UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2021

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: 001-32046

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. ☐

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

The registrant was not a public company as of June 30, 2021, the last business day of its most recently completed second fiscal quarter, and therefore, cannot calculate the aggregate market value of its voting and non-voting common equity held by non-affiliates as of such date. The registrant's common stock began trading on the Nasdaq Capital Market on November 11, 2021.

As of March 30, 2022, 9,715,234 shares of the registrant's common stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of the registrant's definitive proxy statement to be delivered to its shareholders in connection with the registrant's 2022 Annual Meeting of Shareholders are incorporated by reference into Part III of this Annual Report on Form 10-K. Such definitive proxy statement will be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Table of Contents

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 ("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;
- our expectations regarding the effects of the COVID-19 pandemic on our business, our suppliers and our customers, including the ability to secure sufficient electronic parts to meet demand; 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

Tivic Health is a consumer health technology company focused on bioelectronic medicine. Bioelectronic medicine treats disease and conditions by modulating the electrical signals carried along various nerve pathways. The field grew out of the multi-billion-dollar neuromodulation industry and relied, historically, on implantable devices (e.g. pacemakers, spinal implants, deep brain stimulators). We have demonstrated with our first product that non-invasive bioelectronic therapy can safely and comfortably deliver therapeutic benefits with a favorable safety profile.

Tivic Health's first product is a non-invasive trigeminal nerve stimulation device sold as ClearUP® Sinus Relief ("ClearUP"). The patented handheld device uses ultra-low current electrical waves to relieve symptoms of sinus and nasal inflammation. ClearUP is a US 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). ClearUP consistently receives high customer ratings across multiple sales platforms.

We have brought bioelectronic medicine to the home treatment market for nasal allergies, sinus infections, chronic sinusitis, cold and flu. This $9.9 billion U.S. market is currently dominated by pharmaceuticals. However, through a market research study commissioned by the Company, in which 600 individuals reported ongoing sinus conditions were electronically surveyed, we discovered that:

- 70% of sufferers are not completely satisfied with over-the-counter treatment options;
- 90% are interested in treatments that reduce use of medications; and
- 66% are concerned about side effects of pharmaceutical treatments.

We conducted two published clinical studies with leading research institutions. The first clinical study was a randomized controlled double-blind trial conducted by the Standard 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 substantive side effects.

We are currently preparing a second-generation version of ClearUP, "ClearUP Gen 2," for market. Covered by the same patents, ClearUP Gen 2 is expected to lower cost of goods by lowering product 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 that ClearUP Gen 2 to be covered by the same regulatory clearances as ClearUP.

We are currently conducting a clinical trial in concert with the Icahn School of Medicine at Mount Sinai, testing a new signal variant 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. Similarly, we are reviewing post-market data from use of ClearUP indicating users receive some relief from migraine headaches and are evaluating clinical, regulatory and go-to-market pathways for a migraine indication.

First Product in Market

Tivic Health's first product in market, based on our core technology, is ClearUP® Sinus Relief. ClearUP has received FDA clearance for treating various symptoms of allergic rhinitis (nasal allergies), sinusitis and cold and flu. It is available without prescription.

Market Opportunity

The FDA initially provided clearance to the 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.

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 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, which electronically surveyed 600 individuals reporting ongoing sinus conditions) indicating that 27% of consumers are willing to pay the current retail price for ClearUP, 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 on Amazon and 65% from the manufacturer's website.

According to Mintel Group Ltd., over-the-counter allergy, cough, cold and flu treatments were a $9.9 billion market in 2019 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 the European Union, United Kingdom, Australia, New Zealand and numerous other countries that recognize the CE Mark for regulatory governance. We believe that ClearUP is an international opportunity.

Customers

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

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 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.

Sales Channels

ClearUP is sold over the counter without a prescription through our own website, Amazon.com, Walmart.com, BestBuy.com, FSAStore.com, and other specialty online retailers.

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 audiences.

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 daily direct-to-consumer sales volume as we continue to expand and optimize marketing and advertising tactics.

Core Technology

Tivic Health's technology combines 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. 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. While 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-invasive*ly 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 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.

  - **Nasal irrigation with saline**, rinsing the nasal passages with saline solution, is the most common non-pharmaceutical treatment, representing approximately $706 million in sales in the U.S. Example products include Sinus Rinse and Navage Nasal Care. 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, 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 an emerging new product offering in the non-drug category and currently has small market share.

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, US10537738; 10 patents pending)

- ***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, US10596374; 7 patents pending)

- ***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, US10537738; 10 patents pending)

- ***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; 3 patents pending)

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 ClearUP Gen 2 for market. Covered by the same patents, ClearUP Gen 2 is expected to lower cost of goods by lowering product 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 ClearUP Gen 2 to be covered by the same regulatory clearances as 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 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 began in the first quarter of 2022.

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 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 medical product companies. While 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.

Manufacturing

The ClearUP device uses conventional, off-the-shelf electronic components. Suppliers must be registered with the FDA and certified for manufacturing of products of the class of product. Our products require no specialty manufacturing capabilities.

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 COVID-related shortages, customs and port management issues.

We have 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. We are currently 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 and our business operations and financial condition may be materially harmed.

Electronic components are assembled onto printed circuit boards in the San Francisco Bay Area, near our final assembly and test house. ClearUP is assembled, tested, and warehoused at, and distributed from the San Francisco Bay Area.

We continue investing in development of ClearUP Gen 2, which is expected to lower product, fulfillment and shipping costs and increase flexibility for line extensions. In order to allow the Company to capitalize on cost-saving opportunities while managing global supply chain risks, elements of the ClearUP Gen 2 program may be introduced in a step wise fashion.

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.
- 18 patents pending in the U.S. and abroad.

- 4 provisional patent applications have been filed in the U.S.
- 7 trademarks granted in the U.S. and China.

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

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.

The FDA classifies our peripheral nerve stimulation platform as a Transcutaneous Electrical Nerve Stimulator ("TENS") regulated as a Class II medical device.

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.

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, United Kingdom, 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, United Kingdom 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 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. The CCPA, 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.

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 $12,273 per month, plus the Company's pro rata share of operating, which are currently approximately $4,500 per month.

Human Capital Resources

As of December 31, 2021, we had seven full-time employees and five 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.

On November 10, 2021, the Company completed an initial public offering (the "IPO") of 3,450,000 shares of its 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 $17,250,000 and its shares stared trading on The NASDAQ Capital Market under the ticker symbol "TIVC." The Company received approximately $14,887,000 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 an aggregate of 2,227,116 shares of common stock and the outstanding convertible notes payable borrowings of $4,384,000 converted to 1,204,160 shares of common stock.

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 common stock 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 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. Recently, we have 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. 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 have a relatively limited operating history and may not be able to execute on our business strategy.
- 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, we may not achieve or maintain profitability in the future, and there is substantial doubt about our ability to continue as a going concern.
- We have identified a material weakness in our internal control over financial reporting associated with staffing levels.
- We expect that we will need additional capital, which, if obtainable, could dilute the ownership interest of investors.
- Our business plan depends heavily on 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 due to the ongoing military conflict between Russia and Ukraine, could harm our financial condition and results of operations.
- 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 product 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.
- 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, including COVID-19.

- 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.

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

- 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 the shares of common stock being issued in connection with this offering.

- 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.

- A significant portion of our total outstanding shares are restricted from immediate resale, but such shares may be sold into the market in the near future. This could cause the market price of our common stock to drop significantly, even if our business is doing well.

- 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 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. Recently, we have 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. 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. The circumstances relating to the COVID-19 pandemic, as well as other disasters, have caused significant shortages in the supply of the electronic parts and certain other components used in our products. Recently, we have 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. 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 have experienced lengthened lead times throughout our supply chain as a result of supply chain constraints and material shortages that have occurred in the recent months, and may continue through 2022. This has been exacerbated by the recent resurgence of the COVID-19 pandemic in certain parts of China, which has 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.

We are currently 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, including as a result of circumstances relating to the COVID-19 pandemic, 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. 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 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 ClearUP Gen 2, 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, 2021 and 2020, we incurred net losses of $8,494,000 and $3,639,000, respectively, and at December 31, 2021, we had working capital of $13,070,000 and an accumulated deficit of $19,546,000. Since inception through December 31, 2021, we have spent approximately $14,528,000 on organizational and start-up activities, to recruit key managers and employees, to develop our products, to develop our manufacturing know-how and customer support resources and for research and development. The net losses we incur may fluctuate significantly from quarter to quarter and may increase as a result of a continuation of the COVID-19 pandemic. 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 its markets, complete development of new products, obtain regulatory approvals, launch and commercialize our products and continue research and development programs. Although the Company believes it has adequate cash and financial resources to operate for at least the next twelve months from the date hereof, no assurances can be given.

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. We may seek additional funds through equity or debt offerings and/or borrowings under additional 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.

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.

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, 2021 and 2020, we and our independent registered public accounting firm 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 in our case 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. 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 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. To the extent that cash from operations and the proceeds from our IPO are insufficient to fund our operations, we may need to raise additional funds through the issuance of equity, equity-related or convertible debt, or other securities. 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 Annual Report on Form 10-K.

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, including Jennifer Ernst, our Chief Executive Officer and founder. We have not entered into employment agreements our executive officers or other key personnel that 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 sales and support 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 or disruptions caused by the COVID-19 pandemic, including global supply chain constraints. Additionally, we rely on third parties such as Amazon.com, BestBuy.com, Walmart.com, FSAStore.com 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; and (vi) 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 product 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. Since launching in late 2019 and through the date hereof, we have accrued return and warranty reserves equal to approximately 10.3% of revenue (before return and warranty reserves) and believe our reserve of $16,000 for return and warranty as of December 31, 2021 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 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 new clinical standards and 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;
- respond to technological advances and emerging industry standards and practices on a cost-effective and timely basis; and
- respond to 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 distribution arrangements and out-bound 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 salespeople and distributors;
- 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. ClearUP Gen 2 is a design modification of the ClearUP device. Given that ClearUP Gen 2 is 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 the ClearUP Gen 2 device is covered under the same regulatory clearances as ClearUP. If the FDA were to determine that our products do not properly satisfy the conditions for FDA clearance as Class II devices, or that our ClearUP Gen 2 device is not covered by the same regulatory clearances as our existing ClearUP device, we could be forced to cease distribution of our products until we obtain regulatory clearance or approval, and we could be subject to additional enforcement action by the FDA. All existing FDA clearances, including those covering our first generation 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, financial condition, results of operations and growth may be impacted by the effects of the COVID-19 pandemic.

We are subject to risks related to public health crises, such as the global pandemic associated with COVID-19. In December 2019, a novel strain of coronavirus, SARS-CoV-2, was reported to have surfaced in Wuhan, China. Since then, SARS-CoV-2, and the resulting disease COVID-19, has spread to most countries, and all 50 states within the United States. Of significant current concern is the emergence of a number of SARS-CoV-2 variants, some of which have increased transmissibility and may be resistant to current vaccines being administered throughout the world. The impact of such variants cannot be predicted at this time, and could depend on numerous factors, including vaccination rates among the population, the effectiveness of COVID-19 vaccines against such variants and the response by governmental bodies and regulators. The continuing COVID-19 pandemic may negatively impact our operations and revenues and overall financial condition by harming the ability or willingness of customers to pay for our products due to macro-economic conditions resulting from the pandemic or the operations of manufacturers, suppliers and other third parties with which we do business. These challenges will likely continue for the duration of the pandemic, which is uncertain, and the macro-economic effects of the pandemic will likely continue far beyond the duration of the pandemic.

Numerous foreign, state and local jurisdictions have imposed, and others in the future may impose, "shelter-in-place" orders, quarantines, executive orders and similar government orders and restrictions for their residents to control the spread of COVID-19. The electronics supply chain on which we depend has been materially impacted by plant closures and reduced operations, resulting in global parts shortages for the electronic industry as a whole. The governor of California, where our headquarters are located, previously issued "shelter-in-place" or "stay at home" orders restricting non-essential activities, travel and business operations, which could potentially be put in place again in the future. Such orders or restrictions have resulted in our offices closing, work stoppages, slowdowns and delays, travel restrictions and cancellation of events, among other effects, thereby negatively impacting our operations. Other potential disruptions may include 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.

While the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, the widespread pandemic has resulted in, and may continue to result in, significant disruption of global financial markets, reducing our ability to access capital, which could negatively affect our future liquidity, including our ability to repay our existing indebtedness. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock. The COVID-19 pandemic has also resulted in a significant increase in unemployment in the United States, which may continue even after the pandemic subsides. The occurrence of any such events may lead to reduced disposable income and reduced consumer demand, which could adversely affect the number of our products sold after the pandemic has subsided.

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, there has been a recent resurgence of COVID-19 in certain parts of China, which has resulted in manufacturing plants being temporarily closed in some areas, which 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

We expect that our stock price may fluctuate significantly, and investors may not be able to resell their shares at or above the initial public offering price. 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 shares you purchase in this offering without 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 the COVID-19 pandemic and/or inflationary 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 stock being issued in connection with this offering.

We anticipate that we will issue shares of capital stock in conjunction with future funding requirements. Any issuance of new shares of stock, or securities exercisable for or convertible into shares of 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 will be required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. In addition, beginning

with our second annual report on Form 10-K, we will be 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. 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, 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 SEC or other regulatory authorities, which could require additional financial and management resources.

A significant portion of our total outstanding shares of common stock are restricted from immediate resale but may be sold into the market in the near future. This could cause the market price of our common stock to drop significantly, even if our business is doing well.

Subject to certain exceptions, without the prior written consent of ThinkEquity LLC, as representative of the underwriters, our pre-initial public offering stockholders, during the period ending 6 months after the date of our initial public offering, and our officers and directors and, during the period ending 12 months after the date of our initial public offering, have agreed not to: (i) offer, sell, contract to sell, pledge, grant any option to purchase, make any short sale or otherwise transfer or dispose of, directly or indirectly, any shares of common stock or any securities convertible into, exchangeable for or that represent the right to receive shares of common stock; (ii) file any registration statement with the Commission relating to the offering of any shares of common stock or any securities convertible into or exercisable or exchangeable for common stock; or (iii) enter into any swap or other arrangement that transfers, in whole or in part, any of the economic consequences of ownership of common stock, subject to certain exceptions. ThinkEquity, in its sole discretion, may release the common stock and other securities subject to the lock-up agreements described above in whole or in part at any time with or without notice.

The market price of our common stock may decline significantly when the restrictions on resale by our existing stockholders lapse. A decline in the market price of our common stock might impede our ability to raise capital through the issuance of additional shares of common stock or other equity securities.

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 Report 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 will incur increased costs and become subject to additional 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 Commission, and the Nasdaq Capital Market. The expenses generally incurred by public companies for reporting and corporate governance purposes have been increasing. We expect these rules and regulations to increase our legal and financial compliance costs and to make some activities more time-consuming and costly, although we are currently unable to estimate these costs with any degree of certainty. These laws and regulations also could 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 could 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 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 approximately $12,300.00 per month, 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 30, 2022, there were approximately 93 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

All share and per share data included in this Item 15 has been retrospectively adjusted to reflect the 1-for-4 reverse stock split of our common stock, which was effected on August 31, 2021.

Convertible Debt

From December 2017 through November 2018, we issued unsecured convertible promissory notes (the "$7 Million Cap Notes") in the aggregate amount of approximately $1.98 million to accredited investors pursuant to the terms of a Note Purchase Agreement dated December 2017, as amended September 2018. Each of the $7 Million Cap Notes had a maturity date of December 2019, and were generally convertible into the Company's equity securities at a per share conversion price that was computed on the basis of a valuation cap (the "Cap") of $7 million, or a discount rate of 20% to the next round of financing (the "Discount Rate"), whichever resulted in the issuance of a greater number of equity securities to the investors, and were converted into shares of our Series Seed-3 Preferred Stock in connection with our preferred stock financing, discussed in further detail below.

From August 2018 through April 2019, we issued unsecured convertible promissory notes (the "$14 Million Cap Notes") in the aggregate amount of approximately $1.53 million to accredited investors pursuant to the terms of a Note Purchase Agreement dated August 2018. Each of the $14 Million Cap Notes had a maturity date of September 2020, and were generally convertible into the Company's equity securities at a per share conversion price that was computed on the basis of a Cap of $14 million, or a Discount Rate of 15%, whichever resulted in the issuance of a greater number of equity securities to the investors, and were converted into shares of our Series Seed-4 Preferred Stock in connection with

our preferred stock financing, discussed in further detail below.

In May 2019, we issued an unsecured convertible promissory note (the "May 2019 Note") in the amount of $455,000 to an accredited investor pursuant to the terms of a Note Purchase Agreement dated May 2019. The May 2019 Note had a maturity date of September 2021, and was generally convertible into the Company's equity securities at a per share conversion price that was computed on the basis of a Cap of $14 million, or a Discount Rate of 15%, whichever resulted in the issuance of a greater number of equity securities to the investors, and were converted into shares of our Series Seed-4 Preferred Stock in connection with our preferred stock financing, discussed in further detail below.

From June 2020 through December 2020, we issued unsecured convertible promissory notes (the "2020 Bridge Notes") in the amount of approximately $1.57 million to accredited investors pursuant to the terms of a Note Purchase Agreement dated June 2020, as amended October 2020. The 2020 Bridge Notes have a maturity date of June 2022, and are generally convertible into the Company's equity securities at a per share conversion price that will be computed on the basis of a Cap of $40 million or a Discount Rate of 25%, whichever results in the issuance of a greater number of equity securities to the investors. In August 2021, the 2020 Bridge Notes were amended to provide that, in addition to the foregoing conversion terms, in the event that the Company consummates an initial public offering of its common stock prior to the occurrence of a Qualified Financing, a Change of Control or the Maturity (all as defined in the 2020 Bridge Note), then, at the election of the Company, all accrued but unpaid interest thereon shall be converted into shares of common stock as of immediately prior to the consummation of the initial public offering at a per share price equal to the lesser of (i) 75% of the per share public offering price and (ii) the quotient resulting from dividing the $40 million Cap by the Company's capitalization on a fully diluted basis, as of immediately prior to closing of the initial public offering.

From March 2021 through April 2021, we issued unsecured convertible promissory notes in the amount of approximately $0.4 million to accredited investors. These notes were issued as part of the same offering as the 2020 Bridge Notes, accrue interest at a rate of 3% per annum, and mature on June 1, 2022.

The 2020 Bridge Notes, including those issued from March to April 2021, in the aggregate principal amount of approximately $1,987,500, converted into an aggregate of 545,613 shares of our common stock in connection with closing of the IPO, based on accrued interest of approximately $58,600 as of November 10, 2021, and a conversion price of $3.75 per share (75% of the IPO price per share).

From June 2021 through July 2021, we issued convertible notes payable for total proceeds of approximately $1.86 million to accredited investors, of which proceeds a total of $0.45 million was not received by the Company until July 2021. The notes were issued at an original issue discount of approximately $0.24 million with principal outstanding of approximately $2.11 million. The notes are unsecured, have a term of twenty-three months, and accrue interest at a rate of 3% per annum.

In June 2021, we issued a convertible note payable to our Chief Executive Officer for total proceeds of $0.10 million. The note is unsecured, has a term of twenty-three months, and accrues interests at a rate of 3% per annum.

In June 2021, we issued convertible notes payable for total proceeds of approximately $0.23 million. The notes are unsecured, have a term of twenty-three months, and accrue interest at a rate of 3% per annum.

All of the convertible notes payable issued in June 2021 (collectively, the "2021 Notes") are generally convertible into the Company's equity securities at a per share conversion price that will be computed on the basis of a Cap of $40 million or a Discount Rate of 25%, whichever results in the issuance of a greater number of equity securities to the investors. In the event that the Company consummates an initial public offering of its common stock prior to the occurrence of a Qualified Financing, a Change of Control or the Maturity (all as defined in the 2021 Notes), then the outstanding principal amount and, at the election of the Company, all accrued but unpaid interest thereon as of the date of conversion shall be converted into shares of common stock as of immediately prior to the consummation of the initial public offering at a per share price equal to the lesser of (i) 75% of the per share public offering price and (ii) the quotient resulting from dividing the $40 million Cap by the Company's capitalization on a fully diluted basis, as of immediately prior to closing of the initial public offering. The 2021 Notes, in the aggregate principal amount of approximately $2,442,221, converted into an aggregate of 658,547 shares of our common stock in connection with the IPO, based on accrued interest of approximately $27,352 as of November 10, 2021, and a conversion price of $3.75 per share (75% of the IPO price per share).

Simple Agreements for Future Equity

From December 2016 through August 2018, we entered into Simple Agreements for Future Equity (the "SAFEs") with accredited investors in the aggregate amount of $870,000. The SAFEs had a Discount Rate of 20%, and were converted into shares of our Series Seed-2 Preferred Stock in connection with our preferred stock financing, discussed in further detail below.

Preferred Stock Financing

From July 2019 through January 2020, we issued an aggregate of 2,794,979 shares of our Series Seed-1 Preferred Stock at a purchase price of $1.4034 per share for an aggregate purchase price of approximately $3.9 million to accredited investors pursuant to the terms of a Series Seed-1, Seed-2, Seed-3 and Seed-4 Preferred Stock Investment Agreement (the "Preferred Stock Financing"). In connection with the Preferred Stock Financing, the SAFEs were converted into an aggregate of 774,894 shares of our Series Seed-2 Preferred Stock at a conversion price of $1.1227 per share; the $7 Million Cap Notes, including accrued interest, were converted into an aggregate of 3,615,580 shares of our Series Seed-3 Preferred Stock at a conversion price of $0.5841 per share; the $14 Million Cap Notes, including accrued interest, were converted into an aggregate of 1,331,150 shares of our Series Seed-4 Preferred Stock at a conversion price of $1.1681 per share; and the May 2019 Note, including accrued interest, was converted into 391,997 shares of our Series Seed-4 Preferred Stock at a conversion price of $1.1681 per share.

All outstanding shares of Series Seed-1 Preferred Stock, Series Seed-2 Preferred Stock, Series Seed-3 Preferred Stock and Series Seed-4 Preferred Stock will convert into shares of our common stock on a 4:1 basis (with any fractional shares resulting from the conversion to be cashed out by the Company) in connection with this offering.

Stock Option Exercises

In March 2021, one employee purchased 50,000 shares of our common stock at an exercise price of $0.12 per share, for total consideration of $6,000.00, upon the exercise of stock options granted pursuant to our 2017 Equity Incentive Plan. In August 2021, six employees and one former employee purchased an aggregate of 346,980 shares of our common stock at a weighted average exercise price of $0.16 per share, for total consideration of approximately $55,800, upon the exercise of stock options granted pursuant to our 2017 Equity Incentive Plan. The shares of common stock issued upon exercise of these stock options were unregistered at the time of issuance, but were subsequently registered under the S-8 Registration Statement (File No. 333-261044), filed by the Company with the SEC on November 12, 2021, after completion of the IPO.

Stock Option Grants

In June 2021, we granted options to purchase 50,000 shares of our common stock, all of which are outstanding. All such stock options have an exercise price of $1.60 per share.

These stock options were unregistered at the time of issuance, but were subsequently registered under the S-8 Registration Statement (File No. 333-261044), filed by the Company with the SEC on November 12, 2021, after completion of the IPO.

Restricted Stock Grants

On July 29, 2021, we issued 112,500 shares of restricted stock under our 2017 Equity Incentive Plan to our CFO. These shares were unregistered at the time of issuance, but were subsequently registered under the S-8 Registration Statement (File No. 333-261044), filed by the Company with the SEC on November 12, 2021, after completion of the IPO.

Warrants

On July 1, 2021, we issued a warrant to purchase 50,000 shares of our common stock to a consultant as partial consideration for services provided to the Company, and issued an additional 50,000 warrants to purchase common stock in November 2021 after completion of the IPO. The warrants are exercisable upon issuance, have an exercise price of $1.04 per share and have a term of five years.

Applicable Exemptions

No underwriters were used in the foregoing transactions, and no discounts or commissions were paid for the transactions described in this item. All sales of securities described in this item were exempt from the registration requirements of the Securities Act in reliance on Section 4(a)(2) of the Securities Act, Rule 701 promulgated under the Securities Act or Regulation D promulgated under the Securities Act, relating to transactions by an issuer not involving a public offering. All of the foregoing securities are deemed restricted securities for purposes of the Securities Act.

During the fiscal year ended December 31, 2021, there were no other unregistered sales of our securities.

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"). At the closing of the offering on November 15, 2021, we sold 3,000,000 shares of common stock at an initial public offering price of $5.00 per share and received gross proceeds of $15,000,000, which resulted in net proceeds to us of approximately $12,806,000, after deducting underwriting discounts and commissions of $1,125,000, underwriter non-accountable expenses of $150,000, and underwriter offering-related transaction costs of $919,000. None of the expenses associated with the initial public offering were paid to directors, officers, persons owning ten percent or more of any class of equity securities, or to their associates, or to our affiliates. ThinkEquity LLC ("ThinkEquity") acted as sole book-running manager for the offering.

On November 16, 2021, the underwriters fully exercised their over-allotment option to purchase an additional 450,000 shares of common stock at the public offering price of $5.00 per share. The Company received gross proceeds of $2,250,000 for the over-allotment, which resulted in net proceeds to us of $2,081,250, after deducting underwriting discounts and commissions of $168,750.

As partial consideration for the underwriting services provided by ThinkEquity in connection with the IPO, we issued ThinkEquity warrants to purchase an aggregate of 172,500 shares of our common stock. The warrants will be exercisable for a four-and-one-half year period commencing 180 days following consummation of the IPO at an exercise price of $6.25 per share.

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 device company delivering non-invasive neuromodulation products for treatment of inflammatory 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.

Business Developments

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 losses in each year since our inception. Our net loss was $8,494,000 and $3,639,000 for the years ended December 31, 2021 and 2020, respectively. As of December 31, 2021, we had an accumulated deficit of $19,546,000. We currently have one product approved for sale with two United States indications and CE Mark. We expect to incur sales and marketing costs to drive adoption and market access in the United States market, with later expansion under the CE Mark. We expect to incur additional research and development expenses related to extending the indications for our product(s). We expect to incur additional general and administrative expenses related to scaling our operations and operating as a public company.

In February 2018, we initiated the FDA pivotal trial for ClearUP Sinus Pain Relief, a handheld neuromodulation device targeting the symptoms of sinus inflammation, and secured FDA clearance in January 2019. In February 2020, we were granted the CE Mark for ClearUP and in March 2021, the FDA extended the use of ClearUP to allow broader marketing. 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. We expect to continue to incur significant losses for the foreseeable future.

We have funded our operations primarily from the proceeds from the IPO, issuance and sale of convertible preferred stock and convertible notes payable and the sale of our

products. As of December 31, 2021, we had $12,975,000 in cash and cash equivalents.

We currently generate sales revenue direct-to-consumer though our own websites, Amazon.com and Walmart.com. We also sell major and specialty U.S. online retailers such as BestBuy.com and FSAStore.com. 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. Adequate funding may not be available to us on acceptable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, scale back or discontinue the development and commercialization of our products and/or future product candidates.

We 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. We expect to increase headcount selectively but will continue to rely significantly on third-party service providers with specialized expertise and/or facilities.

Components of Results of Operations

Revenue

Revenue is generated by the sale of our ClearUP product and ancillary products, including accessories and accelerated shipping charges and is net of return and warranty reserve allowances. We currently sell direct-to-consumer through our own websites, Amazon.com and Walmart.com. We also sell to major and specialty U.S. online retailers such as BestBuy.com and FSAStore.com. Product revenue and net product average order value include product and ancillary revenues net of selling expenses but exclude return and warranty reserve allowances.

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 (1) the release of ClearUP Gen 2 and (2) the allocation of fixed and semi-fixed expenses over increasing unit sales volume.

Gross Margin

Our gross margin has been and will continue to be affected by and likely 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 the launch of ClearUP Gen 2 and increasing sales volume over which fixed and semi-fixed costs are allocated.

Operating Expenses

Research and Development Expenses

Our 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 expand the marketing of our products and pursue sales growth.

General and Administrative Expenses

General and administrative expenses include 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 as we build our operational infrastructure. We expect general and administrative expenses will decrease as a proportion of revenue as revenue scales against fixed and semi-fixed administrative expenses.

Other Income / Expense, Net

Other expense, net primarily consists of the fair value adjustments related to the derivative liability for conversion rights, amortization of debt discount included in interest expense and the loss from the extinguishment of debt from the conversion of the convertible notes to common stock.

Results of Operations

Comparison of the Years Ended December 31, 2021 and 2020

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

	Year Ende Ended December 31,		
Statement of operations data:	**2021**	**2020**	**Change**
Revenue	$ 1,166	$ 860	$ 306
Cost of sales	1,295	1,085	210
Gross loss	(129)	(225)	(96)
Operating expenses:			
Research and development	878	659	219
Sales and marketing	1,696	1,306	390
General and administrative	2,929	1,014	1,915
Total operating expenses	5,503	2,979	2,524

Loss from operations	(5,632)	(3,204)	(2,428)
Other income (expense):			
Interest expense	(1,823)	(423)	(1,400)
Change in fair value of derivative liabilities	436	(27)	463
Loss on extinguishment of debt	(1,636)	-	1,636
Other income	162	15	147
Total other income (expense)	(2,861)	(435)	(2,426)
Loss before provision for income taxes	(8,493)	(3,639)	(4,854)
Provision for income taxes	1	-	1
Net loss and comprehensive loss	$ (8,494)	$ (3,639)	$ (4,855)

Revenue

Revenue increased $306,000 (36%) from $860,000 for the year ended December 31, 2020 to $1,166,000 for the year ended December 31, 2021, primarily attributable to increased unit sales of 21% from approximately 10,400 units for the year ended December 31, 2020 to approximately 12,600 units for the year ended December 31, 2021 and increases in net product average order value for the year ended December 31, 2021 as compared to December 31, 2020 as described in more detail below. Ancillary revenues were less than 1% of total revenue for both of the years ended December 31, 2020 and 2021.

	Year Ended December 31,		
Statement of operations data (in thousands):	**2021**	**2020**	**Change**
Product Revenue			
Direct-to-consumer	$ 691	$ 551	$ 140
Retail	592	415	177
Return and Warranty Reserves	(117)	(106)	(11)
Revenue	$ 1,166	$ 860	$ 306

Direct-to-consumer product revenue increased $140,000 (25%) from $551,000 for the year ended December 31, 2020 to $691,000 for the year ended December 31, 2021, which increase is primarily attributable to increased unit sales of 17% from approximately 4,800 units for the year ended December 31, 2020 to approximately 5,600 units for the year ended December 31, 2021. Net product average order value increased to $123.39 for the year ended December 31, 2021 from $114.79 for the year ended December 31, 2020 primarily due to a reduction in consumer pricing incentives during the year ended December 31, 2021 from the year ended December 31, 2020.

Retail channel product revenue increased $177,000 (44%) from $415,000 for the year ended December 31, 2020 to $592,000 for the year ended December 31, 2021, which increase is primarily attributable to increased unit sales of 25% from approximately 5,600 units for the year ended December 31, 2020 to approximately 7,000 units for the year ended December 31, 2021. Average product order value increased to $84.57 for the year ended December 31, 2021 from $74.11 for the year ended December 31, 2020 primarily due to our focus on selling product through higher margin retail channel customers for the year ended December 31, 2021 from the year ended December 31, 2020.

Return and warranty reserves as a percentage of product revenue was approximately 11.1% for the year ended December 31, 2020, as compared to 9.1% for the year ended December 31, 2021. We lowered the return and warranty reserve due to lower return rates which we believe were a result of our efforts to provide more effective online and print media on how to use our products.

Cost of Sales

Cost of sales for the year ended December 31, 2021 was $1,295,000 compared to $1,085,000 for the year ended December 31, 2020, an increase of $210,000 or 19%. The period over period increase was primarily attributable to increased unit sales of 21% from approximately 10,400 unit for the year ended December 31, 2020 to approximately 12,600 units for the year ended December 31, 2021.

Variable cost of goods sold includes product costs, fulfillment, shipping and other variances and adjustments. Variable cost of goods sold was $1,039,000 or $82.46 per unit given 12,600 units for the year ended December 31, 2021 as compared to $737,000 or $70.87 per unit given 10,400 units for the year ended December 31, 2020. The increase in variable cost of goods sold was due to increased costs related to global supply chain issues. Fulfillment and shipping costs are significantly lower for retail channel bulk orders.

Fixed cost of goods sold includes allocation of fixed and semi-fixed expenses, including, non-cash Company personnel allocation and monthly minimum management, storage and processing fees from our third-party logistics provider. Fixed cost of goods sold decreased to $256,000 for the year ended December 31, 2021 as compared to $348,000 for the year ended December 31, 2020 primarily due to lower non-cash Company personnel allocation as the Company refined its production management processes. Non-cash Company personnel allocation for the fourth quarter of 2021 was $22,500.

Revenue less variable cost of goods sold for the year ended December 31, 2021 was $127,000 compared to $123,000 for the year ended December 31, 2020. Gross loss for the year ended December 31, 2021 was $(129,000) compared to $(225,000) for the year ended December 31, 2020.

Our gross margin has been and will continue to be affected by and likely 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 the launch of ClearUP Gen 2 and increasing sales volume over which fixed and semi-fixed costs are allocated.

Research and Development Expenses

Research and development expenses increased by $219,000 from $659,000 for the year ended December 31, 2020 compared to $878,000 for the year ended December 31, 2021. The emphasis of activity in 2020 was primarily related to completion of a four-week at home clinical study supporting the application for a CE Mark for ClearUP. Activity in 2021 was primarily focused on developing ClearUP Gen 2, and preparation for seeking FDA approval for a second indication for the ClearUP product line.

Sales and Marketing Expenses

Sales and marketing expenses increased to $1,696,000 for the year ended December 31, 2021, compared to $1,306,000 for the year ended December 31, 2020. The increase of $390,000 primarily related to $300,000 of increased fourth quarter spending in anticipation of and use of proceeds of our November 2021 IPO to expand our sales and marketing efforts, including (i) expanding advertising; (ii) growing our social media presence; (iii) upgrading and optimizing ecommerce infrastructure, online/website design; and (iv) other initiatives marketing initiatives.

General and Administrative Expenses

General and administrative expenses increased by $1,915,000 from $2,929,000 for the year ended December 31, 2021, compared to $1,014,000 for the year ended December 31, 2020, primarily due to increase salaries, consulting fees, audit fees and other professional services to upgrade the accounting and finance function and to obtain an audit.

Other Income (Expense), Net

Other income (expense), net for the year ended December 31, 2021 is primarily due to the loss on extinguishment of debt upon conversion of the convertible notes payable to common stock of $1,636,000, amortization of debt discount of $1,747,000 and interest expense of $76,000 offset by the income from the forgiveness of the PPP loan and the change in the fair value of the conversion feature derivative liabilities. Other income (expense), net for the year ended December 31, 2020 is primarily due to the amortization of debt discount of $411,000.

Liquidity and Capital Resources

Sources of Liquidity

From our inception through December 31, 2021, we have generated $2,446,000 in revenue from product sales and have incurred operating losses and negative cash flows from our operations. As of December 31, 2021, we had cash and cash equivalents of $12,975,000, working capital of $13,070,000 and an accumulated deficit of $19,546,000. We have financed our operations to date primarily through issuances of SAFE instruments, convertible notes and convertible preferred stock and the proceeds from the IPO in November 2021. In 2019, we sold an aggregate of 2,787,854 shares of our convertible preferred stock to accredited investors, generating net proceeds of $3,843,000, and borrowings from convertible notes payables issued to investors in the amount of $1,710,000. In 2020, we borrowed $1,573,000 by issuing convertible notes and issued notes payable to borrow $195,000. In November 2021, we completed our IPO, generating net proceeds to the Company of approximately $14,887,000. During the year ended December 31, 2021, we borrowed $2,613,000 by issuing convertible notes payable.

In addition, on October 28, 2021, we entered into a Revolving Line of Credit Note with Tethered LLC ("Tethered") providing us with a $250,000 revolving line of credit (the "Line of Credit"), pursuant to which we may request advances until December 3, 2022. Advances drawn under the Line of Credit bear interest at an annual rate of 6.0%, and each advance will be payable on the maturity date with the interest on outstanding advances payable monthly. We may, at our option, prepay any borrowings under the Line of Credit, in whole or in part, at any time prior to the maturity date, without premium or penalty. To date, we have not drawn down on the Line of Credit.

During the years ended December 31, 2021 and 2020, we incurred net losses of $8,494,000 and $3,639,000, respectively, and used $5,612,000 and $3,027,000 of cash for operations, respectively. 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.

Recent Developments

In April 2021, we issued a convertible note payable for total proceeds of $115,000. The note is unsecured, has interest accrued at a rate of 3% per annum and has a term of thirteen months.

On May 11, 2021, the SBA approved forgiveness of our PPP Loan, including accrued interest. The amount forgiven by the SBA was $157,000.

Effective as of June 7, 2021, the Company reincorporated as a Delaware corporation.

From June 2021 through July 2021, we issued convertible notes payables for total proceeds of $1,866,000. The notes were issued at an original issue discount of $244,000 with principal outstanding of $2,110,000. The notes are unsecured, have a term of twenty-three months, and accrue interest at a rate of 3% per annum.

In June 2021, we issued convertible notes payable for total proceeds of $132,000. The notes are unsecured, have a term of twenty-three months, and accrue interest at a rate of 3% per annum.

In June 2021, we issued a convertible notes payable to our Chief Executive Officer for total proceeds of $100,000. The note is unsecured, has a term of twenty-three months, and accrues interests at a rate of 3% per annum.

In August 2021, after receiving Board approval of the same on July 29, 2021, holders of a majority of our issued and outstanding securities authorized our Board, acting in its sole discretion without further approval of our stockholders, to effect a reverse split of our issued and outstanding common stock, at a ratio of not less than 1-for-2, but not more than 1-for-15, at any time on or before July 29, 2021. On August 29, 2021, our Board approved a reverse split ratio of 1-for-4, and on August 31, 2021, we filed a Certificate of Amendment to our Certificate of Incorporation to implement the reverse stock split.

On October 28, 2021, the Company entered into a Revolving Line of Credit Note with Tethered LLC ("Tethered") providing the Company with a $250,000 revolving line of credit (the "Line of Credit"). The Line of Credit allows the Company to request advances thereunder until December 3, 2022 (the "Maturity Date"). Advances drawn under the Line of Credit bear interest at an annual rate of 6.0%, and each advance will be payable on the Maturity Date with the interest on outstanding advances payable monthly. The Company may, at its option, prepay any borrowings under the Line of Credit, in whole or in part at any time prior to the Maturity Date, without premium or penalty. The Company has not drawn down on the Line of Credit as of the date hereof.

In November 2021, the Company completed 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 $17,250,000 and its shares stared trading on The NASDAQ Capital Market under the ticker symbol "TIVC." The Company received approximately $14,887,000 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 an aggregate of 2,227,116 shares of common stock and the outstanding convertible notes payable borrowings of $4,384,000 converted into an aggregate of 1,204,160 shares of common stock.

We intend to raise additional capital through the issuance of additional equity and debt. If financing is not available at adequate levels, we may need to reevaluate our operating plans. Based on projected activities, management believes the Company has adequate cash and financial resources to operate for at least the next twelve months.

Plan of Operation and Future Funding Requirements

We use our capital resources primarily to fund operating expenses, primarily marketing and advertising for ClearUP and general operating expenses. We plan to increase our marketing and advertising investments to drive sales of ClearUP through existing and new channels. We plan to increase our research and development investments to identify and validate new product candidates, move them through pre-clinical and clinical development, and develop go-to-market strategies that leverage our existing sales channels and call points. At this time, due to the inherently unpredictable nature of research and new product adoption, as well as supply chain constraints that we are currently facing, 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 ramp-up 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 sell-in 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.

We have generated operating losses in each period since inception. We have incurred an accumulated deficit of $19,456,000 through December 31, 2021. We expect to incur additional losses in the future as we expand both our marketing and research and development activities. Based on our current plans, we believe that we have adequate cash and financial resources to operate for at least the next twelve months. We have based this estimate on assumptions that may prove to be wrong, however, and we could use our capital resources sooner than we expect.

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

- 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 progress of sales initiatives driving top-line revenue;
- the timing and adoption rate of ClearUP Gen 2 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;
- 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; and
- 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.

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,	
	2021	2020
Cash used in operating activities	$ (5,612)	$ (3,027)
Cash provided by financing activities	17,543	1,760
Net increase (decrease) in cash and cash equivalents	$ 11,931	$ (1,267)

Operating Activities

Net cash used in operating activities for the year ended December 31, 2021, was $5,612,000, which consisted primarily of net loss of $8,494,000 decreased by non-cash charges of $3,285,000 and increased by a net change of $403,000 in our net operating assets. The non-cash charges primarily consisted of debt discount amortization of $1,747,000, loss on extinguishment of debt from conversion of convertible notes payable to common stock of $1,636, stock-based compensation of $57,000, accounts receivable allowances of $66 and issuance of warrant for consulting services of $280,000 offset by the change in fair value remeasurement of derivative liabilities of $436,000 and the forgiveness of the PPP loan of $157,000. 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 in 2021.

Net cash used in operating activities for the year ended December 31, 2020, was $3,027,000, which consisted primarily of net loss of $3,639,000 decreased by non-cash charges of $568,000 and decreased by a net change of $44,000 in our net operating assets. The non-cash charges primarily consisted of debt discount amortization of $411,000, stock-based compensation of $78,000, and change in fair value remeasurement of derivative liabilities of $27,000. The change in our net operating assets and liabilities was primarily due to an increase in inventory, accompanied by a decrease in accrued liabilities in 2020.

Investing Activities

We had no investing activities during the years ended December 31, 2021 and 2020.

Financing Activities

Our financing activities provided $17,543,000 of cash during the year ended December 31, 2021, which consisted primarily of the proceeds from the IPO, net of issuance costs, of $14,887,000, convertible notes payable borrowings of $2,613,000 and from issuance of common stock from exercise of stock options of $62,000 offset by notes payable repayment of $19,000.

Our financing activities provided $1,760,000 of cash during the year ended December 31, 2020, which consisted primarily of convertible notes payable borrowings of $1,573,000, borrowings of $156,000 in the form of the federal Paycheck Protection Program and borrowings of $39,000 to finance our insurance policies.

Known Trends or Uncertainties

As discussed in this Annual Report, the world has been affected due to the COVID-19 pandemic. The pandemic has 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. Until the pandemic has passed, there remains uncertainty as to the effect of COVID-19 on our business in both the short and long-term.

Inflation

Inflation has increased during the periods covered by this Annual Report, 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 COVID-19 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

Convertible Promissory Notes

From June 2020 through December 2020, we issued unsecured convertible promissory notes (the "2020 Bridge Notes") in the amount of approximately $1.57 million to accredited investors pursuant to the terms of a Note Purchase Agreement dated June 1, 2020, as amended in October 2020. The 2020 Bridge Notes have a maturity date of June 1, 2022, and are generally convertible into the Company's equity securities at a per share conversion price that will be computed on the basis of a Cap of $40 million or a Discount Rate of 25%, whichever results in the issuance of a greater number of equity securities to the investors. In August 2021, the 2020 Bridge Notes were amended to provide that, in addition to the foregoing conversion terms, in the event that the Company consummates an initial public offering of its common stock prior to the occurrence of a Qualified Financing, a Change of Control or the Maturity (all as defined in the 2020 Bridge Note), then the outstanding principal amount and, at the election of the Company, all accrued but unpaid interest thereon as of the date of conversion shall be converted into shares of common stock as of immediately prior to the consummation of the initial public offering at a per share price equal to the lesser of (i) 75% of the per share public offering price and (ii) the quotient resulting from dividing the $40 million Cap by the Company's capitalization on a fully diluted basis, as of immediately prior to closing of the initial public offering.

From March 2021 through April 2021, we issued unsecured convertible promissory notes in the amount of approximately $0.4 million to accredited investors. These notes were issued as part of the same offering as the 2020 Bridge Notes, accrue interest at a rate of 3% per annum, and mature on June 1, 2022.

The 2020 Bridge Notes, including those issued from March to April 2021, having aggregate principal amount of approximately $1,987,500, converted into an aggregate of 545,613 shares of our common stock in connection with this offering, based on accrued interest of approximately $58,595 as of November 10, 2021, and a conversion price of $3.75 per share (75% of the initial public offering price per share).

From June 2021 through July 2021, we issued convertible notes payables for total proceeds of approximately $1.86 million to accredited investors. The notes were issued at an original issue discount of approximately $0.24 million with principal outstanding of approximately $2.11 million. The notes are unsecured, have a term of twenty-three months, and accrue interest at a rate of 3% per annum.

In June 2021, we issued a convertible note payable to our Chief Executive Officer for total proceeds of $0.10 million. The note is unsecured, has a term of twenty-three months, and accrues interests at a rate of 3% per annum.

In June 2021, we issued convertible notes payable for total proceeds of approximately $0.23 million. The notes are unsecured, have a term of twenty-three months, and accrue interest at a rate of 3% per annum.

All of the convertible notes payable outstanding at the time of the IPO of $4,384,000 converted to 1,204,160 shares of common stock on November 10, 2021.

Warrants

On July 1, 2021, the Company issued a warrant to purchase 50,000 shares of our common stock to a consultant as partial consideration for services provided to the Company and issued an additional 50,000 warrants to purchase common stock 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.

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 have a term of five years.

Office 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. 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 cost recorded during the year ended December 31, 2021 was $49,000. Rent expense recorded during the year ended December 31, 2020 was $55,000.

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 on notice, 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 retailers. 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.

Based on the Company's assessment, it was determined that there were no contract assets as of December 31, 2021 and 2020 because receivables outstanding are unconditional and only the passage of time is required before payment of that consideration is due. 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, 2021, the total compensation cost related to nonvested service-based awards not yet recognized is $690,000. The weighted-average period over which the nonvested awards is expected to be recognized is 3.5 years. The aggregate intrinsic value of stock options outstanding as of December 31, 2021 was $1,163,000, of which $902,000 related to vested options and $261,000 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 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 has 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 derivative financial liability related to convertible notes issued in 2018 and 2019 was derecognized upon conversion of the convertible notes in 2019 to preferred stock. The derivative financial liability related to convertible notes issued in 2020 and 2021 was derecognized upon conversion of the convertible notes to 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, 2021, included elsewhere in this Form 10-K.

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 August 31, 2021, 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.

Based on this assessment, management has concluded that our internal control over financial reporting was effective as of the end of the fiscal year to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external reporting purposes in accordance with U.S. GAAP. We reviewed the results of management's assessment with the Audit Committee of our Board of Directors.

Inherent Limitations on Effectiveness of Controls

Our management, including the CEO and CFO, 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

No change in the Company's internal controls over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) of the Exchange Act) occurred during the Company's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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

Information required by Item 10 is incorporated by reference from the Company's definitive proxy statement, to be filed with the Commission within 120 days after the fiscal year ended December 31, 2021.

Item 11 – Executive Compensation

Information required by Item 11 is incorporated by reference from the Company's definitive proxy statement, to be filed with the Commission within 120 days after the fiscal year ended December 31, 2021.

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

Information required by Item 12 is incorporated by reference from the Company's definitive proxy statement, to be filed with the Commission within 120 days after the fiscal year ended December 31, 2021.

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

Information required by Item 13 is incorporated by reference from the Company's definitive proxy statement, to be filed with the Commission within 120 days after the fiscal year ended December 31, 2021.

Item 14 – Principal Accounting Fees and Services

Information required by Item 14 is incorporated by reference from the Company's definitive proxy statement, to be filed with the Commission within 120 days after the fiscal year ended December 31, 2021.

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.	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.			X
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†	Master Services Agreement, between Tivic Health Systems, Inc. and Extron Logistics LLC, dated April 27, 2019.	S-1A	9/9/2021	
10.11†	Letter Agreement, between Tivic Health Systems, Inc. and Future Electronics Corp., dated April 6, 2020.	S-1A	9/9/2021	
10.12†	Form of United States Special Product Agreement for Bonded Inventory, between Tivic Health Systems, Inc. and Future Electronics Corp.	S-1A	9/9/2021	
10.13	Form of Note Purchase Agreement, dated June 17, 2021, and Unsecured Convertible Promissory Note.	S-1	8/3/2021	
10.14	Form of Unsecured Convertible Promissory Note.	S-1	8/3/2021	
10.15	Form of (OID) Unsecured Convertible Promissory Note.	S-1	8/3/2021	
10.16#	Executive Offer Letter, between Tivic Health Systems, Inc. and Briana Benz, dated July 29, 2021.	S-1A	9/9/2021	
10.17#	Restricted Stock Purchase Agreement, between Tivic Health Systems, Inc. and Briana Benz, dated July 30, 2021.	S-1A	9/9/2021	
10.18#	Executive Offer Letter, between Tivic Health Systems, Inc. and Jennifer Ernst, dated July 31, 2021.	S-1A	9/9/2021	
10.19	Form of Note Amendment Agreement.	S-1A	9/9/2021	
10.20	Revolving Line of Credit Note, between the Company and Tethered LLC, dated October 28, 2021.	S-1A	10/29/2021	
10.21	Sublease Agreement, between the Company and Czarnowski Display Services, Inc., dated November 17, 2021.			X
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, 2022

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, 2022
/s/ Briana Benz Briana Benz	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 31, 2022
/s/ Sheryle Bolton Sheryle Bolton	*Chair of the Board of Directors*	March 31, 2022
/s/ Karen Drexler Karen Drexler	*Director*	March 31, 2022
/s/ Dean Zikria Dean Zikria	*Director*	March 31, 2022

TIVIC HEALTH SYSTEMS, INC.

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors 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, 2021 and 2020, and the related consolidated statements of operations, stockholder's equity (deficit), and cash flows for the years ended December 31, 2021 and 2020, and the related notes (collectively referred to as the "financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of Tivic Health Systems, Inc. as of December 31, 2021 and 2020, and the results of their operations and their cash flows for the years ended December 31, 2021 and 2020, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. Tivic Health Systems, Inc. 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 entity'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 consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

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

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

Somerset, New Jersey
March 31, 2022

Tivic Health Systems, Inc.
Balance Sheets
December 31, 2021 and 2020
(in thousands, except share and per share data)

	December 31, 2021	December 31, 2020
ASSETS		
Current assets		
Cash and cash equivalents	$ 12,975	$ 1,044
Accounts receivable, net	51	52
Inventory, net	429	241
Prepaid expenses and other current assets	834	160
Total current assets	14,289	1,497
Property and equipment, net	11	19
Right-of-use assets, operating lease	687	-
Other assets	49	15
Total assets	$ 15,036	$ 1,531
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities		
Accounts payable	$ 789	$ 370
Other accrued expenses	267	152
Operating lease liability, current	163	-
Notes payable, current	-	36
Conversion feature derivative liability	-	717
Total current liabilities	1,219	1,275
Operating lease liability	545	-
Notes payable	-	139
Convertible notes payable, net of debt discount	-	1,294
Total liabilities	1,764	2,708
Stockholders' equity (deficit)		
Convertible preferred stock, $0.0001 par value, none and 10,113,621 shares authorized at December 31, 2021 and 2020, respectively; 0and 8,908,600 shares issued and outstanding at December 31, 2021 and 2020, respectively	-	1
Preferred stock, $0.0001 par value, 10,000,000 and none shares authorized at December 31, 2021 and 2020, respectively, no shares issued and outstanding at December 31, 2021 and 2020, respectively	-	-
Common stock, $0.0001 par value, 200,000,000 and 25,000,000 shares authorized at December 31, 2021 and 2020, respectively; 9,715,234 and 2,324,479 shares issued and outstanding at December 31, 2021 and 2020, respectively	1	-
Additional paid in capital	32,817	9,874
Accumulated deficit	(19,546)	(11,052)
Total stockholders' equity (deficit)	13,272	(1,177)
Total liabilities and stockholders' equity (deficit)	$ 15,036	$ 1,531

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

Tivic Health Systems, Inc.
Statements of Operations and Comprehensive Loss
Years Ended December 31, 2021 and 2020
(in thousands, except share and per share data)

	Years Ended December 31,	
	2021	2020
Revenue	$ 1,166	$ 860
Cost of sales	1,295	1,085
Gross loss	(129)	(225)
Operating expenses:		
Research and development	878	659
Sales and marketing	1,696	1,306
General and administrative	2,929	1,014
Total operating expenses	5,503	2,979
Loss from operations	(5,632)	(3,204)
Other income (expense):		
Interest expense	(1,823)	(423)

Change in fair value of derivative liabilities	436	(27)
Loss on extinguishment of debt	(1,636)	-
Other income	162	15
Total other income (expense)	(2,861)	(435)
Loss before provision for income taxes	(8,493)	(3,639)
Provision for income taxes	1	-
Net loss and comprehensive loss	$ (8,494)	$ (3,639)
Net loss per share - basic and diluted	$ (2.43)	$ (1.58)
Weighted-average number of shares - basic and diluted	3,493,267	2,303,237

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

Tivic Health Systems, Inc.
Statements of Stockholders' Equity (Deficit)
Years Ended December 31, 2021 and 2020
(in thousands except share and per share data)

	Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity (Deficit)
Balances at January 1, 2020	8,901,475	1	2,300,000	-	9,783	(7,413)	2,371
Issuance of convertible preferred stock, net of issuance costs	7,125	-	-	-	10	-	10
Exercise of stock options	-	-	24,479	-	3	-	3
Stock-based compensation expense	-	-	-	-	78	-	78
Net loss	-	-	-	-	-	(3,639)	(3,639)
Balances at December 31, 2020	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	0	$ 0	9,715,234	$ 1	$ 32,817	$ (19,546)	$ 13 ,272

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

Tivic Health Systems, Inc.
Statements of Cash Flows
Years Ended December 31, 2021 and 2020
(in thousands)

	Years Ended December 31,	
	2021	2020
Cash flows from operating activities		
Net loss	$ (8,494)	$ (3,639)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock based compensation	57	78
Depreciation	8	8
Change in fair value of derivative liabilities	(436)	27
Amortization of debt discount	1,747	411
Loss on extinguishment of debt	1,636	-
Amortization of right-of-use asset	16	-
Noncash interest	76	-
Forgiveness of PPP loan	(157)	-
Issuance of common stock warrant	280	-
Accounts receivable allowances	66	36
Reserve for inventory obsolescence	(8)	8
Changes in operating assets and liabilities:		
Accounts receivable	(66)	(75)
Inventory	(181)	227
Prepaid expenses and other current assets	(707)	23
Accounts payable	419	1
Accrued expenses	128	(132)
Lease liabilities	4	-
Net cash used in operating activities	(5,612)	(3,027)
Cash flows from financing activities		

Proceeds from notes payable borrowings	-	195
Repayment of notes payable borrowings	(19)	(21)
Proceeds from convertible notes payable borrowings	2,513	1,573
Proceeds from convertible notes payable borrowings – related party	100	-
Proceeds from exercise of stock options	62	3
Proceeds from issuance of common stock, net of issuance costs	14,887	-
Proceeds from issuance of convertible preferred stock, net of issuance costs	-	10
Net cash provided by financing activities	17,543	1,760
Net increase (decrease) in cash and cash equivalents	11,931	(1,267)
Cash and cash equivalents		
Beginning of period	1,044	2,311
End of period	$ 12,975	$ 1,044
Supplemental disclosures of cash flow information		
Cash paid for income tax	$ 1	$ 1
Cash paid for interest	$ -	$ 1
Supplemental disclosure on noncash financing activities		
Issuance of conversion feature derivative liability	$ 1,355	$ 699
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.

Tivic Health Systems, Inc.
Notes to Financial Statements
December 31, 2021 and 2020
(in thousands except share and per share data)

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 microcurrent therapy solutions to address inflammation. The Company's primary product, ClearUP, is a medical device intended to relieve sinus and nasal inflammation. The Company is headquartered in Hayward, California.

Effective as of June 7, 2021, the Company reincorporated as a Delaware corporation, which included establishment of $0.0001 par value for convertible preferred stock and common stock. The financial statements have been retroactively adjusted as if the change in corporation status occurred on January 1, 2020.

The Company has experienced losses and negative cash flows from operations. During the year ended December 31, 2021, the Company incurred a net loss of $8,494 and used $5,612 of cash for operations. At December 31, 2021, the Company had an accumulated deficit of $19,546. Cash and cash equivalents at December 31, 2021 were $12,975. Management expects to incur substantial additional operating losses for at least the next two years to expand its markets, complete development of new products, obtain regulatory approvals, launch and commercialize our products and continue research and development programs. The Company believes it has adequate cash and financial resources to operate for at least the next twelve months from 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. We may seek additional funds through equity or debt offerings and/or borrowings under additional 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.

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 1Inputs 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 2Inputs 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 3Inputs 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, 2021 and 2020, cash equivalents was $12,793 and $639, 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, 2021 and 2020, the allowance for doubtful accounts activity was $82 and $5, respectively. As of December 31, 2021 and 2020, the reserve for sales returns was $16 and $31, 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, 2021 and 2020, the reserve for obsolescence was $0 and $8, respectively.

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, four years. Depreciation expense was $8 and $8 for the years ended December 31, 2021 and 2020, 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 has 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 8 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 independent distributors. Revenue is recognized when control of the promised goods is transferred to the customers or distributor, 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 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, 2021 and 2020, the Company's deferred revenue for unrecognized extended warranties was $12 and $14, respectively, and is included in "Other Accrued Expenses" on the accompanying balance sheets.

Based on the Company's assessment, it was determined that there were no contract assets as of December 31, 2021 and 2020 because receivables outstanding are unconditional and only the passage of time is required before payment of that consideration is due. 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, 2021 and 2020, the contract liability related to the Company's deferred revenues approximated $3 and $2, 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.

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, 2021 and 2020 were $5 and $6, respectively. Shipping costs for delivery of product to customers in the years ended December 31, 2021 and 2020 were $90 and $71, respectively.

Product Warranty

The Company 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 $660 and $688 for the years ended December 31, 2021 and 2020, 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

Basic net loss per share is computed using the "two-class" method which includes the weighted average number of shares of common stock outstanding during the period and other securities that participate in dividends (a participating security). The Company's convertible preferred stock are participating securities as defined by ASC 260-10, *Earnings per Share*. During the periods where the Company incurs net losses, the Company allocates no loss to participating securities because these securities have no contractual obligation to share in the losses of the Company. Under the two-class method, basic net loss per share applicable to common stockholders is computed by dividing the net loss applicable to common stockholders by the weighted average number of common shares outstanding for the period. 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. The Company allocates net earnings on a *pari passu* (equal) basis to both common and preferred stockholders. Net losses are not allocated to preferred stockholders as they do not have an obligation to share in the Company's net losses. For all periods presented, basic and diluted net loss per share are the same, as 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 financial institution in the United States. At times, such deposits may be in excess of insured limits. Management believes that the financial institution 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, 2021 and 2020, the Company had cash and cash equivalents balances exceeding FDIC insured limits by $12,543 and $107, 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.

As of December 31, 2021, the Company had two customers whose accounts receivable balances each totaled more than 10% or more of the Company's total accounts receivable (54% and 39%) compared with one such customer at December 31, 2020 (100%).

For the year ended December 31, 2021, the Company had two customers who individually accounted for 10% or more of the Company's total revenue (22% and 12%) compared with two customers for the year ended December 31, 2020 (23% and 15%).

COVID-19

In March 2020, the World Health Organization declared the outbreak of the COVID-19 virus a global pandemic. The pandemic continues to cause major disruptions to businesses and markets worldwide as the virus spreads or has a resurgence in certain jurisdictions. A number of countries as well as many states and cities within the United States have implemented measures in an effort to contain the virus, including physical distancing, travel restrictions, border closures, limitations on public gatherings, work from home and closure of or restrictions on nonessential businesses. The effects of the outbreak are still evolving, and the ultimate severity and duration of the pandemic and the implications on global economic conditions remains uncertain.

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 adopted accounting standards and recently issued accounting pronouncements

Recently adopted accounting standards:

ASU 2016-02, Leases (Topic 842)

In February 2016, the Financial Accounting Standards Board ("FASB") issued ASU 2016-02, which changes how lessees account for leases. For most leases qualified as operating, the standard requires a liability to be recorded on the balance sheet based on the present value of future lease obligations with a corresponding right-of-use asset. For leases classified as operating leases, the Company is now required to recognize lease costs on a straight-line basis based on the combined amortization of the lease obligation and the right-of-use asset. Similar to capital leases under the previous accounting standard, leases are accounted for as finance leases when the relevant criteria are met. On June 3, 2020, the FASB extended the adoption date for all other entities, including emerging growth companies ("EGCs"), as defined by the SEC, that have elected to defer adoption until the standard is effective for non-public business entities, to annual periods beginning after December 15, 2021, and interim periods within annual periods beginning after December 15, 2022, with early adoption permitted. The Company adopted the accounting standard update effective January 1, 2021. The adoption of this ASU did not have a material impact to the Company's financial statements.

ASU 2019-12 - Simplifying the Accounting for Income Taxes

In December 2019, the FASB issued ASU 2019-12 which reduces the complexity of accounting for income taxes by eliminating certain exceptions to the general principles in Accounting Standards Codification ("ASC") 740, *Income Taxes.* Additionally, the ASU simplifies GAAP by amending the requirements related to the accounting for "hybrid" tax regimes and also by adding the requirement to evaluate when a step up in the tax basis of goodwill should be considered part of the business combination and when it should be considered a separate transaction. Certain of the provisions are to be applied retrospectively with other provisions applied prospectively.

The Company adopted this new ASU effective January 1, 2021. The adoption of this ASU did not have a material impact to the Company's financial statements.

Recently issued accounting pronouncements:

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

In June 2016, the Financial Accounting Standards Board ("FASB") issued ASU 2016-13 (which was then further clarified in subsequent ASUs), which requires that credit losses for certain types of financial instruments, including accounts receivable, be estimated based on expected credit losses among other changes. This guidance is effective for annual and interim periods beginning after December 15, 2019 for SEC filers, December 15, 2020 for public business entities that are not SEC filers, and December 15, 2021 for all other entities, including EGCs that have elected to defer adoption until the guidance becomes effective for non-public entities, with early adoption permitted. The Company elected to defer adoption of the ASU as an ECG. The Company is currently evaluating the impact of the accounting standard update on its financial statements.

ASU 2021-04 - Earnings Per Share (Topic 260), Debt-Modifications and Extinguishments (Subtopic 470-50), Compensation - Stock Based Compensation (Topic 718), and Derivatives and Hedging - Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options

In May 2021, the FASB issued ASU 2021-04 which clarified an issuer's accounting for modification or exchanges of freestanding equity-classified written call options that remain equity classified after modification or exchange. The provisions of ASU No. 2021-04 are effective for annual reporting periods beginning after December 15, 2021, and interim reporting periods within those annual periods, with early adoption permitted, including adoption in any interim period for public business entities for periods for which financial statements have not yet been issued or made available for issuance. This ASU shall be applied on a prospective basis. The Company is currently evaluating the impact of the accounting standard update on its financial statements.

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 equivalents and conversion right liability's carrying value and fair value at December 31, 2021 and 2020:

	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	$ -	$ -

	As of December 31, 2020				
	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	$ 639	$ 639	$ 639	$ -	$ -
Total assets	$ 639	$ 639	$ 639	$ -	$ -
Liabilities					
Conversion feature derivative liability	$ 717	$ 717	$ -	$ -	$ 717
Total liabilities	$ 717	$ 717	$ -	$ -	$ 717

Cash equivalents – Cash equivalents of $12,793 and $639 as of December 31, 2021 and 2020, 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 is derived through the Monte Carlo method and is 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
Balance at January 1, 2020	-
Issuance of convertible rights	690
Changes in fair value	27
Balance at December 31, 2020	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, 2021 and 2020. 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, 2021 and 2020.

4. Accounts Receivable Factoring

The Company entered into an accounts receivable factoring arrangement with a financial institution (the "Factor") in May 2020. Pursuant to the terms of the arrangement, the Company, from time to time, sells to the Factor certain of its accounts receivable balances on a non-recourse basis for credit approved accounts. During the year ended December 31, 2020, the Company factored accounts receivable in the amount of $58 for a factored amount of $54. During the year ended December 31, 2021, the Company factored accounts receivable in the amount of $68 for a factored amount of $61. The fees related to factoring was $7 and $5 for the years ended December 31, 2021 and 2020, respectively, and recorded in general and administrative expenses. At December 31, 2021 and 2020, the outstanding amount of unpaid advances to the Factor was $0 and $4, respectively.

5. Inventory, net

	December 31, 2021	December 31, 2020
Raw materials	$ 281	$ 171
Work in process	-	13
Finished goods	148	65
Inventory at cost	429	249
Less reserve for obsolescence	-	(8)
Inventory, net	$ 429	$ 241

6. Commitments

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. 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.

The lease cost for the year ended December 31, 2021 is as follows:

Operating lease cost	$ 21
Short term lease cost	28
Total lease cost	$ 49

Amounts reported in the balance sheet for leases where the Company is the lessee as of December 31, 2021 are as follows:

Right-of-use assets, operating lease	$ 503
Operating lease liabilities, current	$ 163
Operating lease liabilities, non-current	545
Total operating lease liabilities	$ 708
Remaining lease term (in years)	3.83
Discount rate	6.0%

Other information related to leases for the year ended December 31, 2021 is as follows:

Cash paid for amounts included in the measurement of lease liabilities	$ -

Future minimum lease payments remaining as of December 31, 2021 under the operating lease by fiscal year are as follows:

Fiscal Year	
2022	$ 202
2023	206
2024	210
2025	178
Total minimum lease payments	796
Less imputed interest	(88)
Present value of lease payments	$ 708

Rent expense recorded during the year ended December 31, 2020 was $55.

At December 31, 2021, there were no purchase commitments with third-party suppliers.

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, 2021.

7. 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, 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 bears interest at a fixed rate of 1.00% per annum. Monthly principal and interest payments, less the amount of any potential forgiveness (discussed below), will commence 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 provides for customary events of default, including those relating to failure to make payment, bankruptcy, breaches of representations and material adverse effects. The Company may prepay the principal of the PPP Loan 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. The Lender will have 90 days to review borrower's forgiveness application and the SBA will have an additional 60 days to review the Lender's decision as to whether the borrower's loan may be forgiven. Under the CARES Act, loan forgiveness is available for the sum of documented payroll costs, covered rent payments, and 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 exclude compensation of an individual employee earning more than $100, 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 or less annually are reduced by more than 25%. The Company obtained forgiveness of the PPP Loan on May 11, 2021.

On August 10, 2020, the Company entered into an agreement with Alliant Insurance Services, Inc. to finance its 2020 to 2021 insurance premiums with First Insurance Funding Corp. in the amount of $39. The interest rate on the note payable is 4.20% and the note is payable with a down payment at borrowing of $6 and nine equal monthly instalment payments beginning in September 2020. The outstanding balance as of December 31, 2020 was $19. The note was paid off in 2021.

On October 28, 2021, the Company entered into a Revolving Line of Credit Note with Tethered LLC ("Tethered") providing the Company with a $250,000 revolving line of credit (the "Line of Credit"). The Line of Credit allows the Company to request advances thereunder until December 3, 2022 (the "Maturity Date"). Advances drawn under the Line of Credit bear interest at an annual rate of 6.0%, and each advance will be payable on the Maturity Date with the interest on outstanding advances payable monthly. The Company may, at its option, prepay any borrowings under the Line of Credit, in whole or in part at any time prior to the Maturity Date, without premium or penalty. The Company has not drawn down on the Line of Credit as of December 31, 2021.

8. Convertible Notes Payable

In the year ended December 31, 2020, the Company issued convertible notes payable to various investors for total proceeds of $1,595. The notes are unsecured, have interest accrued at a rate of 3% per annum and have a term of two years.

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

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

In June 2021, the Company issued convertible notes payable to various investors for $1,592 with original issue discount of $176, and total proceeds of $1,416. The notes are unsecured, have interest accrued at a rate of 3% per annum and mature on June 1, 2023.

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

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

Auto Conversion upon Qualified Financing

Qualified Financing is 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 will convert) received by the Company is at least $2,000 in the aggregate.

The Notes shall 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, shall 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 shall 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 will 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 shall 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 $1,636 upon conversion of the convertible notes payable.

Convertible notes issued, converted and outstanding are as follows:

	Convertible Notes Payable
Balance at January 1, 2020	-
Issuance of convertible notes payable	1,572
Matured	-

Balance at December 31, 2020	$	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, 2020	-
Debt discount recognized	690
Amortized to interest expense	(412)
Balance at December 31, 2020	$ 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	-

9. Convertible Preferred Stock

In July 2019, the Company raised $3,843 by issuing 2,787,854 shares of Series Seed Convertible Preferred Stock. Coincident with the issuance of Series Seed Preferred Stock, $870 of SAFEs converted to 774,894 shares of Series Seed Preferred Stock and $4,124 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.

The holders of preferred stock have the rights, preferences, privileges and restrictions as set forth below:

Dividends:

The holders of preferred stock are entitled to receive dividends prior to and in preference to any declaration of payment of dividends on common stock, when and if declared by the Board of Directors. Any additional dividends will be paid ratably to holders of common and preferred stock, with the holders of preferred stock participating on an as-if converted basis. No dividends have been declared or paid prior to conversion to common stock in November 2021.

Voting Rights:

The holders of each share of preferred stock are entitled to voting rights equal to the number of shares of common stock into which the shares could be converted. As long as 2,419,099 shares of preferred stock remain outstanding, the holders of preferred stock, voting together as a class, shall be entitled to elect two members of the Company's Board of Directors. The holders of common stock, voting together as a single class, shall be entitled to elect two members of the Company's Board of Directors. Remaining members of the Company's Board of Directors will be elected by the holders of a majority of the shares of preferred stock and common stock, voting together as a single class.

Liquidation Rights / Redemption Provision:

In the event of any liquidation, dissolution or winding up of the Company or a deemed liquidation event, whether voluntary or involuntary, the holders of preferred stock have liquidation preferences, before any distribution or payment is made to holders of any common stock, an amount per share equal to the original issue price of $5.6136 for Series Seed-1 preferred stock, $4.4908 for Series Seed-2 preferred stock, $2.3364 for Series Seed-3 preferred stock and $4.6724 for Series Seed-4 preferred stock as adjusted for stock splits, stock dividends, combinations, recapitalizations and the like, plus any declared but unpaid dividends. If the assets and funds to be distributed among the holders of preferred stock are insufficient to permit the payment to such holders, then the entire assets and funds of the Company legally available for distribution will be distributed ratably among the holders of preferred stock in proportion to the preferential amount each such holder is otherwise entitled to receive.

Upon completion of the payment of the full liquidation preference of preferred stock, the remaining assets of the Company, if any, shall be distributed ratably to the holders of preferred stock and common stock on a *pari passu* basis.

Redemption:

The preferred stock is not redeemable. Upon certain change in control events that are outside of the Company's control, including liquidation, sale or transfer of control of the Company, the preferred stock is contingently redeemable.

Conversion:

Each share of preferred stock is convertible into shares of common stock, at the option of the holder, at any time after date of issuance. Each share of preferred stock automatically converts to the number of shares of common stock determined in accordance with the conversion rate upon the earlier of (i) written consent of a majority of the then outstanding shares of preferred stock, voting together as a single class or (ii) the closing of a public offering, in which the gross cash proceeds are at least $20,000. At December 31, 2020, the conversion price for each share of Series Seed-1 preferred stock, Series Seed-2 preferred stock, Series Seed-3 preferred stock and Series Seed-4 preferred stock is $5.6136, $4.4908, $2.3364 and $4.6724, respectively. The conversion price is subject to downward adjustment if the Company issues options or convertible securities with exercise or conversion terms more favorable than the preferred stock.

Protective Provisions:

The holders of preferred stock have certain protective provisions. As long as 2,419.099 of the shares of Series Seed Preferred remain outstanding (as adjusted for any stock splits, stock dividends, combinations, subdivisions, recapitalizations, reorganizations, reclassifications or the like), the Company shall not, either directly or by amendment, merger, consolidation, reclassification or otherwise, amend, alter or repeal any provision of the Company's Certificate of Incorporation or Bylaws in a manner that would adversely alter the rights, preferences, and privileges of the Series Seed Preferred without first obtaining approval of the majority of the outstanding shares of Series Seed Preferred.

10. Preferred Stock

There were no series of preferred stock designated and no shares issued or outstanding at December 31, 2021 and 2020.

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.

11. Common Stock

At December 31, 2021 and 2020, there were 9,715,234 and 2,324,479 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 $17,250 and its shares stared trading on The NASDAQ Capital Market under the ticker symbol "TIVC." The Company received approximately $14,887 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 $4,384,000 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, 2021, no dividends on common stock had been declared by the Company. At December 31, 2021 and 2020, the Company had reserved shares of common stock for issuance as follows:

	December 31, 2021	December 31, 2020
Convertible preferred stock outstanding	-	2,227,116
Warrants to purchase common stock	272,680	-
Options issued and outstanding	607,219	799,469
Shares available for future stock option grants	707,250	157,321
Total	1,587,149	3,183,906

12. 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 consulting agreement is effective as of February 2021, has a monthly fee of $5 and a term of two years. The warrant 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 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 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	0%

A summary of the Company's outstanding warrants as of December 31, 2021 is as follows:

Class of Shares	Number of Warrants	Exercise Price	Expiration Date
Common Stock	50,000	$1.07	July 1, 2026
Common Stock	50,000	$1.07	November 15, 2026
Common Stock	172,680	$6.25	November 10, 2026

13. Equity Incentive Plans

2021 Equity Incentive Plan

In 2021, the Company adopted the 2021 Equity Incentive Plan (the "2021 Plan"). As of December 31, 2021, there were 937,500 shares of common stock authorized and 707,250 shares available for issuance under 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, at the time of grant. 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 on December 31st of the preceding calendar year or (ii) such number of shares determined by the board of directors, in its discretion.

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 so purchased shall be subject to repurchase by the Company at the original exercise price of the option.

2017 Equity Incentive Plan

In 2017, the Company adopted the 2017 Equity Incentive Plan (the "2017 Plan"). On November 10, 2021, the 2017 Plan was replaced by the 2021 Plan, and future issuances of incentive instruments will be governed by that 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.

The following table summarizes the option activity for the years ended December 31, 2021 and 2020:

			Options Outstanding			
	Shares Available For Grant	Number of Options	Weighted Average Exercise Price	Weighted-Average Grant Date Fair Value	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in 000s)
Balances, January 1, 2020	397,519	583,750	$ 0.15	$ 0.07	8.26	$ 496
Options granted	(246,448)	246,448	$ 1.01	$ 0.44		
Options forfeited / cancelled	4,558	(4,558)	$ 1.00	$ 0.45		
Options expired	1,692	(1,692)	$ 1.00	$ 0.45		
Options exercised	-	(24,479)	$ 0.12	$ 0.06		
Balances, December 31, 2020	157,321	799,469	$ 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	607,219	$ 2.23	$ 1.06	8.56	$ 1,163
At December 31, 2021						
Vested and exercisable		280,090	$ 0.66	0.28	7.40	$ 902

The weighted-average grant date fair value per share of stock options granted in 2021 and 2020 was $1.95 and $0.44, respectively. The aggregate intrinsic value of options vested and exercisable as of December 31, 2021 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 2021 and 2020 was $523 and $1, 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, 2020	119,792	$ -
Vested	(119,792)	$ -
Non-vested as of December 31, 2020	-	$ -
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

The fair value of restricted stock awards vested during the years ended December 31, 2021 and 2020 was $17 and $0, respectively.

Stock-Based Compensation

Options generally vest over four years whereby 25% vest upon the first anniversary of the issuance date and 1/48th per month thereafter. Stock-based compensation expense recognized during the years ended December 31, 2021 and 2020 was $57 and $78, respectively. As of December 31, 2021, there were total unrecognized compensation costs of $690 related to share-based payment awards which is expected to be recognized over a weighted-average amortization period of 3.5 years.

The grant date fair market value of the shares of common stock underlying stock options has historically been determined by the Company's Board of Directors. Because

there has been no public market for the Company's common stock, the Board of Directors exercises reasonable judgment and considers a number of objective and subjective factors to determine the best estimate of the fair market value, which include 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.

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:

	2021	2020
Expected life (in years)	5.50 – 6.08	5.00 - 6.05
Expected volatility	49.60% - 51.57%	46.39% - 52.10%
Risk-free interest rate	1.07% - 1.33%	0.22% - 1.42%
Dividend yield	0%	0%

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 and general and administrative expense as follows:

	2021	2020
Cost of sales	$ -	$ 2
Research and development	6	30
Sales and marketing	1	2
General and administrative	50	44
Total stock-based compensation	$ 57	$ 78

14. 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, 2021 and 2020.

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, 2021	December 31, 2020
Income tax provision at statutory rate	21%	21%
State income taxes, net of federal benefit	5%	6%
Interest expense	-3 %	0%
Loss on extinguishment of debt	-4%	0%
Other	-%	-3%
Change in valuation allowance	-19%	-24%
Effective income tax rate	0%	0%

For the years ended December 31, 2021 and 2020, 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:

	For the Years Ended	
	December 31, 2021	December 31, 2020
Deferred tax assets:		
Net operating loss carryforwards	$ 4,172	$ 2,607
Derivative liability	-	81
Research and development credits	98	61
Lease liability	198	-
Other temporary differences	63	56
Total deferred tax assets	4,531	2,805
Valuation allowance	(4,339)	(2,724)
Deferred tax assets recognized	192	81
Deferred tax liabilities:		
Debt discount	-	(81)

Right-of-use assets	(192)	-
Total deferred tax liabilities	(192)	(81)
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 $1,616 and $885 for the years ended December 31, 2021 and 2020, respectively due to current and previous year losses and credits claimed.

At December 31, 2021 and 2020, the Company had federal net operating loss carryforwards of approximately $14,965 and $9,370, respectively, which will begin to expire in 2036. Approximately $14,520 of federal net operating losses can be carried forward indefinitely. At December 31, 2021 and 2020, the Company had state net operating loss carryforwards for California of approximately $14,546 and 9,184, respectively, which will begin to expire in 2031. The Company also has state research and development credit carryforward of approximately $178 at December 31, 2021. 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 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:

	For the Years Ended	
	December 31, 2021	December 31, 2020
Unrecognized tax benefits, beginning of year	$ 33	$ 26
Additions related to current year tax positions	20	7
Net deferred tax assets	$ 53	$ 33

During the years ended December 31, 2021 and 2020, the amount of unrecognized tax benefits increased by $20 and $7, respectively, due to additional research and development credits generated during those years. As of December 31, 2021 and 2020, the total amount of unrecognized tax benefits was $53 and 33, 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 and comprehensive loss. As of December 31, 2021, and 2020, 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 2021 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

In March 2020, the Coronavirus Aid, Relief and Economic Security (CARES) Act (the "Act") was signed into law. The Act includes provisions relating to refundable payroll tax credits, deferment of the employer portion of certain payroll taxes, net operating loss carryback periods, alternative minimum tax credit refunds, modifications to the net interest deduction limitations and technical corrections to tax depreciation methods for qualified improvement property. The Company was able to defer $35 related to certain payroll taxes, received a PPP loan of $156 and an EIDL grant of $8 during the year ended December 31, 2020. The PPP loan was forgiven in May 2021.

15. 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,	
	2021	2020
Convertible preferred stock (as converted)	-	2,227,116
Common stock warrants	272,680	-
Common stock options issued and outstanding	607,219	799,469
Total	879,899	3,026,585

	For the Years Ended December 31,	
	2021	2020
Net loss	$ (8,494)	$ (3,639)
Weighted-average number of shares - basic and diluted	3,493,267	2,303,237
Net loss per share - basic and diluted	$ (2.43)	$ (1.58)

16. Related Party Transactions

Dr. Subinoy Das is both a consultant and investor in the Company. The Company entered into a consulting agreement with Dr. Das on May 1, 2019 to provide support for research and clinical activities. On December 30, 2020, the Board granted Dr. Das 28,323 Non-statutory Stock Options to replace amounts accrued for his services for fiscal years ended December 31, 2020 and 2019. The fair value of this grant is $13 and was expensed in the year ended December 31, 2020. The Company recognized a gain on settlement of $117 which is included in research and development expense for the year ended December 31, 2020. The consulting agreement was terminated in 2021. No amounts were paid to Dr. Das in the year ended December 31, 2021.

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

The Company engaged a former employee and investor in December 2021 as a consultant. There were no consulting fees paid in the year ended December 31, 2021. The Company owed the investor $3 at December 31, 2021.

DESCRIPTION OF SECURITIES

The following is a summary of the material terms and provisions of the securities of Tivic Health Systems, Inc. ("us," "our," "we" or the "Company") that are registered under Section 12 of the Securities Exchange Act of 1934, as amended, and certain provisions of our certificate of incorporation, as amended and restated, and bylaws, as amended and restated, that are currently in effect. This summary does not purport to be complete and is qualified in its entirety by the provisions of our amended and restated certificate of incorporation ("Charter") and amended and restated bylaws ("Bylaws"), each previously filed with the Securities and Exchange Commission ("SEC") and incorporated by reference as an exhibit to the Annual Report on Form 10-K of which this Exhibit 4.1 is a part, as well as to the applicable provisions of the Delaware General Corporation Law (the "DGCL"). We encourage you to read our Charter, Bylaws and the applicable portions of the DGCL carefully.

General

Our authorized capital stock consists of 210,000,000 shares, all with a $0.0001 par value of per share, of which:

- 200,000,000 shares are designated as common stock; and
- 10,000,000 shares are designated as preferred stock.

Common Stock

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

Voting Rights

Holders of our common stock are entitled to one vote for each share of common stock held of record for the election of our directors and all other matters requiring stockholder action, except with respect to amendments to our Charter to alter or change the powers, preferences, rights or other terms of any outstanding preferred stock if the holders of such affected series of preferred stock are entitled to vote on such an amendment. Holders of our common stock do not have cumulative voting rights. In the case of election of directors, all matters to be voted on by our stockholders must be approved by a plurality of the votes entitled to be cast by all shares of common stock. Accordingly, the holders of a majority of the outstanding shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they so choose, other than any directors that holders of any preferred stock we may issue may be entitled to elect. Except as otherwise provided by our Charter, bylaws, the rules or regulations of any stock exchange applicable to the Company, or applicable law or pursuant to any regulation applicable to the Company or its securities, all other matters presented to our stockholders at a duly called or convened meeting, at which a quorum is present, shall be decided by the affirmative vote of the majority of shares present in person or represented by proxy at the meeting and entitled to vote on the subject matter.

Dividends

Dividends may be declared and paid on shares of our common stock as and when determined by our board of directors, subject to any preferential dividend or other rights of any then outstanding preferred stock and to the requirements of applicable law. Subject to preferences that may apply to any shares of preferred stock outstanding at the time, the holders of our common stock will be entitled to share equally, identically and ratably in any dividends that our board of directors may determine to issue from time to time.

Liquidation Rights

In the event of any voluntary or involuntary liquidation, dissolution or winding up of our affairs, holders of our common stock would be entitled to share ratably in our assets that are legally available for distribution to stockholders after payment of our debts and other liabilities. If we have any preferred stock outstanding at such time, holders of the preferred stock may be entitled to distribution and/or liquidation preferences. In either such case, we must pay the applicable distribution to the holders of our preferred stock before we may pay distributions to the holders of our common stock.

Other Rights

Our stockholders have no preemptive, conversion or other rights to subscribe for additional shares, and there are no redemption or sinking funds provisions applicable to the common stock. The rights, preferences and privileges of the holders of our common stock will be subject to, and may be adversely affected by, the rights of the holders of shares of any series of our preferred stock that we may designate and issue in the future.

Preferred Stock

No series of preferred stock are currently designated, and there are no shares of preferred stock currently outstanding. Under the terms of our Charter, our board of directors has the authority, without further action by our stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the dividend, voting and other rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon, and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in our control and may adversely affect the market price of the common stock and the voting and other rights of the holders of common stock. We have no current plans to issue any shares of preferred stock.

Anti-Takeover Effects of Delaware Law and Our Charter and Bylaws

Some provisions of Delaware law, our Charter and our Bylaws contain provisions that could make the following transactions more difficult: an acquisition of us by means of a tender offer; an acquisition of us by means of a proxy contest or otherwise; or the removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions which provide for payment of a premium over the market price for our shares.

These provisions, summarized below, are intended to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of the increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these

proposals could result in an improvement of their terms.

Classified Board of Directors

Our board of directors is divided into three classes serving three-year terms, with one class being elected each year by a plurality of the votes cast by the stockholders entitled to vote on the election.

Removal of Directors

Our Bylaws provide that, subject to the rights of the holders of the shares of any series of preferred stock, no member of our board of directors may be removed from office by our stockholders except for cause.

Stockholders Not Entitled to Cumulative Voting

Our Charter does not permit stockholders to cumulate their votes in the election of directors. Accordingly, the holders of a majority of the outstanding shares of our common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they choose, other than any directors that holders of our preferred stock may be entitled to elect.

Board Vacancies

Our Bylaws generally provide that only our board of directors (and not the stockholders) may fill vacancies and newly created directorships.

While the foregoing provisions of our Charter, Bylaws and Delaware law may have an anti-takeover effect, these provisions are intended to enhance the likelihood of continuity and stability in the composition of our board of directors and in the policies formulated by our board of directors, and to discourage certain types of transactions that may involve an actual or threatened change of control. In that regard, these provisions are designed to reduce our vulnerability to an unsolicited acquisition proposal. The provisions also are intended to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and, as a consequence, they also may inhibit fluctuations in the market price of our common stock that could result from actual or rumored takeover attempts. Such provisions also may have the effect of preventing changes in our management.

Proposals of Business and Nominations.

Our Bylaws generally regulate proposals of business and nominations for election of directors by stockholders. In general, Section 2.5 requires stockholders intending to submit proposals or nominations at a stockholders meeting to provide the Company with advance notice thereof, including information regarding the stockholder proposing the business or nomination as well as information regarding the proposed business or nominee. Sections 2.4 and 2.5 provide a time period during which business or nominations must be provided to the Company that will create a predictable window for the submission of such notices, eliminating the risk that the Company finds a meeting will be contested after printing its proxy materials for an uncontested election and providing the Company with a reasonable opportunity to respond to nominations and proposals by stockholders.

Blank Check Preferred Stock

Our Board has the right to issue preferred stock in one or more series and to determine the designations, rights, preferences of such preferred stock without stockholder approval.

Stockholder Meetings

Our Bylaws provide that a special meeting of stockholders may be called only by chairman of our board of directors, chief executive officer or president, or by a resolution adopted by a majority of our board of directors, but such not by any other person or persons (including our stockholders).

Delaware Anti-Takeover Statute

We are subject to the provisions of Section 203 of the Delaware General Corporation Law ("Section 203") regulating corporate takeovers. In general, Section 203 prohibits a publicly-held Delaware corporation from engaging, under certain circumstances, in a business combination with an interested stockholder for a period of three years following the date the person became an interested stockholder unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, the outstanding voting stock owned by the interested stockholder, (i) shares owned by persons who are directors and also officers and (ii) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

---

- at or subsequent to the date of the transaction, the business combination is approved by the board of directors of the corporation and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

Generally, a business combination includes a merger, asset, stock sale or other transaction resulting in a financial benefit to the interested stockholder. An interested stockholder is a person who, together with affiliates and associates, owns or, within three years prior to the determination of interested stockholder status, did own 15% or more of a corporation's outstanding voting stock. We expect the existence of Section 203 to have an anti-takeover effect with respect to transactions our Board does not approve in advance. We also anticipate that Section 203 may discourage business combinations or other attempts that might result in a premium over the market price for the shares of common stock held by our stockholders.

Choice of Forum

Our Charter and Bylaws provide that, unless we consent in writing to the selection of an alternative form, 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) will be the sole and 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 Charter or our Bylaws; (iv) any action to interpret, apply, enforce or determine the validity of our Charter or 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 does 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 Charter and 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 Charter and Bylaws preclude stockholders that assert claims under the Exchange Act from bringing such claims in state or federal court, subject to applicable law. Our Charter also provides that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock will be deemed to have notice of and to have consented to this choice of forum provision. It is possible that a court of law could rule that the choice of forum provision contained in our Charter is inapplicable or unenforceable if it is challenged in a proceeding or otherwise.

Exhibit 10-21

SUBLEASE

1. **PARTIES.**
This Sublease, dated November, 2021, is made between Czarnowski Display Service, Inc., an Illinois Corporation ("Sublessor"), and Tivic Health Systems, Inc., a Delaware corporation ("Sublessee").

2. **MASTER LEASE.**
Sublessor is the lessee under that certain Lease, dated May 12, 2005, as amended by that certain First Amendment to Lease dated October 2009, that certain Second Amendment to Lease dated April 2016, and that certain Third Amendment to Lease dated February 14, 2019 (collectively referred to as the "Master Lease") wherein Multi-Employer Property Trust, a trust organized under 12 C.F. R. Section 9.18, as predecessor in interest to GI ETS Hayward LLC, a Delaware limited liability company ("Lessor") leased to Sublessor the real property located at Suite 100, 25821 Industrial Blvd, Hayward, California 94545 commonly known as Building D ("Master Premises").

3. **PREMISES.**
Sublessor hereby subleases to Sublessee on the terms and conditions set forth in this Sublease the entire Master Premises ("Premises"), and Sublessor's right to use eighteen (18) unreserved parking stalls.

4. **WARRANTY BY SUBLESSOR.**
Sublessor warrants and represents to Sublessee that the Master Lease has not been amended or modified except as expressly set forth in Section 2 above, that Sublessor is not now, and as of the commencement of the Term hereof will not be, in default or breach of any of the provisions of the Master Lease, that Sublessor has no knowledge of any claim by Lessor that Sublessor is in default or breach of any of the provisions of the Master Lease, and that Lessor is not now, and as of the commencement of the Term hereof will not be in default or breach of any of the provisions under the Master Lease.

5. **TERM.**
The Term of this Sublease and Sublessee's obligation to pay Base Rent and OPEX in accordance with Section 6 below shall commence on the date Possession (defined below) of the Premises and a Consent to Sublease executed by Lessor and Sublessor in a form reasonable acceptable to Sublessee ("Consent to Sublease") have been delivered by Sublessor to Sublessee ("Commencement Date"), and expire on October 31, 2025 ("Expiration Date"), unless otherwise sooner terminated in accordance with the provisions of this Sublease. Within ten (10) days after the Commencement Date, Sublessor and Sublessee shall execute a memorandum setting forth the actual Commencement Date of the Term. Possession of the Premises ("Possession") shall be delivered to Sublessee within five (5) business days after written notice from Sublessee verifying that Sublessee is a publicly-traded company ("Delivery Date"). If for any reason Sublessor does not deliver Possession to Sublessee on or before the Delivery Date, Sublessor shall not be subject to any liability for such failure, the Expiration Date shall not be extended by the delay, and the validity of this Sublease shall not be impaired, but Base Rent and OPEX shall abate until the Commencement Date. If Sublessor permits Sublessee to take Possession prior to the Delivery Date, such early Possession shall not advance the Expiration Date and shall be subject to the provisions of this Sublease, including without limitation Sublessee's obligation to commence the payment of Base Rent and OPEX on the Commencement Date. In the event the Delivery Date does not occur by December 31, 2021 ("Delivery Deadline"), Sublessee shall be entitled to terminate this Sublease upon ten (10) days' prior written notice to Sublessor. In the event of such termination, Sublessor shall refund to Sublessee within three (3) business days after such termination all amounts paid by Sublessee to Sublessor, and thereafter Sublessor and Sublessee shall no longer have any rights or obligations to each other under this Sublease.

---

6. **RENT.**
Minimum Rent; OPEX. Beginning with the third full calendar month following the Commencement Date, in advance on the first day of each month of the Term, Sublessee shall pay to Sublessor as minimum rent, without deduction, setoff, notice, or demand, at 2287 S. Blue Island Ave., Chicago, Illinois 60608 or at such other place as Sublessor shall designate from time to time by notice to Sublessee, the sum of $12,272.85 per month ("Base Rent"), plus Tenant's Pro Rata Share (as defined in Rider 1 of the Master Lease) of Operating Costs (as defined in Rider 1 of the Master Lease), on a pass-through basis, without mark-up, of such amounts incurred by Sublessor under the Maser Leases ("OPEX"), currently $4,467.78 per month. Sublessor and Sublessee agree that the first two (2) full calendar months of minimum rent under the Sublease shall be abated; provided however Sublessee shall pay the OPEX during such period that minimum rent is abated. The Sublessor and Sublessee also agree that minimum rent shall increase annually by 3% per annum on each anniversary of the Commencement Date. If the Term begins or ends on a day other than the first or last day of a month, the minimum rent and OPEX for the partial month in which the Commencement Date occurs shall be prorated on a per diem basis and such prorated amount shall paid by Sublessee to Sublessor on the Commencement Date.

7. **SECURITY DEPOSIT.**
Sublessee shall deposit with Sublessor upon execution of this Sublease the sum of $33,500 as Sublessee's faithful performance of Sublessee's obligations hereunder ("Security Deposit") provide however, said Security Deposit shall be reduced by $16,750, and $16,750 shall be refunded by Sublessor to Sublessee, upon the three (3) year anniversary of the Commencement Date; provided that Sublessee (prior to the 3-year anniversary of the Commencement Date) has timely paid the Minimum Rent and OPEX and provided further Sublessee is not otherwise in default. If Sublessee fails to pay rent or other charges when due under this Sublease or fails to perform any of its other obligations hereunder, Sublessor may use or apply all or any portion of the Security Deposit for the payment of any rent or other amount then due hereunder and unpaid, or for any actual loss or damage sustained by Sublessor as a result of Sublessee's default or breach. If Sublessor so uses any portion of the Security Deposit, Sublessee shall, within ten (10) days after written demand by Sublessor, restore the Security Deposit to the full amount originally deposited, and Sublessee's failure to do so shall constitute a default under this Sublease. Sublessor shall not be required to keep the Security Deposit separate from its general accounts and shall have no obligation or liability for payment of interest on the Security Deposit. In the event Sublessor assigns its interest in this Sublease, Sublessor shall deliver to its assignee so much of the Security Deposit as is then held by Sublessor. Within thirty (30) days after the Term has expired, or Sublessee has vacated the Premises, whichever shall last occur, and provided Sublessee is not then in default of any of its obligations hereunder, the Security Deposit, or so much thereof as had not theretofore been applied by Sublessor, shall be returned to Sublessee or to the last assignee, if any, of Sublessee's interest hereunder.

8. **USE OF PREMISES.**
The Premises shall be used and occupied only for general office and light warehouse use, and for no other use or purpose.

9. **ASSIGNMENT AND SUBLETTING.**
Sublessee shall not assign this Sublease or further sublet all or any part of the Premises without the prior written consent of Sublessor (and the consent of Lessor, if such is required under the terms of the Master Lease), which consent with respect to the Sublessor shall not be unreasonably withheld, conditioned or delayed.

---

10. OTHER PROVISIONS OF SUBLEASE.

All applicable terms and conditions of the Master Lease are incorporated into and made a part of this Sublease as if Sublessor was the lessor thereunder, Sublessee was the lessee thereunder, and the Premises were the Master Premises, except for the following provisions under the Master Lease: Section 2.10 (Relocation), Section 3 (Rent), Section 5.10 (Hazardous Substances) as applicable to Sublessee only during the Term of this Sublease, and Rider 2 Section R2.1 (Security Deposit) as applicable to Sublessee only in regard to the amount of the Security Deposit set forth in Article 7 of this Sublease. Certain furniture and kitchen appliances shall remain in the Premises to be used by Sublessee as more particularly itemized in Exhibit A to this Sublease at no additional cost or expense to Sublessee. However, Sublessor shall continue to own the furniture at the end of the Term and Sublessee agrees to maintain the furniture and return same to Sublessee in substantially the same condition as received at the commencement of this Sublease, reasonable wear and tear excepted. Sublessee assumes and agrees to perform Sublessor's obligations under the Master Lease during the Term to the extent that such obligations are applicable to the Premises, except that the obligation to pay rent to Lessor under the Master Lease shall be considered performed by Sublessee to the extent and in the amount rent is paid to Sublessor in accordance with Section 6 of this Sublease. Sublessee shall not commit or suffer any act or omission that will violate any of the provisions of the Master Lease. Sublessor shall exercise commercially reasonable efforts in attempting to cause Lessor to perform its obligations under the Master Lease for the benefit of Sublessee. If the Master Lease terminates, this Sublease shall terminate and the parties shall be relieved of any further liability or obligation under this Sublease, provided however, that if the Master Lease terminates as a result of a default or breach by Sublessor or Sublessee under this Sublease and/or the Master Lease, then the defaulting party shall be liable to the non-defaulting party for the actual damages (excluding consequential, incidental, punitive, indirect or special damages) suffered as a result of such termination. Notwithstanding the foregoing, if the Master Lease gives Sublessor any right to terminate the Master Lease in the event of the partial or total damage, destruction, or condemnation of the Master Premises or the building or project of which the Master Premises are a part, the exercise of such right by Sublessor shall not constitute a default or breach hereunder. If Sublessee fails to surrender all or any part of the Premises at the termination of this Sublease, occupancy of the Premises after termination shall be that of a tenancy at sufferance. Sublessee's occupancy shall be subject to all the terms and provisions of the Master Lease, and Sublessee shall pay an amount (on a per month basis without reduction for partial months during the holdover) equal to 200% of the sum of the minimum rent set forth in Section 6 of the Sublease due for the period immediately preceding the holdover ("Holdover Rent"). No holdover by Sublessee or payment by Sublessee after the termination of this Sublease shall be construed to extend the Term or prevent Lessor or Sublessor from immediate recovery of possession of the Premises by summary proceedings or otherwise. If Lessor is unable to deliver possession of the Premises to a new tenant or to perform improvements for a new tenant as a result of Sublessee's holdover and Sublessee fails to vacate the Premises within 15 days after notice from Lessor or Sublessor, Sublessee shall be liable to Sublessor and Lessor for all damages that Lessor actually suffers from the holdover in addition to the Holdover Rent set forth above.

11. ATTORNEYS' FEES.

If Sublessor or Sublessee shall commence an action against the other arising out of or in connection with this Sublease, the prevailing party shall be entitled to recover its costs of suit and reasonable attorney's fees.

12. AGENCY DISCLOSURE:

Sublessor and Sublessee each warrant that they have dealt with no other real estate broker in connection with this transaction except: Cushman & Wakefield ("Sublessee's Broker") who represents Sublessee and Cushman & Wakefield ("Sublessor's Broker"), who represents Sublessor.

---

13. COMMISSION.

Upon execution of this Sublease, and consent thereto by Lessor (if such consent is required under the terms of the Master Lease), Sublessor shall pay Sublessor's Broker a real estate brokerage commission in accordance with Sublessor's contract with Sublessor's Broker for subleasing of the Premises ("Commission"), for services rendered in effecting this Sublease and Sublessor's Broker shall pay the applicable portion of said Commission to Sublessee's Broker. Sublessor represents and warrants to Sublessee and Sublessee represents and warrants to Sublessor that neither has dealt with any real estate broker or agent in connection with this Sublease except for Sublessor's Broker and Sublessee's Broker, and Sublessor and Sublessee shall each indemnify and hold harmless the other from any cost, expense or liability for any compensation, commission or fees claimed by any real estate broker or agent arising out of this Sublease (other than the Commission paid to Sublessor's Broker) related to such party's acts or omissions in regard to such claims.

14. NOTICES.

All notices and demands, which may or are to be required or permitted to be given by either party on the other hereunder shall be in writing. All notices and demands by the Sublessor to Sublessee shall be sent by United States Mail, postage prepaid or by nationally recognized overnight carrier addressed to the Sublessee at the Premises, and to the address hereinbelow, or to such other place as Sublessee may from time to time designate in a notice to the Sublessor. All notices and demands by the Sublessee to Sublessor shall be sent by United States Mail, postage prepaid or by nationally recognized overnight carrier, addressed to the Sublessor at the address set forth herein, and to such other person or place as the Sublessor may from time to time designate in a notice to the Sublessee.

To Sublessor: Attn: Czarnowski
4150 Industrial Center Dr., #650
North Las Vegas, NV 89030
Attn: Sam Panice

With a copy to: Kelly McCloskey Cherf
Czarnowski Display Service, Inc.
2287 S. Blue Island Ave.
Chicago, Illinois 60608

To Sublessee: Tivic Health Systems, Inc.
Suite 100,
25821 Industrial Blvd.
Hayward, California 94545
Attn: Briana Benz

15. SIGNAGE.

Sublessor hereby consents to Sublessee installing signs (at Sublessee's sole cost and expense) in the same or similar location as Sublessor's signs with substantially similar signage bearing the name and/or logo of Sublessee. At the time Sublessee installs its sign, Sublessee shall at Sublessee's sole cost and expense first remove all of Sublessor's signs from Building D and the Premises, and repair any damage to Building D and the Premises resulting from the removal of such signage. In addition, Sublessee shall remove its signs from Building D and the Premises prior to the expiration of the Term of this Sublease, and repair any damage to Building D and the Premises resulting from the removal of such signage.

16. CONSENT BY LESSOR.

THIS SUBLEASE SHALL AUTOMATICALLY TERMINATE AND BE OF NO FORCE OR EFFECT IF A FULLY- EXECUTED (BY LESSOR AND SUBLESSOR) CONSENT TO SUBLEASE IS NOT DELIVERED TO LESSEE WITHIN 30 DAYS AFTER EXECUTION HEREOF, IF SUCH CONSENT IS REQUIRED UNDER THE TERMS OF THE MASTER LEASE.

Sublessor:	*Czarnowski Display Service, Inc.*	*Sublessee:*	Tivic Health Systems, Inc
By:	*/s/ Courtney Buik*	*By:*	/s/ Briana Benz
Title:	Chief Financial Officer	Title:	Chief Financial Officer
By:	*Courtney Buik*	*By:*	Briana Benz
Date:	11/11/2021	By:	11/11/2021

CONSULT YOUR ADVISORS – this document has been prepared for approval by your attorney. No representation or recommendation is made by Broker as to the legal sufficiency or tax consequences of this document or the transaction to which it relates. These are questions for your attorney.

In any real estate transaction, it is recommended that you consult with a professional, such a s civil engineer, industrial hygienist or other person, with experience in evaluating the condition of the property, including the possible presence of asbestos, hazardous materials and underground storage tanks.

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. 333-227671) of Tivic Health Systems, Inc. (the "Company") of our report dated March 31, 2022, relating to the Company's financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2021.

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

Somerset, New Jersey
March 31, 2022

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) [paragraph omitted in accordance with Exchange Act Rule 13a-14(a)];

   (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, 2022

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, Briana Benz 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) [paragraph omitted in accordance with Exchange Act Rule 13a-14(a)];

   (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, 2022

By: /s/ Briana Benz

Briana Benz
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, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jennifer Ernst, Chief Executive Officer of the Company, 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, 2022

By: /s/ Jennifer Ernst
Jennifer Ernst
Chief Executive Officer
(Principal Executive Officer)

Date: March 31, 2022

By: /s/ Briana Benz
Briana Benz
Chief Financial Officer
(Principal Financial and Accounting Officer)