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, 2024

or

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

For the transition period from _____ to _____

Commission file number: 001-41052

Tivic Health Systems, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**81-4016391**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
47685 Lakeview Blvd., Fremont, CA 94538	**(888) 276-6888**
(Address of principal executive offices including zip code)	(Registrant's telephone number, including area code)

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT:

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on Which Registered
Common Stock, par value $0.0001 per share	**TIVC**	**The Nasdaq Stock Market LLC**

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

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

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

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

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

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

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

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

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

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant as of June 30, 2023, the last business day of the registrant's most recently completed second fiscal quarter, based upon the closing price of the common stock as reported by The Nasdaq Capital Market on such date, was approximately $3.0 million. This calculation does not reflect a determination that persons are affiliates for any other purposes.

As of March 17, 2025, 620,137 shares of the registrant's common stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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 our partnerships, licenses, strategic transactions, governmental regulation, economic conditions, managing and maintaining growth, the operations of the Company, volatility of stock price, commercial viability of our product candidates and any other factors discussed in this and other registrant filings with the Securities and Exchange Commission (the "Commission").

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

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

- our ability to continue as a going concern;
- our anticipated needs for working capital, and our ability to secure additional financing on favorable terms, if at all;
- the availability of electronic parts and other components for our products, as well as our ability to source such parts and components at favorable prices;
- the demand for our products;
- our sales, marketing, and distribution prospects;
- our financial performance;
- the level of expenses related to our product development and operations;
- our efforts to expand our products and our business, including, specifically, related to the exclusive license rights to Toll-like Receptor 5 Agonists recently acquired from Statera Biopharma, Inc. and our non-invasive cervical vagus nerve stimulation research;
- the implementation of our business model and strategic plans for our business and technology;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- our expectations regarding the effects of a potential recession, market volatility and macroeconomic factors on our business, our suppliers and our customers; and
- developments and projections relating to our competitors and our industry.

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

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

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

PART I

Item 1 – Business

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

Business Overview

Tivic Health is a diversified therapeutics company harnessing the power of the immune and autonomic nervous systems to fight disease and restore health. Tivic Health's bioelectronic program is developing non-invasive medical devices to meaningfully improve treatment options in neurologic, cardiac and autonomic-related diseases. Tivic Health currently offers a bioelectronic, FDA-approved over-the-counter device, ClearUP®, that treats sinus pain, pressure and congestion. ClearUP® is available through online retailers, commercial distributors and at tivichealth.com. The bioelectronic portfolio today is primarily focused on non-invasive vagus nerve stimulation. Tivic Health's biologic program focuses on immunotherapeutics and the lead product candidate is the late-stage TLR5 agonist, Entolimod™, to treat acute radiation syndrome. The FDA has granted Fast Track and Orphan Drug designation to Entolimod™..

Commercial Product

Tivic Health currently markets one commercial product under the brand name "ClearUP Sinus Pain Relief." ClearUP is built on our patented, handheld neuromodulation design and was developed by Tivic Health for the treatment of sinus and allergy-related conditions. It uses ultra-low current electrical waves to relieve sinus pain and congestion symptoms that are prevalent in nasal allergies, sinus infections, chronic sinusitis, cold and flu and sinonasal immune responses. ClearUP has been approved by the U.S. Federal Drug Administration ("FDA") for the treatment of sinus pain and congestion and is the first FDA-approved bioelectronic treatment of the foregoing indications.

A 2023 study with over 2,000 representative consumers conducted by Intellego Insights (commissioned by Tivic Health) identified that approximately 85 million U.S. adults experience inflammation-related symptoms related to allergies, congestion, head pain, and sinus issues. Of the consumers that participated in the study, 58% of sufferers try to avoid medication, if at all possible.

Clinical Pipeline

Non-invasive Cervical Vagus Nerve Stimulation ("ncVNS")

Tivic has also developed a proprietary approach to precision, non-invasive cervical vagus nerve stimulation ("ncVNS") based on our experience building evidence-based bioelectronic therapies. The vagus nerve is the tenth cranial nerve and the longest autonomic nerve in the body. The vagus nerve is responsible for regulating several bodily functions, including system immune responses, digestion, heart rate, breathing, cardiovascular activity, and visceral reflexes. Because the vagus nerve regulates the immune system and many organ systems associated with chronic disease, modulating activity in this nerve pathway is of significant interest in the healthcare industry.

Vagus nerve stimulation ("VNS") has been steadily emerging as a transformative technology in medicine, mostly based on surgically implanted simulators. Polaris Research forecasts that the VNS market will be worth $21 billion in the next five years, growing at a compounded annual growth rate of 10.6%. Implanted stimulators have been approved for—or are nearing approval for—treatment of depression, epilepsy, chronic stroke and rheumatoid arthritis in the U.S. and additional conditions overseas. The companies behind these devices are driving both practitioner awareness and reimbursement pathways.

Tivic's approach to non-invasive cervical VNS aims to leverage improvements in engineering, circuitry, and stimulation parameters to increase efficacy and reliability compared to the current state of the art in both implanted and non-invasive medical devices. We have completed an initial clinical validation study with the Feinstein Institute for the Bioelectronic Medicine at Northwell Health ("Feinstein"). The study had the following results: (i) compared to baseline measurement, Tivic's ncVNS intervention resulted in a 97% increase in the root mean square of successive differences ("RMSSD") measure of heart rate variability, which is a widely accepted proxy for vagus nerve activity;

(ii) measurements of brain activity using EEG demonstrated that Tivic's ncVNS intervention increased frontal theta power by 24% and reduced gamma power in several brain regions, including a 66% reduction in frontal gamma power - these changes in brain activity are consistent with reduced arousal and anxiety; and (iii) during ncVNS stimulation, subjects had sustained pupil constriction, a 9.5% reduction in pupil diameter, an outcome associated with engagement of the vagus nerve and activation of the parasympathetic nervous system.

Based upon these encouraging results, Tivic has initiated a second collaborative research study with Feinstein to identify VNS device parameters, including frequency and duration of treatment, that optimally influence autonomic nervous system ("ANS") function. The results will be used to inform clinical indication priority and commercial development.

Tivic partnered with Fletcher Spaght, a leading healthcare growth strategy firm, to conduct a comprehensive market assessment of Tivic's ncVNS technology drawing from clinical outcomes from Tivic's clinical study results. Fletcher Spaght initially identified approximately 30 potential medical use cases for Tivic's ncVNS technology in neurologic, cardiac, psychiatric and autonomic nervous system diseases. Working closely with Tivic's scientific and clinical leadership, the firm has identified a set of prioritized target indications with the strongest potential for market entry, based on market research, clinical reviews and interviews with key opinion leaders and payers.

Tivic will overlay the results of the clinical research with the Company's proprietary market research to prioritize targets for disease-specific trials planned for 2025.

Toll-like Receptor 5 ("TLR5") Agonist

As announced on February 12, 2025, Tivic has acquired worldwide exclusive license rights from Statera Biopharma, Inc. ("Statera") to the late-stage TLR5 agonist Entolimod for the treatment of acute radiation syndrome ("ARS"). In addition, we acquired an exclusive option to license five additional indications and clinical use cases for Entolimod and second generation product candidate, Entolasta. Entolimod and Entolasta have been the subject of more than forty animal and human trials and $140 million of prior investment. Including $35.6 million from the Department of Defense, Defense Threats Reduction Agency (DTRA), NASA, NIH and the Department of Army. The FDA has granted Fast Track and Orphan Drug designation to Entolimod for the prevention and treatment of ARS and to mitigate the likelihood of death following a potential lethal dose of total body ionization during or after a radiation disaster.

Our immediate focus with Entolimod will be validation of the manufacturing process, including first lot manufacturing and bioequivalency testing sufficient to submit a biologics license application ("BLA") to the FDA. A BLA is a request to the FDA to market a biologic product in the United States. The FDA uses the information and testing results presented in the BLA to ensure that biologic processes meet rigorous safety, purity and potency standards. If the BLA is approved, the FDA will issue Tivic a biologics license, at which point we may begin marketing of the biologic compound in the United States. Prior to such approval, we may have opportunities to market Entolimod for emergency use in markets outside of the U.S.

Market Opportunity

ClearUP

According to Mintel Group Ltd., over-the-counter allergy, cough, cold and flu treatments were projected to be an $11.1 billion market by 2025 in the U.S. alone. Market research commissioned by Tivic identified a $6 billion market opportunity for ClearUP under current FDA approvals, extensible to $9.1 billion with closely adjacent indications requiring additional FDA review.

In 2023, we completed, with Intellego Intelligence, a 2000-person market segmentation study that identified the following additional addressable markets in the United States, based on the Company's current pricing structure for ClearUP:

- Individuals with severe sinus conditions representing a $0.9 billion addressable market, of which the Company has achieved less than 0.002% penetration.

- Allergy sufferers seeking to avoid pharmaceutical side effects, representing $1.2 billion addressable market, of which the Company has achieved less than 0.002% penetration.
- High-performance athletes seeking improved breathing to enhance performance, representing a $2.4 billion addressable market that the Company has not yet targeted.
- CPAP and Sleep Apnea sufferers for whom congestion is a significant contributing factor to lack of quality sleep and/or CPAP compliance, representing a $0.6 billion addressable market.
- Individuals for whom sinus conditions cascade into severe headaches and migraine, representing a $4.0 billion addressable market. Claims for migraine would require separate FDA submissions beyond the Company's currently approved indications.

Clinical Pipeline

In 2024, the Company commissioned market research led by Fletcher Spaght, a strategic growth consulting firm focused on healthcare, to identify the top opportunities for the Company's ncVNS approach. The research identified 10+ potential market applications with over $1 billion each in market potential, with some segments over $20 billion in opportunity.

For the TLR5 program, CoherentMI estimated the ARS market to be valued at approximately $5.2 billion in 2024, and further estimates that it will reach $7.3 billion by 2031. The primary drivers were identified as increasing global concerns about nuclear emergencies and radiation exposure and advancement in biological therapies and radiation countermeasures in cancer treatment.

Sales and Marketing

ClearUP is sold directly to consumers through our own website at TivicHealth.com. We also sell to major online retailers, such as McKesson-affiliate Simply Medical and Cardinal Health. Through our online retailers, ClearUP is available through Amazon, McKesson, Optum Store, Walmart, Target, Best Buy, and FSA/HSA Store. Expansion of our ClearUP sales channels has been gradual and measured to maintain pricing integrity, cultivate consumer acceptance and establish strong channel relationships.

The TLR5 program is entering the regulatory approval process, and we have not yet made any sales or engaged in any marketing efforts with respect to Entolimod. The Company has responded to inbound inquiries in manners consistent with potential emergency use directives.

Our ncVNS program is in development and the Company is working on defining its sales and marketing strategy concurrently with target indications and research outcomes.

The Company anticipates all products stemming from both its ncVNS bioelectronic program and its TLR5 biologics program will be prescription solutions, requiring support from key opinion leaders and healthcare professionals.

Technology

Our bioelectronic technology combines proprietary algorithms, programmable stimulation parameters, and a patented delivery mechanism to modulate nerve signals. We are researching the utility of this stimulation approach for various clinical conditions.

Key elements of our current commercial platform for sinus and allergy treatment include:

- a proprietary algorithmic means of detecting areas of dense nerve innervation and blood vessels, which help guide a user to the optimal treatment locations;
- a proprietary algorithmic means of adapting treatment currents and detection to the unique physiological attributes of the technology's user at the time of use;

- a proprietary algorithmic means of dynamically adjusting treatment levels to maintain both efficacy and comfort;

- programmability of the stimulation protocols via firmware to deliver varied stimulation protocols for different physical and disease targets, providing accelerated opportunities for new product applications; and

- a unique monopolar design that enables ultra-low currents to pass through skin and tissue while maintaining nearly imperceptible current levels.

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

We have extended this technology to a research-stage design directed to non-invasive cervical vagus nerve stimulation, which is currently undergoing clinical evaluation in partnership with Northwell Health, Feinstein. Multiple acute and chronic conditions could be the target for our non-invasive vagus nerve treatment platform, including:

- acute and chronic inflammation (e.g., sepsis, brain injury, major depressive disorder);
- auto-immune inflammation (e.g., rheumatoid arthritis, Crohn's disease); and
- autonomic nervous system dysfunction (e.g., dysautonomia, post-traumatic stress disorder)

We believe that this non-invasive, low-risk nature of Tivic's approach to bioelectronic medicine has the potential to accelerate new product development by: (i) extending the device platforms to other clinical areas, thereby reducing research and development time, and (ii) continuing to benefit from low-risk non-invasive device designations and regulatory pathways by the FDA, which typically result in shorter time to approval when compared with invasive devices or new drugs. Although it is our intention to bring new products to market, medical device development is inherently uncertain and there is no guarantee that our research and development efforts will lead to approved products for other clinical indications.

Entolimod is a recombinant protein engineered from bacterial flagellin, specifically designed as a selective agonist of Toll-like receptor 5 (TLR5), a key receptor in the body's innate immune system. When administered, Entolimod binds to TLR5 receptors on immune cells, triggering a rapid activation of the NF-κB signaling pathway. activation initiates a cascade of immune and protective responses, including the secretion of cytokines, chemokines, and growth factors, enhancing the body's natural ability to resist and repair tissue damage.

The technology behind Entolimod harnesses recombinant DNA techniques to optimize its immune-stimulating effects while minimizing unwanted inflammatory responses. Its engineered design selectively maintains potent TLR5 activation, making it particularly effective as a radioprotective agent. By boosting innate immune defenses and facilitating regeneration, Entolimod provides critical protection against acute radiation injury, demonstrating significant therapeutic potential for both civilian and military applications involving radiation exposure, as well as potential use as an immune modulator in oncology treatments.

Competitive Landscape

ClearUP

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

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

- Congestion is treated with a variety of approaches:

    - **Antihistamine medications** are often a first-line therapy for allergy-related symptoms and research indicates that they are effective for treating allergy symptoms such as itchiness, but are less effective for congestion.

    - **Oral decongestants** (e.g., phenylephrine/Sudafed) used to treat congestion have been demonstrated to exert poor to moderate efficacy. Some variants have been removed from shelves by mandate of the FDA due to lack of efficacy.

    - **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.

    - **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.

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

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.

In the Fall of 2023, a panel of U.S. health experts found that many widely used products containing phenylephrine are ineffective. According to a Yale School of Medicine news article, an FDA advisory committee unanimously concluded that phenylephrine, an ingredient found in popular nasal decongestants sold under such brand names as Sudafed and Dayquil, works no better than a placebo in treating cold and allergy symptoms. Subsequent to this study, certain products were removed from market by the FDA.

According to our 2023 Intellego Insight study, many consumers are seeking natural, non-pharmaceutical treatment options. Alternative options currently include, without limitation:

- **Nasal irrigation with saline**, rinsing the nasal passages with saline solution is a common non-pharmaceutical treatment. Example products include NeilMed Sinus Rinse, Navage Nasal Care and Vicks Sinex Severe. Nasal irrigation is understudied, but there is some evidence of improved quality of life and clearance of mucus. However, saline can irritate an already inflamed sinonasal tissue and nasal irrigation using tap water has been found to carry risk of parasite-driven encephalitis.

- **Bioelectronic devices.** ClearUP is the first device to have been approved 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., SoundHealth, and Vapore LLC.

ClearUP is a novel product offering in the non-drug category, an emerging bioelectronic medicine segment, and currently has small market share compared to the existing establishments, most of which offer pharmaceutical options.

Non-invasive Cervical Vagus Nerve Stimulation

The competitive landscape for vagus nerve stimulators is largely dominated by two classes of devices. Vagus nerve stimulation ("VNS") has been steadily emerging as a transformative technology in medicine, mostly based on surgically implanted simulators. Polaris Research forecasts that the VNS market will be worth $21 billion in the next five years, growing at a compounded annual growth rate of 10.6%. Implanted stimulators have been approved for—or are nearing approval for—treatment of depression, epilepsy, chronic stroke rehabilitation and rheumatoid arthritis in the U.S. and additional conditions overseas. The companies behind these devices are driving both practitioner awareness and adoption and reimbursement pathways.

Tivic's approach to non-invasive VNS aims to leverage improvements in engineering, circuitry, and stimulation parameters to increase efficacy and reliability compared to the current state of the art in both implanted and non-invasive medical devices. We have completed an initial clinical validation study with the Feinstein Institute for the Bioelectronic Medicine at Northwell Health ("Feinstein"). The study had the following results: (i) compared to baseline measurement, Tivic's ncVNS intervention resulted in a 97% increase in the root mean square of successive differences ("RMSSD") measure of heart rate variability, which is a widely accepted proxy for vagus nerve activity; (ii) measurements of brain activity using EEG demonstrated that Tivic's ncVNS intervention increased frontal theta power by 24% and reduced gamma power in several brain regions, including a 66% reduction in frontal gamma power - these changes in brain activity are consistent with reduced arousal and anxiety; and (iii) during ncVNS stimulation, subjects had sustained pupil constriction, a 9.5% reduction in pupil diameter, an outcome associated with engagement of the vagus nerve and activation of the parasympathetic nervous system.

Based upon these encouraging results, Tivic has initiated a second collaborative research study with Feinstein to identify VNS device parameters, including frequency and duration of treatment, that optimally influence autonomic nervous system ("ANS") function. The results will be used to inform clinical indication priority and commercial development.

Tivic partnered with Fletcher Spaght, a leading healthcare growth strategy firm, to a conduct comprehensive market assessment of Tivic's ncVNS technology drawing from clinical outcomes from Tivic's clinical study results. Fletcher Spaght initially identified approximately 30 potential medical use cases for Tivic's ncVNS technology in neurologic, cardiac, psychiatric and autonomic nervous system diseases. Working closely with Tivic's scientific and clinical leadership, the firm has identified a set of target indications with the strongest potential for market entry by interviewing clinical key opinion leaders, patients and payers.

TLR5 Program

Specific competition for Entolimod includes FDA-approved drugs filgrastim (Neupogen™), peg-filgrastim (Neulasta™), sargramostim (Leukine™) and romiplostim (NPLATE™) for Hematopoietic Syndrome of Acute Radiation Syndrome (HS-ARS). In addition, we are aware of a number of companies also developing radiation countermeasures to treat the effects of ARS including: Aeolus Pharmaceuticals, Araim Pharmaceuticals, Inc., Cellerant Therapeutics, Inc., Humanetics Corporation, Neumedicines, Inc., Pluristem Therapeutics, Inc, RxBio, Inc., and Soligenix, Inc. Our ability to sell to the government may also be influenced by competition from the products, such as Neupogen®, Neulasta®, Leukine®, and NPLATE®, which were previously purchased by the U.S. government for the National Stockpile.

We believe the fundamental properties of Entolimod and Entolasta, based on prior clinical trials, will provide competitive market advantages, including, but not limited to, prevention and treatment of ARS. Additionally, Entolimod and Entolasta have clinical effects on the hematopoietic function as well as gastrointestinal protection. Prior studies have indicated superior efficacy and support for GI tract health not provided by other anti-radiation measures. In addition, Entolimod works on mechanistic pathways that are differentiated from current stockpiled drugs and may offer improvements to survival rates when used in conjunction with existing commercialized compounds.

Clinical Research

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.

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).

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.

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.

Our ncVNS program is undergoing clinical trials that have not yet been published. However, we believe our commitment to non-invasive bioelectronic medicine simplifies clinical trial approaches, improves the safety profile important in regulatory matters, and lowers barriers to adoption once in the market. These factors could afford us a unique opportunity for a rapid pace of innovation relative to other therapeutic companies. While it is our intention to bring new products to market, therapeutic development is inherently uncertain and there is no guarantee that our research and development efforts will lead to approved products for other clinical indications.

Clinical reports on our licensed biopharmaceutical assets, Entolimod and Entolasta include:

Brackett CM, Kojouharov B, Veith J, Greene KF, Burdelya LG, Gollnick SO, Abrams SI, Gudkov AV. Toll-like receptor-5 agonist, entolimod, suppresses metastasis and induces immunity by stimulating an NK-dendritic-CD8+ T-cell axis. Proc Natl Acad Sci U S A. 2016 Feb 16;113(7):E874-83. doi: 10.1073/pnas.1521359113. Epub 2016 Feb 1. PMID: 26831100; PMCID: PMC4763744.

Abstract: Innate immune modulators can generate a potent antitumor T-cell response and are thus a desirable approach to immunotherapy. However, their use is limited by the risk of induction of acute inflammation. In this regard, bacterial flagellin is unique among other innate immune modulators because of a significantly safer cytokine profile induced upon activation by its target, Toll-like receptor 5 (TLR5). We show here that systemic administration of entolimod, a pharmacologically optimized flagellin derivative, induces a cascade of cell–cell signaling resulting in mobilization to the liver of various components of innate and adaptive immunity, followed by suppression of liver metastases and development of long-term antitumor immune memory. Thus, TLR5 agonists can be considered as an organ-specific immunotherapy for the treatment and prevention of metastases.

Vijay K. Singh, Thomas M. Seed,
Entolimod as a radiation countermeasure for acute radiation syndrome,

Drug Discovery Today, Volume 26, Issue 1, 2021, Pages 17-30,

Abstract: High doses of total-body or partial-body radiation exposure can result in a life-threatening acute radiation syndrome as manifested by severe morbidity. Entolimod is effective in protecting against, and mitigating the development of, the hematopoietic and gastrointestinal subsyndromes of the acute radiation syndrome in rodents and nonhuman primates. Entolimod treatment reduces radiation-induced apoptosis and accelerates the regeneration of progenitors in radiation-damaged tissues. The drug has been evaluated clinically for its pharmacokinetics (PK), toxicity, and biomarkers. The FDA has granted investigational new drug, fast-track, and orphan drug statuses to Entolimod.

Component Sourcing and Manufacturing

The ClearUP device, our only currently commercial product, is comprised of conventional, off-the-shelf electronic components.

Certain of our electronic components are sourced primarily from China. To increase predictability in sourcing and pricing of electronic components used in our products, we maintain an agreement with Future Electronics, Inc., one of the largest global electronic component distributors.

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

Electronic components are assembled, tested, warehoused at, and distributed from North America.

The Company has ISO 13485 certification (70488) required to validate the internal processes, which assists in being compliant with the FDA 21 CFR Part 820. The Company was re-certified in 2023, with certificates extended until the fourth quarter of 2026.

Intellectual Property / Barriers to Entry

Intellectual Property

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

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

Our bioelectronic related intellectual property portfolio currently consists of:

- 16 issued patents in the U.S. and abroad.
- 11 patents pending in the U.S. and abroad.
- 7 trademarks granted in the U.S. and China.
- 2 trademark applications have been filed in the U.S.

As discussed elsewhere in this Report, in February 2025 we entered into a License Agreement with Statera, pursuant to which we acquired worldwide exclusive license rights to the late-stage TLR5 agonist Entolimod for the treatment of ARS. In addition, we acquired an exclusive option to license five additional indications and clinical use cases for Entolimod and its derivative, Entolasta. The TLR5 related intellectual property portfolio currently consists of over 60 active patents and patents pending. In addition to the patents, Entolimod and Entolasta are eligible for biological exclusivity in the U.S. and Europe, which provides additional competitive protection and barriers to entry.

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 with our ClearUP product has secured a high volume and proportion of positive reviews on our websites and other e-commerce channels.

We believe that each of the assets described above, in addition to our intellectual property and regulatory clearances, will create barriers to entry for competitors.

Government Regulation - Medical Devices

ClearUP is a U.S. FDA Class II medical device that has two regulatory clearances: (US FDA 510(k) number K182025 and US FDA De Novo number DEN200006. Our previously granted EU CE Mark Certificate became inactive in September 2024 due to the European Union's conversion from Medical Device Directive to Medical Device Requirements in 2024. As we have not previously secured sales outside of the U.S., we elected not to incur the costs associated with a reinstatement of the CE Mark under the European Union's new Medical Device Requirements. We may in the future elect to pursue reinstatement of the CE Mark, but there is no guarantee that the Company would be able to reestablish the CE Mark.

Regulation by the FDA

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

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

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

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

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

Labeling

All medical devices commercially distributed in the U.S. must comply with specific FDA labeling requirements. These requirements address the labeling (e.g., device label, Instruction for Use, package label, etc.) that must be affixed to the device or packaging and, in the case of devices used by the consumer, provided to all users of the device. Our ClearUP labeling has been reviewed by the FDA as part of our regulatory clearances and our quality management system provides for control of documents to prevent changes that might invalidate the 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 ("cGMP") requirements, as set forth in the 21 CFR 820 QSR (the "QSR"), which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all phases of the design and manufacturing process. We are also required to verify that our suppliers maintain facilities, procedures and operations that comply with applicable quality and regulatory requirements. The FDA enforces the QSR through periodic announced or unannounced inspections of medical device manufacturing facilities, which may include the facilities of contractors. FDA regulations also require investigation and correction of any deviations from the QSR and impose reporting and documentation requirements upon us and our third-party manufacturers.

Post-market surveillance

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

In addition to post-market quality and safety actions, labeling and promotional activities are subject to scrutiny by the FDA and, in certain circumstances, by the Federal Trade Commission (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 current exposure under certain laws such as the Sunshine Act.

Coverage and reimbursement

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

Government Regulation - Biopharmaceutical

In the United States, drug products are regulated under the FD&C Act and applicable implementing regulations and guidance. The failure of an applicant to comply with the applicable regulatory requirements at any time during the product development process, including non-clinical testing, clinical testing, the approval process or the post-approval process, may result in delays to the conduct of a study. In rare instances involving willful or exceptionally negligent conduct on the part of a company, it could result in civil or criminal penalties.

An applicant seeking approval to market and distribute a new drug in the United States generally must satisfactorily complete each of the following steps before the FDA will consider approving the product candidate:

- preclinical testing, including laboratory tests, animal studies and formulation studies, which must be performed in accordance with the FDA's good laboratory practice ("GLP") regulations and standards;
- submission to the FDA of an Investigational New Drug ("IND") application for human clinical testing, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board ("IRB") representing each clinical site before each clinical trial may be initiated; and
- preparation and submission to the FDA of a Biological License Application ("BLA") for a biological-bsed drug product, which includes the results of the clinical trials and manufacturing validation tests.

Preclinical Studies

Before an applicant begins testing a product candidate with potential therapeutic value in humans, the product candidate enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as other studies to evaluate, among other things, the toxicity of the product candidate. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND.

The IND and IRB Processes

An IND is an exemption from the FDCA that allows an unapproved product candidate to be shipped in interstate commerce for use in an investigational clinical trial and a request for FDA authorization to administer such

investigational product to humans. IND authorization is required by the FDA before the commencement of any human or animal studies for phased development.

Following commencement of a clinical trial under an IND, the FDA may also place a clinical hold or partial clinical hold on that trial. A clinical hold is an order issued by the FDA to the sponsor to delay a proposed clinical investigation or to suspend an ongoing investigation. A partial clinical hold is a delay or suspension of only part of the clinical work requested under the IND. For example, a partial clinical hold might state that a specific protocol or part of a protocol may not proceed, while other parts of a protocol or other protocols may do so.

A sponsor may choose, but is not required, to conduct a foreign clinical study under an IND. When a foreign clinical study is conducted under an IND, all IND requirements must be met unless waived by the FDA. When a foreign clinical study is not conducted under an IND, the sponsor must ensure that the study complies with certain regulatory requirements of the FDA in order to use the study as support for an IND or application for marketing approval. Foreign studies are expected to be conducted within the conditions laid out by FDA for GCPs.

In addition to the foregoing IND requirements, an IRB representing each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution. An IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the product candidate has been associated with unexpected serious harm to patients.

Expanded Access to an Investigational Drug for Treatment Use

Expanded access, sometimes called "compassionate use," is the use of investigational new drug products outside of clinical trials to treat patients with serious or immediately life-threatening diseases or conditions when there are no comparable or satisfactory alternative treatment options. The rules and regulations related to expanded access are intended to improve access to investigational drugs for patients who may benefit from investigational therapies. FDA regulations allow access to investigational drugs under an IND by the company or the treating physician for treatment purposes on a case-by-case basis for: individual patients (single-patient IND applications for treatment in emergency settings and non-emergency settings), intermediate-size patient populations, and larger populations for use of the drug under a treatment protocol or Treatment IND Application.

On December 13, 2016, the 21st Century Cures Act established (and the 2017 Food and Drug Administration Reauthorization Act later amended) a requirement that sponsors of one or more investigational drugs for the treatment of a serious disease(s) or condition(s) make publicly available their policies for evaluating and responding to requests for expanded access for individual patients. Although these requirements were rolled out over time, they have now come into full effect. This provision requires drug and biologic companies to make publicly available their policies for expanded access for individual patient access to products intended for serious diseases. Sponsors are required to make such policies publicly available upon the earlier of initiation of a Phase 2 or Phase 3 study with respect to an investigational drug, or 15 days after the drug or biologic receives designation as a breakthrough therapy, fast track product, or regenerative medicine advanced therapy.

Human clinical trials are typically conducted in three sequential phases, but the phases may overlap or be combined. Additional studies may also be required after approval.

Phase 1 clinical trials are initially conducted in a limited population to test the product candidate for safety, including adverse effects, dose tolerance, absorption, metabolism, distribution, excretion and pharmacodynamics in healthy humans or in patients. During Phase 1 clinical trials, information about the product candidate's pharmacokinetics and pharmacological effects may be obtained to permit the design of well-controlled and scientifically valid Phase 2 clinical trials.

Phase 2 clinical trials are generally conducted in a limited patient population to identify possible adverse effects and safety risks, evaluate the efficacy of the product candidate for specific targeted indications and determine dose tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more costly Phase 3 clinical trials. Phase 2 clinical trials are well-controlled and closely monitored.

Phase 3 clinical trials proceed if the Phase 2 clinical trials demonstrate that a dose range of the product candidate is potentially effective and has an acceptable safety profile. Phase 3 clinical trials are undertaken within an expanded patient population to further evaluate dosage, provide substantial evidence of clinical efficacy and further test for safety in an expanded and diverse patient population at multiple geographically dispersed clinical trial sites. A well-controlled, statistically robust Phase 3 clinical trial may be designed to deliver the data that regulatory authorities will use to decide whether or not to approve, and, if approved, how to appropriately label a drug. Such Phase 3 clinical trials are referred to as "pivotal" trials.

In some cases, the FDA may approve a BLA for a product candidate but require the sponsor to conduct additional clinical trials to further assess the product candidate's safety and effectiveness after approval. Such post-approval trials are typically referred to as Phase 4 clinical trials. These trials are used to gain additional experience from the treatment of a larger number of patients in the intended treatment group and to further document a clinical benefit in the case of drugs approved under accelerated approval regulations. Failure to exhibit due diligence with regard to conducting Phase 4 clinical trials could result in withdrawal of FDA approval for products.

Review and Approval of a BLA

In order to obtain approval to market a biological drug product in the United States, a marketing application must be submitted to the FDA that provides sufficient data establishing the safety, purity and potency of the product candidate for its intended indication. The application must include all relevant data available from pertinent preclinical and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product candidate's chemistry, manufacturing, controls and proposed labeling, among other things. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of the use of a product candidate, or from a number of alternative sources, including studies initiated by independent investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety, purity and potency of the drug product to the satisfaction of the FDA.

The BLA is a vehicle through which applicants formally propose that the FDA approve a new product for marketing and sale in the United States for one or more indications. Every new drug product candidate must be the subject of an approved BLA before it may be commercialized in the United States. Under federal law, the submission of most BLAs is subject to an application user fee. The sponsor of an approved BLA is also subject to an annual program fee. Certain exceptions and waivers are available for some of these fees, such as a waiver for certain small businesses filing their first BLA.

Following submission of a BLA, the FDA conducts a preliminary review (otherwise known as an administrative review) of the application, generally within 60 calendar days of its receipt, and strives to inform the sponsor by the 74th day after the FDA's receipt of the submission whether the application is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept the application for filing. In this event, the application must be resubmitted with the requested additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review.

Before approving an application, the FDA typically will inspect the facility or facilities where the product is or will be manufactured. These pre-approval inspections may cover all facilities associated with a BLA submission, including component manufacturing, finished product manufacturing and control testing laboratories. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications.

Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with Good Clinical Practices ("GCP"). Under the FDA Reauthorization Act of 2017, the FDA must implement a protocol to expedite review of responses to inspection reports pertaining to certain applications, including applications for products of which there is a shortage or those for which approval is dependent on remediation of conditions identified in the inspection report.

In addition, as a condition of approval, the FDA may require an applicant to develop a risk evaluation and mitigation strategy ("REMS"). REMS use risk minimization strategies beyond the professional labeling to ensure that the benefits of the product outweigh the potential risks. To determine whether a REMS is needed, the FDA will consider the size of the population likely to use the product, seriousness of the disease, expected benefit of the product, expected duration of treatment, seriousness of known or potential adverse events and whether the product is a new molecular entity.

Fast Track, Breakthrough Therapy, Priority Review and Regenerative Advanced Therapy Designations

The FDA is authorized to designate certain products for expedited review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs are referred to as Fast Track Designation, Breakthrough Therapy Designation, priority review designation and regenerative advanced therapy designation.

Specifically, the FDA may designate a product for Fast Track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For Fast Track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a Fast Track product's application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a Fast Track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, the FDA's time period goal for reviewing a Fast Track application does not begin until the last section of the application is submitted. In addition, the Fast Track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Second, a product may be designated as a Breakthrough Therapy if it is intended, either alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect to Breakthrough Therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross-disciplinary project lead for the review team; and taking other steps to design the clinical trials in an efficient manner.

Third, the FDA may designate a product for priority review if it is a product that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines, on a case-by-case basis, whether the proposed product represents a significant improvement when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting product reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, and evidence of safety and effectiveness in a new subpopulation. A priority designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from 10 months to six months.

With passage of the 21st Century Cures Act (the "Cures Act") in December 2016, Congress authorized the FDA to accelerate review and approval of products designated as regenerative advanced therapies. A product is eligible for this designation if it is a regenerative medicine therapy that is intended to treat, modify, reverse or cure a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product has the potential to address unmet medical needs for such disease or condition. The benefits of a regenerative advanced therapy designation include early interactions with the FDA to expedite development and review, benefits available to breakthrough therapies and potential eligibility for priority review and accelerated approval based on surrogate or intermediate endpoints.

Accelerated Approval Pathway

The FDA may grant accelerated approval to a product for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval to a product for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality ("IMM"). The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints, but has indicated that such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a product.

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the product's clinical benefit. As a result, a product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect of the product on the relevant clinical endpoints. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow the FDA to initiate expedited proceedings to withdraw approval of the product. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

The FDA's Decision on a BLA

On the basis of the FDA's evaluation of a BLA and accompanying information, including the results of the inspection of the manufacturing facilities, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the BLA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months, depending on the type of information included. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

If the FDA approves a new product, it may limit the approved indications for use of the product. The agency may also require testing and surveillance programs to monitor the product after the initiation of commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, such as REMS, to help ensure that the benefits of the product outweigh the potential risks. REMS can include medication guides, communication plans for health care professionals, and elements to assure safe use ("ETASU"). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patent registries. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs.

After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Post-Approval Regulation

If regulatory approval for marketing of a product or a new indication for an existing product is obtained, the sponsor will be required to comply with all regular post-approval regulatory requirements, as well as any post-approval requirements that the FDA may have imposed as part of the approval process. The sponsor will be required to report, among other things, certain adverse reactions and manufacturing problems to the FDA, provide updated safety and efficacy information and comply with requirements concerning advertising and promotional labeling requirements.

Manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMP regulations, which impose certain procedural and documentation requirements upon manufacturers. Accordingly, the sponsor and its third-party manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with cGMP regulations and other regulatory requirements.

A product may also be subject to official lot release, meaning that the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release, the manufacturer must submit samples of each lot, together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot, to the FDA. The FDA may perform certain confirmatory tests on lots of some products before releasing the lots for distribution. Finally, the FDA will conduct laboratory research related to the safety, purity, potency and effectiveness of pharmaceutical products.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters, untitled letters, Form 483s or holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates the marketing, labeling, advertising and promotion of prescription drug products placed on the market. This regulation includes, among other things, standards and regulations for direct-to-consumer advertising, communications regarding unapproved uses, industry-sponsored scientific and educational activities, and promotional activities involving the Internet and social media. Promotional claims about a drug's safety or effectiveness are prohibited before the drug is approved. After approval, a drug product generally may not be promoted for uses that are not approved by the FDA, as reflected in the product's prescribing information. In the United States, health care professionals are generally permitted to prescribe drugs for such uses not described in the drug's labeling, known as off-label uses, because the FDA does not regulate the practice of medicine. However, FDA regulations impose rigorous restrictions on manufacturers' communications, prohibiting the promotion of off-label uses. It may be permissible, under very specific, narrow conditions, for a manufacturer to engage in non-promotional, non-misleading communication regarding off-label information, such as distributing scientific or medical journal information.

If a company is found to have promoted off-label uses, it may become subject to adverse public relations and administrative and judicial enforcement by the FDA, the Department of Justice, or the Office of the Inspector General of the Department of Health and Human Services, as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes drug products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion, and has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act ("PDMA") and its implementing regulations, as well as the Drug Supply Chain Security Act ("DSCA"), which regulate the distribution and tracing of prescription drug samples at the federal level, and set minimum standards for the regulation of distributors by the states. The PDMA, its implementing regulations and state laws limit the distribution of prescription pharmaceutical product samples, and the DSCA imposes requirements to ensure accountability in distribution and to identify and remove counterfeit and other illegitimate products from the market.

Animal Rule

In 2002, the FDA amended its requirements applicable to BLAs/NDAs to permit the approval of certain drugs and biologics that are intended to reduce or prevent serious or life-threatening conditions based on evidence of safety from clinical trial(s) in healthy subjects and effectiveness from appropriate animal studies when human efficacy studies are not ethical or feasible. These regulations, which are known as the "Animal Rule," authorize the FDA to rely on animal studies to provide evidence of a product's effectiveness under circumstances where there is a reasonably well-understood mechanism for the activity of the agent. Under these requirements, and with the FDA's prior agreement, drugs used to reduce or prevent the toxicity of chemical, biological, radiological, or nuclear substances may be approved for use in humans based on evidence of effectiveness derived from appropriate animal studies and any additional supporting data. Products evaluated under this rule must demonstrate effectiveness through pivotal animal studies, which are generally equivalent in design and robustness to Phase 3 clinical studies.

We intend to utilize the Animal Rule in seeking marketing approval for Entolimod as a medical radiation countermeasure because we cannot ethically expose humans to lethal doses of radiation. Other countries may not at this time have established criteria for review and approval of these types of products outside their normal review process, i.e. there is no "Animal Rule" equivalent in countries other than the U.S., but some may have similar policy objectives in place for these product candidates.

Public Readiness and Emergency Preparedness Act

The Public Readiness and Emergency Preparedness Act (the "PREP Act") provides immunity for manufacturers from all claims under state or federal law for "loss" arising out of the administration or use of a "covered countermeasure." However, injured persons may still bring a suit for "willful misconduct" against the manufacturer under some circumstances. "Covered countermeasures" include security countermeasures and "qualified pandemic or epidemic products," including products intended to diagnose or treat pandemic or epidemic disease, such as pandemic vaccines, as well as treatments intended to address conditions caused by such products.

Orphan Drug

Under the U.S. Orphan Drug Act, as amended by the FDA Reauthorization Act of 2017, the FDA may grant orphan drug designation to drugs or biologics intended to treat a "rare disease or condition," which is defined as having a prevalence of less than 200,000 individuals in the United States. The FDA is currently implementing a modernization plan which may include new requirements or procedures that could impact the success of an orphan drug designation request. In certain circumstances, a sponsor may need to demonstrate that the product is clinically superior to a previously-approved drug in order to obtain orphan drug status, and the FDA may issue regulations to implement this requirement. Orphan drug designation must be requested before submitting a BLA for the product. The FDA aims to respond to all orphan drug designation requests within 90 days of submission. Orphan drug designation does not shorten the regulatory review and approval process, nor does it provide any advantage in the regulatory review and approval process. However, if an orphan drug later receives approval for the indication for which it has designation, the relevant regulatory authority may not approve any other applications to market the same drug for the same indication, except in very limited circumstances, for seven years in the United States.

Hatch-Waxman Act Patent Certification and the 30-Month Stay

Upon approval of a BLA or a supplement thereto, BLA sponsors are required to list with the FDA each patent with claims that cover the applicant's product or an approved method of using the product. Each of the patents listed by the BLA sponsor is published in the Orange Book. When a biosimilar applicant files its application with the FDA, the applicant is required to certify to the FDA concerning any patents listed for the reference product in the Orange Book, except for patents covering methods of use for which the biosimilar applicant is not seeking approval. To the extent that the Section 505(b)(2) applicant is relying on studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that a biosimilar applicant would. Specifically, the applicant must certify with respect to each patent that:

- the required patent information has not been filed;
- the listed patent has expired;

- the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or
- the listed patent is invalid, is unenforceable or will not be infringed by the new product.

A certification that the new product will not infringe the already approved product's listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification. If the applicant does not challenge the listed patents or indicates that it is not seeking approval of a patented method of use, the application will not be approved until all of the listed patents claiming the referenced product have expired (other than method of use patents involving indications for which the applicant is not seeking approval).

If the biosimilar applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the BLA and patent holders once the biosimilar has been accepted for filing by the FDA. The BLA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of a Paragraph IV certification automatically prevents the FDA from approving the biosimilar until the earliest of 30 months after the receipt of the Paragraph IV notice, expiration of the patent and a decision in the infringement case that is favorable to the biosimilar applicant.

To the extent that the Section 505(b)(2) applicant is relying on studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that a biosimilar applicant would. As a result, approval of a biologic can be stalled until all the listed patents claiming the referenced product have expired, until any non-patent exclusivity, such as exclusivity for obtaining approval of an NCE, listed in the Orange Book for the referenced product has expired, and, in the case of a Paragraph IV certification and subsequent patent infringement suit, until the earliest of 30 months, settlement of the lawsuit and a decision in the infringement case that is favorable to the Section 505(b)(2) applicant.

Pediatric Studies and Exclusivity

Under the Pediatric Research Equity Act of 2003, a BLA or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. Sponsors must also submit pediatric study plans prior to submitting the assessment data. Those plans must contain an outline of the proposed pediatric study or studies the applicant plans to conduct, including study objectives and design, any deferral or waiver requests and other information required by regulation. The applicant, the FDA and the FDA's internal review committee must then review the information submitted, consult with each other and agree upon a final plan. The FDA or the applicant may request an amendment to the plan at any time. In addition, certain products that have received orphan drug designation are exempt from the requirements of the Pediatric Research Equity Act of 2003.

The FDA Reauthorization Act of 2017 established requirements governing certain molecularly targeted cancer indications. Any company that submits a BLA three years after the date of enactment of that statute must submit pediatric assessments with the BLA if the drug is intended for the treatment of an adult cancer and is directed at a molecular target that the FDA determines to be substantially relevant to the growth or progression of a pediatric cancer. The investigation must be designed to yield clinically meaningful pediatric study data regarding the dosing, safety and preliminary efficacy to inform pediatric labeling for the product.

Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity. This six-month exclusivity may be granted if a BLA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data.

Government Regulation - Other

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 General Data Protection Regulation ("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 (the "CCPA"), which took effect on January 1, 2020 and was amended and expanded by the California Privacy Rights Act (the "CPRA"), which took effect on January 1, 2023. The CCPA, as amended by the CPRA, among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information and the right to access information about how their data is being used.

Environmental Matters

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

Facilities

Our principal executive office is located at 47685 Lakeview Blvd., Fremont, California 94538. On May 30, 2024, we entered into a Co-Working Space Agreement, for a total of $1 thousand per month. The agreement has an initial term of six months, commencing June 1, 2024, after which automatically renews on a month to month basis until terminated.

Human Capital Resources

As of December 31, 2024, we had seven full-time employees and two 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 47685 Lakeview Blvd., Fremont, California 94538. Our telephone number is (888) 276-6888. Our website address is www.tivichealth.com. Information contained on, or that can be accessible through, our website is not a part of this Report and the inclusion of our website address in this Report is an inactive textual reference only.

Item 1A – Risk Factors

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

Risk Factor Summary

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

- We have a relatively limited operating history and may not be able to execute on our business strategy.
- Our cash and financial resources may be insufficient to meet our anticipated needs for the next twelve months, which raises substantial doubt about our ability to continue as a going concern.
- Our operating results may be volatile and may not be a reliable indicator of our future performance.
- If we fail to manage our growth effectively, including with respect to our recently in-licensed products from Statera or potential licenses from or acquisitions of other companies, our business could be materially and adversely affected.
- We have a history of net losses, and we may not achieve or maintain profitability in the future.
- We have identified a material weakness in our internal control over financial reporting associated with staffing levels, which is common for the stage and size of the Company.

- We expect that we will need additional capital, which, if obtainable, could dilute the ownership interest of investors.
- Cash expenditures associated with our recent in-license from Statera and developments of our ncVNS program may create liquidity and cash flow risks for us.
- Our business plan depends heavily on product revenues from our core technology and recently in-licensed pharmaceutical products, the clinical and consumer acceptance of which is at this time unproven.
- We have recently licensed biopharmaceutical products, a category in which we have limited to no prior experience. We may not be able to effectively integrate licensed or acquired technology into our operations.
- Disruptions at the FDA and foreign regulatory authorities caused by funding shortages, staffing limitations or global health concerns could negatively impact our business.
- Economic uncertainty and capital markets disruption, which has been significantly impacted by geopolitical instability, could harm our financial condition and results of operations.
- Changes in the relations of the United States with other countries, and China in particular, regulations and/or international trade disputes could have a material adverse effect on our business, financial condition and results of operations.
- We rely on third-party service providers to manage our information systems which may not adequately protect the company; additionally, cybersecurity risks and cyber incidents could adversely affect us.
- We rely on third parties to supply and manufacture our devices, and we expect to continue to rely on third parties to manufacture and supply our devices.
- We depend on our senior management team, and the loss of one or more key personnel or an inability to attract and retain highly skilled personnel may impair our ability to grow our business.
- The guarantees and warranties we provide on our products could have a material adverse effect on our business, financial condition and results of operations.
- Our markets are undergoing continuous change, and our future success will depend on our ability to meet the changing needs of our customers.
- Developing medical technology and biopharmaceutical products entails significant technical, regulatory and business risks.
- The size and expected growth of our available market has not been established with precision and may be smaller than we estimate.
- Our insurance may not adequately cover our operating risk.
- Our business could be disrupted by catastrophic occurrences and similar events.
- Changes in the regulatory landscape for our products and product candidates 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 to make determinations about the regulatory pathway for future products, which may be interpreted to a different effect by the FDA.
- We are subject to consumer protection laws that regulate our marketing practices and prohibit unfair or deceptive acts or practices.

- We may not be able to obtain regulatory approval in a timely manner or at all and the results of future clinical trials and pivotal efficacy studies may not be favorable.

- Compensatory arrangements with our scientific advisors or consultants could result in increased regulatory scrutiny and ultimately lead to the delay or denial of marketing approval for our product candidates.

- We may not be able to obtain fast track designation, breakthrough therapy designation or other expedited pathways for FDA approval of our product candidates, and even if we do, may not actually lead to a faster development or regulatory review or approval process.

- 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.

- Our stock price has fluctuated significantly since our initial public offering ("IPO"), and may continue to fluctuate significantly, and investors may not be able to resell the securities that they purchase at or above the price at which they purchased them.

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

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

- If we are unable to comply with the continued listing requirements of the Nasdaq Capital Market, our common stock could be delisted, which could affect our common stock's market price and liquidity and reduce our ability to raise capital.

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

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

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

Risks Related to Our Financial Condition and Business Model

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

We were originally incorporated in 2016 and began selling our first product in 2019. Additionally, we entered into a license agreement with Statera in February 2025, pursuant to which we acquired a worldwide exclusive license rights from Statera to the late-stage TLR5 agonist Entolimod for the treatment of acute radiation syndrome. Prior to obtaining such license, the Company had no experience in the development of biopharmaceuticals. Accordingly, we have a limited operating history, which makes an evaluation of our future prospects and execution ability difficult. Our revenue and income-producing potential is unproven, and our business model and strategy may continue to evolve. Future revenues are contingent upon several factors, including, without limitation, our ability to successfully develop and scale-up sales of the ClearUP line and future products, including any ncVNS products and/or TLR5 products that we may develop and commercialize in the future, 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, research and development 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:

- strategic transactions that we may enter into from time to time, including the recent license that we acquired from Statera in February 2025 and any other indications that we may choose to license from Statera in the future under the License Agreement, including our obligations related thereto;
- 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 product candidates and obtain new customers in the future. The volume and timing of commercial outcomes for our ClearUP product 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 teams 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, 2024 and 2023, we incurred net losses of $5.7 million and $8.2 million, respectively, and at December 31, 2024, we had working capital of $2.4 million and an accumulated deficit of $43.5 million. During the years ended December 31, 2024 and 2023, we used $5.7 million and $8.5 million of cash, respectively, for operating activities. The net losses we incur may fluctuate significantly from quarter to quarter and may increase as a result of macroeconomic factors. Additionally, future costs relating to product development and operating activities, including as a result of our obligations under the License Agreement recently entered into with Statera, may be significantly higher than our historical costs.

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

Our future capital requirements will depend upon many factors, including, without limitation, progress with developing, manufacturing and marketing our technologies and product candidates; the time and costs involved in obtaining regulatory approvals for our product candidates; the time and costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other proprietary rights; our ability to successfully execute our strategy to expand our business, including through the closing of potential acquisitions or licenses and integrating new business into our own; our ability to establish collaborative arrangements; marketing activities; and competing technological and market developments. Our ability to generate revenue and achieve profitability requires us to successfully market and secure purchase orders for our products and services from customers currently identified in our sales pipeline as

well as new customers. We will also be required to efficiently manufacture and deliver equipment on those purchase orders. These activities, including our planned research and development efforts, will require significant uses of working capital. There can be no assurance that we will generate revenue and cash as expected in our current business plan. We expect that we will need to raise additional capital to continue operating our business and fund our planned operations, including to execute on our strategy to expand our business, research and development, clinical trials and, if regulatory approval is obtained, commercialization of future product candidates. We may seek additional funds through equity or debt offerings and/or borrowings under notes payable, lines of credit or other sources. We do not know whether additional financing will be available on commercially acceptable terms, or at all, when needed. If adequate funds are not available or are not available on commercially acceptable terms, our ability to fund our operations, support the growth of our business or otherwise respond to competitive pressures could be significantly delayed or limited, which could materially and adversely affect our business, financial conditions, or results of operations.

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

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

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

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

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

In connection with the audit of our financial statements for the years ended December 31, 2024 and 2023, we identified a material weakness in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. Due to the small size of our accounting and financial reporting team, as well as recent staff turnover, even with processes and procedures in place to mitigate the risk of a material misstatement, we believe that there is still a reasonable possibility that a material misstatement of our annual or interim financial statements may not be prevented or detected on a timely basis. If we are unable to remedy our material weakness, or if we generally fail to establish and maintain effective internal controls appropriate for a public company, we may be unable to produce timely and accurate financial statements, and we may continue to conclude that our internal control over financial reporting is not effective, which could adversely impact our investors' confidence and our stock price.

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

We anticipate we will need additional capital to market our products, develop additional products and fund our operations, which we may raise through the sale and issuance of equity, equity-related or convertible debt, or other

securities. Our future capital requirements depend on many factors, including our need to market our products, acquire or develop additional products and fund our operations. We cannot be certain that additional financing will be available to us on acceptable terms when required, or at all.

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

Cash expenditures associated with our recent in-license from Statera and developments of our ncVNS program may create liquidity and cash flow risks for us.

We incurred significant transaction costs and expect to incur integration costs in connection with our recent in-license of rights to certain products from Statera. While we expected that the transactions costs would be incurred, there are many factors beyond our control that could affect the total amount of the integration expenses associated with the license. Moreover, many of the expenses that will be incurred are, by their nature, difficult to estimate accurately. In addition to integration-related expenses that we will incur, pursuant to the License Agreement, we are obligated to develop and commercialize the licensed products, at our own cost and expense, to make payments to Statera upon achievement of certain milestones, and to make certain royalty payments. In addition,we have certain on-going commitments associated with the development of our ncVNS program. To the extent the integration and/or development and commercialization expenses are higher than anticipated, we may experience liquidity or cash flow issues.

Our business plan depends heavily on revenues from our core technology and recently in-licensed pharmaceutical 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 our products and product candidates. 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 have recently licensed biopharmaceutical assets, a category in which we have limited to no prior experience. We may not be able to effectively integrate licensed or acquired assets into our operations (including regulatory, quality, product development, marketing and manufacturing operations).

We have historically operated solely as a medical device company. We have recently in-licensed exclusive rights to late-stage biopharmaceutical products from Statera that will require us to operate in, among others, regulatory, quality, product development, manufacturing and marketing environments with which we have limited experience. While we have hired experienced staff to support this new dimension of the business, we may not be able to successfully create or integrate new capabilities into our overall business. This may ultimately limit or substantively damage our ability to capitalize on the licensed assets.

Disruptions at the FDA and foreign regulatory authorities caused by funding shortages, staffing limitations or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA and foreign regulatory authorities to review or approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's or foreign regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's or foreign regulatory authorities' ability to perform routine functions including a rapid substantial influx of applications from numerous sponsors, as occurred with COVID-19. Average review times at the FDA and foreign regulatory authorities have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. For example, in recent years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA

employees and stop critical activities and, recently, the current administration has been implementing significant budget cuts, eliminating grant programs and terminating employees throughout many different sectors of the federal government. Disruptions at the FDA and other agencies may also slow the time necessary for new devices and drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business.

We are currently operating in a period of economic uncertainty and capital markets disruption, which has been significantly impacted by geopolitical instability and the ongoing military conflicts between Russia and Ukraine and Israel and Hamas. 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 and the Middle East and/or geopolitical tensions.

U.S. and global markets are experiencing volatility and disruption, and the global economy has been, and may continue to be, negatively impacted by Russia's ongoing military conflict with Ukraine. As a result of Russia's invasion of Ukraine in February 2022, the U.S., the European Union, the United Kingdom, other G7 countries, as well as various other countries, have imposed substantial financial and economic sanctions on certain industry sectors and parties in Russia. Broad restrictions on exports to Russia have also been imposed. These measures include: (i) comprehensive financial sanctions against major Russian banks; (ii) additional designations of Russian individuals with significant business interests and government connections; (iii) designations of individuals and entities involved in Russian military activities; and (iv) enhanced export controls and trade sanctions limiting Russia's ability to import various goods. Russian military actions and the resulting sanctions could continue to 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.

In October 2023, Hamas militants and members of certain other organizations infiltrated Israel's southern border from the Gaza Strip and conducted a series of attacks on civilian and military targets. Shortly thereafter, Israel's security cabinet declared war against Hamas and launched an aerial bombardment of various targets within the Gaza Strip. It is possible that other countries and/or regional organizations will join the hostilities as well, including without limitation Hezbollah in Lebanon, and Palestinian military organizations in the West Bank, resulting in further expansion of the conflict. The conflict between Israel and Hamas is ongoing, and the length and impact of the ongoing military conflict is highly unpredictable.

Although our business has not been materially impacted by the ongoing military conflicts between Russia and Ukraine or Israel and Hamas, geopolitical tensions, or record inflation 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 conflicts in Ukraine and the Middle East, geopolitical tensions, record inflation, 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 herein.

Changes in United States and China relations, as well as relations with other countries, and/or regulations may adversely impact our business, our operating results, our ability to raise capital and the market price of our shares.

The U.S. government, including the SEC, has made statements and taken certain actions that led to changes to U.S. and international relations, and will impact companies with connections to the United States or China, including imposing several rounds of tariffs affecting certain products manufactured in China, imposing certain sanctions and restrictions in relation to China and issuing statements indicating enhanced review of companies with significant China-based operations. It is unknown whether and to what extent new legislation, executive orders, tariffs, laws or regulations will be adopted, or the effect that any such actions would have on companies with significant connections to the U.S. or to China, our industry or on us. Any unfavorable government policies on cross-border relations and/or international trade, including increased scrutiny on companies with significant China-based operations, capital controls or tariffs, may affect our ability to raise capital and the market price of our shares.

If any new legislation, executive orders, tariffs, laws and/or regulations are implemented, if existing trade agreements are renegotiated or if the U.S. or Chinese governments take retaliatory actions due to the recent U.S.-China tension, such changes could have an adverse effect on our business, financial condition and results of operations, our ability to raise capital and the market price of our shares. Any additional executive action, legislative action or potential sanctions with China could materially impact our current manufacturing partners and our agreements with them.

Additionally, any additional executive action, legislative action or potential sanctions with China could materially impact our current manufacturing partners and our agreements with them.

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.

In recent years, including after the most recent presidential election, the U.S has instituted or proposed changes in trade policies that include the negotiation or termination of trade agreements, the imposition of higher tariffs on imports into the U.S., economic sanctions on individuals, corporations or countries, and other government regulations affecting trade between the U.S. and other countries where we conduct our business, in particular China, Mexico and Canada. A number of other nations have proposed or instituted similar measures directed at trade with the United States in response. As a result of these developments, there may be greater restrictions and economic disincentives on international trade that could adversely affect our business. As additional trade-related policies are instituted, we may need to modify our business operations to comply and adapt to such developments, which may be time-consuming and expensive.

Cybersecurity risks and cyber incidents, as well as other significant disruptions of our information technology networks and related systems and resources, could adversely affect our business, disrupt operations and expose us to liabilities to employees, customers, governmental regulators, and other third parties.

We use information technology and other computer resources to carry out important operational activities and to maintain our business records. As part of our normal business activities, we permit certain employees to perform some or all of their business activities remotely, we collect and store certain personal identifying and/or confidential information relating to our employees, customers, vendors and suppliers, and we maintain operational and financial information related to our business. Furthermore, we rely on products and services provided by third-party suppliers to operate certain critical business systems, including without limitation, cloud-based infrastructure, encryption and authentication technology, email, and other functions, which exposes us to supply-chain attacks or other business disruptions.

We face risks associated with security breaches through cyber-attacks or cyber-intrusions, malware, computer viruses and malicious codes, ransomware, attachments to e-mail, unauthorized access attempts, denial of service attacks, phishing, social engineering, persons with access to systems inside our organization, and other significant disruptions of our information technology networks and related systems. The risk of a security breach has generally increased as the frequency, intensity and sophistication of attempted attacks and intrusions from around the world have increased. Even the most well protected information, networks, systems and facilities remain potentially vulnerable because the techniques, tools and tactics used in such attempted security breaches evolve and generally are not recognized until launched against a target, and in some cases are designed to not be detected and, in fact, may not be detected. Accordingly, we may be unable to anticipate these techniques or to implement adequate security barriers, disaster recovery or other preventative or corrective measures, and thus it is impossible for us to entirely counteract this risk or fully mitigate the harms after such an attack.

We have implemented certain systems and processes intended to address ongoing and evolving cybersecurity risks, secure our information technology, applications and computer systems, and prevent unauthorized access to or loss of sensitive, confidential and personal data. Although we and our service providers employ what we believe are adequate security, disaster recovery and other preventative and corrective measures, our security measures, taken as a whole, may not be sufficient for all possible situations and may be vulnerable to, among other things, fraud, hacking, employee error, system error, and faulty password management. Additionally, we rely on third-parties for virtually all of our operating infrastructure, who may themselves have standards of materiality of cybersecurity risks that differ from the materiality standards of Tivic itself.

Our ability to conduct our business may be impaired if our or our services providers' information technology networks, systems or resources, including our and their websites or e-mail systems, are compromised, degraded, damaged or fail, whether due to a virus or other harmful circumstance, fraud, intentional penetration or disruption of our or their information technology resources by:

- a third party,

- natural disaster,
- a failure of hardware or software due to a design or programmatic flaw,
- a failure of hardware or software security controls,
- telecommunications system failure,
- service provider error or failure,
- fraudulent transactions,
- intentional or unintentional personnel actions,
- lost connectivity to our networked resources, or
- a failure of disaster recovery system.

A significant and extended disruption could damage our business or reputation and cause, amongst other things, loss of revenues or customer relationships, unintended and/or unauthorized public disclosure or the misappropriation of proprietary, personal identifying and confidential information, and us to incur significant expenses to address and remediate or otherwise resolve these kinds of issues. Our disaster recovery procedures and contingency planning rely heavily on third-party providers and may prove insufficient to fully protect Tivic operations and business interests

The release of confidential information may also lead to litigation or other proceedings against us by affected individuals, business partners and/or regulators, and the outcome of such proceedings, which could include losses, penalties, fines, injunctions, expenses and charges recorded against our earnings and cause us reputational harm and/or could have a material and adverse effect on our business, financial position or results of operations.

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

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

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

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

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

We may be adversely affected by the effects of inflation.

Inflation has the potential to adversely affect our liquidity, business, financial condition and results of operations by increasing our overall cost structure, particularly if we are unable to achieve commensurate increases in the prices we charge our customers. The existence of inflation in the economy has recently resulted in, and may in the future 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 cost increases. Although we may take measures to mitigate the impact of this inflation, if these measures are not effective our business, financial condition, results of operations and liquidity could be materially adversely affected. Even if such measures are effective, there could be a difference between the timing of when these beneficial actions impact our results of operations and when the cost inflation is incurred.

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

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

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

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

For us to be successful, third parties providing us with sales, marketing, manufacturing, distribution and other business operations services must be able to provide us with such services in compliance with regulatory requirements, in accordance with agreed upon specifications, at acceptable costs, and on a timely basis. While our service providers have generally met our expectations in the past, their ability and willingness to continue to do so going forward, and the ability and willingness of any new service provider to meet our expectations in the future, may be limited for several reasons, including our relative importance as a customer. Additionally, we rely on third-party online retailers, as well as the parties that we have entered into distribution agreements with, 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 or channels. Accordingly, we may be exposed to disruptions or reduced quality 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 licensed assets or acquisitions or to successfully manage the impacts of such transactions on our operations.

Part of our business strategy includes investigating growth through in-licenses of assets, such as our recent in-license of assets from Statera, and acquisitions. In connection with the recent license transaction with Statera, we have in-licensed new assets, created a new biopharmaceutical program and brought on new employees to help us develop our TLR5 program. In the future, we may further expand our business through additional licenses, including by exercising our option to license additional indications from Statera, or by making strategic acquisitions to enhance our growth.

Material in-licenses, 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) increases in our capital expenditures; (v) the anticipated benefits and cost savings of those transactions not being realized fully, or at all, or taking longer to realize than anticipated; (vi) an increase in the scope and complexity of our operations; (vii) exposure to unknown liabilities, and (viii) the loss or reduction of control over certain of our assets.

The pursuit of strategic transactions may pose certain risks to us. We may not be able to identify license or 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 strategic transaction opportunities, whether or not we consummate such transactions, which may divert management's attention from our day-to-day business.

Additionally, even if we are able to complete in-licenses or acquisitions on agreeable terms, we may not be able to successfully integrate the licensed assets and/or their operations with ours. Achieving the anticipated benefits of any transaction will depend in significant part upon whether we integrate such 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 in-licenses or acquisitions within the anticipated timing, or at all. The benefits from any such transactions will be offset by the costs incurred in integrating the businesses and operations. We may also assume liabilities in connection with transactions to which we would not otherwise be exposed. An inability to realize any or all of the anticipated synergies or other benefits of a license or acquisition as well as any delays that may be encountered in the integration process, which may delay the timing of such synergies or other benefits, could have an adverse effect on our business, results of operations and financial condition.

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

We provide product guarantees to our customers, pursuant to which we allow for the return of products from customers within 60 days after the original sale. We also provide one- and two-year warranties for any defective product. Existing and future product guarantees and warranties place us at the risk of incurring future returns and repair and/or replacement costs. While we engage in product quality programs and processes, including monitoring and evaluating the quality of our components sourced from our suppliers, our guaranty and warranty obligation is affected by actual product defect rates, parts and equipment costs and service labor costs incurred in correcting a product defect. During the years ended December 31, 2024 and 2023, we accrued return reserves equal to approximately 9.5% and 10%, respectively, of gross revenues. We believe our reserve as of December 31, 2024 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.

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.

Risks Related to Our Bioelectronic Business and Markets

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

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

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

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

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

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

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

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

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

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

We may face risks associated with expanding to international markets.

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

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

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

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

Our 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 Relating to Regulatory Drug Approval

We may not be able to obtain regulatory approval in a timely manner or at all and the results of future clinical trials and pivotal efficacy studies may not be favorable.

The testing, marketing, and manufacturing of any product for use in the U.S. and the E.U. will require approval from the FDA and the EMA, respectively. We cannot predict with any certainty the amount of time necessary to obtain FDA approval and whether any such approval will ultimately be granted. Preclinical studies, animal efficacy studies, or clinical trials may reveal that one or more products are ineffective or unsafe, in which event, further development of such products could be seriously delayed, terminated or rendered more expensive.

In addition, we expect to rely on the FDA Animal Rule to obtain approval for Entolimod's biodefense indication in the U.S. The Animal Rule permits the use of animal efficacy studies together with human clinical safety trials to support an application for marketing approval of products when human efficacy studies are neither ethical nor feasible. These regulations have limited prior use and we have limited experience in the application of these rules to the product candidates that we are developing. We cannot guarantee that the FDA will review the data submitted in a timely manner, or that the FDA will accept the data when reviewed. If we are not successful in completing the development, licensure, and commercialization of Entolimod for its biodefense indication, or if we are significantly delayed in doing so, our business will be materially harmed.

Even if we eventually complete clinical trials and receive approval for our product candidates, the FDA or EMA may grant approval contingent on the performance of costly additional clinical trials, including Phase 4 clinical trials, and/or the implementation of a REMS, which may be required to ensure safe use of the drug after approval.

Delays in obtaining FDA, EMA, or any other necessary regulatory approvals of any proposed product or the failure to receive such approvals would have an adverse effect on our ability to develop such product, the product's potential commercial success and/or on our business, prospects, financial condition and results of operations.

Compensatory arrangements with our scientific advisors or consultants could result in increased regulatory scrutiny and ultimately lead to the delay or denial of marketing approval for our product candidates.

Principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between the Company and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

Failure to obtain regulatory approval in international jurisdictions could prevent us from marketing our products abroad.

We intend to market our product candidates, in the U.S., Europe, Ukraine and other countries and regulatory jurisdictions. In order to market our product candidates in the U.S., Europe, Ukraine, and other jurisdictions, we must obtain separate regulatory approvals in each of these countries and territories. The procedures and requirements for obtaining marketing approval vary among countries and regulatory jurisdictions and may involve additional clinical trials or other tests. In addition, we do not have in-house experience and expertise regarding the procedures and requirements to file for and obtain marketing approval for drugs in countries outside of the U.S., and may need to engage and rely upon expertise of third parties when we file for marketing approval in countries outside of the U.S. Also, the time required to obtain approval in markets outside of the U.S. may differ from that required to obtain FDA approval, while still including all of the risks associated with obtaining FDA approval. We may not be able to obtain

all of the desirable or necessary regulatory approvals on a timely basis, if at all. Approval by a regulatory authority in a particular country or regulatory jurisdiction, such as the FDA in the U.S. or the EMA in the E.U., does not ensure approval by a regulatory authority in another country.

We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our product candidates in any or all of the countries or regulatory jurisdictions in which we desire to market our product candidates. At this time, to our knowledge, other countries do not have an equivalent to the Animal Rule and, as a result, such countries do not likely have established criteria for review and approval for this type of product outside their normal review process.

The fast track designation for Entolimod may not actually lead to a faster development or regulatory review or approval process.

Statera previously obtained a fast track designation from the FDA for Entolimod's biodefense indication. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply to the FDA for fast track designation. However, we may not experience a faster development process, review, or approval compared to conventional FDA procedures. The FDA may withdraw our fast track designation if the FDA believes that the designation is no longer supported by data from our clinical or pivotal development program. Our fast track designation does not guarantee that we will qualify for or be able to take advantage of the FDA's expedited review procedures or that any application that we may submit to the FDA for regulatory approval will be accepted for filing or ultimately approved.

We may seek breakthrough therapy designation for some of our product candidates. The designation may not be granted and, even if granted by the FDA, such designation may not lead to a faster development of any product candidate or approval process for any product candidate.

We may seek a breakthrough therapy designation for some of our product candidates. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs and biologics that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA may also be eligible for priority review if supported by clinical data at the time the BLA is submitted to the FDA.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. Even if we receive a breakthrough therapy designation, the receipt of such designation for a product candidate may not result in a faster development of any product candidate or approval process for product candidate. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

If the FDA does not conclude that certain of our product candidates satisfy the requirements for the Section 505(b)(2) regulatory approval pathway, or if the requirements for such product candidates under Section 505(b)(2) are not as expected, the approval pathway for those product candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful.

We plan to seek FDA approval through the Section 505(b)(2) regulatory pathway for several of our product candidates. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, added Section 505(b)(2) to the FDCA. Section 505(b)(2) permits the filing of a BLA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505(b)(2), if applicable to the Company under the FDCA, would allow a BLA submitted by us to the FDA to rely in part on data in the public domain or the FDA's prior conclusions regarding

the safety and effectiveness of approved compounds, which could expedite the development program for our product candidates by potentially decreasing the amount of clinical data that we would need to generate in order to obtain FDA approval. If the FDA does not allow us to pursue the Section 505(b)(2) regulatory pathway as anticipated, we may need to conduct additional clinical trials, provide additional data and information, and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for these product candidates, and complications and risks associated with these product candidates, would likely substantially increase. We may need to obtain additional funding, which could result in significant dilution to the ownership interests of our then existing stockholders to the extent we issue equity securities or convertible debt. We cannot guarantee that we would be able to obtain such additional financing on terms acceptable to us, if at all. Moreover, inability to pursue the Section 505(b)(2) regulatory pathway would likely result in new competitive products reaching the market more quickly than our product candidates, which would likely materially adversely impact on our competitive position and prospects. Even if we are allowed to pursue the Section 505(b)(2) regulatory pathway, there is no guarantee that our product candidates will receive the requisite approvals for commercialization.

Moreover, even if our product candidates are approved under Section 505(b)(2), the approval may be subject to limitations on the indicated uses for which the products may be marketed or to other conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the products.

If physicians and patients do not accept and use our drugs, we will not achieve sufficient product revenues and our business will suffer.

Even if we gain marketing approval of our drug candidates, government purchasers, physicians and/or patients may not accept and use them. Acceptance and use of these products may depend on a number of factors including:

- perceptions by members of the government healthcare community, including physicians, about the safety and effectiveness of our drugs;
- published studies demonstrating the safety and effectiveness of our drugs;
- adequate reimbursement for our products from payors; and
- effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

The failure of our drugs, if approved for marketing, to gain acceptance in the market would harm our business and could require us to seek additional financing.

Risks Related to Legal and Other Regulatory Matters

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

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

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

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

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

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

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

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

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

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws and anti-money laundering laws and regulations.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, and various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, and anti-corruption and anti-money laundering laws and regulations, including the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, clinical research organizations, contractors and other collaborators and partners from authorizing, promising, offering, providing, soliciting or receiving, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties for clinical trials outside of the U.S., to sell our products abroad once it enters a commercialization phase, and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We may have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, clinical research organizations, contractors and other collaborators and partners, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal

fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

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, and has proposed to further raise in the future, tariffs on several Chinese goods. China has retaliated with increased tariffs on United States goods. Moreover, China's legislature has adopted a national security law to substantially change the way Hong Kong has been governed since the territory was handed over by the United Kingdom to China in 1997. This law increases the power of the central government in Beijing over Hong Kong, limits the civil liberties of residents of Hong Kong and could restrict the ability of businesses in Hong Kong to continue to conduct business or to continue to with business as previously conducted. The U.S. State Department has indicated that the U.S. no longer considers Hong Kong to have significant autonomy from China. The U.S. State Department previously enacted sanctions related to China's governing of Hong Kong, and the U.S. may impose the same tariffs and other trade restrictions on exports from Hong Kong that it places on goods from mainland China. 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. For example, the Uyghur Forced Labor Prevention Act bans imports from China's Xinjiang Uyghur Autonomous Region unless it can be shown that the goods were not produced using forced labor and this legislation may have an adverse effect on global supply chains which could adversely impact our business and results of operations. Additionally, China has recently implemented significant restrictions on the export of gallium and germanium, both of which are used for the manufacture of computer chips. Changes to regulations in China and/or 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.

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 our 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 IP rights throughout the world.

The laws of some foreign countries do not protect IP 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 IP protection we can obtain throughout the world may vary. Many companies have encountered significant problems in protecting and defending IP 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 IP 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 IP 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 IP.

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 price at which they purchased them.

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

- the effect of macroeconomic factors on our business and operations and on market conditions generally;
- the success of our products and of competitive products or technologies;
- regulatory or legal developments in the United States and other countries;
- the level of expenses related to our products or development programs;
- announcements by us, our partners or our competitors of new products or therapies, significant contracts, strategic partnerships, joint ventures, collaborations, commercial relationships, or capital commitments;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- issuance of new or updated research or reports by securities analysts or recommendations for our stock;

- disputes or other developments related to proprietary rights (including patents), litigation matters, and our ability to obtain patent protection for our technologies;
- commencement of, or our involvement in, litigation;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- manufacturing disputes or delays;
- any future sales of our common stock or other securities;
- any change to the composition of the board of directors or key personnel;
- general economic conditions and slow or negative growth of our markets;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcement or expectation of additional debt or equity financing efforts; and
- other factors described in this section of the Report.

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

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

In the year ended December 31, 2024, we sold an aggregate of 470,220 shares of our common stock to certain investors through a registered public offering and an at-the-market equity distribution program, which resulted in aggregate net proceeds of approximately $4.5 million. Additionally, after the end of the fiscal year, we issued Statera 55,635 shares of common stock and 359.6691 shares of our Series A Nonvoting Convertible Preferred Stock, which (subject to certain limitations, including shareholder approval) shares are convertible into an aggregate of approximately 211,570 shares of our common stock. We anticipate that we will issue additional shares of capital stock in conjunction with future funding requirements. Any issuance of shares of our common stock, or securities exercisable for or convertible into shares of our common stock, for the purpose of securing capital will result in the dilution of the ownership interests of our existing stockholders.

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

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

If we are unable to comply with the continued listing requirements of the Nasdaq Capital Market, our common stock could be delisted, which could affect our common stock's market price and liquidity and reduce our ability to raise capital.

Our common stock is listed on the Nasdaq Capital Market, a national securities exchange, which imposes continued listing requirements with respect to issuers whose securities are listed on Nasdaq. If we fail to satisfy the continued listing standards, such as, for example, Nasdaq's minimum bid price requirement or stockholders equity requirements, Nasdaq may issue a non-compliance letter or initiate delisting proceedings.

As previously disclosed, on June 28, 2024, we received a notification letter from the Listing Qualifications Department of the Nasdaq Stock Market LLC notifying us that, because the closing bid price for our common stock was below $1.00 per share for 33 consecutive business days, we are not currently in compliance with the minimum bid price requirement for continued listing on the Nasdaq Capital Market, as set forth in Nasdaq Marketplace Rule 5550(a)(2) (the "Minimum Bid Price Requirement"). On December 27, 2024, we received an additional letter from Nasdaq, notifying us that we had not regained compliance with the Minimum Bid Price Requirement and wee not eligible for a second 180-day remediation period, and that, unless we timely requested a hearing before a Hearings Panel (the "Panel"), our securities would be subject to suspension/delisting. After a hearing in front of the Panel, on March 6, 2025, we received a letter from the Nasdaq hearings panel granting our request for continued listing on the Nasdaq Capital Market provided that we implemented the reverse stock split on March 7, 2025 (which we did) and demonstrated compliance with all such continued listing requirements for the Nasdaq Capital Market as of March 20, 2025. As of March 21, 2025, we believe that we have regained compliance; however, we have not yet received confirmation from Nasdaq and no assurances can be provided.

If we are unable to maintain compliance with the continued listing requirements of Nasdaq in the future, our common stock could be delisted, making it could be more difficult to buy or sell our securities and to obtain accurate quotations, and the price of our securities could suffer a material decline. Delisting could also impair our ability to raise capital.

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.

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

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

In addition, we are currently a "smaller reporting company," as defined in the Securities Exchange Act of 1934, as amended ("Exchange Act"), and have elected to take advantage of certain of the scaled disclosures available to smaller reporting companies. To the extent that we continue to qualify as a "smaller reporting company" as such term is defined in Rule 12b-2 under the Exchange Act, after we cease to qualify as an emerging growth company, certain of the exemptions available to us as an "emerging growth company" may continue to be available to us as a "smaller

reporting company," including exemption from compliance with the auditor attestation requirements pursuant to the Sarbanes-Oxley Act and reduced disclosure about our executive compensation arrangements. We will continue to be a "smaller reporting company" until we have more than $250 million in public float (based on our common stock) measured as of the last business day of our most recently completed second fiscal quarter or, in the event we have no public float (based on our common stock), annual revenues of more than $100 million during the most recently completed fiscal year.

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

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

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. In addition, we are required to furnish a report by management on the effectiveness of our internal control over financial reporting, pursuant to Section 404 of the Sarbanes-Oxley Act. As of December 31, 2024, based on an analysis completed by management, our internal controls were not effective due to the existence of a material weakness. The process of designing, implementing and testing the internal control over financial reporting required to comply with this obligation is time consuming, costly and complicated. If we identify material weaknesses in our internal control over financial reporting (as we have for the period covered by this Report), if we are unable to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to assert that our internal control over financial reporting is effective, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could decline, and we could also become subject to investigations by the stock exchange on which our common stock is listed, the Commission or other regulatory authorities, which could require additional financial and management resources.

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

We may, but are not obligated to, provide public guidance on our expected operating and financial results for future periods. Any such guidance will be comprised of forward-looking statements subject to the risks and uncertainties described in this 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, as amended ("Certificate of Incorporation"), and amended and restated bylaws, as amended ("Bylaws"), may have the effect of delaying or preventing a change of control or changes in our management. Our Certificate of Incorporation and 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 Certificate of Incorporation and 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 Certificate of Incorporation and 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 Certificate of Incorporation or our Bylaws; (iv) any action to interpret, apply, enforce or determine the validity of our Certificate of Incorporation or our 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 Certificate of Incorporation 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 our Certificate of Incorporation or 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 Certificate of Incorporation and Bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

General Risk Factors

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

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

We have and will continue to incur significant costs and are subject to heightened regulations and requirements as a result of being 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, 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. These rules and regulations have increased and will continue to increase our legal and financial compliance costs and to make some activities more time-consuming and costlier, although we are currently unable to estimate these costs with any degree of certainty. These laws and regulations also make it more difficult or costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. These laws and regulations may also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on our board committees or as our executive officers. Furthermore, if we are unable to satisfy our ongoing obligations as a public company, we could be subject to delisting of our common stock, fines, sanctions, other regulatory action and potentially civil litigation.

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

The global data protection landscape is rapidly evolving, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business. We are subject to numerous state, federal and foreign laws, requirements and regulations governing the collection, transmission, use, disclosure, storage, retention and security of personal and personally-identifying information, such as information that we may collect in connection with conducting our business in the United States and abroad. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards or perception of their requirements may have on our business. This evolution may create uncertainty in our

business; affect our ability to operate in certain jurisdictions; or to collect, store, transfer use and share personal information; necessitate the acceptance of more onerous obligations in our contracts; result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulation, our internal policies and procedures, or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, fines, imprisonment of company officials and public censure, claims by third parties, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition and results of operations.

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

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

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

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

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

Item 1B – Unresolved Staff Comments

None.

Item 1C – Cybersecurity

Risk management and strategy

Due to the size of our company, we have not yet developed robust policies and processes for assessing, identifying, and managing material risk from cybersecurity threats. We have implemented access controls with respect to our systems, which we monitor regularly and audit annually. We currently rely heavily on products and services provided by third-party suppliers to operate certain critical business systems, including without limitation, cloud-based infrastructure, encryption and authentication technology, email, and other functions. We rely on third party providers and outsourced IT services to monitor and address cybersecurity related risks, including installing software for threat protection and malware. Such third party providers are tasked with notifying management of any material risks or cybersecurity concerns that they identify, which management then assesses and may bring to our board of directors to discuss if deemed necessary or appropriate. Based on the results of our risk assessments, if deemed necessary or appropriate, we take steps to re-design, implement, and maintain reasonable safeguards to minimize identified risks; reasonably address any identified gaps in existing safeguards; and regularly monitor the effectiveness of our safeguards.

We intend to work with outside counsel and third party service providers to further develop our expertise, processes and procedures with respect to cybersecurity protection and our response plan.

To date, we have not (to our knowledge) encountered cybersecurity challenges that have materially impaired our operations or financial standing. For additional information regarding risks from cybersecurity threats, please refer to Item 1A, "Risk Factors," in this Report.

Governance

Our management team is primarily responsible for assessing and managing our strategic risk exposures, including material risks from cybersecurity threats, with assistance from third-party service providers. Management oversees our cybersecurity process on a day-to-day basis, including those described in "Risk Management and Strategy" above.

Our audit and risk committee is tasked with general oversight of our risk management process, including risks from cybersecurity threats. Members of management provide periodic briefings to the audit and risk committee of our board of directors regarding our cybersecurity risks and activities, including any recent cybersecurity incidents and related responses, cybersecurity systems testing, activities of third parties, and the like. In furtherance thereof, the committee is responsible for monitoring and assessing strategic risk exposure. Our audit and risk committee provides regular updates to the board of directors on such reports.

Item 2 – Properties

Our principal executive office is located at 47685 Lakeview Blvd., Fremont, California 94538. On May 30, 2024, we entered into a Co-Working Space Agreement, pursuant to which we rent office space for a total of $1 thousand per month. The agreement has an initial term of six months, commencing June 1, 2024, after which it will automatically renew on a month to month basis until terminated.

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. Prior to our initial public offering, there was no public market for our common stock.

Holders

As of March 17, 2025, there were approximately 120 shareholders of record of our common stock. A substantially greater number of holders of our common stock are "street name" or beneficial holders, whose shares are held by banks, brokers, and other financial institutions.

Dividends

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

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

During the fiscal year ended December 31, 2024, there were no unregistered sales of our securities that were not reported in a Current Report on Form 8-K or our Quarterly Reports on Form 10-Q.

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

Tivic Health is a diversified therapeutics company harnessing the power of the immune and autonomic nervous systems to fight disease and restore health. Tivic Health's bioelectronic program is developing non-invasive medical devices to meaningfully improve treatment options in neurologic, cardiac and autonomic-related diseases. Tivic Health currently offers a bioelectronic, FDA-approved over-the-counter device (ClearUP™) that treats sinus pain, pressure and congestion. ClearUP is available through online retailers and commercial distributors and at tivichealth.com. Tivic Health is further developing its bioelectronic portfolio with a focus on non-invasive vagus nerve stimulation.

Tivic Health's biopharma program focuses on immunotherapeutics and the lead product candidate is the late-stage TLR5 agonist, Entolimod™, to treat acute radiation syndrome. The FDA has granted Fast Track and Orphan Drug designation to Entolimod™.

Business Overview

Bioelectronic medicine is an emerging market. Since our formation in September 2016, we have devoted substantially all of our efforts to the development and marketing of our proprietary technology platform to provide noninvasive, drug-free treatments and treatment candidates for various diseases and conditions. In 2019, we launched ClearUP in the U.S. market. ClearUP is approved by the FDA for sale in the U.S. for the two FDA-approved indications noted above. We currently sell ClearUP directly to consumers online through our own website and to resellers such as McKesson-affiliate Simply Medical, Cardinal Health and AmerisourceBergen. Through our online retailers, ClearUP is available through Amazon, McKesson, Optum Store, Walmart, Target, Best Buy, Cardinal Health and FSA/HSA Store. We have also developed a proprietary approach to precision, non-invasive cervical vagus nerve stimulation based on our experience building evidence-based bioelectronic therapies.

In early 2025, through the license with Statera, Tivic added biologic immunotherapy to its clinical pipeline. Biopharmaceuticals (also known as biologics) refers to pharmaceutical products that are extracted from, manufactured in or semi-synthesized from biological sources.

Recent Events

In the first quarter of 2025:

- We acquired a worldwide exclusive license from Statera Biopharma to the late-stage TLR5 agonist Entolimod for the treatment of ARS. In addition, we acquired an exclusive option to license five additional indications and clinical use cases for Entolimod and its derivative, Entolasta.
- Following the licensing of Entolimod and Entolasta, we hired Michael Handley, previous Chief Executive Officer, President and Chairman of Statera Biopharma, as Chief Operating Officer of Tivic and President of our new Tivic Biopharma division, a role in which he will lead the establishment of a biopharmaceutical capability within Tivic.
- Effective March 7, 2025, we implemented a reverse stock split of our issued and outstanding shares of common stock at a ratio of 1-for-17.
- On March 18, 2025, we entered into an Equity Purchase Agreement, pursuant to which we will have the right, but not the obligation, to sell up to $25 million shares of Company common stock to the investor from time to time over a two-year period, subject to certain conditions precedent and other limitations.

Business Updates

VNS Clinical Research

In May 2024, we announced the final results of our pilot research study with Feinstein. Through this collaboration, we have confirmed the effectiveness of our patent-pending ncVNS approach, which induces responses in the autonomic, cardiac, and central nervous systems and can be expected to have clinical utility in several major disease areas.

- Compared to baseline measurement, our ncVNS intervention resulted in a 97% increase in the root mean square of successive differences ("RMSSD") measure of heart rate variability, which is a widely accepted proxy for vagus nerve activity.
- Measurements of brain activity using EEG demonstrated that our ncVNS intervention increased frontal theta power by 24% and reduced gamma power in several brain regions, including a 66% reduction in frontal gamma power. These changes in brain activity are consistent with reduced arousal and anxiety.
- During ncVNS stimulation, subjects had sustained pupil constriction, a 9.5% reduction in pupil diameter, an outcome associated with activation of the parasympathetic nervous system.

The magnitude of our ncVNS data imply potential for greater clinical effects and enhanced reproducibility than demonstrated by previous studies of non-invasive VNS devices. These results in healthy subjects suggest our ncVNS approach may have clinical utility in several patient populations, including those with post-traumatic stress disorder, cardiac disease, inflammatory conditions, and ischemic stroke, among others.

In May 2024, we entered into a Collaboration and Research Support Agreement with Feinstein to further optimize responses in Autonomic Nervous System ("ANS") function in response to our ncVNS. Total length of the project is expected to be one year. The study, being run by Feinstein, will identify device parameters, including frequency and duration of treatment, that optimally influence ANS function.

In September 2024, we announced approval for the contracted clinical work by Northwell Health's Institutional Review Board, required before enrollment of subjects.

In October 2024, we announced enrollment of the first subject in this optimization study for our patent pending, non-invasive vagus nerve stimulation device. The results will be used to inform clinical indication priority and commercial development. Enrollment was completed in November 2024.

VNS Commercial Strategy

In September, 2024, we announced our partnership with Fletcher Spaght, Inc ("FSI"), a leading healthcare growth strategy firm, to accelerate development of our commercial strategy for ncVNS. The firm has begun a comprehensive market assessment of our ncVNS technology, drawing from clinical outcomes from our Phase 1 trial. FSI and Tivic initially identified approximately 30 potential medical use cases for our ncVNS technology in neurologic, cardiac, psychiatric and autonomic nervous system diseases. FSI is now working closely with our scientific and clinical leadership to identify the strongest market entry points by interviewing clinical key opinion leaders and payers. The work with FSI will help us narrow our go-to-market strategy, clinical study plans, reimbursement pathway, and product development pipeline for our vagus nerve stimulation program.

Postoperative Pain Clinical Research

In August 2024, we received the final report from an investigator-led double-blind study funded by the Icahn School of Medicine at Mount Sinai on the use of microcurrent as an alternative for the treatment of pain following functional endoscopic sinus surgery, rhinoplasty and other forms of sino-nasal surgeries. No statistically significant differences were identified between users of the active microcurrent device and sham device. Given the relatively small market size and lack of definitive indicators of clinical utility, we currently have no plans to fund additional research in this area, prioritizing, instead, our work on vagus nerve stimulation.

ALOM Agreement Termination

In August, 2024, we terminated the Fulfillment Services Agreement with ALOM Technologies Corporation ("ALOM") in furtherance of our efforts to continue to reduce both direct and indirect costs associated with product manufacturing and distribution of our ClearUP device. ALOM provided assembly, procurement, storage, returns, and fulfillment services to our end customers and retailers within the United States. We are now utilizing third-party logistics and storage services from alternate suppliers without material minimums and have established in-house assembly and testing capabilities. We completed the transition with no disruptions to service and foresees current capacity will be sufficient to meet demand for the foreseeable future.

September 2024 Equity Distribution Agreement

In September 2024, we entered into an Equity Distribution Agreement (the "Distribution Agreement") with Maxim Group LLC ("Maxim"), pursuant to which we may offer and sell, from time to time, through or to Maxim, as sales agent or principal, shares of our common stock. We will pay Maxim a commission of 3% of the aggregate gross proceeds from each sale of shares. We also agreed to reimburse Maxim for certain specified fees and expenses of up to $40 thousand, plus an additional $5 thousand for each bringdown. The agreement will terminate upon the earlier of (i) the sale of all shares of common stock having an aggregate offering price of $10 million; (ii) twenty four months from the date of the agreement; (iii) the mutual termination of the agreement upon fifteen days' prior written notice; and (iv) as otherwise permitted therein. In 2024, we sold a total of 193,161 shares of our common stock with gross proceeds of $1.2 million. The Company paid Maxim $37 thousand in commissions. Net proceeds to the Company, after deducting commissions and offering expenses paid by the Company, was approximately $1.1 million.

Appointment of Lisa Wolf as interim Chief Financial Officer

Effective October 1, 2024, Lisa Wolf was appointed as the Company's new interim Chief Financial Officer and Principal Financial and Principal Accounting Officer. Ms. Wolf was retained to provide such services as a non-employee consultant of the Company. Ms. Wolf has played a key role in supporting our accounting and Commission reporting functions on an out-sourced basis since June 2022, when she joined Murdock Martell as Vice President.

Resignation of Kimberly Bambach as interim Chief Financial Officer

On September 12, 2024, Kimberly Bambach tendered her resignation from her role as interim Chief Financial Officer of the Company, effective October 1, 2024. Ms. Bambach continues to provide services to the Company in an advisory role after the effective date of her resignation.

Nasdaq Compliance

On June 28, 2024, we received a notification letter from the Listing Qualifications Department of the Nasdaq notifying us that, because the closing bid price for our common stock was below $1.00 per share for 33 consecutive business days, we are not currently in compliance with the Minimum Bid Price Requirement. The notification had no immediate effect on the listing of our common stock on the Nasdaq Capital Market.

In accordance with Nasdaq Marketplace Rule 5810(c)(3)(A), we had a period of 180 calendar days from June 27, 2024, or until December 26, 2024, to regain compliance with the Minimum Bid Price Requirement. We did not regain compliance during the compliance period ending on December 26, 2024. As a result, on December 27, 2024, Nasdaq provided notice that our common stock may be subject to delisting unless we filed an appeal on or before January 3, 2025. We then appealed that determination to a Nasdaq hearings panel. The appeal with the Nasdaq hearings panel was conducted on February 18, 2025. On March 6, 2025, we received a letter from the Nasdaq hearings panel granting our request for continued listing on the Nasdaq Capital Market provided that we implemented the reverse stock split on March 7, 2025 and demonstrated compliance with all such continued listing requirements for the Nasdaq Capital Market as of March 20, 2025.

The contemplated reverse split was subsequently completed in the ratio of 1-for-17 and went effective on March 7, 2025. As of March 21, 2025, we believe that we have regained compliance; however, we have not yet received confirmation from Nasdaq and no assurances can be provided.

Amended and Restated 2021 Equity Incentive Plan

On August 9, 2024, we adopted the Amended and Restated 2021 Equity Incentive Plan (the "A&R 2021 Plan"), which amends and restates our 2021 Equity Incentive Plan in full to, amongst other things, increase the number of shares of common stock authorized for issuance thereunder from 5,434 shares to 58,823 shares. Our Board of Directors ("Board") unanimously approved the adoption of the A&R 2021 Plan, subject to stockholder approval, on June 15, 2024, and our stockholders approved the A&R 2021 Plan at our 2024 Annual Meeting of Stockholders held on August 9, 2024.

Reverse Stock Split - 2025

Effective March 7, 2025, our Board approved a reverse stock split of our issued and outstanding shares of common stock, par value $0.0001 per share, at a ratio of 1-for-17. As a result of the reverse stock split, the total number of shares of common stock held by each stockholder of the Company were converted automatically into the number of shares of common stock equal to the number of issued and outstanding shares of common stock held by each such stockholder immediately prior to the reverse stock split divided by 17. We issued one whole share of the post reverse stock split common stock to any stockholder who otherwise would have been entitled to receive a fractional share as a result of the reverse stock split. As a result, no fractional shares were issued in connection with the reverse stock split and no cash or other consideration was paid in connection with any fractional shares that would otherwise have resulted from the reverse stock split. Also, all options, warrants and other convertible securities of the Company outstanding immediately prior to the reverse stock split were adjusted by dividing the number of shares of common stock into which such options, warrants and other convertible securities were exercisable or convertible by 17 and multiplying the exercise or conversion price thereof by 17, all in accordance with the terms of the plans, agreements or arrangements governing such options, warrants and other convertible securities and subject to rounding pursuant to such terms. There was no change to the par value, or authorized shares, of either the common stock or preferred stock, as a result of the reverse stock split.

All share and per share amounts for our common stock, as well as the number of shares of common stock issuable upon conversion of outstanding preferred stock and upon exercise of options and warrants outstanding, and exercise prices thereof, from dates prior to completion of the reverse stock split that are included in this Report, including the financial statements and footnotes thereto included herein, have been retroactively restated to give effect to the reverse stock split.

Reverse Stock Split - 2023

Effective August 23, 2023, the Company implemented a reverse stock split of the Company's issued and outstanding shares of common stock at a ratio of 1-for-100. As a result of the reverse stock split, the total number of shares of Common Stock held by each stockholder of the Company were converted automatically into the number of shares of Common Stock equal to the number of issued and outstanding shares of Common Stock held by each such stockholder immediately prior to completion of the reverse stock split divided by 100. The Company issued one whole share of the post reverse stock split common stock to any stockholder who otherwise would have been entitled to receive a fractional share as a result of the reverse stock split. As a result, no fractional shares were issued in connection with the reverse stock split and no cash or other consideration was paid in connection with any fractional shares that would otherwise have resulted from the reverse stock split. Also, all options, warrants and other convertible securities of the Company outstanding immediately prior to the reverse stock split were adjusted by dividing the number of shares of common stock into which such options, warrants and other convertible securities were exercisable or convertible by 100 and multiplied the exercise or conversion price thereof by 100, all in accordance with the terms of the plans, agreements or arrangements governing such options, warrants and other convertible securities and subject to rounding pursuant to such terms. There was no change to the par value, or authorized shares, of either the common stock or preferred stock, as a result of the reverse stock split.

All share and per share amounts for our common stock, as well as the number of shares of common stock issuable upon exercise of the options and warrants outstanding and exercise prices thereof, from dates prior to completion of the reverse stock split that are included in this Report, including the financial statements and footnotes thereto included herein, have been retroactively restated to give effect to the reverse stock split.

2024 Capital Raises

On May 13, 2024, the Company sold 277,059 shares of its common stock, together with Series A warrants (the "Series A Warrants") to purchase an aggregate of up to 277,059 shares of common stock and Series B warrants (the "Series B Warrants," and collectively with the Series A Warrants, the "Common Warrants") to purchase up to an aggregate of 415,589 shares of common stock, to certain investors in a registered public offering. Each share of common stock was sold together with one Series A Warrant and one and a half Series B Warrants at a combined price of $14.45 per share and Common Warrants, resulting in gross proceeds to the Company of approximately $4 million. Net proceeds to the Company, after deducting placement agent fees and offering expenses paid by us, was approximately $3.3 million. The net proceeds were allocated between the common stock and Common Warrants issued in the offering based on the relative fair values, which were $1.4 million and $1.9 million, respectively. Each of the Common Warrants are exercisable immediately upon issuance and have an exercise price of $14.45 per share, subject to certain adjustments. The Series A Warrants will expire one year from the date of issuance and the Series B Warrants will expire five years from the date of issuance. As compensation for services rendered by the placement agent, we paid the placement agent a cash fee of 7.0% of the gross proceeds of the offering (amounting to approximately $280 thousand) at closing, as well as $100 thousand for the reimbursement of certain expenses. Additionally, as partial consideration for services rendered in connection with the offering, we issued the placement agent registered warrants to purchase an aggregate of 11,083 shares of common stock, equal to 4.0% of the aggregate shares of common stock sold in the offering. The placement agent warrants have an initial exercise price of $15.90 per share (equal to 110% of the combined offering price per share and Common Warrants), have a term of five years from the commencement of sales in the offering, and are exercisable commencing six months from closing.

On September 13, 2024, we entered into the Distribution Agreement with Maxim, pursuant to which we may offer and sell, from time to time, through or to Maxim, as sales agent or principal, shares of our common stock. We will pay Maxim a commission of 3% of the aggregate gross proceeds from each sale of shares. We also agreed to reimburse Maxim for certain specified fees and expenses of up to $40 thousand, plus an additional $5 thousand for each bringdown, as provided in the Distribution Agreement. The agreement will terminate upon the earlier of (i) the sale of all shares of common stock having an aggregate offering price of $10 million; (ii) twenty four months from the date of the agreement; (iii) the mutual termination of the agreement upon fifteen days' prior written notice; and (iv) as otherwise permitted therein. During the year ended December 31, 2024,we sold a total of 193,161 shares of its common stock pursuant to the Distribution Agreement for gross proceeds of $1.2 million. We paid Maxim $37 thousand in commissions. Net proceeds to the Company, after deducting commissions and offering expenses paid by us, was approximately $1.1 million.

Equity Line of Credit

On March 18, 2025, we entered into an Equity Purchase Agreement (the "Purchase Agreement") with Mast Hill Fund, L.P. ("Mast Hill"), pursuant to which we will have the right, but not the obligation, to sell to Mast Hill, and Mast Hill will have the obligation to purchase from us, up to $25 million (the "Maximum Commitment Amount") shares of our common stock (the "Put Shares"), at our sole discretion, over the next 24 months, subject to certain conditions precedent and other limitations.

Unless earlier terminated, the Purchase Agreement will remain in effect until the earlier of March 18, 2027 or the date on which Mast Hill has purchased the Maximum Commitment Amount (the "Commitment Period"). We have the right to terminate the Purchase Agreement at any time, subject to limitations set forth in the Purchase Agreement.

During the Commitment Period, we will have the right, but not the obligation, to direct Mast Hill to make a purchase of the Put Shares by delivering written notice to Mast Hill (a "Put Notice") on any trading day (the "Put Date") to purchase a number of Put Shares pursuant to a formula set forth in the Purchase Agreement. The purchase price for the Put Shares under the Purchase Agreement will be equal to 95% of the lowest VWAP (as defined in the Purchase Agreement) of our common stock on the Principal Market (as defined in the Purchase Agreement) on any trading day during the pricing period, and the pricing period for each sale of Put Shares will be the 5 trading days immediately after receipt of the Put Shares by Mast Hill, subject to adjustment as provided in the Purchase Agreement.

Each Put Notice shall direct Mast Hill to purchase Put Shares (i) in a minimum amount not less than $50 thousand and (ii) in a maximum amount up to $500 thousand, provide further that the number of Put Shares in each respective Put shall not exceed 100% of the average trading volume of our common stock during the 5 trading days immediately

preceding the date of the Put Notice. Mast Hill's obligation to purchase Put Shares is subject to a 4.99% beneficial ownership blocker. Additionally, pursuant to the Purchase Agreement,we may not sell or issue to Mast Hill more than 19.99% of the number of shares of our common stock issued and outstanding immediately prior to execution of the Purchase Agreement unless and until we obtain stockholder approval to issue additional shares, in accordance with applicable Nasdaq rules.

As consideration for Mast Hill's commitment to purchase shares of our common stock under the Purchase Agreement, we issued Mast Hill 29,800 restricted shares of common stock following the execution of the Purchase Agreement (the "Commitment Shares").

Craft Capital Management LLC acted as our placement agent in connection with this transaction. As compensation for such services, we will pay Maxim a commission of 3.0% of the aggregate gross proceeds from each sale of Put Shares under the Purchase Agreement.

In connection with the Purchase Agreement, the Company and Mast Hill also entered into a registration rights agreement (the "Registration Rights Agreement"), pursuant to which we agreed to, within 45 calendar days from the date of the Registration Rights Agreement, file with the Commission an initial registration statement covering (i) all of the Put Shares issuable under the Purchase Agreement the Commitment Shares (collectively, the "Registrable Securities") so as to permit the resale of such securities by Mast Hill. The Company shall use reasonable best efforts to have the registration statement declared effective by the SEC within 90 calendar days from the date of the Registration Rights Agreement. Pursuant to the Registration Rights Agreement, we shall keep the registration statement effective, including but not limited to pursuant to Rule 415 promulgated under the Securities Act and available for the resale by Mast Hill of all of the Registrable Securities covered thereby at all times until the date on which Mast Hill shall have sold all the Registrable Securities and the Maximum Commitment Amount has been drawn down by the Company.

The Purchase Agreement and Registration Rights Agreement contain customary representations, warranties and agreements, as well as customary conditions to Mast Hill's obligation to purchase the Put Shares.

Exclusive License Agreement – Statera BioPharma

On February 11, 2025, we entered into the License Agreement with Statera, whereby we acquired (i) an exclusive worldwide license to the proprietary TLR5 agonist program of Statera known as Entolimod (the "Licensed Molecules") as it relates to the ARS indication (the "Initial Indication") and (ii) an exclusive option (the "Exclusive Option") to acquire the exclusive worldwide license to additional indications, including Lymphocyte Exhaustion, Immunosenescence, Neutropenia and/or Vaccine Adjuvant (the "Subsequent Indications") and to the TLR5 agonist program of Statera known as Entolasta, in each case as described in more detail below. The License Agreement transaction was consummated concurrently therewith on February 11, 2025 (the "Closing Date").

Under the terms of the License Agreement, Statera has granted the Company an exclusive worldwide license, with the right to grant and authorize sublicenses, under Statera's patents and know-how to develop, test, make and use Entolimod to develop, test, make, have made, use, sell, offer for sale, import and otherwise exploit the product as it relates to the Initial Indication during the term of the License Agreement.

As consideration for the License Agreement, we agreed to pay Statera a license fee of $1,500,000 consisting of (i) $300,000 in cash consideration and (ii) $1,200,000 in stock consideration, as described below. The Company remains liable to Statera for certain royalty payments on net sales for ARS as monotherapy, and, if it exercises the Exclusive Option, net sales for all Subsequent Indications, within certain royalty periods.

The License Agreement further provides us with the Exclusive Option to expand the Initial Indications to include the treatment of the Subsequent Indications or to expand the use from a monotherapy to include uses as Vaccine Adjuvant, or several or all of them, at any time during the term of the License Agreement, and on one or more occasions, at its discretion. As part of exercise of the Exclusive Option, the license grant would be expanded to include uses of Entolasta, in addition to Entolimod, both for ARS and for the Subsequent Indications.

In conjunction with the License Agreement, Statera additionally transferred to the Company the title to fifteen kilograms (15kg) of frozen manufactured Entolimod lots and associated quality records associated with their production and applicable verification records (the "Materials"). In connection with this acquisition of ownership of the Materials, we will be negotiating a $1 per year lease with an affiliate of Statera for the proper care, storage and handling of the Materials.

The License Agreement also includes a buyout provision (the "Buyout") by which we maintain the right to acquire from Statera at any time all right, title and interest in and to all technology licensed or otherwise subject to the Exclusive Option under the License Agreement. Should we elect to invoke this buyout right, it must provide Statera with a buyout payment equal to (a) the lesser of (i) the aggregate amount of payments due to Statera for achievement of all milestone events (described below), less the amount of payments paid for the achievement of one or more of such milestone events, and (ii) an amount negotiated in good faith and mutually agreed by the parties in writing as representing the risk adjusted net present value of the aggregate royalties that would have been payable absent such exercise; less (b) the amount of payments paid or payable by the Company to extinguish an existing lien on the licensed technology.

The License Agreement obligates us to develop and commercialize the licensed products, at our own cost and expense, inclusive of licensed products with respect to any Subsequent Indications obtained upon exercise of an Exclusive Option. In the development and commercialization process, we are obligated to meet certain milestones, and must provide Statera with certain milestone payments, payable in either the form of cash or Company stock (at our sole discretion), upon accomplishing each milestone as outlined below.

Event	**Payment**
Validation of current inventory of Materials for distribution and sales	$750,000
Filing of BLA with FDA for Acute Radiation Syndrome	$1,000,000
Total Acute Radiation Syndrome Development Milestones	$1,750,000

Upon exercise of an Exclusive Option with respect to one or more Subsequent Indications, the following corresponding applicable milestones and milestone payments, payable in in either the cash or Company stock (at our sole discretion), become obligations of the Company as well:

Event	**Payment**
File IND and Initiate Phase 2 Clinical Study for Neutropenia	$500,000
Phase III Completion - successfully meets endpoint required to secure FDA approval for treatment of Neutropenia	$750,000
File BLA with FDA and achieve FDA Approval for Neutropenia	$1,500,000
File IND and Initiate Phase 2 study of Lymphocyte Exhaustion	$500,000
Phase III Completion - successfully meets endpoint required by FDA for treatment of Lymphocyte Exhaustion	$750,000
File BLA with FDA and achieve FDA Approval for Lymphocyte Exhaustion	$1,500,000
IND approval and initiation of Phase 3 study as a Vaccine Adjuvant	$500,000
File US BLA with FDA and achieve FDA Approval for use as a Vaccine Adjuvant	$500,000
Total Potential Development Milestones for additional Indications (as applicable)	$6,500,000

In conjunction with the License Agreement, Statera may nominate one individual to sit on Board. Statera's nominee must have the relevant industry experience in biopharmaceuticals, meet all requirements for service as an Independent Board Member, as defined by Nasdaq listing requirements. Approval of such Statera nominee shall be at the sole reasonable discretion of the Board.

Pursuant to the License Agreement, we have agreed to hold a stockholders' meeting within 120 days of the Closing Date to submit the approval of the conversion of shares of Series A Preferred Stock into shares of Company common stock in accordance with the rules of the Nasdaq Stock Market LLC (the "Conversion Proposal") to its stockholders for their consideration. In connection therewith, we have agreed to file a proxy statement on Schedule 14A with the SEC. If the requisite stockholder approval is not obtained within the time period referenced above, then we shall convene additional stockholder meetings every 90 days thereafter until the requisite stockholder approval is obtained.

Securities Purchase Agreement

On February 11, 2025, the Company entered into a Securities Purchase Agreement (the "Securities Purchase Agreement") with Statera. Pursuant to the Securities Purchase Agreement, the Company agreed to issue and sell to Statera an aggregate of (i) 55,635 shares of Company common stock and (ii) 359.6691 shares of Series A Preferred Stock (collectively, the "Securities") for an aggregate price of approximately $1.2 million. Each share of Series A Preferred Stock is convertible into approximately 588 shares of common stock, as described below. The powers, preferences, rights, qualifications, limitations and restrictions applicable to the Series A Preferred Stock are set forth in the Certificate of Designation (as defined and described below).

The Securities Purchase Agreement also provides Statera with registration rights related to the Securities. Specifically, the Company is required to prepare and file a resale registration statement with the Commission within 60 calendar days following the Closing Date (the "Filing Deadline"), with respect to the common stock and the shares of common stock underlying the Series A Preferred Stock.

The closing of the issuance of Securities occurred concurrently with the Closing Date of the License Agreement on February 11, 2025.

Operational Updates

Fiscal 2024

In 2024, we invested in our product, innovation and development as follows:

- We restructured our supply chain for ClearUP, incurring one-time expenses that subsequently served to reduce cost of sales and improve gross margin. Additionally, we identified obsolete and excess inventory holdings accumulated during supply chain shortages. These resulted in adjustments in the form of write-offs and reserves that negatively impacted reporting of gross profit.
- We invested in new web infrastructure for our e-commerce commercial site, which was subsequently deployed in Q1 2025.
- We completed our first external clinical validation work on a novel, non-invasive approach to cervical Vagus Nerve Stimulation (ncVNS). The study was conducted with the Feinstein, one of the world leaders in the fields of VNS and bioelectronic medicine. In May, the parties reported that Tivic's ncVNS demonstrated meaningful impact on clinical biomarkers pertinent to neurologic, cardiac, and autonomic diseases.
- In May, we initiated an additional study on our ncVNS, again with the Feinstein. This second study focused on identify the parameters used during stimulation that provide the strongest optimization of the autonomic nervous system response. Enrollment in the study was completed in November 2024. Preliminary results were reported in March 2025 in conjunction with a presentation at the Sixth Bioelectronic Medicine Forum and full results are anticipated to be reported in Q2 2025.
- We continued to invest in development and expansion of our intellectual property portfolio. During the year, we were granted three new patents in the U.S. and Europe for ClearUP. We also advanced the prosecution of new patent filings related to our ncVNS program, including new filings and validation of European patents in Great Britain, Germany, and France.
- In September, we began a partnership with FSI to support development of our commercial strategy for VNS. The two-phase study has provided us with broad competitive market context to assist in selection

of target indications and clinical populations for the next phase of work. We expect to enter disease-specific trials with strong market opportunity in late 2025.

- Throughout the year, we evaluated opportunities for inorganic growth through in-licensing, acquisition, or other forms of business combinations that could strengthen our near-term revenue potential. As a result, we entered into a licensing agreement with Statera in early 2025 for a Phase III immunotherapy product.

We have continued to intentionally maintain a small core team at this stage of the Company, including decreasing our headcount to reduce operating expenses. We have relied, and continue to rely, heavily on third-party service providers, including marketing agencies, contract manufacturing organizations, software-as-a-service platforms, clinical research organizations, academic research partnerships, finance and accounting support, and legal support to carry out our operations.

Components of Results of Operations

Revenue

Revenue is currently generated solely by the sale of our ClearUP and ancillary products, including accessories and accelerated shipping charges, and is net of return reserves. We currently sell ClearUP directly to consumers online through our own website and to resellers such as McKesson-affiliate Simply Medical, Cardinal Health and AmerisourceBergen. Through our online retailers, ClearUP is available through Amazon, McKesson, Optum Store, Walmart, Target, Best Buy, Cardinal Health and FSA/HSA Store.

Cost of Sales

Cost of sales consists primarily of the materials and services to manufacture our products, the internal personnel costs to oversee manufacturing and supply chain functions, and the shipment of goods to customers. A significant portion of our cost of sales is currently in fixed and semi-fixed expenses associated with the management of manufacturing and supply chain. Cost of sales is expected to increase on an absolute basis as sales volume increases. Cost of sales is expected to decrease as a proportion of revenue with (i) the continued optimization of our supply chain, and (ii) the allocation of fixed and semi-fixed expenses over increasing unit sales volume over time. Cost of sales also includes inventory adjustments and reserves which may be necessary due to excess or obsolete inventory. Cost of sales is expected to fluctuate as adjustments or additional reserves become necessary.

Gross Margin

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

Operating Expenses

Research and Development Expenses

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

Sales and Marketing Expenses

Sales and marketing expenses include personnel costs and expenses for advertising and other marketing services. Personnel costs consist of salaries, bonuses, benefits and stock-based compensation expense.

General and Administrative Expenses

General and administrative expenses include D&O insurance, personnel costs, expenses for outside professional services and other expenses. Personnel costs consist of salaries, bonuses, benefits and stock-based compensation expense. Outside professional services consist of legal, finance, accounting and audit services, and other consulting fees. We expect general and administrative expenses to remain relatively flat.

Other Income

Other income includes interest income from our money market savings account.

Results of Operations

Comparison of the Years Ended December 31, 2024 and 2023

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

	Year Ended December 31,		
Statement of operations data:	**2024**	**2023**	**Change**
Revenue	$ 780	$ 1,176	$ (396)
Cost of sales	778	889	(111)
Gross profit	2	287	(285)
Operating expenses:			
Research and development	1,313	1,655	(342)
Sales and marketing	1,187	2,125	(938)
General and administrative	3,163	4,752	(1,589)
Total operating expenses	5,663	8,532	(2,869)
Loss from operations	(5,661)	(8,245)	2,584
Other income:			
Interest income	6	1	5
Total other income	6	1	5
Net loss	$ (5,655)	$ (8,244)	$ 2,589

Revenue

Revenue (net of returns) decreased $396 thousand, or -34%, to $0.8 million for the year ended December 31, 2024 from $1.2 million for the year ended December 31, 2023, which decrease was primarily attributable to decreased unit sales of -41%. Unit sales were approximately 4,400 for the year ended December 31, 2024 and were approximately 7,400 for the year ended December 31, 2023. Ancillary revenues were less than 1.8% of total revenue for both of the years ended December 31, 2024 and 2023.

	Year Ended December 31,		
Statement of operations data (in thousands):	**2024**	**2023**	**Change**
Product Revenue			
Direct-to-consumer	$ 656	$ 1,079	$ (423)
Reseller	206	261	(55)
Returns	(82)	(164)	82
Revenue	$ 780	$ 1,176	$ (396)

Direct-to-consumer product revenue decreased $423 thousand, or -39%, to $0.7 million for the year ended December 31, 2024 from $1.1 million for the year ended December 31, 2023, which was due to decreased unit sales of -43%. Direct-to-consumer unit sales were approximately 3,100 for the year ended December 31, 2024 compared to approximately 5,400 for the year ended December 31, 2023. The decrease in unit sales was primarily due to the reduction of marketing spend.

Reseller channel product revenue decreased $55 thousand, or -21%, to $206 thousand for the year ended December 31, 2024 from $261 thousand for the year ended December 31, 2023, attributable to decreased unit sales of -35%. Reseller channel unit sales were approximately 1,300 for the year ended December 31, 2024 and were approximately 2,000 for the year ended December 31, 2023. Average reseller channel selling prices increased 23% in 2024 compared to 2023. The decrease in unit sales was primarily attributed to a reduction in marketing spend. The increase in average selling price was primarily due to the introduction of a more profitable reseller channel in 2024.

Returns as a percentage of product revenue was approximately 9.5% for the year ended December 31, 2024 and 12% for the year ended December 31, 2023.

Cost of Sales

Cost of sales for the year ended December 31, 2024 was $0.8 million, compared to $0.9 million for the year ended December 31, 2023, a decrease of $111 thousand, or -12%. The decrease was primarily attributable to the -41% decrease in overall unit sales. During 2024, we recorded inventory reserves of $354 thousand compared to $32 thousand in 2023. The inventory reserves are related to excess raw materials inventory on hand at year-end. In 2024, we also incurred $21 thousand of disposal costs associated with our move to a new logistics provider in August 2024. We expect reduced product support and fulfillment charges in the future with the new provider.

Variable cost of goods sold includes product costs, fulfillment, shipping and purchase price variances and other inventory adjustments. Variable cost of goods sold was $0.7 million, or $156.83 per unit, for the year ended December 31, 2024, as compared to $0.6 million, or $86.61 per unit, for the year ended December 31, 2023. The increase in variable costs of goods sold was primarily due to the inventory reserves and disposal costs recorded in 2024. Excluding inventory reserves recorded in 2024 and 2023, the per unit variable costs of goods sold was $79.77 and $82.29, respectively. The reduction in variable costs, exclusive of the inventory reserves, was associated with the change in the logistics provider in August 2024. We expect reduced variable costs going forward.

Fixed cost of goods sold includes third-party product support and logistic fees and allocated overhead costs. Fixed cost of goods sold decreased to $91 thousand for the year ended December 31, 2024, as compared to $248 thousand for the year ended December 31, 2023, primarily due to decreased product support costs in 2024 due to the move to a new logistics provider. Additionally, allocated overhead costs were lower in 2024, as internal staffing costs related to supply chain were reduced.

Gross profit for the year ended December 31, 2024 was $2 thousand compared to a gross profit of $287 thousand for the year ended December 31, 2023. The reduction in gross profit for 2024 was primarily due to $354 thousand of inventory reserves recorded for the year ended December 31, 2024, compared to $32 thousand for the year ended December 31, 2023.

Research and Development Expenses

Research and development expenses decreased by $342 thousand to $1.3 million for the year ended December 31, 2024 from $1.7 million for the year ended December 31, 2023. The decrease was primarily due to reduced compensation costs related to decreased headcount and certain expenses in 2023 which did not recur in 2024. The emphasis of research and development activities in 2024 was primarily related to our work with Feinstein on vagus nerve stimulation and intellectual property protection.

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

Sales and Marketing Expenses

Sales and marketing expenses decreased to $1.2 million for the year ended December 31, 2024, compared to $2.1 million for the year ended December 31, 2023. The decreases were due to reductions in advertising spend of $332 thousand, reduced headcount and consulting fees of $271 thousand, and reductions in agency, website, public relations and other costs.

General and Administrative Expenses

General and administrative expenses decreased to $3.2 million for the year ended December 31, 2024, compared to $4.8 million for the year ended December 31, 2023, primarily due to reduced headcount, resulting in savings of approximately $730 thousand, reduced lease expenses of $117 thousand, lower consulting and professional fee expenses of $262 thousand, reduced insurance costs of $291 thousand, and a reduction of Delaware franchise taxes of $175 thousand.

Other Income

Other income was immaterial for the years ended December 31, 2024 and 2023, and consists of interest income from money market accounts.

Liquidity and Capital Resources

Sources of Liquidity

Since our formation in September 2016, we have devoted substantially all of our efforts to research and development, to regulatory clearance and to early market development and testing for our first product, released September 2019 in the United States, and product candidates deriving from such product. We are not profitable and have incurred net losses and negative cash flows from our operations in each year since our inception. During the years ended December 31, 2024 and 2023, we generated revenue of $0.8 million and $1.2 million, respectively. Additionally, during the years ended December 31, 2024 and 2023, we incurred net losses of $5.7 million and $8.2 million, respectively, and used $5.7 million and $8.5 million of cash for operations, respectively. As of December 31, 2024, we had cash and cash equivalents of $2.0 million, working capital of $2.4 million and an accumulated deficit of $43.5 million.

We have financed our operations to date primarily through issuances of SAFE instruments, convertible notes and convertible preferred stock and the proceeds from registered offerings of our securities. In 2021, we completed our IPO, generating net proceeds to the Company of approximately $14.9 million, and we borrowed $2.6 million by issuing convertible notes payable, the outstanding balance of all of which converted into shares of our common stock in connection with our IPO. On February 13, 2023, we completed the sale of 11,765 shares of our common stock in a firm commitment, fully underwritten registered public offering, resulting in net proceeds to the Company of approximately $3.6 million. From July 11, 2023 to August 9, 2023, we sold an aggregate of 68,779 shares of our common stock to certain investors in a series of registered public offerings, resulting in aggregate net proceeds to the Company of approximately $4.3 million. Additionally, in May 2024, we sold an aggregate of 277,059 shares of our common stock, together with Series A warrants to purchase an aggregate of 277,059 shares of common stock and Series B warrants to purchase an aggregate of 415,589 shares of common stock, to certain investors in a registered public offering, resulting in net proceeds to the company of approximately $3.3 million.

On September 13, 2024, we entered into the Distribution Agreement with Maxim, pursuant to which we may offer and sell, from time to time, through or to Maxim, as sales agent or principal, up to $10 million in shares of our common stock, subject to our then current "baby shelf" limitation under General Instruction I.B.6. of Form S-3. To date, we have sold an aggregate of 193,161 shares of common stock pursuant to the Distribution Agreement, for gross proceeds of $1.2 million. We paid Maxim $37 thousand in commissions in connection with such sales.

On March 18, 2025, we entered into the Purchase Agreement, pursuant to which we will have the right, but not the obligation, to sell to Mast Hill up to $25 million in shares of our common stock from time to time over a two-year period, subject to certain conditions precedent and other limitations. As a condition to our ability to effect sales under the Purchase Agreement, the shares must be registered for resale by Mast Hill pursuant to an effective registration statement. Additionally, until such time that we have obtained stockholder approval to sell and issue shares of our common stock under the Purchase Agreement, in accordance with Nasdaq rules, the number of shares we may sell under the Purchase Agreement (including the Commitment Shares we issued to Mast Hill) may not exceed 19.99% of the number of shares of our common stock issued and outstanding immediately prior to execution of the Purchase Agreement.

Although we have taken measures to decrease our operating expenses, we expect that our operating expenses may increase significantly as we discover, acquire, validate and develop additional product candidates; seek regulatory

approval and, if approved, proceed to commercialization of new products; obtain, maintain, protect and enforce our intellectual property portfolio; and hire additional personnel. Furthermore, we have incurred and will continue to incur additional costs associated with operating as a public company that we did not experience as a private company. Management expects to incur substantial additional operating losses for the foreseeable future to expand our markets, complete development or acquisition of new product lines, obtain regulatory approvals, launch and commercialize our products and continue research and development programs. Based on the Company's current cash levels and burn rate, amongst other things, the Company believes its cash and financial resources may be insufficient to meet the Company's anticipated needs for the twelve months following the date of issuance of the financial statements for the year ended December 31, 2024, included elsewhere in this Report, which raises substantial doubt about the Company's ability to continue as a going concern within one year from the issuance date of the financial statements.

Plan of Operation and Future Funding Requirements

We have used our capital resources primarily, to date, to fund marketing and advertising for ClearUP, development of both our trigeminal and our vagus nerve platforms and product candidates, evaluating and conducting diligence on potential licensing and acquisition candidates, and the establishment of public company operating infrastructure and general operations. Although we have taken measures to decrease our operating expenses, we expect that our operating expenses may increase as we advance our vagus nerve platform, as well as discover, acquire, validate or develop additional product candidates; seek regulatory approval and, if approved, proceed to commercialization of new products; obtain, maintain, protect and enforce our intellectual property portfolio; hire additional personnel; and maintain compliance with material government (in addition to environmental) regulations. We plan to increase our research and development investments in our vagus nerve platform and clinical applications thereof in 2025. We also plan to advance the development of our licensed TLR5 agonist programs, known as Entolimod and Entolasta. Furthermore, we have incurred, and will continue to incur, costs associated with operating as a public company that we did not experience as a private company. We expect to continue to incur losses for the foreseeable future. At this time, due to the inherently unpredictable nature of research and new product adoption as well as other macroeconomic factors, we cannot reasonably estimate the costs we will incur and the timelines that will be required to complete development, obtain marketing approval and commercialize future product candidates, if at all. For the same reasons, we are also unable to predict how quickly we will generate significant revenue from ClearUP product sales or whether, or when, if ever, we may achieve profitability from the sales of one or more products. Clinical and preclinical development timelines, the probability of success, and costs can differ materially from expectations. In addition, we cannot forecast which product candidates may be best developed and/or monetized through future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

As previously disclosed, we encountered disruptions in our supply of various materials and components in 2022 due to the well-documented shortages and constraints in the global supply chain. Although we currently do not anticipate a supply shortage, unforeseen shortages may continue to pose a material risk for the Company in the near term or future. Additionally, high levels of safety stock can (and did in Q4 2024) result in the Company holding significant reserves against future obsolescence. We regularly evaluate alternative and secondary source suppliers in order to ensure that we are able to source sufficient components and materials to manufacture our products. Global supply chain shortages (especially when coupled with the increase in tariffs, inflation and other economic factors) could result in an increase in the cost of the components used in our products, which could result in a decrease of our gross margins or in us having to increase the price at which we sell our products until supply chain constraints are resolved. Additionally, in the event that we are unable to source sufficient components and materials from our current suppliers, or to develop relationships with additional suppliers, to manufacture enough of our products to satisfy demand, we may have to cease or slow down production and our business operations and financial condition may be materially harmed and we may need to alter our plan of operation.

In addition to the foregoing, we may, from time to time, consider opportunities for strategic acquisitions, licensing or business combinations that we believe will align with our growth plan, complement our product offerings and be in the best interest of the Company and our shareholders. If any such strategic transactions are identified and pursued, a substantial portion of our cash reserves may be required to complete such transactions. If we identify an attractive opportunity that would require more cash to complete than we are willing or able to use from our cash reserves, we will consider financing options to complete the acquisition, including through equity and/or debt financings.

We have generated operating losses in each period since inception. We have incurred an accumulated deficit of $43.5 million through December 31, 2024. We expect to incur additional losses in the future as we expand both our research and development activities. Based on our current cash levels and burn rate, amongst other things, we believe our cash and financial resources may be insufficient to meet our anticipated needs for the next twelve months. As a result, we expect that we will need to raise additional capital to continue operating our business and fund our planned operations, including research and development, clinical trials and, if regulatory approval is obtained, commercialization of future product candidates.

We currently sell ClearUP directly to consumers online through our own website and to resellers such as McKesson-affiliate Simply Medical, Cardinal Health and AmerisourceBergen. Through our online retailers, ClearUP is available through Amazon, McKesson, Optum Store, Walmart, Target, Best Buy, Cardinal Health and FSA/HSA Store. 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 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, foundation or government funding sources, or through other sources of financing. We do not know whether additional financing will be available on commercially acceptable terms, or at all, when needed. If adequate funds are not available or are not available on commercially acceptable terms, our ability to fund our operations, support the growth of our business or otherwise respond to competitive pressures could be significantly delayed or limited, which could materially adversely affect our business, financial conditions or results of operations, and we may have to significantly delay, scale back or discontinue the development and commercialization of our products and/or future product candidates.

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

- our ability to raise additional capital if and when necessary and on terms favorable to the Company;
- the timing and progress of sales initiatives driving top-line revenue;
- the availability of electronic parts, other components and materials for our products and product candidates, as well as our ability to source such parts, components and materials at favorable prices;
- the timing and adoption rate of ClearUP line extensions at lower cost of goods;
- the payment terms and timing of commercial contracts entered into for manufacturing and sales of our products to and through online third-party retailers;
- the timing and progress of preclinical and clinical development activities;
- the number and scope of preclinical and clinical programs we decide to pursue;
- the timing and amount of milestone payments we may receive or be required to pay under any future collaboration agreements;
- whether we close potential future strategic opportunities, and if we do, our ability to successfully integrate acquired assets and/or businesses with our own;
- our ability to source new business opportunities through licenses and research and development programs and to establish new collaboration arrangements;
- the costs involved in prosecuting and enforcing patent and other intellectual property claims;
- the cost and timing of additional regulatory approvals beyond those currently held by us;

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

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

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

Cash Flows

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

	Year Ended December 31,	
	2024	**2023**
Cash used in operating activities	$ (5,725)	$ (8,511)
Cash used in investing activities	—	(118)
Cash provided by financing activities	4,332	8,507
Net decrease in cash and cash equivalents	$ (1,393)	$ (122)

Operating Activities

Net cash used in operating activities for the year ended December 31, 2024 was $5.7 million, which consisted primarily of net loss of $5.7 million decreased by non-cash charges of $935 thousand and increased by a net change of $1 million in our net operating assets and liabilities. The non-cash charges primarily consisted of stock-based compensation of $229 thousand, amortization of right-of-use assets of $349 thousand, and reserves for inventory obsolescence of $354 thousand. The change in our net operating assets and liabilities was primarily due to a decrease in accounts payable of $588 thousand, a decrease in lease liabilities of $369 thousand and a decrease in accrued expenses of $348 thousand, offset by decreases in our operating assets.

Net cash used in operating activities for the year ended December 31, 2023 was $8.5 million, which consisted primarily of net loss of $8.2 million decreased by non-cash charges of $485 thousand and increased by a net change of $752 thousand in our net operating assets and liabilities. The non-cash charges primarily consisted of stock-based compensation of $271 thousand and amortization of right-of-use assets of $174 thousand. The change in our net operating assets and liabilities was primarily due to a decrease in accounts payable of $610 thousand, an increase in prepaid and other current assets of $92 thousand, a decrease in lease liabilities of $161 thousand and an increase in accrued expenses of $103 thousand.

Investing Activities

There was no cash used in investing activities for the year ended December 31, 2024. Net cash used in investing activities during the year ended December 31, 2023 was related to the purchases of property and equipment.

Financing Activities

Our financing activities provided $4.3 million of cash during the year ended December 31, 2024, which consisted of $3.2 million of net proceeds from the sale of 277,059 shares of our common stock and common warrants to purchase an aggregate of 692,648 shares of common stock in May 2024, net of offering discounts and other costs plus approximately $1.1 million of net proceeds related to the sale of 193,161 shares of our common stock sold pursuant to the ATM agreement, net of commissions and other offering costs.

Our financing activities provided $8.5 million of cash during the year ended December 31, 2023, which consisted primarily of proceeds from the sale of an aggregate of 80,543 shares of our common stock, net of offering discounts and other costs.

Known Trends or Uncertainties

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

We encountered disruptions in our supply of various materials and components in 2022 due to the well-documented shortages and constraints in the global supply chain. We experienced increased pricing, longer lead-times, unavailability of product and limited supplies, protracted delivery dates, and shortages of certain parts and supplies that were necessary components for our products. As a result, we carried increased inventory balances in 2023 and 2024 to ensure availability of necessary products and to secure pricing. Although we currently do not anticipate a supply shortage will continue to pose a material risk for the Company in the near term, as a matter of business, we evaluate alternative and secondary source suppliers in order to ensure that we are able to source sufficient components and materials to manufacture our products. Global supply chain shortages (especially when coupled with inflation, tariffs, and other economic factors) could result in an increase in the cost of the components and other materials used in our products and product candidates, which could result in a decrease of our gross margins or in us having to increase the price at which we sell our products until supply chain constraints are resolved. Additionally, in the event that the price of our components or other materials increases significantly or we are unable to source sufficient components and materials from our current suppliers, or to develop relationships with additional suppliers, to manufacture enough of our products to satisfy demand, we may have to cease or slow down production and our business operations and financial condition may be materially harmed and we may need to alter our plan of operation.

Recently, the current administration has implemented, and continues to implement, significant budget cuts, eliminated grant programs and terminated a significant number of employees throughout many different sectors of the federal government. There is still significant uncertainty regarding the ultimate effects these actions may have on the industries in which we operate or our business. Disruptions at the FDA and other agencies may slow the time necessary for new devices and drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business.

The United States has recently implemented or threatened to implement tariffs on certain imported goods, including on certain items imported from China, Canada and and other countries. In addition, China, Canada and other countries have imposed, or threatened to impose, tariffs on a wide range of American products and placed restrictions on the export of certain items in retaliation for these American tariffs. As a result, there is a concern that the imposition of additional tariffs by the United States could result in the adoption of additional tariffs or export restrictions by China, Canada and/or other countries. This has recently led to significant volatility in the capital markets and increased economic uncertainty. Additionally, any resulting trade war could negatively impact our business. The imposition of

tariffs on items imported by us from China, Canada or other countries could increase our costs and could result in lowering our gross margin on products sold.

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

Although our business has not been materially impacted by the ongoing military conflict between Russia and Ukraine or the conflict between Hamas and Israel to date, it is impossible to predict the extent to which our operations, including the newly in-licensed TLR5 assets, or those of our suppliers and manufacturers, will be impacted in the short and long term, or the ways in which the conflict may impact our business. The extent and duration of the military action, sanctions and resulting market disruptions are impossible to predict, but could be substantial. We are continuing to monitor the situation in Ukraine and globally and assessing its potential impact on our business.

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

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

Inflation

Inflation increased significantly in 2024; although it has decreased recently, future rates are unknown. 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 the ongoing conflicts between Russia and Ukraine, employee availability and wage increases, trade tariffs imposed on certain products from China and increased component and services pricing.

Off-Balance Sheet Arrangements

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

Contractual Obligations and Commitments

Office Lease

The Company previously entered into a noncancelable operating lease for approximately 9,091 square feet of office space in Hayward, California as its headquarters. The lease was set to expire in October 2025 and there was no option to renew for an additional term. The Company was obligated to pay, on a pro-rata basis, real estate taxes and operating

costs related to the premises. The lease was terminated on May 31, 2024 and the Company has no further obligations with regard to the lease.

On May 30, 2024, we entered into a Co-Working Space Agreement, pursuant to which we rent office space located at 47685 Lakeview Blvd., Fremont, California for a total of $1 thousand per month. The agreement has an initial term of six months, commencing June 1, 2024, after which it will automatically renew on a month to month basis until terminated.

Lease costs recorded during the years ended December 31, 2024 and 2023 were $118 thousand and $222 thousand, respectively.

Purchase Commitments

The Company has entered into multiple contracts related to the development of Tivic's ncVNS technology, including a collaboration and research support agreement and a research study to substantiate clinical indications that have potential to be addressed by Tivic's patent-pending ncVNS system. The contracts require milestone payments to be made upon the successful completion of certain deliverables. As of December 31, 2024, the Company had remaining commitments to pay a total of $171 thousand for milestones not yet achieved. Of the remaining commitment, $86 thousand was paid in March 2025 and the remainder is expected to be incurred in the second quarter of 2025.

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

Critical Accounting Policies and Significant Judgments and Estimates

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

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

Inventory Valuation and Reserves

Inventories are stated at the lower of cost or net realizable value, with cost determined on a first-in, first-out ("FIFO") basis. A reserve for excess or obsolete inventory is estimated based on a review of inventory to identify slow-moving inventory based on anticipated sales activity, as well as alternate uses for such inventory. As of December 31, 2024, the reserve was estimated as $338 thousand.

Revenue Recognition

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

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

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

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

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

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

Stock-Based Compensation

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

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

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

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

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

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

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

- *Fair Value of Common Stock*—Prior to our IPO, the fair value of the shares of common stock underlying the stock-based awards was determined by our Board 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, 2024, the total compensation cost related to nonvested service-based stock option awards not yet recognized is $220 thousand. The weighted-average period over which the nonvested stock option awards is expected to be recognized is 1.13 years. The aggregate intrinsic value of stock options outstanding as of December 31, 2024 was $2 thousand and $8 thousand for vested and unvested options, respectively.

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 with input from management and contemporaneous third-party valuations. We believe that our Board 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 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 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 is 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 may be listed on in the future, on the date of grant or as otherwise provided in our A&R 2021 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 $1.235 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.

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, 2024, included elsewhere in this Report.

Item 7A – Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

Item 8 - Financial Statements and Supplementary Data

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

Item 9 – Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A - Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our Chief Executive Officer and our Interim Chief Financial Officer, after evaluating our "disclosure controls and procedures" (as defined in 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 our Interim Chief Financial Officer, where appropriate, to allow timely decisions regarding required disclosure.

Management Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP. Management assessed our internal control over financial reporting as of December 31, 2024, the end of our fiscal year. Management based its assessment on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Management's assessment included evaluation of elements such as the design and operating effectiveness of key financial reporting controls, process documentation, accounting policies, and our overall control environment.

In connection with this assessment, management determined that there was a material weakness in the Company's internal controls over financial reporting due to the small size of our accounting and financial reporting team. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. Due to the material weakness, management concluded that as of December 31, 2024, the Company's internal control over financial reporting was not effective. Management reviewed the results of management's assessment with the Audit and Risk Committee of our Board.

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

As a result of the enactment of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, and the resulting amendment of Section 404 of the Sarbanes-Oxley Act of 2002, as a smaller reporting company, the Company is not required to provide an attestation report by our independent registered public accounting firm regarding internal control over financial reporting for the fiscal year ended December 31, 2024 or thereafter, until such time as we are no longer eligible for the exemption for smaller issuers set forth within the Sarbanes-Oxley Act.

Inherent Limitations on Effectiveness of Controls

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

Changes in Internal Control over Financial Reporting

There were no material changes in our internal controls over financial reporting during the year ended December 31, 2024, that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's goal is to continue to improve upon our internal control environment as we refine our processes and procedures to address our growing business and operations in other geographies. As we continue to evaluate and take actions to improve our internal control over financial reporting, we may determine to take additional actions to address control deficiencies or determine to modify certain of the remediation measurements that we are anticipating to make, which may include, without limitation, retaining a third party to assist with the implementation of any such remediations. The retention of third-party service providers for purposes of remediation may involve us incurring material costs in the future.

Item 9B - Other Information

Securities Trading Plans of Directors and Executive Officers

During the three months ended December 31, 2024, none of our directors or officers entered into, modified or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," that were intended to satisfy the affirmative defense conditions of Rule 10b5-1, in each case as defined in Item 408 of Regulation S-K.

Item 9C – Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10 – Directors, Executive Officers, and Corporate Governance

Directors

The following table sets forth the names, ages, and positions of our directors as of March 17, 2025. There are no arrangements or understandings between any director and any other person pursuant to which any director was or is to be selected as a director.

Name	Age	Position
Jennifer Ernst	56	Chief Executive Officer and Director
Sheryle Bolton	78	Chair of the Board
Christina Valauri	69	Director
Dean Zikria	57	Director

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

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

Christina Valauri has served as a director on our Board since July 1, 2024, prior to which she served as a strategic advisor to the Company starting in April 2023, and brings over 30-years of experience as a seasoned capital markets professional with extensive analytical and management experience. Ms. Valauri has a proven track record as a senior healthcare analyst, U.S. and Global Head of Equity Research, senior broker-dealer manager, strategic business consultant, and board director and advisor. As a managing director and senior manager within capital markets, she has successfully developed and executed transformational business strategies in the U.S. and internationally to drive growth, and provide enhanced operating performance and comprehensive regulatory and supervisory oversight. She has held leadership roles at U.S. and international firms, including as the Global Director of Research at Cantor Fitzgerald, and senior research management roles at Credit Lyonnais, ING and Natixis. Ms. Valauri's career in equity securities research expands the Boards' deep expertise in pharmaceutical, biotech, and med-tech industries. She has extensive experience identifying and analyzing the commercial potential of breakthrough innovations, as well as mentoring and advising C-suite teams of private and public early-stage healthcare companies through product development, regulatory, go-to-market strategies, potential mergers and acquisitions, and IPOs. Ms. Valauri currently serves as an Entrepreneur in Residence at Weill Cornell Medicine BioVenture eLab, where she applies her skills and experience in life sciences and business. She supports and facilitates the organization's mission to foster an entrepreneurial ecosystem related to the innovations of researchers and clinicians. Ms. Valauri is the founder and CEO of Sagestone Advisory, LLC., and also serves as a senior advisor with Hanover International, Inc. and Astia.org. She has been recognized by The Wall Street Journal's "Best on The Street" All-Star Analyst Survey and has received the Award for Excellence in Medical Education Public.

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

Board Classification

In accordance with the terms of our Certificate of Incorporation, our Board is divided into three staggered classes, and each of our directors is assigned to one of the three classes, Class I, Class II and Class III. Each class of directors is elected for a three-year term, as set forth below. Currently, our directors are divided among the three classes as follows:

- the Class I director is Christina Valauri, and her current term will expire at our 2025 annual meeting of stockholders;
- the Class II director is Dean Zikria, and his current term will expire at our 2026 annual meeting; and
- the Class III directors are Sheryle Bolton and Jennifer Ernst, and their current terms will expire at our 2027 annual meeting of stockholders.

Board Committees

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

Audit and Risk Committee

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

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

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

Compensation Committee

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

- reviewing all overall compensation policies and practices;
- administering the Company's compensation recovery policy;
- approving corporate goals and objectives relevant to executive officer compensation and evaluate executive officer performance in light of those goals and objectives;
- determining and approving executive officer compensation, including base salary and incentive awards;
- reviewing and approving, or making recommendations to the Board regarding, compensation plans;
- administering our equity incentive plan, subject to Board approval; and
- reviewing succession planning for key executives.

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

Nominations and Corporate Governance Committee

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

- recruiting new directors, consider director nominees recommended by stockholders and others and recommend nominees for election as directors;
- reviewing the size and composition of our Board and committees;
- overseeing the evaluation of the Board;
- recommending actions to increase the Board's effectiveness; and
- developing, recommending and overseeing our corporate governance principles, including our Code of Business Conduct and Ethics and our Corporate Governance Guidelines.

Nomination of Directors

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

(1) The appropriate size of the Board;

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

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

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

Other than the foregoing, there are no stated minimum criteria for director nominees, although the Nominations and Corporate Governance Committee may also consider such other factors as it deems to be in the Company's and its stockholders' best interests, including diversity. The Nominations and Corporate Governance Committee does, however, believe it appropriate for at least one member of the Board to meet the criteria for an "audit committee financial expert," as defined by Commission rules, and for a majority of the members of the Board to meet the definition of an "independent director" under Nasdaq listing standards. The Nominations and Corporate Governance Committee also believes it is appropriate for our chief executive officer to serve on our Board.

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

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

Executive Officers

The following table sets forth the names, ages, and positions of our executive officers as of March 17, 2025. There are no arrangements or understandings between any executive officer and any other person pursuant to which any executive officer was selected to serve in such role.

Name	Age	Position
Jennifer Ernst	56	Chief Executive Officer and Director
Lisa Wolf	62	Interim Chief Financial Officer
Blake Gurfein, PhD	41	Chief Scientific Officer
Michael Handley	54	Chief Operating Officer

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

Lisa Wolf currently serves as our Interim Chief Financial Officer, a role she has held since October 1, 2024. Ms. Wolf brings over 30 years of experience in public accounting and private industry, including for both public and private companies spanning multiple industries. Ms. Wolf has played a key role in supporting the Company's accounting and Securities and Exchange Commission reporting functions on an out-sourced basis since June 2022, when she joined Murdock Martell as Vice President. In addition to her role as interim Chief Financial Officer of the Company, Ms. Wolf will continue to serve as Vice President at Murdock Martell. Murdock Martell is a consulting and recruiting firm offering cutting-edge finance, accounting and human relations solutions focused primarily on life science and technology sectors. Prior to joining Murdock Martell, Ms. Wolf spent eight years at Resonant, Inc. (Nasdaq: RESN),

a micro-cap public technology company that was acquired by Murata Electronics North America, Inc. in March 2022, initially serving as Vice President of Finance and then Chief Accounting Officer of Resonant, Inc. Ms. Wolf holds a B.S. in Business Administration from California State University, Northridge and earned her CPA while working at Arthur Andersen.

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

Michael Handley has served as our Chief Operating Officer since February 18, 2025. Mr. Handley also holds the title of President of Tivic Biopharma. Prior to joining the Company, from July 2021 until February 2025, Mr. Handley served as President, Chief Executive Officer and Chairman of Statera. From July 2019 to March 2020, he served as the Chief Executive Officer and a director of Immune Therapeutics. Prior to that, from 2012 to 2018, Mr. Handley served as the Chief Executive Officer and a director of Armis Biopharma, a development-stage healthcare company, where Mr. Handley was responsible for day-to-day operations, executing a profitable growth strategy, obtaining global product approvals, overseeing intellectual property strategy, product commercialization, business development and financing. Mr. Handley founded Vessix Vascular, Inc. in 2011 and served as its Vice President of Clinical, Quality and Regulatory until 2012, when it was acquired. Mr. Handley also served as the Global Head of Regulatory at Acclarent, Inc. from 2010 to 2011 until it was acquired. Prior to that, he served in senior executive roles at Spectranetics (Nasdaq: SPNC), a medical device company, and Accelapure Corporation, a biotechnology company. Prior to beginning his business career, Mr. Handley spent several years in various consulting and drug development roles at the public biotech companies Genentech, Inc. (Nasdaq: DNA), Amgen Inc. (Nasdaq: AMGN) and Gliatech Inc. (formerly Nasdaq: GLIA). Mr. Handley graduated cum laude from Colorado State University with Bachelor of Science degrees in molecular biology, physiology and minors in chemistry, and neurobiology in 1995. Mr. Handley attended The Graziadio Business School of Pepperdine University for his Executive Master of Business Administration degree.

Family Relationships

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

Legal Proceedings

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

Code of Business Conduct and Ethics

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

Compensation Recovery Policy

In November 2023, we adopted a compensation recovery policy (the "Compensation Recovery Policy") that is designed to comply with, and will be interpreted in a manner consistent with, Section 10D and Rule 10D-1 of the Exchange Act and the applicable rules of the Nasdaq Stock Market, including any interpretive guidance provided by Nasdaq. Under our Compensation Recovery Policy, in the event of an accounting restatement due to the Company's material noncompliance with any financial reporting requirement under the securities laws, including any required accounting restatement to correct a material error in previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period, the Company must recover erroneously awarded incentive-based compensation previously paid to the Company's executive officers in accordance with the terms of such Compensation Recovery Policy. Furthermore, under the Compensation Recovery Policy, the Company is prohibited from indemnifying any executive officer or former executive officer against the loss of erroneously awarded incentive-based compensation and from paying or reimbursing an executive officer for purchasing insurance to cover any such loss.

A copy of our Compensation Recovery Policy is attached as Exhibit 97.1 to this Report.

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires the Company's directors and executive officers and persons who beneficially own more than ten percent of a registered class of the Company's equity securities to file with the Commission initial reports of ownership and reports of changes in ownership of Common Stock and other equity securities of the Company. Officers, directors and greater than ten percent beneficial stockholders are required by Commission regulations to furnish us with copies of all Section 16(a) forms they file. To the best of the Company's knowledge based solely on a review of Forms 3, 4, and 5 (and any amendments thereof) received by us during or with respect to the year ended December 31, 2024 and written representations that no other reports were required, each of Kimberly Bambach, Jennifer Ernst and Blake Gurfein inadvertently failed to timely file Form 4 in March 2024; there were no other late Section 16 filings during the year ended December 31, 2024.

Item 11 – Executive Compensation

Overview

This section discusses the material components of the executive compensation program for our named executive officers who are named in the "Summary Compensation Table," below. For the fiscal year ending December 31, 2024, our "named executive officers" and their positions were as follows:

- Jennifer Ernst, our Chief Executive Officer;
- Blake Gurfein, our Chief Scientific Officer; and
- Kimberly Bambach, our former interim Chief Financial Officer.

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

Summary Compensation Table

The following table sets forth, for the fiscal years ended December 31, 2024 and December 31, 2023, the dollar value of all cash and noncash compensation earned by our named executive officers, as set forth above.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)[1]	Option Awards ($)[2]	All Other Compensation ($)[3]	Totals ($)
Jennifer Ernst, CEO and Director	2024	275,000	—	113,000	36,160	42,456	430,456
	2023	275,000	—	—	15,393	38,947	313,947
Blake Gurfein, PhD Chief Scientific Officer	2024	350,000	33,000	50,850	11,300	52,674	486,524
	2023	303,409	40,625	—	12,315	48,672	392,706
Kimberly Bambach Former Interim Chief Financial Officer[4]	2024	—	—	10,050	—	204,275	214,325
	2023	—	—	—	—	197,755	197,755

(1) Amounts shown in the "Stock Awards" column represent the aggregate grant date fair value of restricted stock awards and restricted stock units issued in fiscal 2024. These amounts represent the grant date fair value of stock awards granted in fiscal 2024 computed in accordance with FASB ASC Topic 718. See Note 11 to our financial statements included in Report regarding assumptions underlying the valuation of equity awards. There were no stock awards earned by our named executive officers in 2023.

(2) Amounts shown in the "Option Awards" column represent the aggregate grant date fair value of stock options issued in fiscal 2024 and 2023. These amounts represent the grant date fair value of stock options granted in fiscal 2024 and 2023 computed in accordance with FASB ASC Topic 718. We do not include any impact of estimated forfeitures related to service-based vesting terms in these calculations. See Note 11 to our financial statements included in Report regarding assumptions underlying the valuation of equity awards.

(3) For Jennifer Ernst and Blake Gurfein, employees of the Company, the amount includes the cost of health insurance coverage and benefits paid by the Company that is not reimbursed. For Kimberly Bambach, a former consultant to the Company, the amount includes compensation for services rendered.

(4) Kimberly Bambach provided services as a contractor for the period from April 2023 until September 2024. Ms. Bambach tendered her resignation from her role as Interim Chief Financial Officer of the Company, effective October 1, 2024; she continues to provide services to the Company in an advisory role. Effective October 1, 2024, Lisa Wolf was appointed as the Company's new interim Chief Financial Officer.

Narrative to the summary compensation table

Employment Agreements/Arrangements

As of the year ended December 31, 2024, we had executive offer letters in place with Jennifer Ernst, our Chief Executive Officer, and Blake Gurfein, our Chief Science Officer; as well as a consulting agreement with Lisa Wolf, our Interim Chief Financial Officer. A summary of the terms of such agreements is set forth below. Prior to her resignation, we had a consulting agreement in place with Kimberly Bambach for services she rendered in her capacity as Interim Chief Financial Officer of the Company. A summary of the material terms of such agreements is set forth below.

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

Executive Offer Letter with Jennifer Ernst

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

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

Executive Offer Letter with Blake Gurfein

In January 2018, we entered into a standard at will offer letter with Blake Gurfein, which was amended in part in February 2019. Pursuant to his offer letter, Mr. Gurfein is entitled to a base salary of $350 thousand per annum and is eligible to receive, at the sole discretion of the Board, an annual end-of-year incentive bonus in an amount up to 25% of his base salary. The annual end-of-year incentive bonus, if earned, will be determined by the Board, in its sole discretion, and will be based on subjective or objective criteria, as approved by the Board.

Mr. Gurfein's employment is "at will," meaning that either he or the Company are entitled to terminate Mr. Gurfein's employment at any time and for any reason, with or without cause. In the event that his employment with the Company is terminated for any reason before December 31 of any given year, he will not be entitled to receive an annual end-of-year bonus. In the event that Mr. Gurfein's employment terminates as a result of an involuntary Separation of Service (as defined in the regulations interpreting Section 409A of the Internal Revenue Code), other than for cause, Mr. Gurfein will be eligible to receive his full base salary for a period of six months after termination, as well as reimbursement for COBRA premiums him and his covered dependents for six months after termination. Notwithstanding the foregoing, such severance benefits shall be waived in the event that a Separation of Services occurs within 12 months of a change of control that results in proceeds to Mr. Gurfein of $2,000,000 or more.

Agreement with Kimberly Bambach

Kimberly Bambach was appointed as the Company's Interim Chief Financial Officer, effective April 28, 2023, and was retained to provide such services as a non-employee consultant pursuant to a consulting agreement through the effective date of her resignation (October 1, 2024). Pursuant to such agreement, Ms. Bambach was entitled to receive $200 per hour for services provided in her capacity as Interim Chief Financial Officer. The agreement shall remain effective until such time as it is terminated by either party.

Agreement with Lisa Wolf

Effective October 1, 2024, Lisa Wolf was appointed as the Company's Interim Chief Financial Officer and Principal Financial and Principal Accounting Officer. Ms. Wolf has been retained to provide such services as a non-employee consultant of the Company. In connection with her appointment as Interim Chief Financial Officer, the Company entered into a consulting agreement with Ms. Wolf, whereby Ms. Wolf is entitled to receive $275 per hour for services provided in her capacity as Interim Chief Financial Officer.

Outstanding Equity Awards at Fiscal Year-End 2024

The following table provides information regarding the outstanding equity awards held by our named executive officers as of December 31, 2024. See "Equity Incentive Plan Information," below, for additional information regarding our equity incentive plans.

	Outstanding Equity Awards at Fiscal Year-End									
	Option Awards					Stock Awards				
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)	Option Expiration Date	Number of Shares of Stock That Have Not Vested (#)	Market Value of Shares of Stock That Have Not Vested ($)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested ($)
Jennifer Ernst	34	—	—	$ 224.40	4/1/2028	—	—	—	—
	84	34 (1)	—	$ 3,111.00	2/4/2027	—	—	—	—
	30	44 (2)	—	$ 221.00	5/8/2033	—	—	—	—
	—	1,883 (5)	—	$ 22.78	3/12/2034	—	—	—	—
	—	—	—	—	—	—	—	29,412 (7)	173,000
Blake Gurfein	37	12 (3)	—	$ 7,803.00	12/14/2031	—	—	—	—
	5	—	—	$ 204.00	4/3/2028	—	—	—	—
	4	—	—	$ 204.00	6/27/2028	—	—	—	—
	15	6 (4)	—	$ 2,839.00	2/4/2032	—	—	—	—
	24	35 (2)	—	$ 221.00	5/8/2033	—	—	—	—
	—	589 (5)	—	$ 22.78	3/12/2034				
	—	—	—	—	—	—	—	13,236 (7)	77,850
Kimberly Bambach	—	—	—	—	—	111 (6)	2,513	—	—

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

(2) The options vest as follows: (i) 25% on May 8, 2024, and (ii) the remaining 75% in equal installments over the next 36 months.

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

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

(5) The options vest as follows: (i) 50% on March 12, 2025, and (ii) the remaining 50% in equal monthly installments over the next 12 months.

(6) The restricted stock award vests as follows: (i) 53.33% vest in a series of 12 equal monthly installments, rounded downward to the nearest whole share, commencing on the one month anniversary, and (ii) the remaining shares vest on the one year anniversary.

(7) The restricted stock units vest as follows: (i) 50% on December 18, 2025, and (ii) the remaining 50% in a series of eight successive equal quarterly installments.

2017 Equity Incentive Plan

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

Share reserve. Under the 2017 Plan, 578 shares of our common stock were reserved for issuance pursuant to a variety of stock-based compensation awards, including stock options, restricted stock awards, and other stock-based awards. With respect to the share reserve under the 2017 Plan:

- to the extent that an award terminated, expired or lapsed for any reason or an award was settled in cash without the delivery of shares prior to the effectiveness of the 2021 Plan, any shares subject to the award at such time would have been available for future grants under the 2017 Plan; and

- prior to the effectiveness of the 2021 Plan, to the extent that shares of our common stock were repurchased by us prior to vesting so that shares were returned to us, such shares would have been available for future grants under the 2017 Plan.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Amended and Restated 2021 Equity Incentive Plan

In August 2021, the Board adopted and our stockholders approved the 2021 Plan, which became effective upon the completion of our IPO. Upon the effectiveness of the 2021 Plan, it replaced the 2017 Plan, except with respect to awards outstanding under the 2017 Plan, and no further awards may be made under the 2017 Plan. Additionally, any awards that are canceled or expire under the 2017 Plan will not be reissued.

On August 9, 2024, the Company amended and restated the 2021 Plan (as amended and restated, the ("A&R 2021 Plan"), which amends and restates the 2021 Plan in full. The Board unanimously approved the adoption of the A&R 2021 Plan, subject to stockholder approval, on June 15, 2024, and the Company's stockholders approved the A&R 2021 Plan at the Company's 2024 Annual Meeting of Stockholders held on August 9, 2024.

The principal purpose of the A&R 2021 Plan is to attract, retain and incentivize the Company's employees and other service providers through the granting of certain stock-based awards, including performance-based awards. The material terms of the A&R 2021 Plan are summarized below.

Share reserve. Under the 2021 Plan (prior to its amendment and restatement), 552 shares of our common stock were initially reserved for issuance pursuant to a variety of stock-based compensation awards, including stock options, restricted stock awards, restricted stock units, stock bonus awards and performance-based awards as of the date of its adoption by the Company. With respect to the share reserve under the A&R 2021 Plan:

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

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

In addition, the A&R 2021 Plan provides that additional shares will automatically be added to the shares authorized for issuance under the A&R 2021 Plan on January 1 of each year. The number of shares added each year will be equal to the lesser of: (i) 5.0% of the outstanding on December 31st of the preceding calendar year or (ii) such number of shares determined by the Board, in its discretion. On January 1 of 2022, 2023 and 2024, the number of shares of our common stock authorized for issuance under the 2021 Plan automatically increased from to 838 shares, 1,122 shares, and 5,434 shares, respectively, each of which increases equaled 5% of the number of our outstanding shares of common stock as of December 31 of the prior year. On August 9, 2024, upon adoption of the A&R 2021 Plan, the number of shares of common stock authorized for issuance under the A&R 2021 Plan was increased to 58,823 shares. Additionally, on January 1, 2025, the number of shares of our common stock authorized for issuance under the A&R 2021 Plan automatically increased from 58,823 to 86,669 shares (an increase equal to 5% of the number of our outstanding shares of common stock as of December 31, 2024).

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

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

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

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

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

- Stock Options. Options granted under the A&R 2021 Plan may become exercisable in cumulative increments ("vest") as determined by the Administrator. Such increments may be based on continued service to the Company over a certain period of time, the occurrence of certain performance milestones, or other criteria. Options granted under the A&R 2021 Plan may be subject to different vesting terms.

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

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

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

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

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

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

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

Equity Award Grant Timing

We do not have a written policy in place regarding the timing of the grant and issuance of stock options in relation to the release of material non-public information. Historically, we have typically granted stock option awards shortly after the completion of our annual meeting of shareholders, and as may otherwise be deemed appropriate by our Board or compensation committee from time to time based on the facts and circumstances, as applicable. We have not intentionally timed the grant of stock options in anticipation of the release of material nonpublic information, nor have we intentionally timed the release of material nonpublic information based on stock option grant dates.

During fiscal year 2024, we did not grant stock options (or similar awards) to any of our named executive officers during the period beginning four business days before and ending one business day after the filing of any Company periodic report on Form 10-Q or Form 10-K, or the filing or furnishing of any Company Form 8-K that disclosed any material non-public information.

Director Compensation

The following table sets forth information regarding the compensation awarded to, earned by, or paid to our non-employee directors who served on our Board for the year ended December 31, 2024.

Name	Fees earned or paid in cash ($)[1]	Stock awards ($)	Option awards ($)[2][3]	Non-equity incentive plan compensation ($)	Nonqualified deferred compensation earnings ($)	All other compensation ($)	Total ($)
Sheryle Bolton	65,250	—	3,930	—	—	—	69,180
Karen Drexler	36,000	—	1,050	—	—	—	37,050
Dean Zikria	35,000	—	3,354	—	—	—	38,354
Christina Valauri	20,500	—	3,354	—	—	—	23,854

(1) These amounts reflect the cash payments that we made as compensation for Board services during fiscal year 2024.

(2) These amounts represent the grant date fair value of stock options granted in fiscal 2024 computed in accordance with FASB ASC Topic 718. We do not include any impact of estimated forfeitures related to service-based vesting terms in these calculations.

(3) As of December 31, 2024, the number of shares subject to all outstanding option awards and stock awards held by our non-employee directors were as follows:

Director	Number of Shares Subject to Option Awards	Number of Shares Subject to Stock Awards
Sheryle Bolton	1,115	—
Dean Zikria	938	—
Christina Valauri	899	—

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

- Annual Retainer for all Directors: $35,000

- Chairperson of the Board: $15,000
- Chairperson of the Audit and Risk Committee: $13,000
- Chairperson of the Compensation Committee: $9,000
- Chairperson of the Nominating and Governance Committee: $6,000

To the extent that an individual serves as a director, committee member or committee chair for a portion of the year, they shall be entitled to a pro rata portion of the compensation set forth above for the portion of the year that they serve in such role.

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

The following table sets forth certain information regarding the beneficial ownership of our outstanding common stock as of March 17, 2025 by: (i) each of our directors, (ii) each of our named executive officers (as defined by Item 402(a)(3) of Regulation S-K promulgated under the Exchange Act), and (iii) all of our current directors and executive officers as a group. As of March 17, 2024, there are no persons known to us to beneficially own more than 5% of each class of our outstanding common stock. As of March 17, 2024, there were 620,137 shares of our common stock issued and outstanding.

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

Beneficial owner [1]	Amount and Nature of Beneficial Ownership	Percent of Class
Directors and Named Executive Officers		
Jennifer Ernst[2]	1,979	*
Blake Gurfein, PhD[3]	517	*
Dean Zikria[4]	471	*
Sheryle Bolton[5]	546	*
Christina Valauri[6]	444	*
Kimberly Bambach[7]	442	*
All current directors and executive officers as a group (7 persons)	3,957	*

* Less than 1%

(1) Unless otherwise indicated in the footnotes to the table, the address for each beneficial owner listed is c/o Tivic Health Systems, Inc., 47685 Lakeview Blvd., Fremont, CA 94538.

(2) Includes 706 shares of common stock held by Ms. Ernst, and options to purchase 1,273 of common stock that are vested and exercisable (or will be vested and exercisable within 60 days of March 17, 2025).

(3) Includes 66 shares of common stock held by Dr. Gurfein, as well as options to purchase 451 shares of common stock that are vested and exercisable (or will be vested and exercisable within 60 days of March 17, 2025).

(4) Includes options to purchase 471 shares of common stock that are vested and exercisable (or will be vested and exercisable within 60 days of March 17, 2025).

(5) Includes options to purchase 546 shares of common stock that are vested and exercisable (or will be vested and exercisable within 60 days of March 17, 2025).

(6) Includes options to purchase 444 shares of common stock that are vested and exercisable (or will be vested and exercisable within 60 days of March 17, 2025).

(7) Includes 442 shares of common stock held by Ms. Bambach.

(8) Consists of the shares described in Notes (2) through (6) above, less the 442 shares of common stock held by Ms. Bambach, who resigned as Interim Chief Financial Officer of the Company effective October 1, 2024. Lisa Wolf, Interim Chief Financial Officer of the Company, and Michael Handley, Chief Operating Officer of the Company and President of the Tivic Biopharma, are excluded from the table because they do not beneficially own any shares of Company common stock as of March 17, 2025, but are included in the total number of current directors and executive officers of the Company.

Equity Incentive Plan Information

The following table provides information as of December 31, 2024, regarding our equity compensation plans:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans
Equity compensation plans approved by security holders [1]	150,349	$ 12.62	94,430
Equity compensation plans not approved by security holders	—	—	—
Total	150,349	$ 12.62	94,430

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

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

There have not been any transactions or any series of similar transactions, since January 1, 2023, nor are we aware of any such pending transactions, to which we were a party or will be a party, in which:

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

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

Policies and Procedures Regarding Related Party Transactions

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

Director Independence

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

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

Item 14 – Principal Accounting Fees and Services

Independent Registered Public Accounting Firm Fee Information

The following table sets forth the aggregate fees billed by Rosenberg Rich Baker Berman, P.A. ("RRBB"), independent registered public accounting firm, for the services indicated for each of the years ended December 31, 2024 and 2023:

	December 31, 2024	December 31, 2023
Audit fees [(1)]	$ 135,000	$ 143,075
Audit related fees	—	—
Tax fees	—	—
All other fees	—	—
Total	$ 135,000	$ 143,075

(1) Includes fees for (i) the audit of our annual financial statements for the fiscal years ended December 31, 2024 and 2023 included in this Report; and the S-1 Registration Statement, as amended, initially filed with the Commission in 2022 in connection with our public offering that closed in February 2023; and with the prospectus supplements to our S-3 Registration Statement that were filed in 2024 and 2023 in connection with our equity offerings that closed in 2024 and 2023; (ii) the review of our interim period financial statements for fiscal years 2024 and 2023; and (iii) related services that are normally provided in connection with regulatory filings or engagements.

Audit Committee Pre-Approval Policies and Procedures

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

PART IV

Item 15 – Exhibits, Financial Statement Schedules

(a)

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

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

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

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

EXHIBIT INDEX

Exhibit number	Exhibit description	Incorporated by Reference (Form Type)	Filing Date	Filed herewith
1.1	Form of Equity Distribution Agreement, by and between Tivic Health Systems, Inc. and Maxim Group LLC, dated September 13, 2024.	8-K	9/13/2024	
3.1	Amended and Restated Certificate of Incorporation, dated November 12, 2021.	8-K	11/15/21	
3.2	Amended and Restated Bylaws, dated November 12, 2021.	8-K	11/15/21	
3.3	Certificate of Amendment to the Amended and Restated Bylaws of the Company, dated July 5, 2023.	8-K	7/6/2023	
3.4	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Tivic Health Systems, Inc., filed August 21, 2023 (effective August 23, 2023).	8-K	8/22/2023	
3.5	Certificate of Designation of Series A Non-Voting Convertible Preferred Stock of Tivic Health Systems, Inc., dated February 10, 2025.	8-K	2/12/2024	
3.6	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Tivic Health Systems, Inc., filed March 4, 2025 (effective March 7, 2025).	8-K	3/5/2025	
4.1	Specimen Stock Certificate.	S-1/A	9/9/2021	
4.2	Form of Representative's Warrant (IPO).	S-1/A	9/9/2021	
4.3	Warrant to Purchase Common Stock issued to Hannover International, Inc., dated July 1, 2021.	S-1/A	10/29/2021	
4.4	Description of Securities.	10-K	3/31/2022	
4.5	Form of Representative's Warrant (February 2023 offering).	8-K	2/13/2023	
4.6	Placement Agent Warrant, dated July 11, 2023.	8-K	7/11/2023	

4.7	Placement Agent Warrant, dated July 19, 2023.	8-K	7/19/2023
4.8	Placement Agent Warrant, dated August 9, 2023.	8-K	8/9/2023
4.9	Form of Series A Warrant, dated May 13, 2024.	8-K	5/13/2024
4.10	Form of Series B Warrant, dated May 13, 2024.	8-K	5/13/2024
4.11	Placement Agent Warrant, dated May 13, 2024.	8-K	5/13/2024
4.12	Warrant Agency Agreement, dated May 13, 2024, by and between Tivic Health Systems, Inc. and Equiniti Trust Company, LLC.	8-K	5/13/2024
10.1(a)#	2017 Equity Incentive Plan, as amended, dated April 13, 2017.	S-1	8/3/2021
10.1(b)#	Form Agreements under 2017 Equity Incentive Plan.	S-1	8/3/2021
10.2(a)#	2021 Equity Incentive Plan, dated August 7, 2021.	S-1/A	9/9/2021
10.2(b)#	Form Agreements under 2021 Equity Incentive Plan.	S-1/A	9/9/2021
10.3#	Form of Restricted Stock Purchase Agreement.	S-1/A	9/9/2021
10.4#	Form of Indemnification Agreement for directors and officers.	S-1/A	9/9/2021
10.5†	Letter Agreement, between Tivic Health Systems, Inc. and Future Electronics Corp., dated April 6, 2020.	S-1/A	9/9/2021
10.6†	Form of United States Special Product Agreement for Bonded Inventory, between Tivic Health Systems, Inc. and Future Electronics Corp.	S-1/A	9/9/2021
10.7#	Executive Offer Letter, between Tivic Health Systems, Inc. and Jennifer Ernst, dated July 31, 2021.	S-1/A	9/9/2021
10.8	Sublease Agreement, between the Company and Czarnowski Display Services, Inc., dated November 17, 2021.	10-K	3/31/2022
10.9#	Executive Offer Letter, between Tivic Health Systems, Inc. and Veronica Cai, dated April 1, 2022.	8-K	4/5/2022
10.10#	Executive Offer Letter, between Tivic Health Systems, Inc. and Ryan Sabia, dated April 1, 2022.	8-K	4/5/2022
10.11†	Manufacturing Agreement, between Tivic Health Systems, Inc. and Microart Services, Inc., dated October 21, 2022.	8-K	10/25/2022
10.12†	Fulfillment Services Agreement, between Tivic Health Systems, Inc. and ALOM Technologies Corporation, dated November 25, 2022.	8-K	12/1/2022
10.13	Form of Securities Purchase Agreement, dated July 10, 2023, by and between Tivic Health Systems, Inc. and the investors party thereto.	8-K	7/11/2023

10.14	Form of Securities Purchase Agreement, dated July 14, 2023, by and between Tivic Health Systems, Inc. and the investors party thereto.	8-K	7/19/2023	
10.15	Form of Securities Purchase Agreement, dated August 6, 2023, by and between Tivic Health Systems, Inc. and the investors party thereto.	8-K	8/9/2023	
10.16	Amendment #1 to Fulfillment Services Agreement, between Tivic Health Systems, Inc. and ALOM Technologies Corporation, dated March 5, 2024.	10-K	3/25/2024	
10.17	Form of Securities Purchase Agreement, dated May 9, 2024, by and between Tivic Health Systems, Inc. and the investors party thereto.	8-K	5/13/2024	
10.18†	Collaboration and Research Support Agreement, dated May 17, 2024, by and between Tivic Health Systems, Inc. and The Feinstein Institutes for Medical Research.	8-K	5/22/2024	
10.19	Sublease Termination Agreement, dated May 21, 2024, by and between Tivic Health Systems, Inc. and Czarnowski Display Service, Inc.	8-K	5/30/2024	
10.21#	Tivic Health System, Inc. Amended and Restated 2021 Equity Incentive Plan, dated August 9, 2024.	8-K	8/13/2024	
10.22†	Exclusive License Agreement, dated February 11, 2025, by and between the Tivic Health Systems, Inc. and Statera Biopharma, Inc.	8-K	2/12/2025	
10.22	Securities Purchase Agreement, dated February 11, 2025, by and between the Tivic Health Systems, Inc. and Statera Biopharma, Inc.	8-K	2/12/2025	
10.23#	Executive Employment Agreement, by and between Tivic Health Systems, Inc. and Michael Handley, dated February 18, 2025.	8-K	2/24/2025	
10.24	Equity Purchase Agreement, by and between Tivic Health Systems, Inc. and Mast Hill Fund, L.P., dated March 18, 2025.	8-K	3/21/2025	
10.25	Registration Rights Agreement, by and between Tivic Health Systems, Inc. and Mast Hill Fund, L.P., dated March 21, 2025.	8-K	3/21/2025	
19.1	Tivic Health Systems, Inc. Insider Trading Policy.	10-K	3/25/2024	
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			*
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			*
97.1#	Tivic Health Systems, Inc. Compensation Recovery Policy.	10-K	3/25/2024	
101 INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.			**
101 SCH	Inline XBRL Taxonomy Extension Schema with Embedded Linkbase Documents			**
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101 attachments)			**

# 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.

* Furnished herewith.

** The XBRL related information in Exhibit 101 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to liability of that section and shall not be incorporated by reference into any filing or other document pursuant to the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing or document.

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 21, 2025

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 Officer) and Director*	March 21, 2025
/s/ Lisa Wolf Lisa Wolf	Interim Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 21, 2025
/s/ Sheryle Bolton Sheryle Bolton	*Chair of the Board of Directors*	March 21, 2025
/s/ Christina Valauri Christina Valauri	*Director*	March 21, 2025
/s/ Dean Zikria Dean Zikria	*Director*	March 21, 2025

TIVIC HEALTH SYSTEMS, INC.

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Tivic Health Systems, Inc. (the Company) as of December 31, 2024 and 2023, and the related statements of operations, stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2024, and the related notes (collectively referred to as the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2024, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

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

Basis for Opinion

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

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

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

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

We have served as the Company's auditor since 2020

Somerset, New Jersey
March 21, 2025

Tivic Health Systems, Inc.
Balance Sheets
December 31, 2024 and 2023
(in thousands, except share and per share data)

	December 31, 2024	December 31, 2023
ASSETS		
Current assets		
Cash and cash equivalents	$ 2,002	$ 3,395
Accounts receivable, net	69	174
Inventory, net	319	756
Prepaid expenses and other current assets	249	327
Total current assets	2,639	4,652
Property and equipment, net	119	122
Right-of-use assets, operating lease	—	349
Deferred offering costs	49	—
Other assets	—	34
Total assets	$ 2,807	$ 5,157
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 125	$ 713
Other accrued expenses	147	495
Operating lease liability, current	—	193
Total current liabilities	272	1,401
Operating lease liability	—	176
Total liabilities	272	1,577
Commitments and contingencies (Note 6)		
Stockholders' equity		
Preferred stock, $0.0001 par value, 10,000,000 shares authorized, no shares issued or outstanding at December 31, 2024 and 2023, respectively	—	—
Common stock, $0.0001 par value, 200,000,000 shares authorized; 556,978 and 86,241 shares issued and outstanding at December 31, 2024 and 2023, respectively	1	—
Additional paid in capital	46,075	41,466
Accumulated deficit	(43,541)	(37,886)
Total stockholders' equity	2,535	3,580
Total liabilities and stockholders' equity	$ 2,807	$ 5,157

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

Tivic Health Systems, Inc.
Statements of Operations
Years Ended December 31, 2024 and 2023
(in thousands, except share and per share data)

	Years Ended December 31,	
	2024	**2023**
Revenue	$ 780	$ 1,176
Cost of sales	778	889
Gross profit	2	287
Operating expenses:		
Research and development	1,313	1,655
Sales and marketing	1,187	2,125
General and administrative	3,163	4,752
Total operating expenses	5,663	8,532
Loss from operations	(5,661)	(8,245)
Other income:		
Interest income	6	1
Total other income	6	1
Net loss	$ (5,655)	$ (8,244)
Net loss per share - basic and diluted	$ (19.68)	$ (176.80)
Weighted-average number of shares - basic and diluted	287,370	46,650

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

Tivic Health Systems, Inc.
Statements of Stockholders' Equity
Years Ended December 31, 2024 and 2023
(in thousands except share and per share data)

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount			
Balances at January 1, 2023	—	$ —	5,693	$ —	$ 33,272	$ (29,642)	$ 3,630
Issuance of common stock, net of issuance costs	—	—	80,543	—	7,560	—	7,560
Issuance of warrants	—	—	—	—	363	—	363
Issuance of common stock in lieu of fractional shares for stock split	—	—	5	—	—	—	—
Stock-based compensation expense	—	—	—	—	271	—	271
Net loss						(8,244)	(8,244)
Balances at December 31, 2023	—	$ —	86,241	$ —	$ 41,466	$ (37,886)	$ 3,580
Issuance of common stock for restricted stock award	—	—	442	—	—	—	—
Issuance of common stock and warrants, net of issuance costs and warrants issued to placement agents	—	—	470,295	1	4,310	—	4,311
Issuance of warrants	—	—	—	—	70	—	70
Stock-based compensation expense	—	—	—	—	229	—	229
Net loss	—	—	—	—	—	(5,655)	(5,655)
Balances at December 31, 2024	—	$ —	556,978	$ 1	$ 46,075	$ (43,541)	$ 2,535

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

Tivic Health Systems, Inc.
Statements of Cash Flows
Years Ended December 31, 2024 and 2023
(in thousands)

	Years Ended December 31,	
	2024	**2023**
Cash flows from operating activities		
Net loss	$ (5,655)	$ (8,244)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock based compensation	229	271
Depreciation	3	8
Amortization of right-of-use asset	349	174
Reserve for inventory obsolescence	354	32
Changes in operating assets and liabilities:		
Accounts receivable	105	(67)
Inventory	83	75
Prepaid expenses and other current assets	78	(92)
Accounts payable	(588)	(610)
Accrued expenses	(348)	103
Lease liabilities	(369)	(161)
Other assets	34	—
Net cash used in operating activities	(5,725)	(8,511)
Cash flows from investing activities		
Acquisition of property and equipment	—	(118)
Net cash used in investing activities	—	(118)
Cash flows from financing activities		
Proceeds from issuance of common stock, net of issuance costs	4,381	8,507
Offering costs in advance of sale of common stock	(49)	—
Net cash provided by financing activities	4,332	8,507
Net decrease in cash and cash equivalents	(1,393)	(122)
Cash and cash equivalents		
Beginning of period	3,395	3,517
End of period	$ 2,002	$ 3,395
Supplemental disclosure on noncash financing activities		
Issuance of common stock warrant	$ 70	$ 363
Deferred offering costs charged to additional paid-in-capital	$ —	$ 584
Write-off of ROU asset and lease liability	$ 290	$ —

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

1. Formation and Business of the Company

Tivic Health Systems, Inc. (the "Company"), was incorporated in the state of California on September 22, 2016 for the purpose of developing and commercializing non-invasive bioelectronic medicine. In June 2021, the Company was reincorporated as a Delaware corporation. The Company's first commercial platform is a handheld design that interfaces non-invasively with the trigeminal, sympathetic, and other facial and cranial nerve structures. This platform is the basis for the Company's existing product, currently marketed with FDA approval as ClearUP Sinus Pain Relief, for the treatment of sinus pain and congestion. The Company's second platform is a research-stage platform directed to vagus nerve stimulation, which is currently undergoing clinical evaluation. The Company is headquartered in Fremont, California.

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.

Going Concern Uncertainty

The accompanying financial statements have been prepared as if the Company will continue as a going concern. The Company has experienced losses and negative cash flows from operations; incurred a net loss of $5.7 million during the year ended December 31, 2024; had cash and cash equivalents of $2.0 million as of December 31, 2024; and had an accumulated deficit of $43.5 million as of December 31, 2024. The Company's working capital as of December 31, 2024 was approximately $2.4 million. The aforementioned factors raise substantial doubt about the Company's ability to continue as a going concern within one year from the issuance date of the financial statements. The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The financial statements do not include any adjustments relating to the recoverability and classification of asset amounts or the classification of liabilities that might be necessary should the Company be unable to continue as a going concern within one year after the date the financial statements are issued.

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; completion of any acquisitions or other strategic transactions; 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 existing as well as new customers. We also will be required to efficiently manufacture and deliver on those purchase orders. These activities, including our planned research and development efforts, may require significant uses of working capital. There can be no assurance that we will generate revenue and cash as expected in our current business plan.

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

Reverse Stock Splits

In August 2023, the Company's Board of Directors and stockholders approved an amendment to the Company's amended and restated certificate of incorporation to effect a 1-for-100 reverse stock split of the issued and outstanding shares of the Company's common stock, which was effected on August 23, 2023. There was no change to the par value, or authorized shares, of either the common stock or preferred stock, as a result of the reverse stock split. Fractional shares were not issued, and instead, the Company issued one whole share of the post reverse split common stock to any stockholder who otherwise would have been entitled to receive a fractional share as a result of the reverse stock split. Consequently, 5 shares of common stock were issued in lieu of fractional shares. In addition, all options, warrants and other convertible securities of the Company outstanding immediately prior to the reverse stock split were adjusted by dividing the number of shares of common stock into which such options, warrants and other convertible securities were exercisable or convertible by 100 and multiplying the exercise or conversion price thereof by 100, all in accordance with the terms of the plans, agreements or arrangements governing such options, warrants and other convertible securities and subject to rounding pursuant to such terms. All share and per share amounts for the common stock, as well as the stock options, and warrants outstanding and exercise prices thereof, included in the financial statements and these footnotes thereto have been retroactively restated to give effect to the reverse stock split.

In February 2025, the Company's Board of Directors and stockholders approved an amendment to the Company's amended and restated certificate of incorporation to effect a 1-for-17 reverse stock split of the

issued and outstanding shares of the Company's common stock, which was effected on March 7, 2025. There was no change to the par value, or authorized shares, of either the common stock or preferred stock, as a result of the reverse stock split. Fractional shares were not issued, and instead, the Company issued one whole share of the post reverse split common stock to any stockholder who otherwise would have been entitled to receive a fractional share as a result of the reverse stock split. Consequently, 77 shares of common stock were issued in lieu of fractional shares. In addition, all options, warrants and other convertible securities of the Company outstanding immediately prior to the reverse stock split were adjusted by dividing the number of shares of common stock into which such options, warrants and other convertible securities were exercisable or convertible by 17 and multiplying the exercise or conversion price thereof by 17, all in accordance with the terms of the plans, agreements or arrangements governing such options, warrants and other convertible securities and subject to rounding pursuant to such terms. All share and per share amounts for the common stock, as well as the stock options, and warrants outstanding and exercise prices thereof, included in the financial statements and these footnotes thereto have been retroactively restated to give effect to the reverse stock split

Use of Estimates

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

Fair Value of Financial Instruments

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

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

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

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

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

Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less at date of purchase to be cash equivalents. As of December 31, 2024 and 2023, cash equivalents include investments held in our money market account and were $1.8 million and $3.2 million, respectively.

Accounts Receivable

Trade accounts receivable are recorded at the invoiced amount, net of allowances for credit losses. The allowance for credit losses is based on our assessment of the collectability of accounts. Management regularly reviews the adequacy of the allowance for credit losses 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 credit losses when identified. As of each December 31, 2024 and 2023, the allowance for credit losses was zero. For the year ended December 31, 2024 we recorded bad debt expense of $5,000. There was no bad debt expense recorded for the year ended December 31, 2023.

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, 2024 and 2023, the reserve for obsolescence was $338 thousand and $32 thousand, respectively.

Deferred Offering Costs

The Company complies with the requirements of Financial Accounting Standards Board ("FASB") Accounting Standard Codification ("ASC") 340-10-S99-1. The Company capitalizes incremental legal, professional, accounting, and other third-party fees that are directly associated with an equity or debt offering as other current assets. As of December 31, 2024, the balance of deferred offering costs was $49 thousand and consisted of legal and accounting fees paid in connection with the filing of Form 1-A in August 2024. If the Company consummates an equity offering, the deferred offering costs will be allocated to additional paid-in capital. If the Company consummates a debt offering, the deferred financing costs will be recorded as a discount to the debt. There were no deferred offering costs as of December 31, 2023.

Property and Equipment

Property and equipment are recorded at cost net of accumulated depreciation. Depreciation is computed on a straight-line method over the estimated useful lives of the assets, three to four years. 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.

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

The Company may 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, 2024 and 2023, the contract liability related to the Company's deferred revenues approximated $2 thousand and $8 thousand, respectively, and are included in "Other Accrued Expenses" on the accompanying balance sheets.

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

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

The table below presents revenue by channel for the years ended December 31, 2024 and 2023 (in thousands):

	Year Ended December 31,	
Product Revenue by Sales Channel	**2024**	**2023**
Product Revenue		
Direct-to-consumer	$ 656	$ 1,079
Reseller	206	261
Returns	(82)	(164)
Revenue	$ 780	$ 1,176

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 each of the years ended December 31, 2024 and 2023 were $1 thousand and $3 thousand, respectively. Shipping costs for delivery of product to customers in the years ended December 31, 2024 and 2023 were $33 thousand and $59 thousand, respectively.

Product Warranty

The Company generally offers a one-year limited warranty on its products. The Company also offers for sale a limited two-year warranty. The limited two-year warranty is occasionally provided to customers in connection with promotional sales. 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.

Returns

The Company estimates a reserve for future product returns based several factors, including historical returns as a percentage of revenue, an understanding of the reasons for past returns and any other known factors that indicate a return is imminent. Reserves for sales returns are estimated and recorded in the same period as the underlying revenue recognition as a deduction to arrive at net product sales and as a liability classified as Other accrued expenses on the balance sheet. As of December 31, 2024 and 2023, the reserve for sales returns was $10 thousand and $52 thousand, respectively.

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 $0.5 million and $0.8 million for the years ended December 31, 2024 and 2023, 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 unless there is an alternative future use.

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. Changes to the group are made on an as needed basis to ensure it remains representative of the Company. 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 chief operating decision-maker ("CODM) in deciding how to allocate resources and assess performance. The Company's CODM is the Chief Executive Officer, who reviews the Company's operations and manages its business as a single operating segment.

Net Loss per Common Share

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

Income Taxes

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

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

Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist of cash and cash equivalents and accounts receivable. Cash and cash equivalents include a checking account and a money market account held at one national financial institution in the United States. At times, such deposits may be in excess of insured limits. Despite recent concerns regarding the stability of certain banking institutions in the United States, management believes that the financial institution at which the Company holds its deposits is financially sound, and accordingly, minimal credit risk exists with respect to the financial institution. The Company has not experienced any losses on its deposits of cash and cash equivalents. As of December 31, 2024 and 2023, the Company had cash and cash equivalents balances exceeding FDIC insured limits by $1.6 million and $3.0 million, respectively.

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

During 2024, the majority, or 74%, of the Company's sales have been to individual consumers. As of December 31, 2024, the Company had one customer whose accounts receivable balance totaled more than 10% or more of the Company's total accounts receivable (95%), compared with one customer at December 31, 2023 (81%).

For the year ended December 31, 2024, the Company had one customer who individually accounted for 10% or more of the Company's total revenue (18%), compared with one customer for the year ended December 31, 2023 (20%).

The ongoing conflicts between Russia and Ukraine as well as Israel and Hamas, certain other macroeconomic factors including tariffs, inflation, and rising interest rates, have contributed to economic uncertainty. Additionally, events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. Furthermore, it is possible that U.S. policy changes, including planned or proposed budget cuts at the federal government level, could increase market volatility in the coming months. These factors, amongst other things, could result in further economic uncertainty and volatility in the capital markets in the near term, and could negatively affect our operations. We will continue to monitor material impacts on our business strategies and operating results.

Leases

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

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

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

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

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

Recently issued accounting pronouncements

In November 2024, the FASB issued ASU 2024-03, Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40)- *Disaggregation of Income Statement Expenses*. The guidance applies to all public business entities and becomes effective for annual periods beginning after December 15, 2026, and interim periods beginning after December 15, 2027. Early adoption is permitted. The guidance requires improved disclosures about expenses, including the types of expenses in commonly presented expense captions (such as cost of sales, SG&A and research and development) which will allow investors to better understand the components of an entity's expenses. In January 2025, the FASB issued ASU 2025-01 to further clarify the effective date as the first annual reporting period beginning after December 15, 2026, and interim periods within annual reporting periods beginning after December 15, 2027. We do not believe that ASU 2024-03 will have a material impact on our financial reporting.

3. Financial Instruments and Fair Value Measurements

The Company’s financial instruments consist of money market funds. The following tables show the Company’s cash equivalent's carrying value and fair value at December 31, 2024 and 2023 (in thousands):

	As of December 31, 2024				
	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	$ 1,819	$ 1,819	$ 1,819	$ —	$ —
Total assets	$ 1,819	$ 1,819	$ 1,819	$ —	$ —

	As of December 31, 2023				
	Carrying Amount	Fair Value	Quoted Priced in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets					
Money market funds	$ 3,243	$ 3,243	$ 3,243	$ —	$ —
Total assets	$ 3,243	$ 3,243	$ 3,243	$ —	$ —

Cash equivalents – Cash equivalents of $1.8 million and $3.2 million as of December 31, 2024 and 2023, 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.

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, 2024 and 2023. 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, 2024 and 2023.

4. Inventory, net (in thousands)

	December 31, 2024	December 31, 2023
Raw materials	$ 460	$ 752
Work in process	5	—
Finished goods	192	36
Inventory at cost	657	788
Less reserve for obsolescence	(338)	(32)
Inventory	$ 319	$ 756

The increase in the reserve for obsolescense is related to raw materials inventory.

5. Property and equipment, net (in thousands)

	December 31, 2024	December 31, 2023
Computers and equipment	$ 11	$ 11
Manufacturing tools and dies	148	148
Total property and equipment	159	159
Less accumulated depreciation	(40)	(37)
Property and equipment, net	$ 119	$ 122

Depreciation expense was $3 thousand and $8 thousand for the years ended December 31, 2024 and 2023, respectively.

6. Commitments and Contingencies

Lease

The Company executed a noncancelable operating lease for approximately 9,091 square feet of office space in Hayward, California in November 2021 as its headquarters. The lease was set to expire in October 2025. The Company was obligated to pay, on a pro-rata basis, real estate taxes and operating costs related to the premises. Upon lease execution, the Company evaluated the lease and determined it should be capitalized as an operating lease. As there was no interest rate implicit in the lease, the Company estimated the incremental borrowing rate at 6% based on the rate available under its revolving credit line, as well as an assessment of the Company's risk based on its financial position at the time and its potential to obtain a collateralized loan for a period similar to the lease term. The lease was terminated effective May 31, 2024. The Company incurred termination fees of $77 thousand, which were partially offset by a remaining security deposit of $16 thousand. The Company recorded a loss of $60 thousand in connection with the lease termination, which is included in general and administrative expense in the statement of operations.

Lease costs for the years ended December 31, 2024 and 2023 are as follows (in thousands):

	December 31, 2024	December 31, 2023
Operating lease cost	$ 84	$ 201
Short term lease cost	34	21
Total lease cost	$ 118	$ 222

Cash paid for amounts included in the measurement of operating lease liabilities were $87 thousand and $206 thousand for the years ended December 31, 2024 and 2023, respectively, which is included in operating activities in the statements of cash flow.

In June 2024, the Company entered into a short-term rental agreement for office space located in Fremont, California. The Company evaluated the agreement and determined the short-term rental agreement does not meet the criteria for capitalization. Monthly rent payments required are $1 thousand per month and the agreement terminated on December 1, 2024. After expiration of the initial term, the agreement automatically renewed on a month to month basis until terminated by either party upon 30 days' advance written notice.

ALOM Fulfillment Service Agreement

On November 25, 2022, the Company entered into a Fulfillment Services Agreement (the "ALOM Agreement"), with ALOM Technologies Corporation ("ALOM"). Pursuant to the ALOM Agreement, commencing on November 28, 2022, ALOM began providing, on a non-exclusive basis, certain assembly, procurement, storage, returns, and fulfillment services to our end customers and retailers within the United States. During the term of the ALOM Agreement, ALOM shall provide the services in accordance with purchase orders issued by us from time to time. The consideration payable by us to ALOM for services rendered under the ALOM Agreement will be calculated and invoiced based on fixed hourly rates and fixed unit pricing, as applicable, subject to certain exceptions; provided that, commencing April 1, 2023, we became subject to $25 thousand minimum monthly purchase requirement. The ALOM Agreement had a three-year initial term, with automatic annual renewals, and could be terminated for convenience by either party upon sixty days written notice to the other party. On March 5, 2024, the ALOM Agreement was amended to waive hourly account management charges and minimum monthly purchase requirements for the period from January 2024 through June 2024, and to extend the initial term of the agreement to December 31, 2024. The ALOM Agreement was terminated effective August 1, 2024. The Company terminated the Agreement for convenience, in accordance with the terms of the ALOM Agreement, in furtherance of its efforts to continue to reduce both direct and indirect costs associated with product manufacturing and distribution. The Company did not incur any material early termination penalties in connection with the termination of the ALOM Agreement. The Company is now utilizing third-party logistics and storage services from alternate suppliers without material minimums and has established in-house assembly and testing capabilities. The Company completed the transition with no disruptions to service and expects current capacity will be sufficient to meet demand for the foreseeable future.

Purchase Commitments

The Company has entered into multiple contracts related to the development of Tivic's ncVNS technology, including a collaboration and research support agreement and a research study to substantiate clinical indications that have potential to be addressed by Tivic's patent-pending ncVNS system. The contracts require milestone payments to be made upon the successful completion of certain deliverables. As of December 31, 2024, the Company had remaining commitments to pay a total of $171 thousand for milestones not yet achieved. Of the remaining commitment, $86 thousand was paid in March 2025 and the remainder is expected to be incurred in the second quarter of 2025.

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, 2024.

7. Other Accrued Expenses (in thousands)

	December 31, 2024	December 31, 2023
Accrued payroll and related	$ —	$ 218
Research study costs	90	51
Legal fees	39	—
Delaware franchise tax	—	160
Other	18	66
Total other accrued expenses	$ 147	$ 495

8. Preferred Stock

There were no series of preferred stock designated and no shares issued or outstanding at December 31, 2024 and 2023.

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.

9. Common Stock

At December 31, 2024 and 2023, there were 556,978 and 86,241 shares of Company common stock issued and outstanding, respectively.

On February 13, 2023, the Company sold 11,765 shares of its common stock in an underwritten public offering at a price of $425.00 per share, less underwriting discounts and commissions, resulting in gross proceeds to the Company of $5.0 million. The net proceeds to the Company, after deducting the underwriting discount and commissions and expenses paid by the Company, was approximately $3.6 million. In addition, pursuant to the underwriting agreement entered into in connection with the offering, the Company granted the underwriter a 45-day option to purchase up to an additional 1,765 shares of common stock, solely to cover over-allotments. This option expired in March 2023, and the underwriter did not exercise its option to purchase any additional shares prior to such expiration. Additionally, as partial consideration for services rendered in connection with the offering, the Company issued warrants to purchase an aggregate of 589 shares of Company common stock to designees of ThinkEquity. The designees paid an aggregate of $100 for the warrants. The warrants have an initial exercise price of $531.25 per share, have a term of four years from the commencement of sales in the offering, and are exercisable commencing six months from closing.

On July 11, 2023, the Company sold 19,118 shares of its common stock to certain investors at a price of $93.50 per share, resulting in gross proceeds to the Company of approximately $1.8 million. Net proceeds to the Company, after deducting placement agent fees and offering expenses paid by the Company, was approximately $1.5 million. As compensation for services rendered by the placement agent, the Company paid the placement agent a cash fee of 8.0% of the aggregate gross proceeds of the offering (amounting to $143 thousand) at closing, as well as $90 thousand for the reimbursement of certain expenses. Additionally, as partial consideration for services rendered in connection with the offering, the Company issued the placement agent unregistered warrants to purchase an aggregate of 765 shares of Company common stock, representing 4.0% of the aggregate shares sold in the offering. The warrants have an initial exercise price of $112.20 per share (equal to 120% of the offering price per share), have a term of five years from the commencement of sales in the offering, and are exercisable commencing six months from closing.

On July 19, 2023, the Company sold 30,148 shares of its common stock to certain investors at a price of $68.00 per share, resulting in gross proceeds to the Company of approximately $2.1 million. Net proceeds to the Company, after deducting placement agent fees and offering expenses paid by the Company, was

approximately $1.7 million. As compensation for services rendered by the placement agent, the Company paid the placement agent a cash fee of 8.0% of the aggregate gross proceeds of the offering (amounting to $164 thousand) at closing, as well as $60 thousand for the reimbursement of certain expenses. Additionally, as partial consideration for services rendered in connection with the offering, the Company issued the placement agent unregistered warrants to purchase an aggregate of 1,206 shares of common stock, representing 4.0% of the aggregate shares sold in the offering. The warrants have an initial exercise price of $81.60 per share (equal to 120% of the offering price per share), have a term of five years from the commencement of sales in the offering, and are exercisable commencing six months from closing.

On August 9, 2023, the Company sold 19,514 shares of its common stock to certain investors at a price of $69.70 per share, resulting in gross proceeds to the Company of approximately $1.4 million. Net proceeds to the Company, after deducting placement agent fees and offering expenses paid by the Company, was approximately $1.1 million. As compensation for services rendered by the placement agent, the Company paid the placement agent a cash fee of 8.0% of the aggregate gross proceeds of the offering (amounting to approximately $109 thousand) at closing, as well as $60 thousand for the reimbursement of certain expenses. Additionally, as partial consideration for services rendered in connection with the offering, the Company issued the placement agent unregistered warrants to purchase an aggregate of 781 shares of Company common stock, representing 4.0% of the aggregate shares sold in the offering. The warrants have an initial exercise price of $83.64 per share (equal to 120% of the offering price per share), have a term of five years from the commencement of sales in the offering, and are exercisable commencing six months from closing.

Effective August 23, 2023, the Company's board of directors approved a reverse stock split of the Company's issued and outstanding shares of common stock, par value $0.0001 per share, at a ratio of 1-for-100. As a result of the reverse stock split, the total number of shares of common stock held by each stockholder of the Company were converted automatically into the number of shares of common stock equal to the number of issued and outstanding shares of common stock held by each such stockholder immediately prior to the reverse stock split divided by 100. The Company issued one whole share of the post reverse stock split common stock to any stockholder who otherwise would have been entitled to receive a fractional share as a result of the reverse stock split. As a result, no fractional shares were issued in connection with the reverse stock split and no cash or other consideration was paid in connection with any fractional shares that would otherwise have resulted from the reverse stock split. Also, all options, warrants and other convertible securities of the Company outstanding immediately prior to the reverse stock split were adjusted by dividing the number of shares of common stock into which such options, warrants and other convertible securities were exercisable or convertible by 100 and multiplying the exercise or conversion price thereof by 100, all in accordance with the terms of the plans, agreements or arrangements governing such options, warrants and other convertible securities and subject to rounding pursuant to such terms. There was no change to the par value, or authorized shares, of either the common stock or preferred stock, as a result of the reverse stock split. All share and per share amounts for the common stock, as well as the warrants outstanding and exercise prices thereof, have been retroactively restated to give effect to the reverse stock split.

On May 13, 2024, the Company sold 277,059 shares of its common stock, together with Series A warrants (the "Series A Warrants") to purchase an aggregate of 277,059 shares of common stock and Series B warrants (the "Series B Warrants" and collectively with the Series A Warrants, the "Common Warrants") to purchase an aggregate of 415,589 shares of common stock, to certain investors in a registered public offering. Each share of common stock was sold together with one Series A Warrant and one and a half Series B Warrants at a combined price of $14.45 per share and Common Warrants, resulting in gross proceeds to the Company of approximately $4 million. Net proceeds to the Company, after deducting placement agent fees and offering expenses paid by the Company, was approximately $3.3 million. The net proceeds were allocated between the common stock and Common Warrants issued in the offering based on the relative fair values, which were $1.4 million and $1.9 million, respectively. Each of the Common Warrants are exercisable immediately upon issuance and have an exercise price of $14.45 per share, subject to certain adjustments. The Series A Warrants will expire one year from the date of issuance and the Series B Warrants will expire five years from the date of issuance. As compensation for services rendered by the placement agent, the Company paid the placement agent a cash fee of 7.0% of the gross proceeds of the offering (amounting to approximately $280 thousand) at closing, as well as $100 thousand for the reimbursement of certain expenses. Additionally, as partial consideration for services rendered in connection with the offering, the Company issued the placement agent

registered warrants to purchase an aggregate of 11,083 shares of Company common stock, equal to 4.0% of the aggregate shares of common stock sold in the offering. The placement agent warrants have an initial exercise price of $15.90 per share (equal to 110% of the combined offering price per share and Common Warrants), have a term of five years from the commencement of sales in the offering, and are exercisable commencing six months from closing.

On September 13, 2024 the Company entered into an Equity Distribution Agreement (the "Distribution Agreement") with Maxim Group LLC ("Maxim"), pursuant to which the Company may offer and sell, from time to time, through or to Maxim, as sales agent or principal, shares of its common stock. The Company will pay Maxim a commission of 3% of the aggregate gross proceeds from each sale of shares. The Company also agreed to reimburse Maxim for certain specified fees and expenses of up to $40 thousand, plus an additional $5 thousand for each bringdown, as provided in the Distribution Agreement. The agreement will terminate upon the earlier of (i) the sale of all shares of common stock having an aggregate offering price of $10 million; (ii) twenty four months from the date of the agreement; (iii) the mutual termination of the agreement upon fifteen days' prior written notice; and (iv) as otherwise permitted therein. During the year ended December 31, 2024, the Company sold a total of 193,161 shares of its common stock pursuant to the Distribution Agreement with gross proceeds of $1.2 million. The Company paid Maxim $37 thousand in commissions. Net proceeds to the Company, after deducting commissions and offering expenses paid by the Company, was approximately $1.1 million.

Effective March 7, 2025, the Company's board of directors approved a reverse stock split of the Company's issued and outstanding shares of common stock, par value $0.0001 per share, at a ratio of 1-for-17. As a result of the reverse stock split, the total number of shares of common stock held by each stockholder of the Company were converted automatically into the number of shares of common stock equal to the number of issued and outstanding shares of common stock held by each such stockholder immediately prior to the reverse stock split divided by 17. The Company issued one whole share of the post reverse stock split common stock to any stockholder who otherwise would have been entitled to receive a fractional share as a result of the reverse stock split. As a result, no fractional shares were issued in connection with the reverse stock split and no cash or other consideration was paid in connection with any fractional shares that would otherwise have resulted from the reverse stock split. Also, all options, warrants and other convertible securities of the Company outstanding immediately prior to the reverse stock split were adjusted by dividing the number of shares of common stock into which such options, warrants and other convertible securities were exercisable or convertible by 17 and multiplying the exercise or conversion price thereof by 17, all in accordance with the terms of the plans, agreements or arrangements governing such options, warrants and other convertible securities and subject to rounding pursuant to such terms. There was no change to the par value, or authorized shares, of either the common stock or preferred stock, as a result of the reverse stock split. All share and per share amounts for the common stock, as well as the warrants outstanding and exercise prices thereof, have been retroactively restated to give effect to the reverse stock split.

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, 2024, no dividends on common stock had been declared by the Company. At December 31, 2024 and 2023, the Company had reserved shares of common stock for issuance as follows:

	December 31, 2024	December 31, 2023
Warrants to purchase common stock	707,234	3,500
Options issued and outstanding	8,868	863
Shares available for future stock option grants	5,555	424
Total	721,657	4,787

10. Common Stock Warrants

Historically, the Company has entered into warrant agreements in connection with certain consulting agreements and equity offerings. In August 2023, the Company implemented a 1-for-100 reverse stock split wherein, per the terms of the agreements, the number of shares of common stock issuable upon exercise of each of the warrants outstanding at that time was reduced by dividing the quantity outstanding by 100 and the exercise price of each such warrant was multiplied by 100. No other terms of the warrants were changed as a result of the reverse stock split. Additionally, in March 2025, the Company implemented a 1-for-17 reverse stock split wherein, per the terms of the agreements, the number of shares of common stock issuable upon exercise of each of the warrants outstanding at that time was reduced by dividing the quantity outstanding by 17 and the exercise price of each such warrant was multiplied by 17. No other terms of the warrants were changed as a result of the reverse stock split.

In July 2021, the Company entered into a consulting agreement, pursuant to which warrants to purchase 30 shares of common stock were granted and warrants to purchase an additional 30 shares of common stock were granted in November 2021. The warrants are exercisable upon issuance, have an exercise price of $1,768.00 per share and have a term of five years. The consulting agreement was effective as of February 2021, had an initial monthly fee of $5 thousand and a term of two years. The agreement was amended in May of 2022 to increase the monthly payment to $7.5 thousand. Currently, the agreement is automatically renewing on a month-to-month basis until terminated by either party. The warrant issuances are indexed to, and settled in, the Company's own common stock and were classified within stockholders' equity.

In November 2021, the Company issued warrants to purchase 102 shares of common stock to designees of ThinkEquity LLC ("ThinkEquity"), the underwriter of the IPO. The warrants may be exercised at any time on or after May 9, 2022, have an exercise price of $10,625.00 per share and have a term of five years. The warrant issuances are indexed to and settled in the Company's own common stock and were classified within stockholders' equity.

In February 2023, the Company issued warrants to purchase 589 shares of common stock to designees of ThinkEquity, the underwriter of the underwritten public offering of 11,765 shares of Company common stock that closed in February 2023. The designees paid an aggregate of $0.1 thousand for the warrants. The warrants may be exercised at any time on or after August 7, 2023, have an exercise price of $531.25 per share, and have a term of four years commencing 180 days following the commencement of sales in the offering. The warrant issuances were indexed to and settled in the Company's own stock and were classified within stockholders' equity.

In July and August 2023, the Company issued warrants to purchase an aggregate of 2,805 shares of common stock to Maxim, the placement agent for each of the three public offerings of the Company's common stock completed during the period. The warrants are exercisable at any time beginning six months after the close of the applicable equity offering and expire five years from the from the commencement of sales under the applicable offering. Of the warrants issued in the offerings, 765 are exercisable beginning on January 11, 2024 at a price of $113.20 per share; 1,206 are exercisable beginning on January 19, 2024 at a price of $81.60 per share; and 781 are exercisable beginning on February 9, 2024 at a price of $83.64 per share.

In May 2024, in connection with the sale of 277,059 shares of common stock, the Company issued Series A Warrants to purchase an aggregate of 277,059 shares of common stock and Series B Warrants to purchase an aggregate of 415,589 shares of common stock to the purchasers of the stock. The warrants are exercisable upon issuance and have an exercise price of $14.45 per share. The Series A Warrants expire on May 13, 2025 and the Series B Warrants expire on May 14, 2029. Additionally, the Company issued warrants to purchase 11,083 shares of common stock to Maxim, the placement agent for the public offering of the Company's securities. The placement agent warrants are exercisable at any time beginning six months after the closing date of the equity offering and expire five years from the from the commencement of sales under the offering.

The Company estimated the value of the warrants issued to the placement agent in May 2024 using the Black-Scholes options valuation model. The fair value of the warrants issued in February 2023 was $195 thousand and was recognized as issuance costs of the common stock issued in the underwritten public offering and was classified within stockholders' equity. The fair value of the warrants issued in July and August 2023 totaled $168 thousand and was recognized as issuance costs of the common stock issued in the three offerings during the period and was classified within stockholders' equity. The fair value of the warrants issued in

May 2024 was $70 thousand and was recognized as issuance costs of the common stock issued in the public offering and was classified within stockholders' equity.

The fair value of the warrants issued to placement agents in 2024 and 2023 was estimated on the date of grant using the following assumptions:

	2024		2023	
	Minimum	Maximum	Minimum	Maximum
Expected life (in years)	5.0	5.0	4.0	5.0
Expected volatility	118.6	118.6	116.11	123.9
Risk-free interest rate	3.83%	4.50%	3.98%	4.24%
Dividend yield	0%	0%	0%	0%

A summary of the number of shares of Company common stock issuable upon exercise of outstanding warrants ("Warrant Shares") and other terms of such warrants as of December 31, 2024 is as follows:

Class of Shares	Number of Warrant Shares	Exercise Price of Warrants	Expiration Date of Warrants
Common Stock	30	$ 1,768.00	July 1, 2026
Common Stock	30	$ 1,768.00	November 15, 2026
Common Stock	102	$ 10,625.00	November 10, 2026
Common Stock	589	$ 531.25	August 9, 2027
Common Stock	765	$ 112.20	July 10, 2028
Common Stock	1,206	$ 81.60	July 14, 2028
Common Stock	781	$ 83.64	August 4, 2028
Common Stock	11,083	$ 15.90	May 9, 2029
Common Stock	277,059	$ 14.45	May 13, 2025
Common Stock	415,589	$ 14.45	May 14, 2029
Total	707,234		

11. Equity Incentive Plans

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

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

2021 Equity Incentive Plan

In 2021, the Company adopted the 2021 Equity Incentive Plan (the "2021 Plan"). The plan allows for the issuance of incentive stock options, nonstatutory stock options, restricted stock awards, restricted stock units, stock bonus awards and performance-based awards. Awards granted under the 2021 Plan are determined by the Compensation Committee of the Company's board of directors, who is responsible for administering the 2021 Plan. The term for stock options shall be no more than ten years from the date of grant. In the case of an Incentive Stock Option granted to an optionee who, at the time the option is granted, owns stock representing more than 10% of the voting power of all classes of stock of the Company or any Parent or Subsidiary, the term of the option shall be five years from the date of grant or such shorter term as may be provided in the option Agreement. To the extent outstanding awards under the 2021 Plan are forfeited or lapse unexercised, the shares of common stock subject to such awards will be available for future issuance under the 2021 Plan. The 2021 Plan provides that additional shares will automatically be added to the shares authorized for issuance under the 2021 Plan on January 1 of each year. The number of shares added each year will be equal to the lesser of: (i) 5.0% of the outstanding shares of the Company's common stock on December 31st of the preceding calendar year or (ii) such number of shares determined by the board of directors, in its discretion. On January 1, 2024, 4,312 shares were automatically added to the number of shares authorized for issuance under 2021 Plan (an increase equal to 5% of the number of the outstanding shares of Company common stock as of December 31, 2023). On January 1, 2025, 27,846 shares were automatically added to the number of shares authorized for issuance under A&R 2021 Plan (an increase equal to 5% of the number of the outstanding shares of Company common stock as of December 31, 2024).

As of December 31, 2024, there were 5,555 shares of common stock available for issuance under the 2021 Plan.

Amended and Restated 2021 Equity Incentive Plan

On August 9, 2024, the Company adopted its Amended and Restated 2021 Equity Incentive Plan (the "A&R 2021 Plan"), which amends and restates the 2021 Plan in full to, amongst other things, increase the number of shares of common stock authorized for issuance thereunder from 5,434 shares to 58,823 shares. The Company's Board of Directors unanimously approved the adoption of the A&R 2021 Plan, subject to stockholder approval, on June 15, 2024, and the Company's stockholders approved the A&R 2021 Plan at the Company's 2024 Annual Meeting of Stockholders held on August 9, 2024.

Stock Options

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

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

The following table summarizes the option activity for the years ended December 31, 2024 and 2023:

			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 thousands)
Balances, January 1, 2023	269	747	$ 3,400.00	$ 18.02	7.77	$ 62
Shares reserved for issuance	285	—				
Options granted	(339)	339	$ 215.56	$ 2.04		
Options forfeited / cancelled	209	(223)	$ 2,234.65	$ 15.30		
Options expired	—	—	$ —	$ —		
Options exercised	—	—	$ —	$ —		
Balances, December 31, 2023	424	863	2,454.97	$ 12.58	7.42	$ —
Shares reserved for issuance	4,312	—				
Added per amendment annual s/h mtg	53,390	—				
Reserved shares cancelled	—	—				
Options granted	(8,118)	8,118	$ 9.86	$ 8.33		
Options forfeited / cancelled	107	(136)	$ 2,208.30	$ 11.39		
Options rounded for reverse stock split	—	23				
RSAs granted	(442)					
RSUs granted	(44,118)					
Options expired	—	—	$ —	$ —		
Options exercised	—	—	$ —	$ —		
Balances, December 31, 2024	5,555	8,868	$ 219.12	$ 8.67	9.22	$ 10
At December 31, 2024						
Vested and exercisable		1,935	$ 764.04	$ 6.52	8.62	$ 2

The weighted-average grant date fair value per share of stock options granted in 2024 and 2023 was $8.33 and $2.04, respectively. The aggregate intrinsic value of options outstanding and options vested and exercisable as of December 31, 2024 is calculated based on the difference between the exercise price and the current fair value of our common stock. As of December 31, 2024 the aggregate intrinsic value of options outstanding was $10 thousand and for vested and exercisable options was $2 thousand.

Stock-Based Compensation for Stock Options

Options generally vest over four years whereby 25% vest upon the first anniversary of the issuance date and 1/36th per month thereafter. Stock-based compensation expense recognized during the years ended December 31, 2024 and 2023 was $229 thousand and $271 thousand, respectively. As of December 31, 2024, there were total unrecognized compensation costs of $220 thousand related to share-based payment awards which is expected to be recognized over a weighted-average amortization period of 1.13 years.

Prior to the IPO, the grant date fair market value of the shares of common stock underlying stock options had historically been determined by the Company's Board of Directors. Because there had been no public market for the Company's common stock, the Board of Directors exercised reasonable judgment and considered a number of objective and subjective factors to determine the best estimate of the fair market value, which included valuations performed by an independent third-party, important developments in the Company's operations, sales of the Company's convertible preferred stock, actual operating results, financial performance, the conditions in the life sciences industry, the economy in general, the stock price performance and volatility of comparable public companies, and the lack of liquidity of the Company's common stock. For 2022 and 2023, the Company has used a comparative peer group for determining the expected volatility rate used in the calculation of fair value. Since the Company's stock has not been publicly traded for a sufficiently long period of time, the expected volatility rate is based on a review of the historical volatilities, over a period of time equivalent to the expected life of the instrument being valued, of similarly positioned public companies within the Company's industry.

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

	2024	2023
Expected life (in years)	5.23 – 5.66	5.71 – 6.08
Expected volatility	114.62% - 119.28%	114.59% - 153.33%
Risk-free interest rate	3.83% - 4.40%	3.50% - 4.01%
Dividend yield	—%	—%

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

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

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

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

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

Restricted Stock Awards

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, 2024	—	$ —
Issuance of restricted common stock	442	$ 22.78
Vested	(331)	$ 22.78
Cancelled	—	$ —
Non-vested as of December 31, 2024	111	$ 22.78

The fair value of restricted stock awards vested during the year ended December 31, 2024 was $8 thousand. There were no restricted stock awards outstanding during the year ended December 31, 2023.

Restricted Stock Units

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

	Number of Shares	Weighted-Average Grant-Date Fair Value Per Share
Non-vested as of January 1, 2024	—	$ —
Granted	44,119	$ 3.91
Vested	—	$ —
Cancelled	—	$ —
Non-vested as of December 31, 2024	44,119	$ 3.91

The fair value of restricted stock units granted during the year ended December 31, 2024 was $170 thousand. There were no restricted stock awards granted during the year ended December 31, 2023.

Total Stock-Based Compensation

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

	2024	2023
Research and development	$ 93	$ 103
Sales and marketing	2	1
General and administrative	134	167
Total stock-based compensation	$ 229	$ 271

12. 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, 2024 and 2023.

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, 2024	December 31, 2023
Income tax provision at statutory rate	21%	21%
State income taxes, net of federal benefit	(4)%	(15)%
Research and development credits	—%	(1)%
Change in valuation allowance	(17)%	(5)%
Effective income tax rate	—%	—%

For the year ended December 31, 2024 the Company's effective tax rate is below the federal statutory income tax rate of 21% due to the Company's position to establish a full valuation allowance on its deferred tax assets. For the year ended December 31, 2023, the Company's effective tax rate is below the federal statutory income tax rate of 21% primarily due to state income taxes, net of federal benefit and the Company's position to establish a full valuation allowance on its deferred tax assets.

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

	For the Years Ended	
	December 31, 2024	December 31, 2023
Deferred tax assets:		
Net operating loss carryforwards	$ 7,627	$ 6,759
Research and development credits	204	186
Research and development costs	489	465
Lease liability	—	103
Other temporary differences	195	158
Total deferred tax assets	8,515	7,671
Valuation allowance	(8,515)	(7,574)
Deferred tax assets recognized	—	97
Deferred tax liabilities:		
Right-of-use assets	—	(97)
Total deferred tax liabilities	—	(97)
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 $0.9 million and $354 thousand for the years ended December 31, 2024 and 2023, respectively, due to current and previous year losses and credits claimed.

At December 31, 2024 and 2023, the Company had federal net operating loss carryforwards of approximately $35.5 million and $30.4 million, respectively, which will begin to expire in 2036. Approximately $35.1 million of federal net operating losses can be carried forward indefinitely. At December 31, 2024 and 2023, the Company had state net operating loss carryforwards for California of approximately $2.6 million and $5.1 million, respectively, which will begin to expire in 2031. The Company also had federal and state research and development credit carryforwards of approximately $26 thousand and $336 thousand, respectively, at December 31, 2024. The federal credits start to expire in 2044. The California 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 performed a 382 study in 2024 to determine if any ownership changes have occurred during 2024 which resulted in some tax attributes expiring prior to being able to be utilized due to Section 382 limitations. The Company had $33.7 million of federal net operating losses incurred prior to the ownership change in 2024. Of this amount, the Company estimated that $70 thousand of these tax attributes can be used each year due to the annual Section 382 limitations.

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

	For the Years Ended	
	December 31, 2024	December 31, 2023
Unrecognized tax benefits, beginning of year	$ 98	$ 115
Additions related to current year tax positions	10	(17)
Deferred tax assets	$ 108	$ 98

During the year ended December 31, 2024 the amount of unrecognized tax benefits increased by $10 thousand due to current year research and development credits generated during the year offset by a reduction in research and development credits available for use due to application of the Section 382 limitations. During the year ended December 31, 2023 the amount of unrecognized tax benefits decreased by $17 thousand due to additional research and development credits generated during the year offset by a reduction in research and development credits available for use due to application of the Section 382 limitations. As of December 31, 2024 and 2023, the total amount of unrecognized tax benefits was $108 thousand and $98 thousand, respectively. The reversal of the uncertain tax benefits would not affect the Company's effective tax rate to the extent that it continues to maintain a full valuation allowance against its deferred tax assets.

The Company recognizes interest and penalties related to unrecognized tax benefits in the provision for income taxes line item in the statements of operations. As of December 31, 2024, and 2023, 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 2017 to 2024 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.

13. 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,	
	2024	2023
Common stock warrants	707,234	3,500
Common stock options issued and outstanding	8,868	863
Total	716,102	4,363

	For the Years Ended December 31,	
	2024	2023
Net loss	$ (5,655)	$ (8,244)
Weighted-average number of shares - basic and diluted	287,370	46,650
Net loss per share - basic and diluted	$ (19.68)	$ (176.80)

14. Related Party Transactions

In December 2021, the Company entered into an agreement with a significant shareholder for certain product development consultation services. During the years ended December 31, 2024 and 2023, the Company incurred $5 thousand and $14 thousand, respectively, of expenses in connection with the agreement. The expenses are included in research and development expense. There were no unpaid balances due to the shareholder at December 31, 2024.

15. Segment Information

Tivic Health is a health tech company focused on bioelectronic medicine. Bioelectronic medicine is a branch of the global neuromodulation market that treats disease and conditions by modulating the electrical signals carried along various nerve pathways. Revenue is derived from sales of the Company's first commercial product, ClearUp. The Company manages the business activities as a single operating segment. Tivic's Chief Executive Officer is the Chief Operating Decision Maker ("CODM"). The CODM utilizes the Company's long-term plan, which includes product development roadmaps and long-term financial models, as key input to resource allocation. The CODM makes decisions on resource allocation, assesses performance of the business, and monitors budget versus actual results using factors such as gross margin, operating expenses, loss from operations and net loss.

Significant expenses within loss from operations, as well as within net loss, include costs of revenue, research and development, selling and marketing and general and administrative expenses, which are each separately presented on the Company's Statements of Operations. Other segment items within net loss include interest income.

During the years ended December 31, 2024 and 2023, all revenue is domestic revenue. To-date we have not sold our product outside of the United States.

The Company's long-lived assets consist primarily of property and equipment, all of which are located in the United States.

16. Subsequent Events

Exclusive License Agreement – Statera BioPharma

On February 11, 2025, the Company entered into an exclusive license agreement (the “License Agreement”) with Statera Biopharma, Inc. (“Statera”) whereby the Company acquired (i) an exclusive worldwide license to the proprietary Toll-like Receptor 5 (“TLR5”) agonist program of Statera known as Entolimod (the “Licensed Molecules”) as it relates to the Acute Radiation Syndrome (“ARS”) indication (the “Initial Indication”) and (ii) an exclusive option (the “Exclusive Option”) to acquire the exclusive worldwide license to additional indications, including Lymphocyte Exhaustion, Immunosenescence, Neutropenia and/or Vaccine Adjuvant (the “Subsequent Indications”) and to the TLR5 agonist program of Statera known as Entolasta, in each case as described in more detail below. The License Agreement transaction was consummated concurrently therewith on February 11, 2025 (the “Closing Date”).

Under the terms of the License Agreement, Statera has granted the Company an exclusive worldwide license, with the right to grant and authorize sublicenses, under Statera’s patents and know-how to develop, test, make and use Entolimod to develop, test, make, have made, use, sell, offer for sale, import and otherwise exploit the product as it relates to the Initial Indication during the term of the License Agreement.

As consideration for the License Agreement, the Company agreed to pay Statera a license fee of $1,500,000 consisting of (i) $300,000 in cash consideration and (ii) $1,200,000 in stock consideration, as described below. The Company remains liable to Statera for certain royalty payments on net sales for ARS as monotherapy, and, if it exercises the Exclusive Option, net sales for all Subsequent Indications, within certain royalty periods.

The License Agreement further provides the Company with the Exclusive Option to expand the Initial Indications to include the treatment of the Subsequent Indications or to expand the use from a monotherapy to include uses as Vaccine Adjuvant, or several or all of them, at any time during the term of the License Agreement, and on one or more occasions, at its discretion. As part of exercise of the Exclusive Option, the license grant would be expanded to include uses of Entolasta, in addition to Entolimod, both for ARS and for the Subsequent Indications.

In conjunction with the License Agreement, Statera additionally transferred to the Company the title to fifteen kilograms (15kg) of frozen manufactured Entolimod lots and associated quality records associated with their production and applicable verification records (the "Materials"). In connection with this acquisition of ownership of the Materials, the Company will be negotiating a $1 per year lease with an affiliate of Statera for the proper care, storage and handling of the Materials.

The License Agreement also includes a buyout provision (the "Buyout") by which the Company maintains the right to acquire from Statera at any time all right, title and interest in and to all technology licensed or otherwise subject to the Exclusive Option under the License Agreement. Should the Company elect to invoke this buyout right, it must provide Statera with a buyout payment equal to (a) the lesser of (i) the aggregate amount of payments due to Statera for achievement of all milestone events (described below), less the amount of payments paid for the achievement of one or more of such milestone events, and (ii) an amount negotiated in good faith and mutually agreed by the parties in writing as representing the risk adjusted net present value of the aggregate royalties that would have been payable absent such exercise; less (b) the amount of payments paid or payable by the Company to extinguish an existing lien on the licensed technology.

The License Agreement obligates the Company to develop and commercialize the licensed products, at its own cost and expense, inclusive of licensed products with respect to any Subsequent Indications obtained upon exercise of an Exclusive Option. In the development and commercialization process, the Company is obligated to meet certain milestones, and must provide Statera with certain milestone payments, payable in either the form of cash or Company stock (at the sole discretion of the Company), upon accomplishing each milestone as outlined below.

Event	**Payment**
Validation of current inventory of Materials for distribution and sales	$750,000
Filing of BLA with FDA for Acute Radiation Syndrome	$1,000,000
Total Acute Radiation Syndrome Development Milestones	$1,750,000

Upon exercise of an Exclusive Option with respect to one or more Subsequent Indications, the following corresponding applicable milestones and milestone payments, payable in in either the cash or Company stock (at the sole discretion of the Company), become obligations of the Company as well:

Event	**Payment**
File IND and Initiate Phase 2 Clinical Study for Neutropenia	$500,000
Phase III Completion - successfully meets endpoint required to secure FDA approval for treatment of Neutropenia	$750,000
File BLA with FDA and achieve FDA Approval for Neutropenia	$1,500,000
File IND and Initiate Phase 2 study of Lymphocyte Exhaustion	$500,000

Phase III Completion - successfully meets endpoint required by FDA for treatment of Lymphocyte Exhaustion	$750,000
File BLA with FDA and achieve FDA Approval for Lymphocyte Exhaustion	$1,500,000
IND approval and initiation of Phase 3 study as a Vaccine Adjuvant	$500,000
File US BLA with FDA and achieve FDA Approval for use as a Vaccine Adjuvant	$500,000
Total Potential Development Milestones for additional Indications (as applicable)	$6,500,000

In conjunction with the License Agreement, Statera may nominate one individual to sit on the Company's Board of Directors (the "Board"). Statera's nominee must have the relevant industry experience in biopharmaceuticals, meet all requirements for service as an Independent Board Member, as defined by Nasdaq listing requirements. Approval of such Statera nominee shall be at the sole reasonable discretion of the Board.

Pursuant to the License Agreement, the Company has agreed to hold a stockholders' meeting within 120 days of the Closing Date to submit the approval of the conversion of shares of Series A Preferred Stock into shares of Company common stock in accordance with the rules of the Nasdaq Stock Market LLC (the "Conversion Proposal") to its stockholders for their consideration. In connection therewith, the Company has agreed to file a proxy statement on Schedule 14A with the SEC. If the requisite stockholder approval is not obtained within the time period referenced above, then the Company shall convene additional stockholder meetings every 90 days thereafter until the requisite stockholder approval is obtained.

Securities Purchase Agreement

On February 11, 2025, the Company entered into a Securities Purchase Agreement (the "Securities Purchase Agreement") with Statera. Pursuant to the Securities Purchase Agreement, the Company agreed to issue and sell to Statera an aggregate of (i) 55,635 shares of Company common stock and (ii) 359.6691 shares of Series A Preferred Stock (collectively, the "Securities") for an aggregate price of approximately $1.2 million. Each share of Series A Preferred Stock is convertible into approximately 588 shares of common stock, as described below. The powers, preferences, rights, qualifications, limitations and restrictions applicable to the Series A Preferred Stock are set forth in the Certificate of Designation (as defined and described below).

The Securities Purchase Agreement also provides Statera with registration rights related to the Securities. Specifically, the Company is required to prepare and file a resale registration statement with the Commission within 60 calendar days following the Closing Date (the "Filing Deadline"), with respect to the common stock and the shares of common stock underlying the Series A Preferred Stock.

The closing of the issuance of Securities occurred concurrently with the Closing Date of the License Agreement on February 11, 2025.

Certificate of Designation of Series A Non-Voting Convertible Preferred Stock

On February 10, 2025, the Company filed a Certificate of Designation of Preferences, Rights and Limitations of the Series A Non-Voting Convertible Preferred Stock (the "Certificate of Designation") with the Secretary of State of the State of Delaware in connection with the License Agreement referenced above. The Certificate of Designation provides for the designation of 6,000 shares of the Company's Series A Non-Voting Convertible Preferred Stock, par value $0.0001 per share (the "Series A Preferred Stock").

Holders of Series A Preferred Stock are entitled to receive dividends on shares of Series A Preferred Stock equal to, on an as-if-converted-to-common-stock basis, and in the same form as dividends actually paid on shares of the common stock.

Except as otherwise required by law, the Series A Preferred Stock does not have voting rights. However, as long as any shares of Series A Preferred Stock are outstanding, the Company will not, without the affirmative vote of the holders of a majority of the then-outstanding shares of the Series A Preferred Stock, (i) alter or change adversely the powers, preferences or rights given to the Series A Preferred Stock or alter or amend the Certificate of Designation, amend or repeal any provision of, or add any provision to, the Charter or bylaws of the Company, or file any articles of amendment, certificate of designations, preferences, limitations and relative rights of any series of preferred stock, in each case if any such action would adversely alter or change the preferences, rights, privileges or powers of, or restrictions provided for the benefit of the Series A Preferred Stock, regardless of whether any of the foregoing actions shall be by means of amendment to the Charter or by merger, consolidation, recapitalization, reclassification, conversion or otherwise, (ii) issue further shares of Series A Preferred Stock, or (iii) enter into any agreement with respect to any of the foregoing.

The Series A Preferred Stock does not have a preference upon any liquidation, dissolution or winding-up of the Company.

Following stockholder approval of the Conversion Proposal, each share of Series A Preferred Stock will automatically convert into approximately 588 shares of common stock, subject to certain limitations, including that a holder of Series A Preferred Stock is prohibited from converting shares of Series A Preferred Stock into shares of common stock if, as a result of such conversion, such holder, together with its affiliates, would beneficially own more than a specified percentage (to be established by the holder between 4.9% and 19.9%) of the total number of shares of common stock issued and outstanding immediately after giving effect to such conversion.

Mike Handley appointed COO and President of Tivic Biopharma

On February 18, 2025, Michael Handley was appointed as Chief Operating Officer of the Company, and President of the Tivic Biopharma. Prior to joining the Company, from July 2021 until February 2025, Mr. Handley served as President, Chief Executive Officer and Chairman of Statera Biopharma, Inc. On February 12, 2025, in connection with his appointment as Chief Operating Officer of the Company and President of Tivic Biopharma, the Company and Mr. Handley entered into an executive employment. Mr. Handley was appointed as Chief Operating Officer of the Company and President of Tivic Biopharma in connection with, and pursuant to, the License Agreement.

Nasdaq Compliance

On June 28, 2024, the Company received a notification letter from the Listing Qualifications Department of Nasdaq notifying it that, because the closing bid price for the Company's common stock was below $1.00 per share for 33 consecutive business days, the Company was not currently in compliance with the minimum bid price requirement for continued listing on the Nasdaq Capital Market, as set forth in Nasdaq Marketplace Rule 5550(a)(2) (the “Minimum Bid Price Requirement”). The notification had no immediate effect on the listing of the Company's common stock on the Nasdaq Capital Market.

In accordance with Nasdaq Marketplace Rule 5810(c)(3)(A), the Company had a period of 180 calendar days from June 27, 2024, or until December 26, 2024, to regain compliance with the Minimum Bid Price Requirement. The Company not regain compliance during the compliance period ending on prior to December 26, 2024. As a result, on December 27, 2024, Nasdaq provided notice that the Company's common stock may be subject to delisting unless the Company filed an appeal on or before January 3, 2025. The Company then appealed that determination to a Nasdaq hearings panel. The appeal with the Nasdaq hearings panel was conducted on February 18, 2025. On March 6, 2025, the Company received a letter from the Nasdaq hearings panel granting its request for continued listing on the Nasdaq Capital Market, provided that the Company implemented a reverse stock split on March 7, 2025 and demonstrated compliance with all such continued listing requirements for the Nasdaq Capital Market as of March 20, 2025.

The contemplated reverse split was subsequently completed in the ratio of 1-for-17 and went effective on March 7, 2025.

Reverse Stock Split

Effective March 7, 2025, the Company's board of directors approved a reverse stock split of the Company's issued and outstanding shares of common stock, par value $0.0001 per share, at a ratio of 1-for-17. As a result of the reverse stock split, the total number of shares of common stock held by each stockholder of the Company were converted automatically into the number of shares of common stock equal to the number of issued and outstanding shares of common stock held by each such stockholder immediately prior to the reverse stock split divided by 17. The Company issued one whole share of the post reverse stock split common stock to any stockholder who otherwise would have been entitled to receive a fractional share as a result of the reverse stock split. As a result, no fractional shares were issued in connection with the reverse stock split and no cash or other consideration was paid in connection with any fractional shares that would otherwise have resulted from the reverse stock split. Also, all options, warrants and other convertible securities of the Company outstanding immediately prior to the reverse stock split were adjusted by dividing the number of shares of common stock into which such options, warrants and other convertible securities were exercisable or convertible by 17 and multiplying the exercise or conversion price thereof by 17, all in accordance with the terms of the plans, agreements or arrangements governing such options, warrants and other convertible securities and subject to rounding pursuant to such terms. There was no change to the par value, or authorized shares, of either the common stock or preferred stock, as a result of the reverse stock split. All share and per share amounts for the common stock, as well as the warrants outstanding and exercise prices thereof, have been retroactively restated to give effect to the reverse stock split.

Equity Line of Credit

On March 18, 2025, the Company entered into an Equity Purchase Agreement (the "Purchase Agreement") with Mast Hill Fund, L.P. (the "Mast Hill"), pursuant to which the Company will have the right, but not the obligation, to sell to Mast Hill, and Mast Hill will have the obligation to purchase from the Company, up to $25 million (the "Maximum Commitment Amount") shares of the Company's common stock (the "Put Shares"), at the Company's sole discretion, over the next 24 months, subject to certain conditions precedent and other limitations.

Unless earlier terminated, the Purchase Agreement will remain in effect until the earlier of March 18, 2027 or the date on which Mast Hill has purchased the Maximum Commitment Amount (the "Commitment Period"). The Company has the right to terminate the Purchase Agreement at any time, subject to limitations set forth in the Purchase Agreement.

During the Commitment Period, the Company will have the right, but not the obligation, to direct Mast Hill to make a purchase of the Put Shares by delivering written notice to Mast Hill (a "Put Notice") on any trading day (the "Put Date") to purchase a number of Put Shares pursuant to a formula set forth in the Purchase Agreement. The purchase price for the Put Shares under the Purchase Agreement will be equal to 95% of the lowest VWAP (as defined in the Purchase Agreement) of the Company's common stock on the Principal Market (as defined in the Purchase Agreement) on any trading day during the pricing period, and the pricing period for each sale of Put Shares will be the 5 trading days immediately after receipt of the Put Shares by Mast Hill, subject to adjustment as provided in the Purchase Agreement.

Each Put Notice shall direct Mast Hill to purchase Put Shares (i) in a minimum amount not less than $50 thousand and (ii) in a maximum amount up to $500 thousand, provide further that the number of Put Shares in each respective Put shall not exceed 100% of the average trading volume of the Company's common stock during the 5 trading days immediately preceding the date of the Put Notice. Mast Hill's obligation to purchase Put Shares is subject to a 4.99% beneficial ownership blocker. Additionally, pursuant to the Purchase Agreement, the Company may not sell or issue to Mast Hill more than 19.99% of the number of shares of Company common stock issued and outstanding immediately prior to execution of the Purchase Agreement unless and until the Company obtains stockholder approval to issue additional shares, in accordance with applicable Nasdaq rules.

As consideration for Mast Hill's commitment to purchase shares of Company common stock under the Purchase Agreement, the Company issued Mast Hill 29,800 restricted shares of common stock following the execution of the Purchase Agreement (the "Commitment Shares").

Craft Capital Management LLC acted as the Company's placement agent in connection with this transaction. As compensation for such services, the Company will pay Maxim a commission of 3.0% of the aggregate gross proceeds from each sale of Put Shares under the Purchase Agreement.

In connection with the Purchase Agreement, the Company and Mast Hill also entered into a registration rights agreement (the "Registration Rights Agreement"), pursuant to which the Company agreed to, within 45 calendar days from the date of the Registration Rights Agreement, file with the Securities and Exchange Commission (the "Commission") an initial registration statement covering (i) all of the Put Shares issuable under the Purchase Agreement the Commitment Shares (collectively, the "Registrable Securities") so as to permit the resale of such securities by Mast Hill. The Company shall use reasonable best efforts to have the registration statement declared effective by the Commission within 90 calendar days from the date of the Registration Rights Agreement. The Company shall keep the registration statement effective, including but not limited to pursuant to Rule 415 promulgated under the Securities Act and available for the resale by Mast Hill of all of the Registrable Securities covered thereby at all times until the date on which Mast Hill shall have sold all the Registrable Securities and the Maximum Commitment Amount has been drawn down by the Company.

The Purchase Agreement and Registration Rights Agreement contain customary representations, warranties and agreements, as well as customary conditions to Mast Hill's obligation to purchase the Put Shares.