not considered to be active;

Level 3 Inputs are unobservable in which there is little or no market data available, which require the reporting entity to develop its own assumptions that are unobservable.

Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability.

Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less at date of purchase to be cash equivalents. As of December 31, 2022 and 2021, cash equivalents were $3.1 million and $12.8 million, respectively.

Accounts Receivable

Trade accounts receivable are recorded at the invoiced amount, net of allowances for doubtful accounts and returns and warranty reserves. The allowance for doubtful accounts is based on our assessment of the collectability of accounts. Management regularly reviews the adequacy of the allowance for doubtful accounts by considering the age of each outstanding invoice, each customer's expected ability to pay, and the collection history with each customer, when applicable, to determine whether a specific allowance is appropriate. Accounts receivable deemed uncollectible are charged against the allowance for doubtful accounts when identified. As of December 31, 2022 and 2021, the allowance for doubtful accounts was zero and $82 thousand, respectively. As of December 31, 2022 and 2021, the reserve for sales returns was $19 thousand and $16 thousand, respectively.

Inventory

Inventories are stated at the lower of cost or net realizable value, with cost determined on a first-in, first-out (FIFO) basis. Inventories are reviewed periodically to identify slow-moving inventory based on anticipated sales activity. As of December 31, 2022 and 2021, the reserve for obsolescence was zero.

Deferred Offering Costs

Deferred offering costs are comprised of costs incurred in connection with financing arrangements that have not closed as of the end of the period. As of December 31, 2022, deferred offering costs primarily consist of legal fees, technical accounting support, printer costs and other regulatory filing fees related to the sale of 20,000,000 shares of our common stock, which closed subsequent to year-end. Deferred offering costs will be reclassified to additional paid in capital upon closing of the financing transaction.

Property and Equipment

Property and equipment are recorded at cost net of accumulated depreciation. Depreciation is computed on a straight-line method over the estimated useful lives of the assets, three to four years. Depreciation expense was $10 thousand and $8 thousand for the years ended December 31, 2022 and 2021, respectively. Upon retirement or sale of assets, the cost and related accumulated depreciation are removed from the balance sheet and the resulting gain or loss is reflected in operations. Repairs and maintenance costs that do not improve or extend the lives of the respective assets are charged to operations as incurred.

Impairment of Long-Lived Assets

The Company evaluates its long-lived assets, including property and equipment, for impairment whenever events or changes in circumstances indicate that the carrying amount of these asset may not be recoverable. Recoverability of these assets is measured by comparison of the carrying amount of each asset to the future undiscounted cash flows the asset is expected to generate over its remaining life. When indications of impairment are present and the estimated undiscounted future cash flows from the use of these assets is less than the assets' carrying value, the related assets will be written down to fair value. There were no impairments of the Company's long-lived assets for the periods presented.

Derivative Instruments

The Company issued certain convertible notes in 2020 and 2021 which contained put options. These embedded put options are not considered clearly and closely related to the debt host and result in embedded derivatives that must be bifurcated and accounted for separately from the debt host. Accordingly, the Company recorded these as a derivative financial liability.

Derivative financial liabilities are initially recorded at fair value, with gains and losses arising for changes in fair value recognized in the statement of operations at each period end while such instruments are outstanding. The liability is being valued using a probability weighted expected return model. The convertible notes issued in 2020 and 2021 were derecognized upon conversion of the convertible notes in 2021. See Note 9 for further discussion of the convertible notes and the embedded derivative liability.

Debt Discounts

Debt discounts and debt issuance costs incurred in connection with the issuance of debt are capitalized and amortized to interest expense based on the related debt agreements using the effective-interest method.

Commitments and Contingencies

Liabilities for loss contingencies arising from claims, assessments, litigation, fines, and penalties and other sources are recorded when it is probable that a liability has been incurred and the amount can be reasonably estimated. Legal costs incurred in connection with loss contingencies are expensed as incurred.

Revenue Recognition

The Company recognizes revenue from product sales in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 606, Revenue from Contracts with Customers ("Topic 606"). The adoption of this guidance did not have a material impact on the Company's financial statements. The standard applies to all contracts with customers, except contracts that are within scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments.

Under Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are in within the scope of Topic 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inceptions, once the contract is determined to be within the scope of Topic 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

The Company sells its products through direct sales and reseller. Revenue is recognized when control of the promised goods is transferred to the customers or the resellers, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those goods. Revenue associated with products holding rights of return are recognized when the Company concludes there is not a risk of significant revenue reversal in the future periods for the expected consideration in the transaction.

The Company may offer an extended warranty to its customers. The extended warranty is considered a separate performance obligation. The Company allocates the transaction price based on estimated relative standalone selling prices of the promised product and services underlying each performance obligation. The Company determines standalone selling prices based on the price at which the performance obligation is sold separately. As of December 31, 2022 and 2021, the Company's deferred revenue for unrecognized extended warranties was $0 and $12 thousand, respectively, and is included in "Other Accrued Expenses" on the accompanying balance sheets.

The Company may receive payments at the onset of the contract and before goods have been delivered. In such instances, the Company records a deferred revenue liability. The Company recognizes these contract liabilities as sales after the revenue criteria are met. As of December 31, 2022 and 2021, the contract liability related to the Company's deferred revenues approximated $2 thousand and $3 thousand, respectively, and are included in "Other Accrued Expenses" on the accompanying balance sheets.

The Company relies on a third party to have procedures in place to detect and prevent credit card fraud as the Company has exposure to losses from fraudulent charges. The Company records the losses related to chargebacks as incurred.

The Company has also elected to exclude from the measurement of the transaction price sales taxes remitted to governmental authorities.

The table below presents revenue by channel for the years ended December 31, 2022 and 2021 (in thousands):

	Year Ended December 31,	
Product Revenue by Sales Channel	**2022**	**2021**
Product Revenue		
Direct-to-consumer	$ 1,635	$ 764
Reseller	416	610
Return Reserves	(211)	(117)
Revenue	$ 1,840	$ 1,257

Sales Tax

Sales tax collected from customers and remitted to governmental authorities is accounted for on a net basis and therefore, is excluded from net sales.

Shipping and Handling

Shipping and handling fees paid by customers are recorded within net sales, with the related expenses recorded in cost of sales. Shipping and handling fees paid by customers in the years ended December 31, 2022 and 2021 were $3 thousand and $5 thousand, respectively. Shipping costs for delivery of product to customers in the years ended December 31, 2022 and 2021 were $96 thousand and $90 thousand, respectively.

Product Warranty

The Company generally offers a one-year limited warranty on its products. The Company estimates the costs associated with the warranty obligation using historical data of warranty claims and costs incurred to satisfy those claims. Estimated warranty costs are expensed to cost of sales.

Sales and Marketing Expenses

Sales and marketing expenses are expensed as incurred and consist primarily of merchandising, customer service and targeted online marketing costs, such as display advertising, keyword search campaigns, search engine optimization and social media and offline marketing costs such as television, radio and print advertising. Sales and marketing expenses also include payroll costs and stock-based compensation expense for employees involved in marketing activities. Sales and marketing expenses are primarily related to growing and retaining the customer base. Advertising and other promotional costs to market the Company's products and services amounted to $1.3 million and $660 thousand for the years ended December 31, 2022 and 2021, respectively.

Research and Development Expenses

Research and development expenses include costs directly attributable to the conduct of research and development programs, including the cost of salaries, payroll taxes, employee benefits, materials, supplies, depreciation on and maintenance of research equipment, the cost of services provided by outside contractors, and the allocable portions of facility costs, such as rent, utilities, insurance, repairs and maintenance, depreciation, and general support services. All costs associated with research and development are expensed as incurred.

Stock-Based Compensation

The Company accounts for stock-based compensation arrangements with employees and non-employee consultants using a fair value method which requires the recognition of compensation expense for costs related to all stock-based payments, including stock options. The fair value method requires the Company to estimate the fair value of stock-based payment awards to employees and non-employees on the date of grant using an option pricing model.

Stock-based compensation costs are based on the fair value of the underlying option calculated using the Black-Scholes option-pricing model and recognized as expense on a straight-line basis over the requisite service period, which is the vesting period. The Company measures equity-based compensation awards granted to non-employees at fair value as the awards vest and recognizes the resulting value as compensation expense at each financial reporting period.

Determining the appropriate fair value model and related assumptions requires judgment, including estimating stock price volatility, expected dividend yield, expected term, risk-free rate of return, and the estimated fair value of the underlying common stock. Due to the lack of company-specific historical and implied volatility data, the Company has based its estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. The historical volatility is calculated based on a period of time commensurate with the expected term assumption. The group of representative companies have characteristics similar to the Company, including stage of product development and focus on the life science industry. The Company uses the simplified method, which is the average of the final vesting tranche date and the contractual term, to calculate the expected term for options granted to employees as it does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. The risk-free interest rate is based on a treasury instrument whose term is consistent with the expected term of the stock options. The Company uses an assumed dividend yield of zero as the Company has never paid dividends and has no current plans to pay any dividends on its common stock. The Company accounts for forfeitures as they occur.

Segment Reporting

Operating segments are identified as components of an enterprise for which separate discrete financial information is available for evaluation by the Company's Chief Executive Officer to make decisions with respect to resource allocation and assessment of performance. To date, the Company has viewed its operations and manages its business as one operating segment.

Net Loss per Common Share

The Company computes net loss per share of common stock in conformity with the two-class method required for participating securities. Diluted net loss per share is computed similar to basic net loss per share except that the denominator is increased to include the number of additional shares for the potential dilutive effects of warrants, convertible preferred stock and stock options outstanding during the period calculated in accordance with the treasury stock method, or the two-class method, whichever is more dilutive. For all periods presented, basic and diluted net loss per share is the same, as inclusion of any additional share equivalents would be anti-dilutive.

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carry forwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Valuation allowances are established when necessary to reduce deferred taxes to the amounts expected to be realized.

The Company recognizes benefits of uncertain tax positions if it is more likely than not that such positions will be sustained upon examination based solely on their technical merit, as the largest amount of benefit that is more likely than not to be realized upon the ultimate settlement. The Company's policy is to recognize interest and penalties related to the underpayment of income taxes as a component of income tax expense or benefit. To date, there have been no interest or penalties charged in relation to the unrecognized tax benefits.

Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist of cash and cash equivalents and accounts receivable. Cash and cash equivalents include a checking account held at one national financial institution in the United States. At times, such deposits may be in excess of insured limits. Despite recent concerns regarding the stability of certain banking institutions in the United States, management believes that the financial institution at which the Company holds its deposits is financially sound, and accordingly, minimal credit risk exists with respect to the financial institution. The Company has not experienced any losses on its deposits of cash and cash equivalents. As of December 31, 2022 and 2021, the Company had cash and cash equivalents balances exceeding FDIC insured limits by $3.0 million and $12.5 million, respectively.

The Company extends credit to customers in the normal course of business and performs credit evaluations of its customers. Concentrations of credit risk with respect to accounts receivable exist to the full extent of amounts presented in the financial statements.

During 2022, the majority, or 89%, of the Company's sales have been to individual consumers. As of December 31, 2022, the Company had two customers whose accounts receivable balances each totaled more than 10% or more of the Company's total accounts receivable (43% and 18%) compared with two customers at December 31, 2021 (54% and 39%).

For the year ended December 31, 2022, the Company had one customer who individually accounted for 10% or more of the Company's total revenue (20%) compared with two customers for the year ended December 31, 2021 (22% and 12%).

The world has been affected by the COVID-19 pandemic, the ongoing conflict between Russia and Ukraine, economic uncertainty in human capital management and certain other macroeconomic factors including climate change, inflation, and rising interest rates. Additionally, events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, in March 2023, Silicon Valley Bank and Signature Bank were closed and taken over by the FDIC, which created significant market disruption and uncertainty for those who bank with those institutions, and which raised significant concern regarding the stability of the banking system in the United States, and in particular with respect to regional banks. These factors, amongst other things, could result in further economic uncertainty and volatility in the capital markets in the near term, and could negatively affect our operations. We will continue to monitor material impacts on our business strategies and operating results.

Leases

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the circumstances present. The Company accounts for a contract as a lease when it has the right to control the asset for a period of time while obtaining substantially all of the asset's economic benefits. The Company determines the initial classification and measurement of its operating right-of-use ("ROU") assets and operating lease liabilities at the lease commencement date, and thereafter if modified. The lease term includes any renewal options that the Company is reasonably assured to exercise. The Company's policy is to not record leases with a lease term of 12 months or less on its balance sheets. The Company's only existing lease is for office space.

The ROU asset represents the right to use the leased asset for the lease term. The lease liability represents the present value of the lease payments under the lease. The present value of lease payments is determined by using the interest rate implicit in the lease, if that rate is readily determinable; otherwise, the Company uses its estimated secured incremental borrowing rate for that lease term.

Lease expense for operating leases is recognized on a straight-line basis over the reasonably assured lease term based on the total lease payments and is included in operating expense in the statement of operations.

The Company's facility lease contracts often include lease and non-lease components. The Company has elected the practical expedient offered by the standard to not separate lease from non-lease components and accounts for them as a single lease component.

The Company has elected, for all classes of underlying assets, not to recognize ROU assets and lease liabilities for leases with a term of twelve months or less. Lease cost for short-term leases is recognized on a straight-line basis over the lease term.

Recently issued accounting pronouncement - Not yet adopted:

ASU 2016-13, Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments and Subsequent Amendments

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments, and issued subsequent amendments to the initial guidance within ASU 2018-19, ASU 2019-04, ASU 2019-05, ASU 2019-11, and ASU 2020-02, (collectively, "Topic 326"). Topic 326 introduces an approach, based on expected losses, to estimate credit losses for certain types of financial instruments, including accounts receivable, among other changes. This guidance is effective for annual and interim periods beginning after December 15, 2019 for public business entities, excluding smaller reporting companies. Topic 326 is effective January 1, 2023 for the Company as a smaller reporting company. The Company determined that the impact of the accounting standard on its financial statements, specifically accounts receivable, upon adoption will not be significant.

3.Financial Instruments and Fair Value Measurements

The Company's financial instruments consist of money market funds and conversion right liability. The following tables show the Company's cash equivalent's carrying value and fair value at December 31, 2022 and 2021 (in thousands):

	As of December 31, 2022				
	Carrying Amount	Fair Value	Quoted Priced in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets					
Money market funds	$ 3,074	$ 3,074	$ 3,074	$ —	$ —
Total assets	$ 3,074	$ 3,074	$ 3,074	$ —	$ —

	As of December 31, 2021				
	Carrying Amount	Fair Value	Quoted Priced in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets					
Money market funds	$ 12,793	$ 12,793	$ 12,793	$ —	$ —
Total assets	$ 12,793	$ 12,793	$ 12,793	$ —	$ —

Cash equivalents – Cash equivalents of $3.1 million and $12.8 million as of December 31, 2022 and 2021, respectively, consisted of money market funds. Money market funds are classified as Level 1 of the fair value hierarchy because they are valued using quoted market prices in active markets.

Conversion feature derivative liability – The fair value of the conversion feature derivative liability was derived through the Monte Carlo method and was based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The conversion right liability outstanding when the Preferred Stock Series Seed was issued in July 2019 was reclassified to additional paid-in capital.

	Conversion Right Liability (in thousands)
Balance at January 1, 2021	$ 717
Issuance of convertible rights	1,355
Changes in fair value	(436)
Reclassification to additional paid-in capital	(1,636)
Balance at December 31, 2021	$ —

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs.

There have been no changes to the valuation methods utilized by the Company during the years ended December 31, 2022 and 2021. The Company evaluates transfers between levels at the end of each reporting period. There were no transfers of financial instruments between levels during the years ended December 31, 2022 and 2021.

4.Accounts Receivable Factoring

The Company may enter into accounts receivable factoring arrangements with financial institutions from time to time. During the year ended December 31, 2021, the Company factored accounts receivable in the amount of $68 thousand for a factored amount of $61 thousand. The fees related to factoring were $7 thousand for the year ended December 31, 2021 and were recorded in general and administrative expenses. There was no accounts receivable factoring arrangement in 2022.

5.Inventory, net (in thousands)

	December 31, 2022	December 31, 2021
Raw materials	$ 724	$ 281
Work in process	23	—
Finished goods	116	148
Inventory at cost	863	429
Less reserve for obsolescence	—	—
Inventory	$ 863	$ 429

6.Commitments and Contingencies

Lease

The Company leased office space in Newark, California under a cancelable operating lease agreement, which was terminated in December 2021.

The Company executed a noncancelable operating lease for approximately 9,091 square feet of office space in Hayward, California in November 2021 as its headquarters. The lease expires in October 2025 and there is no option to renew for an additional term. The Company is obligated to pay, on a pro-rata basis, real estate taxes and operating costs related to the premises. Upon lease execution, the Company evaluated the lease and determined it should be capitalized as an operating lease. As there was no interest rate implicit in the lease, the Company estimated the incremental borrowing rate at 6% based on the rate available under its revolving credit line, as well as an assessment of the Company's risk based on its financial position at the time and its potential to obtain a collateralized loan for a period similar to the lease term.

The lease costs for the years ended December 31, 2022 and 2021 are as follows (in thousands):

	December 31, 2022	December 31, 2021
Operating lease cost	$ 201	$ 21
Short term lease cost	22	28
Total lease cost	$ 223	$ 49

Amounts reported in the balance sheet for leases where the Company is the lessee as of December 31, 2022 are as follows (in thousands):

Right-of-use assets, operating lease	$	523
Operating lease liabilities, current	$	163
Operating lease liabilities, non-current		367
Total operating lease liabilities	$	530
Remaining lease term (in years)		2.75
Discount rate		6.0%

Cash paid for amounts included in the measurement of operating lease liabilities were $189 thousand and $0 for the years ended December 31, 2022 and 2021, respectively, which is included in operating activities in the statements of cash flow.

Future minimum lease payments remaining as of December 31, 2022 under the operating lease by fiscal year are as follows (in thousands):

Fiscal Year		
2023		189
2024		210
2025		178
Total minimum lease payments		577
Less imputed interest		(47)
Present value of lease payments	$	530

Fulfillment Service Agreement

On November 25, 2022, we entered into a Fulfillment Services Agreement (the "ALOM Agreement"), with ALOM Technologies Corporation ("ALOM"). Pursuant to the ALOM Agreement, commencing on November 28, 2022, began providing, on a non-exclusive basis, certain assembly, procurement, storage, returns, and fulfillment services to our end customers and retailers within the United States. During the term of the ALOM Agreement, ALOM shall provide the services in accordance with purchase orders issued by us from time to time. The consideration payable by us to ALOM for services rendered under the ALOM Agreement will be calculated and invoiced based on fixed hourly rates and fixed unit pricing, as applicable, subject to certain exceptions; provided that, commencing April 1, 2023, we will be subject to $25 thousand minimum monthly purchase requirement. The ALOM Agreement has a three-year initial term, with automatic annual renewals, and may be terminated for convenience by either party upon sixty days written notice to the other party.

Contingencies

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of its business activities. The Company accrues a liability for such matters when future expenditures are probable and such expenditures can be reasonably estimated. The Company recorded no liabilities for contingent matters as of December 31, 2022.

7.Other Accrued Expenses (in thousands)

		December 31, 2022		December 31, 2021
Accrued payroll and related	$	145	$	206
Accrued secondary offering costs		150		—
Other		78		61
Total other accrued expenses	$	373	$	267

8.Notes Payable

On April 18, 2020, the Company applied for a loan pursuant to the Paycheck Protection Program under the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"), as administered by the U.S. Small Business Administration (the "SBA"). The loan, in the principal amount of $156 thousand, was disbursed by Bank of the West ("Lender") on May 7, 2020, pursuant to a Paycheck Protection Program Promissory Note and Agreement (the "Note and Agreement").

The program was later amended by the Paycheck Protection Flexibility Act of 2020 whereby debtors were granted a minimum maturity date of the five-year anniversary of the funding date and a deferral of ten months from the end of the covered period. The PPP Loan bore interest at a fixed rate of 1.00% per annum. Monthly principal and interest payments, less the amount of any potential forgiveness (discussed below), commenced after the sixteen-month anniversary of the funding date. The Company did not provide any collateral or guarantees for the PPP Loan, nor did the Company pay any facility charge to obtain the PPP Loan. The Note and Agreement provided for customary events of default, including those relating to failure to make payment, bankruptcy, breaches of representations and material adverse effects. Prepayment of the principal of the PPP Loan was allowed at any time without incurring any prepayment charges.

All or a portion of the PPP Loan may be forgiven by the SBA upon application to the Lender by the Company within 10 months after the last day of the covered period. Under the CARES Act, loan forgiveness was available for the sum of documented payroll costs, covered rent payments, covered utilities, and certain covered mortgage interest payments during the twenty-four-week period beginning on the date of the first disbursement of the PPP Loan. For purposes of the CARES Act, payroll costs excluded compensation of an individual employee earning more than $100 thousand, prorated annually. Not more than 40% of the forgiven amount may be for non-payroll costs. Forgiveness is reduced if full-time headcount declines, or if salaries and wages for employees with salaries of $100 thousand or less annually are reduced by more than 25%. The Company obtained forgiveness of the PPP Loan on May 11, 2021.

On December 1, 2022, the Company entered into an agreement with First Insurance Funding Corp to finance its D&O insurance premiums in the amount of $595 thousand. The interest rate on the note payable is 5.85% and the note is payable in nine equal monthly installment payments net of down payment of $89 thousand. The outstanding principal balance as of December 31, 2022 was approximately $450 thousand.

On October 28, 2021, the Company entered into a Revolving Line of Credit Note with Tethered LLC ("Tethered") providing the Company with a $250 thousand revolving line of credit (the "Line of Credit"). The Line of Credit allowed the Company to request advances thereunder until December 3, 2022 (the "Maturity Date"). Advances drawn under the Line of Credit bore interest at an annual rate of 6.0%, and each advance would be payable on the Maturity Date with the interest on outstanding advances payable monthly. The Company did not draw down on the line of credit prior to its expiration on December 3, 2022.

9.Convertible Notes Payable

In the year ended December 31, 2020, the Company issued convertible notes payable to various investors for total proceeds of $1.6 million. The notes were unsecured, had interest accrued at a rate of 3% per annum and had a term of two years.

In March and April, 2021, the Company issued convertible notes payable to various investors for total proceeds of $415 thousand. The notes were unsecured, had interest accrued at a rate of 3% per annum and matured on June 1, 2022.

In June 2021, the Company issued convertible notes payable to various investors for total proceeds of $332 thousand. The notes were unsecured, had interest accrued at a rate of 3% per annum and matured on June 1, 2023.

In June 2021, the Company issued convertible notes payable to various investors for $1.6 million with original issue discount of $176 thousand, and total proceeds of $1.4 million. The notes were unsecured, had interest accrued at a rate of 3% per annum and matured on June 1, 2023.

In July 2021, the Company issued a convertible note for $518 thousand with original issue discount of $68 thousand, and total proceeds of $450 thousand. The note was unsecured, had interest accrued at a rate of 3% per annum and matured on June 1, 2023. The combined original issue discount for the June and July convertible notes was $244 thousand.

The Notes issued in 2021 and 2020 had the following terms and conditions for conversion:

Auto Conversion upon Qualified Financing

Qualified Financing was defined as the closing of an equity financing undertaken by the Company before the Maturity Date, principally for capital raising purposes, in which the aggregate amount of gross proceeds (not including cancellation of the indebtedness represented by all Notes and other convertible securities that would convert) received by the Company is at least $2.0 million in the aggregate.

The Notes would be automatically canceled on the date of the initial closing of a Qualified Financing, and the outstanding Principal Amount and, at the election of the Company, all accrued but unpaid interest thereon, would be automatically converted at a conversion price per share equal to the lesser of:

(x) a Discount Percentage of the price per share of Qualified Securities sold to the investors in a Qualified Financing of 25%,

and

(y) the quotient of (A) the Cap value divided by (B) the number of outstanding shares of the Company, on a Fully Diluted Basis, as determined immediately prior to the Qualified Financing. The Cap value is $40 million.

The conversion would be deemed to occur immediately prior to the consummation of the Qualified Financing. In the event of a conversion of the Notes in connection with a Qualified Financing, the Company may, solely at its option, elect to convert the Notes into Shadow Preferred.

Shadow Preferred means the shares of a series of Preferred Stock issued in the Qualified Financing, having the identical rights, privileges, preferences and restrictions as the shares of Qualified Securities, other than with respect to:

(i) the per share liquidation preference; and

(ii) the percentage of the conversion price to determine the per share dividend rights.

Conversion Upon Change in Control

In the event of a Change in Control prior to the Maturity Date or prior to the conversion of this Note, the outstanding Principal Amount and, at the election of the Company, all accrued but unpaid interest thereon, on the date of conversion would be converted, immediately prior to the consummation of the transaction constituting a Change in Control, into that number of shares of Common Stock, as follows:

At the election of the holders,

(i) the outstanding Principal Amount and accrued interest will be converted into that number of Preferred Conversion Stock equal to the quotient obtained by dividing (x) the outstanding principal amount and all accrued interest by (y) the Preferred Conversion Price,

or

(ii) Holder would receive an amount equal to 1.5X the principal amount outstanding. Accrued interest which is not converted into Common Stock shall be paid to Holder in cash.

Conversion at Maturity

Based on the terms and conditions of the note, the following would occur at maturity:

The outstanding Principal Amount and all accrued interest shall convert into Preferred Conversion Stock equal to the quotient obtained by dividing (x) the outstanding Principal Amount and accrued interest by (y) the Preferred Conversion Price.

The conversion features in the Notes met the accounting definition of an embedded derivative and required separate accounting. The Company value the embedded derivative on the Notes using the Monte Carlo simulation method which included significant estimates regarding the expected time to conversion, volatility, and discount rate. The estimated fair value of these derivatives was recorded as a discount to the Notes and a derivative liability. The debt discount was amortized to interest expense over the expected term of the Notes. The liability was remeasured to fair value at year end with the offsetting amount recorded in other income, expense.

On November 10, 2021, upon the conversion of the convertible notes payable to common stock, the derivative liability associated with the converted notes was marked to market fair value and reclassified to Additional Paid in Capital. The Company recorded a loss on extinguishment of debt of $1.6 million upon conversion of the convertible notes payable.

A roll-forward of convertible notes issued, converted and outstanding is as follows (in thousands):

		Convertible Notes Payable
Balance at January 1, 2021	$	1,572
Issuance of convertible notes payable		2,857
Converted to common stock		(4,429)
Balance at December 31, 2021		—

Debt discount related to convertible notes are as follows:

		Debt Discount
Balance at January 1, 2021	$	278
Debt discount recognized		1,600
Amortized to interest expense		(1,747)
Reclassified to additional paid-in capital upon conversion of convertible notes payable		(131)
Balance at December 31, 2021		—

10.Convertible Preferred Stock

In July 2019, the Company raised $3.8 million by issuing 2,787,854 shares of Series Seed Convertible Preferred Stock. Coincident with the issuance of Series Seed Preferred Stock, $870 thousand of SAFEs converted to 774,894 shares of Series Seed Preferred Stock and $4.1 million of convertible notes, including accrued interest, converted to 5,338,727 shares of Series Seed Preferred Stock.

The Company is authorized to issue up to 10,113,621 of convertible preferred stock with $0.0001 par value. 4,000,000 shares have been designated as Series Seed-1 convertible preferred stock, 774,894 shares have been designated as Series Seed-2 convertible preferred stock, 3,615,580 shares have been designated as Series Seed-3 convertible preferred stock and 1,723,147 shares have been designated as Series Seed-4 convertible preferred stock (collectively, "Series Seed Preferred" or "preferred stock"). At December 31, 2020, the Company had 8,908,600 of Series Seed Preferred issued and outstanding, respectively. In connection with the Initial Public Offering ("IPO") on November 10, 2021, all of the Company's convertible preferred stock outstanding at the time of the IPO automatically converted into an aggregate of 2,227,116 shares of common stock.

11. Preferred Stock

There were no series of preferred stock designated and no shares issued or outstanding at December 31, 2022 and 2021.

The Company's board of directors is authorized, without action by its stockholders, to designate and issue up to 10,000,000 shares of preferred stock in one or more series, and to fix the voting rights, designations, powers, preferences, the relative, participating, optional or other special rights, if any, and any qualifications, limitations and restrictions thereof, applicable to the shares of any series of preferred stock that they may designate in the future.

12. Common Stock

At December 31, 2022 and 2021, there were 9,677,734 and 9,715,234 shares issued and outstanding, respectively.

On November 10, 2021, the Company completed an initial public offering (the "IPO") of 3,450,000 shares of common stock, at a public offering price of $5.00 per share, including the exercise in full by the underwriters of their option to purchase up to 450,000 additional shares of common stock, for aggregate gross proceeds of $17.3 million and its shares stared trading on The NASDAQ Capital Market under the ticker symbol "TIVC." The Company received approximately $14.9 million in net proceeds after deducting underwriting discounts and commissions and other offering expenses payable by the Company. In connection with the closing of the IPO, all of the Company's outstanding shares of convertible preferred stock at the time of the IPO automatically converted into 2,227,116 shares of common stock and the outstanding convertible notes payable borrowings of $4.4 million converted to 1,204,160 shares of common stock.

Common stockholders are entitled to dividends if and when declared by the Board of Directors subject to the rights of the preferred stockholders. As of December 31, 2022, no dividends on common stock had been declared by the Company. At December 31, 2022 and 2021, the Company had reserved shares of common stock for issuance as follows:

	December 31, 2022	December 31, 2021
Warrants to purchase common stock	272,680	272,680
Options issued and outstanding	1,268,850	607,220
Shares available for future stock option grants	456,381	707,250
Total	1,997,911	1,587,150

13. Common Stock Warrants

In July 2021, the Company entered into a consulting agreement, pursuant to which 50,000 warrants to purchase common stock were granted and an additional 50,000 warrants to purchase common stock were granted in November 2021. The warrants are exercisable upon issuance, have an exercise price of $1.04 per share and have a term of five years. The warrants were accounted for as an equity instrument.

The Company estimated the fair value of warrants granted in July 2021 and November 2021 using the Black-Scholes options valuation model. The fair value of the warrants of $280 thousand is recognized as a General and Administrative expense and Additional Paid-In Capital.

In November 2021, the Company issued warrants to purchase 172,680 shares of common stock to employees of Think Equity, the underwriters of the IPO. The warrants may be exercised at any time on or after May 9, 2022, have an exercise price of $6.25 per share and a term of five years. The warrants were accounted for as an equity instrument.

The Company estimated the value of the warrants in November 2021 using the Black-Scholes options valuation model. The fair value of the warrants of $328 thousand is recognized as issuance costs of the common stock issued in the IPO and Additional Paid- In Capital.

The fair value of the warrants was estimated on the date of grant using the following assumptions:

	2021
Expected life (in years)	5.0
Expected volatility	50.29% - 85.37%
Risk-free interest rate	0.89% - 1.26%
Dividend yield	—%

A summary of the Company's outstanding warrants as of December 31, 2022 is as follows:

Class of Shares	Number of Warrants		Exercise Price	Expiration Date
Common Stock	50,000	$	1.04	July 1, 2026
Common Stock	50,000	$	1.04	November 15, 2026
Common Stock	172,680	$	6.25	November 10, 2026

14.Equity Incentive Plans

In 2017, the Company adopted the 2017 Equity Incentive Plan (the "2017 Plan").

On November 10, 2021, the 2017 Plan terminated and was replaced by the 2021 Plan (defined below), and future issuances of incentive instruments will be governed by the 2021 Plan. To the extent that outstanding awards under the 2017 Plan are forfeited or lapse unexercised, the shares of common stock subject to such awards will no longer be available for future issuance.

2021 Equity Incentive Plan

In 2021, the Company adopted the 2021 Equity Incentive Plan (the "2021 Plan"). Options granted under the 2021 Plan may be Incentive Stock Options or Non-statutory Stock Options, as determined by the Compensation Committee of the Company's board of directors, who is responsible for administering the 2021 Plan. Stock Purchase Rights may also be granted under the 2021 Plan. The term shall be no more than ten years from the date of grant thereof. In the case of an Incentive Stock Option granted to an optionee who, at the time the option is granted, owns stock representing more than 10% of the voting power of all classes of stock of the Company or any Parent or Subsidiary, the term of the option shall be five years from the date of grant or such shorter term as may be provided in the option Agreement. To the extent outstanding awards under the 2021 Plan are forfeited or lapse unexercised, the shares of common stock subject to such awards will be available for future issuance under the 2021 Plan. The 2021 Plan provides that additional shares will automatically be added to the shares authorized for issuance under the 2021 Plan on January 1 of each year. The number of shares added each year will be equal to the lesser of: (i) 5.0% of the outstanding shares of the Company's common stock on December 31st of the preceding calendar year or (ii) such number of shares determined by the board of directors, in its discretion. On January 1, 2022, 485,761 shares were automatically added to the number of shares authorized for issuance under 2021 Plan (an increase equal to 5% of the number of the outstanding shares of Company common stock as of December 31, 2021). Subsequent to the year ended December 31, 2022, on January 1, 2023, 483,887 shares were automatically added to the number of shares authorized for issuance under 2021 Plan (an increase equal to 5% of the number of the outstanding shares of Company common stock as of December 31, 2022).

In the case of an Incentive Stock Option, (i) granted to an employee who, at the time of grant of such option, owns stock representing more than 10% of the voting power of all classes of stock of the Company or any Parent or Subsidiary, the exercise price shall be no less than 110% of the Fair Market Value per Share on the date of grant; (ii) granted to any other employee, the per share exercise price shall be no less than 100% of the Fair Market Value per Share on the date of grant. In the case of a Non-statutory Stock Option, the per share exercise price shall be no less than 100% of the Fair Market Value per Share on the date of grant. Notwithstanding the foregoing, options may be granted with a per share exercise price other than as required above pursuant to a merger or other corporate transaction.

The options may include provisions permitting exercise of the option prior to full vesting. Any unvested shares upon termination shall be subject to repurchase by the Company at the original exercise price of the option. Stock options granted under the Company's equity incentive plans generally vest over four years from the date of grant.

As of December 31, 2022, there were 456,381 shares of common stock available for issuance under the 2021 Plan.

The following table summarizes the option activity for the years ended December 31, 2022 and 2021:

	Shares Available For Grant	Options Outstanding Number of Options	Weighted Average Exercise Price	Weighted-Average Grant Date Fair Value	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Balances, January 1, 2021	157,321	799,470	$ 0.41	$ 0.18	7.88	$ 505
Shares reserved for issuance	937,500	—				
Reserved shares cancelled	(182,842)	—				
Options granted	(280,250)	280,250	$ 4.06	$ 1.95		
Options forfeited / cancelled	25,784	(25,784)	$ 0.40	$ 0.18		
Options expired	49,737	(49,737)	$ 0.71	$ 0.31		
Options exercised	—	(396,979)	$ 0.15	$ 0.07		
Balances, December 31, 2021	707,250	607,220	$ 2.23	$ 1.06	8.56	$ 1,163
Shares reserved for issuance	485,761	—				
Reserved shares cancelled	—	—				
Options granted	(736,630)	736,630	$ 1.71	$ 1.01		
Options forfeited / cancelled	—	(18,750)	$ 1.00	$ 0.44		
Options expired	—	—	$ —	$ —		
Options exercised	—	(56,250)	$ 1.00	$ 0.44		
Balances, December 31, 2022	456,381	1,268,850	$ 2.00	$ 1.06	7.77	$ 62
At December 31, 2022						
Vested and exercisable		357,215	$ 1.73	0.80	7.08	$ 62

The weighted-average grant date fair value per share of stock options granted in 2022 and 2021 was $1.01 and $1.95, respectively. The aggregate intrinsic value of options vested and exercisable as of December 31, 2022 is calculated based on the difference between the exercise price and the current fair value of our common stock. The intrinsic value of options exercised in 2022 and 2021 was $52 thousand and $523 thousand, respectively.

The following table sets forth the status of the Company's non-vested restricted common stock awards issued to employees:

	Number of Shares	Weighted-Average Grant-Date Fair Value Per Share
Non-vested as of January 1, 2021	—	$ —
Issuance of restricted common stock	112,500	$ 0.36
Vested	(11,719)	$ 0.36
Non-vested as of December 31, 2021	100,781	$ 0.36
Vested	(7,031)	$ 0.36
Cancelled	(93,750)	$ 0.36
Non-vested as of December 31, 2022	—	$ —

The fair value of restricted stock awards vested during the years ended December 31, 2022 and 2021 was $11 thousand and $17 thousand, respectively.

Stock-Based Compensation

Options generally vest over four years whereby 25% vest upon the first anniversary of the issuance date and 1/36th per month thereafter. Stock-based compensation expense recognized during the years ended December 31, 2022 and 2021 was $398 thousand and $57 thousand, respectively. As of December 31, 2022, there were total unrecognized compensation costs of $894 thousand related to share-based payment awards which is expected to be recognized over a weighted-average amortization period of 2.98 years.

Prior to the IPO, the grant date fair market value of the shares of common stock underlying stock options had historically been determined by the Company's Board of Directors. Because there had been no public market for the Company's common stock, the Board of Directors exercised reasonable judgment and considered a number of objective and subjective factors to determine the best estimate of the fair market value, which included valuations performed by an independent third-party, important developments in the Company's operations, sales of the Company's convertible preferred stock, actual operating results, financial performance, the conditions in the life sciences industry, the economy in general, the stock price performance and volatility of comparable public companies, and the lack of liquidity of the Company's common stock. For 2022, the Company has used a comparative peer group for determining the expected volatility rate used in the calculation of fair value. Since the Company's stock has not been publicly traded for a sufficiently long period of time, the expected volatility rate is based on a review of the historical volatilities, over a period of time equivalent to the expected life of the instrument being valued, of similarly positioned public companies within the Company's industry.

The Company estimated the fair value of share-based payment awards using the Black-Scholes options valuation model. The fair value of share-based payment awards is being amortized on a straight-line basis over the requisite service period of the awards. The fair value of share-based payment awards was estimated on the date of grant using the following assumptions:

	2022	2021
Expected life (in years)	3.58 – 6.08	5.50 – 6.08
Expected volatility	49.86% - 114.76%	49.60% - 51.57%
Risk-free interest rate	0.99% - 3.85%	1.07% - 1.33%
Dividend yield	—%	—%

Expected Term: The Company uses the simplified method to calculate expected term described in the Securities and Exchange Commission's Staff Accounting Bulletin No. 107, which takes into account vesting term and expiration date of the options.

Volatility: Volatility is based on an average of the historical volatilities of comparable publicly traded companies for the expected term.

Risk Free Interest Rate: The risk-free rate is based on the U.S. Treasury yields in effect at the time of grant for periods corresponding with the expected term of the option.

Dividend Yield: The Company has never declared or paid any cash dividends and does not plan to pay cash dividends in the foreseeable future, and therefore, used an expected dividend yield of zero in the valuation model.

No income tax benefits have been recognized relating to stock-based compensation expenses and no tax benefits have been realized from exercised stock options.

Total Stock-Based Compensation

Total stock-based compensation expense recorded related to share-based payment awards was allocated to research and development, sales and marketing, and general and administrative expense as follows (in thousands):

	2022	2021
Research and development	$ 114	$ 6
Sales and marketing	4	1
General and administrative	280	50
Total stock-based compensation	$ 398	$ 57

15.Income Taxes

The provision for income taxes differs from the amount which would result by applying the federal statutory income tax rate to pre-tax loss for the years ended December 31, 2022 and 2021.

A reconciliation of the provision computed at the federal statutory rate to the provision for income taxes included in the accompanying statements of operations for the Company is as follows.

	For the Years Ended	
	December 31, 2022	December 31, 2021
Income tax provision at statutory rate	21%	21%
State income taxes, net of federal benefit	7%	5%
Research and development credits	1%	—%
Interest expense	—%	(3)%
Loss on extinguishment of debt	—%	(4)%
Other	—%	—%
Change in valuation allowance	(29)%	(19)%
Effective income tax rate	—%	—%

For the years ended December 31, 2022 and 2021, the Company's effective tax rate is below the federal statutory income tax rate of 21% primarily due to state income taxes, net of federal benefit and the Company's position to establish a full valuation allowance on its deferred tax assets.

The tax effects of temporary differences and carryforwards that give rise to significant portions of the net deferred tax assets are presented below (in thousands):

	For the Years Ended	
	December 31, 2022	December 31, 2021
Deferred tax assets:		
Net operating loss carryforwards	$ 6,536	$ 4,172
Research and development credits	231	98
Research and development costs	292	—
Lease liability	145	198
Other temporary differences	159	63
Total deferred tax assets	7,363	4,531
Valuation allowance	(7,220)	(4,339)
Deferred tax assets recognized	143	192
Deferred tax liabilities:		
Right-of-use assets	(143)	(192)
Total deferred tax liabilities	(143)	(192)
Net deferred tax assets	$ —	$ —

The Company has recorded a valuation allowance for its deferred tax assets that it does not believe will be realizable at a more likely than not level based on analysis of all available sources of taxable income. The valuation allowance increased by $2.9 million and $1.6 million for the years ended December 31, 2022 and 2021, respectively, due to current and previous year losses and credits claimed.

At December 31, 2022 and 2021, the Company had federal net operating loss carryforwards of approximately $23.3 million and $15.0 million, respectively, which will begin to expire in 2036. Approximately $22.9 million of federal net operating losses can be carried forward indefinitely. At December 31, 2022 and 2021, the Company had state net operating loss carryforwards for California of approximately $23.2 and $14.5 million, respectively, which will begin to expire in 2031. The Company also had federal and state research and development credit carryforwards of approximately $124 thousand and $260 thousand, respectively, at December 31, 2022. The California state credits carryforward indefinitely.

Federal and state tax laws impose substantial restrictions on the utilization of net operating loss and credit carryforwards in the event of an "ownership change" for tax purposes, as defined in Section 382 of the Internal Revenue code. Accordingly, the Company's ability to utilize these carryforwards may be limited as a result of such ownership changes. Such a limitation could result in limitation in the use of net operating losses in future years and possibly a reduction of the net operating losses available. The Company has not performed a 382 study to determine if any ownership changes have occurred which could potentially limit the utilization of the tax attribute carryforwards.

A reconciliation of the beginning and ending amount of gross unrecognized tax positions is as follows (in thousands):

	For the Years Ended	
	December 31, 2022	December 31, 2021
Unrecognized tax benefits, beginning of year	$ 53	$ 33
Additions related to current year tax positions	62	20
Net deferred tax assets	$ 115	$ 53

During the years ended December 31, 2022 and 2021, the amount of unrecognized tax benefits increased by $62 thousand and $20 thousand, respectively, due to additional research and development credits generated during those years. As of December 31, 2022 and 2021, the total amount of unrecognized tax benefits was $115 thousand and $53 thousand, respectively. The reversal of the uncertain tax benefits would not affect the Company's effective tax rate to the extent that it continues to maintain a full valuation allowance against its deferred tax assets.

The Company recognizes interest and penalties related to unrecognized tax benefits in the provision for income taxes line item in the statements of operations. As of December 31, 2022, and 2021, the Company had not accrued any interest or penalties related to uncertain tax positions. The Company does not anticipate any material change in its unrecognized tax benefits over the next twelve months. The unrecognized tax benefits may change during the next year for items that arise in the ordinary course of business.

The Company files tax returns in U.S. Federal and state jurisdictions. The tax periods from 2016 to 2022 remain open to examination in all jurisdictions. In addition, any tax losses that were generated in prior years and carried forward may also be subject to examination by the respective authorities. The Company is not currently under examination by income tax authorities for federal or state purposes.

For tax years beginning after December 31, 2021, the Tax Cuts & Jobs Act of 2017 eliminated the option to deduct research and development expenditures as incurred and instead required taxpayers to capitalize and amortize them over five or fifteen years beginning in 2022. The Company calculated the amount of research and development expenditures required to be capitalized in 2022. There was no impact on 2022 income tax expense due to the capitalization of research and development expenditures.

16. Net Loss per Share

The following outstanding potentially dilutive common stock equivalents have been excluded from the calculation of diluted net loss per share for the periods presented due to their antidilutive effect:

	For the Years Ended December 31,	
	2022	2021
Common stock warrants	272,680	272,680
Common stock options issued and outstanding	1,268,850	607,220
Total	1,541,530	879,900

	For the Years Ended December 31,	
	2022	2021
Net loss	$ (10,096)	$ (8,494)
Weighted-average number of shares - basic and diluted	9,672,957	3,493,267
Net loss per share - basic and diluted	$ (1.04)	$ (2.43)

17. Related Party Transactions

In June 2021, the Company issued a convertible note payable to its Chief Executive Officer for total proceeds of $100 thousand. The note was unsecured, had a term of twenty-three months and accrued interest at a rate of 3% per annum. The note, including accrued interest expense, converted to common stock on November 10, 2021.

In December 2021, the Company entered into an agreement with a significant shareholder for certain product development consultation services. During the years ended December 31, 2022 and 2021, the Company incurred $18 thousand and $3 thousand, respectively, of expenses in connection with the agreement. The expenses are included in research and development expense. There were no unpaid balances due to the shareholder at December 31, 2022.

18. Subsequent Events

On February 8, 2023, the Company entered into an underwriting agreement (the "Underwriting Agreement") with ThinkEquity LLC, as representative of the underwriters (the "Underwriter"), pursuant to which the Company agreed to issue and sell to the Underwriter in a firm commitment underwritten public offering (the "Offering"), 20,000,000 shares (the "Shares") of the Company's common stock at a public offering price of $0.25 per Share, less underwriting discounts and commissions, resulting in gross proceeds to the Company of $5.0 million. In addition, pursuant to the Underwriting Agreement, the Company granted the Underwriter a 45-day option to purchase up to an additional 3,000,000 shares of common stock, solely to cover over-allotments.

The Offering closed on February 13, 2023, with the sale of 20,000,000 Shares of common stock to the Underwriter. The net proceeds to the Company, after deducting the underwriting discount and commissions and estimated expenses of the Offering payable by the Company, was approximately $3.6 million.

Additionally, pursuant to the Underwriting Agreement, on February 13, 2023, the Company issued designees of the Underwriter warrants to purchase an aggregate of 1,000,000 shares of common stock (the "Representative's Warrants"), representing 5.0% of the aggregate Shares sold in the Offering, as partial consideration for services rendered in connection with the Offering. The Representative's Warrants have an initial exercise price of $0.3125 per share, and will be exercisable for a four-year period commencing 180 days following the commencement of sales in the Offering.

The Company will perform a 382 study to determine whether an ownership change occurred and the impact on the net operating loss and credits carryforwards available to be utilized in future periods.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statement on Form S-8 (File No. 333-261044) of Tivic Health Systems, Inc. (the "Company") of our report dated March 31, 2023, relating to the Company's financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2022.

/s/ Rosenberg Rich Baker Berman, P.A.
Rosenberg Rich Baker Berman, P.A.

Somerset, New Jersey
March 31, 2023

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jennifer Ernst, certify that:

1.I have reviewed this Annual Report on Form 10-K of Tivic Health Systems, Inc.;

2.Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3.Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4.The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a)designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b)Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

(c)evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d)disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5.The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):

(a)all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b)any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 31, 2023

By: /s/ Jennifer Ernst
Jennifer Ernst
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Veronica Cai, certify that:

1.I have reviewed this Annual Report on Form 10-K of Tivic Health Systems, Inc.;

2.Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3.Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4.The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a)designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b)Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

(c)evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d)disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5.The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):

(a)all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b)any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 31, 2023

By: /s/ Veronica Cai
Veronica Cai
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Tivic Health Systems, Inc. (the "Company") for the year ended December 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Jennifer Ernst, Chief Executive Officer of the Company, and Veronica Cai, Chief Financial Officer of the Company, do each hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1)The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2)The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: March 31, 2023

By: /s/ Jennifer Ernst
Jennifer Ernst
Chief Executive Officer
(Principal Executive Officer)

Date: March 31, 2023

By: /s/ Veronica Cai
Veronica Cai
Chief Financial Officer
(Principal Financial and Accounting Officer)