

# Initiation Report

TIVIC HEALTH SYSTEMS, INC.



## Tivic Health Systems, Inc. — Leveraging Platform Technology to Develop a Portfolio of Bioelectronic Medicine for a Host of Inflammatory Conditions

Tivic Health System, Inc. (NASDAQ: TIVC)

Share Price: \$2.40

Valuation: \$4.22



### Key Statistics

52 Week Range	\$1.23 - \$6.50
Avg. Volume (3 months)	105.47K
Shares Outstanding	9.62M
Market Capitalization	\$23.09M
EV/Revenue	4.8x
Cash Balance*	\$10.80M
Analyst Coverage	1

\*Cash balance as of March 2022

### Revenue (in \$mm)

Dec - FY	2021A	2022E	2023E
1Q	0.30	0.43 A	0.69
2Q	0.25	0.46	0.82
3Q	0.25	0.51	0.98
4Q	0.36	0.58	1.17
FY	1.16	1.98	3.66

### EPS (in \$)

Dec - FY	2021A	2022E	2023E
1Q	(0.58)	(0.23) A	(0.25)
2Q	(0.49)	(0.24)	(0.23)
3Q	(0.90)	(0.25)	(0.22)
4Q	(0.56)	(0.26)	(0.22)
FY	(2.43)	(0.98)	(0.92)

### Stock Price Chart (in \$)



## Investment Highlights

- Platform Model Provides Scalability** - Tivic's current product pipeline is centered around its proprietary technology, which is fundamental to the discovery and development of its medical devices. The core technology is a platform in itself, which provides the base Tivic intends to use to develop medical devices for different indications. The technology combines various parameters that modulate the nerve signals to alleviate inflammation-driven symptoms like pain and congestion. The platform is expected to allow for an extension of the core technology beyond the company's current pipeline, providing higher upside potential compared to targeting a single indication.
- Need for Alternatives** - Drug-based treatment has become foundational to healthcare, given its ease of use and effectiveness in treating diseases. Even though drug-based treatment has its benefits, it can carry dangerous side effects for the human body and can also lead to habituation and, in worse cases, drug abuse. Cold, cough, and pain medications (Dextromethorphan, Pseudoephedrine, Acetaminophen) are available over the counter and are commonly found to be misused. This has led to the need for alternative treatment options, aiding the growth of bioelectronics. Tivic's ClearUP® is its first marketable device to treat sinus pain and congestion arising from chronic sinusitis, cold, and allergic rhinitis. ClearUP® is a strong alternative, or complement, to the drug-based treatments that currently dominate the underlying market.
- Effective, Safe, and Easy to Use** - Tivic's first FDA-cleared product, ClearUP® Sinus Relief, treats various symptoms of allergic rhinitis, sinusitis, and cold and flu. ClearUP® underwent two clinical studies demonstrating the safety and efficacy of the medical device in treating sinus pain and congestion. The trials demonstrated an efficacious drug-free alternative with no major side effects. Greater than 95% of the users reported that the device was easy to use, and 82% preferred ClearUP® over existing treatments.
- Large Addressable Market** - Tivic's product targets a large and lucrative addressable market. Tivic estimates that the total available market for ClearUP® is over 200 million U.S. adults. While other potential indications include migraine (39 million cases in the U.S.), temporomandibular joint disorder (31 million cases in the U.S.), and tinnitus (50 million cases in the U.S.). This represents a multi-billion-dollar opportunity for Tivic in the U.S. alone. Additionally, the company has also received a CE mark for ClearUP®, allowing it to market the device in European and numerous other countries.
- Valuation** - We have valued the company using DCF as our preferred methodology. Our investment thesis assumes increasing adoption of bioelectronics, a large addressable market, increasing market share of ClearUP®, and the upside potential of the company's platform technology. We have valued the company at \$41.52 million, or \$4.22 per share, contingent on successful execution by the company.

## Company Description

Tivic Health Systems Inc. is a commercial-phase health technology company that develops and commercializes bioelectronic medicine. The company's first commercial product, ClearUP® Sinus Relief, is a medical device intended to relieve sinus and nasal inflammation.

## Company Overview

Tivic Health Systems, Inc. (NASDAQ: TIVC) is a consumer health technology company focused on the emerging field of bioelectronic medicine. By combining proprietary algorithms, programmable stimulation parameters, and a patented monopolar delivery mechanism, the company has created a platform technology that utilizes a stimulation approach, allowing it to treat various clinical conditions. Tivic's first product based on its core technology is ClearUP<sup>®</sup>, a non-invasive, drug-free approach to treating sinus pain and congestion. The ClearUP<sup>®</sup> has successfully undergone two clinical studies, a randomized, placebo-controlled, double-blinded clinical trial and an open-label prospective trial receiving necessary U.S. FDA clearances allowing it to market the device across multiple sales platforms. Targeting a multi-billion-dollar market, Tivic has access to multiple sales channels, including its own website, Amazon.com, Walmart.com, BestBuy.com, FSASore.com, and other specialty online retailers.

Tivic has two other indications in the pipeline that involve regulating pain and inflammation-related mediators; npdPP (post-operative pain after functional endoscopic sinus surgery) and npdMI (Migraine) are currently in the early stages of research and development and will be undergoing multiple clinical studies. Beyond the three indications currently in the pipeline, Tivic has plans to explore other potential use cases, including inflammatory conditions associated with peripheral nerve activity of the face. This has been made possible due to the initial success of its platform technology observed in clinical results and FDA clearance of ClearUP<sup>®</sup>. The company was incorporated in 2016 and listed publicly in 2021, raising \$17.25 million (before deducting underwriting discounts and offering expenses).

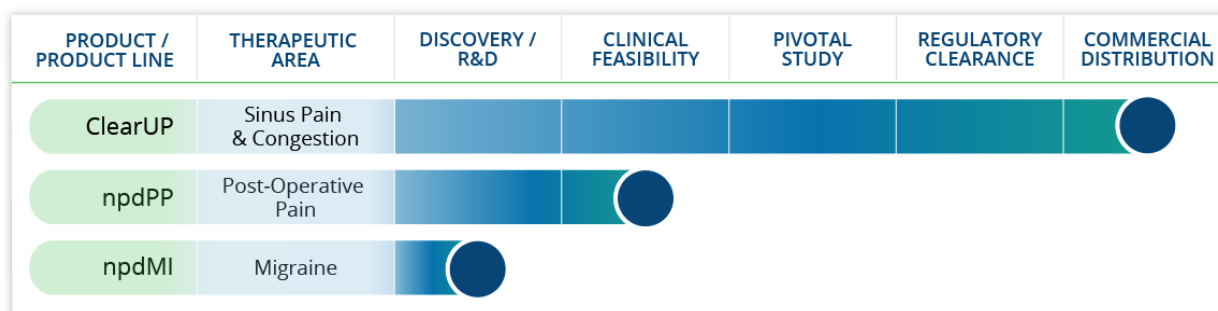


Exhibit 1: Product Pipeline Source: Tivic Health Systems Website

## Bioelectronic Medicine - A Promising Alternative to Drug-based Intervention

There are various themes that dominate today's medical research market, including gene and cell therapy, gene slicing, and immuno-oncology, but there is an under-recognized approach that utilizes human's innate electrical systems to treat various conditions, also known as "Bioelectronic Medicine". It uses targeted electric signals to modulate neural circuits to diagnose and treat diseases. The Bioelectronic medicine market is expected to grow at a compound annual growth rate (CAGR) of 7.9%, reaching a size of \$36.79 billion by 2026.<sup>1</sup> The application of this

<sup>1</sup> <https://www.globenewswire.com/news-release/2021/06/07/2242724/0/en/Global-Bioelectric-Medicine-Market-Share-Estimated-to-Reach-USD-36-Billion-by-2026-Facts-Factors.html>

technology includes the use of pacemakers for abnormal heart rhythms, spinal cord stimulation, deep brain stimulation, and applications in the peripheral nervous system (PNS), including vagus nerve stimulation, sacral nerve stimulation, and others. Aside from cardiac rhythm management and central nervous system (CNS) applications, implantable bioelectronic devices are currently being tested for inflammatory diseases such as rheumatoid arthritis and Crohn’s disease.

Bioelectronic medicine holds compelling advantages over traditional drug-based interventions. Better diagnosis and prevention, precision targeting, tailored to the individual, real-time, continuous, and optimized, are a few factors that support the case for the field’s growth potential. Hundreds of clinical trials are now underway to investigate how harnessing the body’s peripheral wiring might help broadly in the treatment of acute and chronic diseases.<sup>2</sup> The market is highly fragmented, with many new players with innovative technology, while the legacy players include Medtronic (NYSE: MDT), Boston Scientific Corporation (NYSE: BSX), Cochlear Ltd. (ASX: COH), Sonova (SWX: SOON), and LivaNova PLC (NASDAQ: LIVN).

*Bioelectronics is an emerging branch of medicine that combines the application of both biology and electronics, creating new approaches to treat various chronic and acute conditions*

## Innovating Through the Platform Model

Tivic’s medical device pipeline is dependent on the differentiated technology that allows it to create non-invasive solutions for different acute and chronic conditions. Tivic’s technology combines proprietary algorithms, programmable stimulation parameters, and a patented monopolar delivery mechanism to modulate the nerve signals that control inflammation-driven symptoms like pain and congestion.<sup>3</sup>

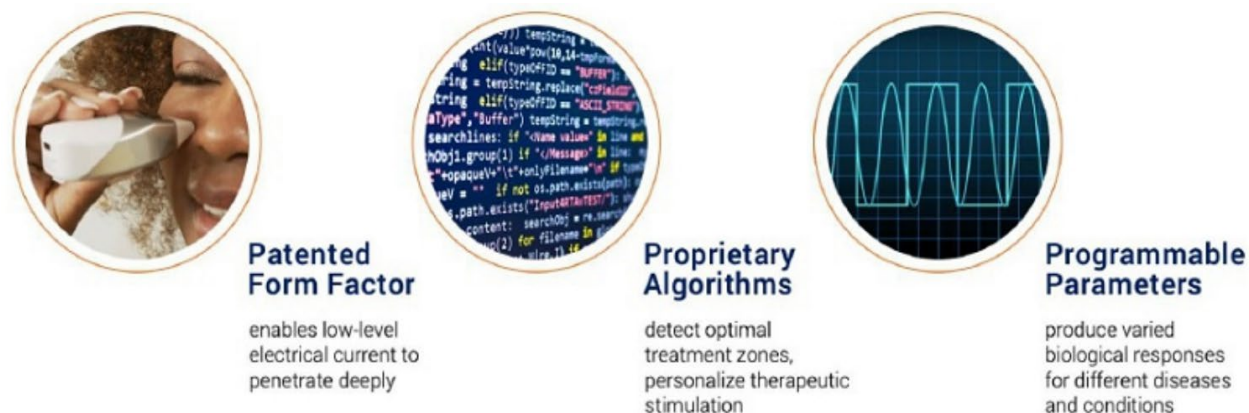


Exhibit 2: Core Technology. Source: Tivic Health S1 Filings

This combination creates a platform that non-invasively influences peripheral nerve activity with a low current level. Creating a platform technology allows the company to scale and explore multiple use cases in addition to those mentioned in the pipeline, reducing research development time and cost. The non-invasive designation and regulatory pathway are also much shorter and offer a higher probability of approval than invasive devices.

<sup>2</sup> <https://www.pnas.org/doi/10.1073/pnas.1919040116>

<sup>3</sup> <https://dd7pmep5szm19.cloudfront.net/2635/0001104659-21-131885.pdf>

## ClearUP® - Sinus Pain and Congestion

Tivic's first FDA-cleared commercial product ClearUP® sinus relief treats sinus pain and congestion non-invasively. The handheld device uses gentle pulsed electron waves to alleviate the symptoms caused due to sinus and nasal inflammation. A U.S. FDA class II and EU class IIa medical device, ClearUP® has obtained necessary regulatory clearances and is available without a prescription. Tivic has created a superior home remedy and a successful alternative to side-effects-causing drugs generally used to treat nasal allergies, sinus infections, chronic sinusitis, cold, and flu. The device classified as Transcutaneous Electrical Nerve Stimulator ("TENS") by U.S. FDA emits a low-level current in the form of pulsed AC stimulation that activates trigeminal and sympathetic nerves relieving pain and congestion.

The technology is protected by a portfolio of patents (5 issued and 18 pending, approximately 100 claims) across the U.S., Europe, China, India, and Australia covering key technical features, including treatment point detection, monopolar circuit, proprietary waveform delivery, and ergonomic design.

*ClearUP® sinus relief is the first device globally that has been cleared under De Novo classification intended to treat sinus pain and congestion*



Exhibit 3: ClearUP® Sinus Relief. Source: Tivic Health Website

### Multiple Clinical Trials Supporting Efficacy and Safety

Tivic conducted a pivotal study and an open-label prospective trial examining the safety and efficacy of the medical device in treating sinus pain from allergic rhinitis and moderate to severe congestion.

**Pivotal Study** – A randomized placebo-controlled double-blinded clinical trial concluded in 2018 at Stanford university sinus center included 71 subjects suffering facial pain attributed to sinus pain and congestions. The subjects were treated with ClearUP® (n=38) or a placebo (n=33) microcurrent emitter for a single five-minute treatment. A visual analogue scale (VAS) for pain severity was administered before and 10 minutes after treatment.<sup>4</sup>

<sup>4</sup> <https://tivichealth.com/wp-content/uploads/2019/05/maul-et-al-2019-international-forum-of-allergy-rhinology-journal-publication.pdf>

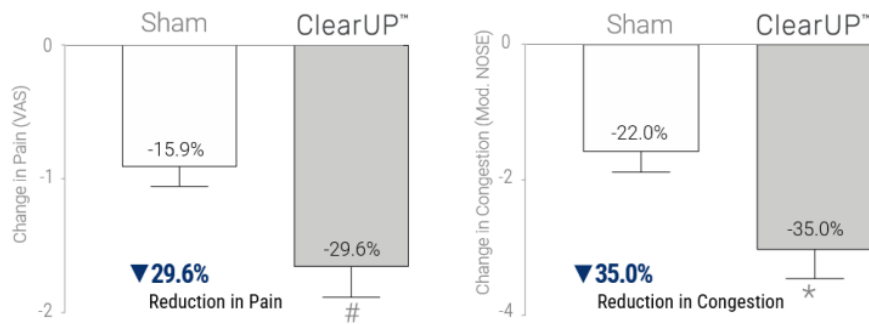


Exhibit 4: Clinical Results. Source: Tivic Health Investor Presentation

Subjects treated with ClearUP<sup>®</sup> sinus relief reported a reduction of mean pain score from 5.63 to 3.97 post-treatment. While patients treated with the sham device or placebo microcurrent emitter reported a mean score of pain reduction of 0.91 compared to 1.61 observed in ClearUP<sup>®</sup>. Notably, 23.7% of patients using the active device had a reduction of 3 or more points by VAS compared to 0% of sham device patients. Aside from one minor development of transient reddening of the area stimulated, no major complications were reported. The trial demonstrated that ClearUP<sup>®</sup> was found to be effective for 74% of users with no major safety complications. Treatment with ClearUP<sup>®</sup> resulted in a rapid and meaningful reduction in sinus pain and congestion.

**Open-label Prospective Trial** – In another clinical study, conducted by Allergy and Asthma Associates of Santa Clara Valley Research Center in San Jose, CA, 30 subjects, which included 21 females and 9 males, were enrolled in a single-arm, prospective interventional study. Subjects with moderate facial pain attributed to sinonasal disease were instructed to self-administer the device for five minutes a day during the study visit and treat themselves at home one to four times daily for four weeks. Pain level was measured weekly during the four weeks study period.

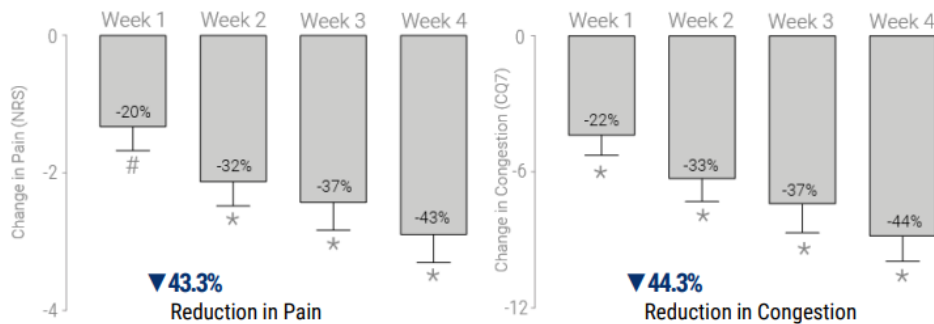


Exhibit 5: Clinical Results. Source: Tivic Health Investor Presentation

The prospective trial demonstrated a successful reduction in both pain and congestion after a week or over a week of self-administration of ClearUP<sup>®</sup>. Self-administered periorbital microcurrent treatment given at home was efficacious in significantly reducing moderate sinus pain for up to six hours and significantly reducing moderate pain and congestion over four weeks of daily use. The device was found effective for 88% of the users after four weeks of administration and was found to be safe with minor side effects that resolved without intervention.

## Sales & Marketing Strategy

Tivic uses a targeted and direct-to-consumer (DTC) approach to market its over-the-counter medical device. ClearUP<sup>®</sup>, launched in late 2019, is sold at a list price of \$149 and is available at Tier 1 online retail stores, including Amazon, Walmart, BestBuy, FSASore, and other specialty online retailers. Tivic creates awareness regarding ClearUP<sup>®</sup> and bioelectronic medicine through cable, social media, and content marketing, driving sales online and through its own website. Tivic has created an efficacious drug-free treatment for sinus pain and congestion that is portable and easy to use. The company has sold over 30,000 units since its launch. We believe Tivic's current marketing strategy is likely to exhibit a compounding effect as patients get more aware of the company's technology and bioelectric medicine as a whole. Tivic's road map to grow its sales also includes leveraging healthcare professionals' referrals, in-store sales, and expansion in international markets.

## Upgrading the Offering

Tivic is currently developing future versions of ClearUP<sup>®</sup>. The upgraded versions are expected to further enhance user experience and lower the cost of sales by decreasing the cost of manufacturing, fulfilment, and shipping cost. The near-term upgrades are expected to be covered by the same set of regulatory clearances as ClearUP<sup>®</sup>.

## Market Opportunity

The sinus pain and allergies market is a multi-billion-dollar market accounting for various chronic and acute diseases. The two most common sinus conditions include sinusitis and allergic rhinitis, commonly known as hay fever which together account for more than 50 million adult cases in the United States. According to Mintel Group Ltd., over-the-counter allergy, cough, cold, and flu treatments were a \$9.9 billion market in 2019 in the U.S. alone.<sup>5</sup> Tivic cites its target market is 200 million adult cases per year in the U.S. In addition, Tivic has recently obtained the CE mark which allows it to market the device in Europe, China, India, and Australia.

*The market for sinus pain and congestion is fragmented with many players marketing their products that includes drug-based alternatives*

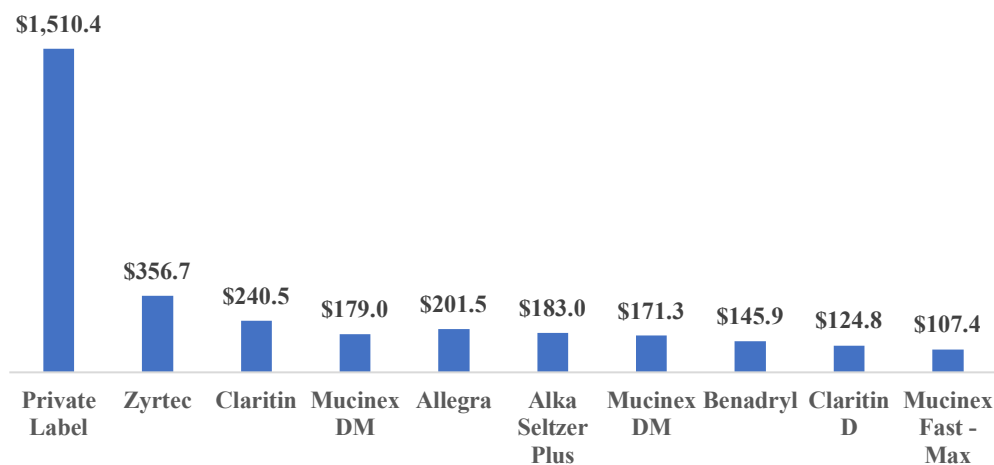


Exhibit 6: Sales of Leading Allergy/Cold/Sinus medications in the U.S. in 2019 (\$mm). Source: [Statista](#)

<sup>5</sup> <https://dd7pmep5szm19.cloudfront.net/2635/0001104659-22-041068.pdf>

Tivic commissioned a survey to understand whether the target population is willing to shift to a drug-free alternative. A national sampling company surveyed 600 individuals reporting ongoing sinus conditions. The research indicated that 90% of sufferers were interested in alternative treatments that decrease the use of side-effects causing drugs, while 43% reported being concerned about drug addiction. Even though the company is targeting a high total addressable market, the key to gaining market share in a fragmented market with established brand names is to create awareness about the device and bioelectronic medicine.

## Post-operative Pain After Sinus Surgery

Tivic's second product candidate is still in the early stages of research & development. npdPP is an at-home use device for treating postoperative pain after sinus surgery. The company recently concluded a pilot study, establishing clinical feasibility and evaluating a new device to treat pain after functional endoscopic sinus surgery (FESS). The study was conducted with the U.S. Institute for Advanced Sinus Care and Research (Cleveland, OH) and included ten patients.

The study was successfully completed by nine out of ten individuals who reported a decrease in the numeric rating scale for pain and opioid medication intake. While it was not designed to establish conclusive and statistically significant results, early trends indicated a positive outlook for the device currently undergoing a controlled clinical study.

*Tivic aims at creating a non-invasive and drug free alternative for postoperative pain management following sinus surgery*

This controlled study aims at investigating whether daily use of a microcurrent neuromodulation device, which applies a small current of electricity to the forehead and maxillary region, will decrease the pain experienced by patients in the days following functional endoscopic sinus surgery (FESS).<sup>6</sup> The clinical study is currently in the recruitment phase, with an estimated enrolment of 60 trial participants. The trial is being performed in collaboration with Icahn School of Medicine at Mt. Sinai and is expected to get completed in Q4 2022.

### Market Opportunity

Functional endoscopic sinus surgery is one of the most common sinonasal surgery performed by Otolaryngologists, with 600,000 surgeries annually in the U.S.<sup>7</sup> Hydrocodone combination analgesic products are commonly prescribed after FESS but, unfortunately, were involved in almost 100,000 abuse-related emergency department visits in the United States in 2011.<sup>8</sup> While healthcare professionals and patients have been looking for alternatives to narcotics, they have become routine prescriptions in the course of postoperative pain management leading to potential abuse.

A study conducted to assess narcotic use in managing post-op pain after functional endoscopic sinus surgery reported that a series of 364 patients found that excess narcotics were prescribed 84.9% of the time.<sup>9</sup> Among patients, 11.8% reported using no narcotics, 52.1% used less than 50%, and 36.1% used more than 50% of their narcotic prescription. There has been a continuous need for a drug-free alternative for postoperative pain management, making the underlying market

<sup>6</sup> <https://clinicaltrials.gov/ct2/show/NCT05198518>

<sup>7</sup> <https://dd7pmep5szm19.cloudfront.net/2635/0001104659-22-041068.pdf>

<sup>8</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7883617/#lio2519-bib-0001>

<sup>9</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7883617/#lio2519-bib-0001>



lucrative for Tivic. As the company creates awareness and establishes a brand name and distribution channel through ClearUP<sup>®</sup>, Tivic will subsequently be able to leverage it for its future potential FDA approved products.

## Migraine

An at-home use device for treating migraine headaches is currently in the discovery phase. The company has analysed the post-market data from the use of ClearUP<sup>®</sup>, indicating relief from migraine headaches. The initial data would allow the management to understand and decide upon the clinical and regulatory pathway, given that the new product will be based on the monopolar platform. The company has completed a study of the market for migraine and in the process of developing a validated commercial pathway.

### Market Opportunity

Migraine is a disabling neurological disease characterized by recurrent episodes of headaches and, in some cases, associated with visual or sensory symptoms. The American Migraine Foundation estimates that at least 39 million Americans live with migraine, but because many people do not get a diagnosis or the treatment they need, the actual number is believed to be even higher.<sup>10</sup>

Headache is consistently the fourth most common reason for visits to the emergency department, accounting for roughly 3% of all emergency department visits annually.<sup>11</sup> The acute treatment for migraine includes the use of over-the-counter prescription medications, pain relievers, and nerve stimulation medical devices.

Company	Medical Device	Treatment Methodology	Status	Cost
Cefaly Technology	Cefaly	External Trigeminal Nerve Stimulation (e-TNS)	FDA approved	<a href="#">\$389</a>
Neuro Relief Inc.	Relivion MG	External Trigeminal Nerve Stimulation (e-TNS)	FDA approved	-
electroCore, Inc.	GammaCore Sapphire	Vagus Nerve Stimulation	FDA approved	<a href="#">\$450</a>
Salvia Bioelectronics	-	Implantable Occipital Nerve Stimulation	Under Development	-
Theranica Bio-Electronics Ltd.	Nerivio	Remote Electrical Neuromodulation	FDA approved	<a href="#">\$599</a>

Exhibit 7: Nerve Stimulation Devices for Migraine Treatment Source: Diamond Equity Research

<sup>10</sup> <https://americanmigrainefoundation.org/resource-library/what-is-migraine/>

<sup>11</sup> <https://headachejournal.onlinelibrary.wiley.com/doi/abs/10.1111/head.13281>

## An Extensible Platform Allowing Other Potential Use Cases

Tivic's core technology platform is extensible to other clinical areas, thereby reducing times and cost of device development. The value of the platform reflects the additive value of multiple potential approvals. The initial success of the platform technology observed with the development of ClearUP<sup>®</sup> increases the probability of success for other indications within the pipeline. Aside from the two indications (npdPP and npdMI), currently being researched, the company is expected to add to its product pipeline other indications that are associated with trigeminal and peripheral nerve activity of the face via internal development or acquisition. The development period of these product candidates are expected to be shorter than the normal 7 to 10 years due to their high safety profile.

**Temporomandibular Joint Disorders (TMD)** - These disorders are a group of musculoskeletal and neuromuscular conditions that arise due to dysfunction of the temporomandibular joint (a small joint located where the skull and lower jaw meet). Over 30 million Americans have TMJ, which ranges from mild discomfort to severe, intractable pain – and from mild jaw dysfunction to needing a feeding tube for nutritional sustenance.<sup>12</sup>

The most effective pharmacological agents used to treat TMD include nonsteroidal anti-inflammatory drugs (NSAIDs), opioids, corticosteroids, anxiolytics, muscle relaxants, antidepressants, and anticonvulsants.<sup>13</sup>

**Tinnitus** - An audiological and neurological disorder in which a person experiences a ringing or buzzing sound in one or both ears. It can be both an acute and chronic condition. The U.S. Centers for Disease Control estimates that nearly 15% of the general public, over 50 million Americans, experience some form of tinnitus.<sup>14</sup> Roughly 20 million people struggle with burdensome chronic tinnitus, while 2 million have extreme and debilitating cases.

The economic impact of tinnitus is severe, which includes lost earnings, productivity, and health expenses amounting to \$30,000 per year, while the cost to society is measured at upwards of \$26 billion. While there is no cure for tinnitus, the condition is managed through the use of medications, hearing aids, and masking devices. Neuromodulation using bioelectronic devices has also gained attention, with 85% of tinnitus patients experiencing resolution of their symptoms when using a neuromodulation device.<sup>15</sup>

**Trigeminal Neuralgia** - A chronic pain condition that involves stabbing, shock-like intense painful episodes on one particular side of the face. This is caused due to irritation in the trigeminal nerve that carries sensation from the face to the brain. This is a rare disease, with 10,000-15,000 cases reported in the U.S. annually.<sup>16</sup>

*The company's platform technology allows it to develop and commercialize other indications typically resulting in shorter approval time thus accelerating new product*

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<sup>12</sup> <https://tmj.org/>

<sup>13</sup> <https://www.frontiersin.org/articles/10.3389/fphar.2020.596099/full>

<sup>14</sup> <https://www.ata.org/understanding-facts>

<sup>15</sup> <https://www.bioworld.com/articles/516307-the-beat-goes-on-bioelectronics-reduce-heart-failure-symptoms-afib-risk-and-tinnitus?v=preview>

<sup>16</sup> <https://rarediseases.org/rare-diseases/trigeminal-neuralgia/#:~:text=Trigeminal%20neuralgia%20affects%20females%20slightly,in%20younger%20adults%20as%20well>

The treatment options for Trigeminal Neuralgia include the use of medication and surgery depending upon the type of pain defined. Medications generally include the use of the anticonvulsant drugs, of which the most commonly prescribed for trigeminal neuralgia is carbamazepine (Tegretol™).<sup>17</sup> While medication has shown to alleviate the pain, in a few cases, this was accomplished with a higher dosage leading to pronounced side effects that include dizziness, unsteadiness, nausea, and drowsiness. Emerging treatments like the use of peripheral nerve field stimulation (PNFS) are also currently being explored and researched for the treatment of intractable facial pain.

**Acute Otitis Media (AOM)** - A painful type of ear infection diagnosed in patients with evidence of middle ear inflammation and infection. This condition is commonly found in children, with 70% of all children in the United States experiencing one or more attacks of AOM before their second birthday.<sup>18</sup> The peak incidence of AOM is in children aged 3 - 18 months. Antibiotics are the preferred treatment for which high-dose of amoxicillin is the antibiotic of choice for treating acute otitis media. In most AOM cases, if the disease is mild, with low-grade fever responding to antipyretics, watchful waiting is advised before administration of antibiotics.

## Competitive Landscape

The current treatment for sinonasal diseases is currently dominated by over-the-counter drugs. Analgesic medications (ibuprofen, Tylenol, naproxen sodium/Aleve) are usually used to manage sinus pain and pressure. On the other hand, congestion is treated with a variety of drugs, including antihistamine medications, oral decongestants, intranasal decongestants, and intranasal glucocorticoids.

The use of these drugs accompanies severe side effects affecting the lifestyle and long-term health of the individual.

<p><b>Intranasal Steroids</b></p> <ul style="list-style-type: none"> <li>• Powerful drug</li> <li>• Burning, stinging, nose bleeds, headache, nausea, vomiting, diarrhea, sore throat, dizziness, cough</li> </ul> 	<p><b>Oral &amp; Intranasal Decongestants</b></p> <ul style="list-style-type: none"> <li>• Insomnia, nervousness, heart palpitations, headache, sweating, nausea, trembling, weakness, rebound</li> </ul> 	<p><b>Antihistamines</b></p> <ul style="list-style-type: none"> <li>• Treat itchiness</li> <li>• Not effective for congestion and pain</li> <li>• Headache, sleepiness, fatigue, dry mouth, and sore throat</li> </ul> 	<p><b>Saline Irrigation</b></p> <ul style="list-style-type: none"> <li>• Messy / impractical</li> <li>• Not portable</li> <li>• \$706M US market</li> </ul> 
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Exhibit 8: OTC Drugs and Their Side-effects. Source: Tivic Health Investor Presentation

<sup>17</sup> <https://www.ucsfhealth.org/conditions/trigeminal-neuralgia/treatment>

<sup>18</sup> <https://www.medscape.com/answers/859316-30596/what-is-the-incidence-and-prevalence-of-acute-otitis-media-aom-in-the-us>

This has created a need for non-pharmaceutical treatments that are effective and safe. Nasal irrigation devices and the use of bioelectronic devices are getting recognized as potential treatments for sinus pain and congestion arising out of various sinonasal conditions. Companies like NeilMed, Rhinosystems Inc., and Vapore LLC have developed nasal irrigation products treating sinus pain and congestion. These products range from \$10 to over \$100 with multiple-use devices and represent the closest competitors to Tivic's ClearUP®.

Bioelectronics is currently on the rise and is being researched for various inflammatory diseases. Neurent Medical is one such company that recently received U.S. FDA clearance for a novel multi-point nerve disruption treatment for chronic rhinitis. The NEUROMARK™ technology uses controlled low-power radio frequency (RF), disrupting the parasympathetic nerve signals and halting the inflammatory response, thus eliminating symptoms such as congestion and rhinorrhea. Neurent Medical's treatment is an in-office procedure (while Tivic's treatment is an at-home procedure), that requires educating healthcare professionals about the mechanisms related to parasympathetic and sympathetic activity. Neurent Medical aims to create innovative treatments for chronic inflammatory sinonasal diseases.

Aside from these treatments, balloon catheter dilation surgery or balloon sinuplasty is being used to treat patients with chronic sinus conditions and has recorded a success rate of 95% with minimal complications.<sup>19</sup> Even though it is a minimally non-invasive procedure that provides a long-term and permanent solution, it carries the same risks that other types of sinus surgery do. The procedure is generally recommended to patients after other treatments for their condition are found to be ineffective.

ClearUp®'s primary competitors include companies developing non-pharmaceutical treatment solutions for sinus pain and congestion. ClearUP® is effective, safe, and highly convenient compared to nasal irrigation (such as Neti-Pot) and other devices on the market. With an effective marketing and branding strategy, ClearUP® is seeking to gain increased market share in the growing U.S. sinonasal treatment market.

*Tivic's platform technology, reduces the company's dependence on ClearUP® allowing it to develop devices for various other indications thus providing diversification for investors*

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<sup>19</sup> <https://www.sinusofsf.com/balloon-sinuplasty/balloon-sinuplasty-success-rate/>

## Management Overview

Tivic is led by an experienced team with deep expertise and extensive experience in consumer healthcare, life sciences technology, and related fields. The management strives to innovate and create non-invasive, drug-free solutions to treat diseases and better lives, while generating value for shareholders.

- **Jennifer Ernst, Chief Executive Officer, and Co-Founder**

Jennifer Ernst holds the role of Chief executive officer (CEO) and serves as Director. Ms. Ernst has held key positions in various technology companies while developing markets with new technologies. She has previously served as the CEO and Chief Strategy Officer of the U.S. subsidiary of Thin Film Electronics ASA. Additionally, working for Xerox PARC for over twenty years, she held multiple roles, including as the director of business development while positioning research for productization and marketing award-winning products. Ms. Ernst earned her Bachelor of Arts Degree from San Francisco State University and Masters of Business Administration (MBA) from Santa Clara University, California.

- **Veronica Cai, Chief Financial Officer**

Veronica Cai assumed the Chief Financial Officer (CFO) role effective April 1, 2022. Ms. Cai brings over twenty-five years of financial and accounting experience in the medical technology and life science industries. Working in both publicly listed and private-equity-backed companies, she has assisted in navigating business from the early development stage to post commercial and fundraising efforts. Before joining Tivic, Ms. Cai served as the Vice President of Accounting & Finance at RefleXion Medical, the Principal Accounting Officer and Corporate Controller at Catalyst Biosciences, the Assistant Controller at Zogenix, an Inspections Specialist at the Public Company Accounting Board (PCAOB), and a Senior Manager at Ernst & Young. She graduated from San Francisco State University by earning a Bachelor of Science in Business Administration, Accounting, and Finance.

- **Blake Gurfein, Ph.D., Chief Scientific Officer**

An expert in neuromodulation device development, Mr. Gurfein leads the scientific and research division at Tivic. He also serves as an adjunct assistant professor of medicine at UCSF. His previous work includes as a research executive and consultant for medical device and pharma companies, including Rio Grande Neurosciences and EMD Serono/Pfizer. He earned his Ph.D. in neuroscience from the Icahn School of Medicine at Mount Sinai and an Sc.B. degree in neuroscience from Brown University.

- **Ryan Sabia, Chief Operating Officer**

With more than eighteen years of experience in global supply chain and sales operation across consumer electronics, automotive, and medical supply, Mr. Sabia currently

assumes the role of COO of Tivic Health Systems Inc. His previous roles include Global Director of Strategic Operations for Mars, Inc., General Manager of Operations for Medelita, LLC, a medical apparel and manufacturing company, Senior Director of Operations for Pinpoint Resources Group, a software technology consulting company, and as a Hedge Fund Financial Reporting Analyst for J.P. Morgan. Mr. Sabia earned a Bachelor of Science in Finance from Suffolk University Sawyer Business School.

## Financial Performance Overview

**Robust Revenue Growth** - Tivic has recorded robust revenue growth since its launch in late 2019. The company managed to grow its revenue at 105% in 2020 (majorly attributable to the lower base effect) and 36% in 2021. In Q1 2022, Tivic reported revenue of \$428,000, a y-o-y growth of 32.5%. The DTC share in total revenue increased from 67.8% in Q1 2021 to 84.8% in Q1 2022. This has been made possible with increased spending on marketing and brand awareness while broadening the advertisement mix. Given the high and growing TAM with a need for non-drug-based alternatives and an optimized marketing mix, we believe the company will be able to increase its market share, aiding its growth runway. We model the company to cross the \$10 million revenue mark by 2025.

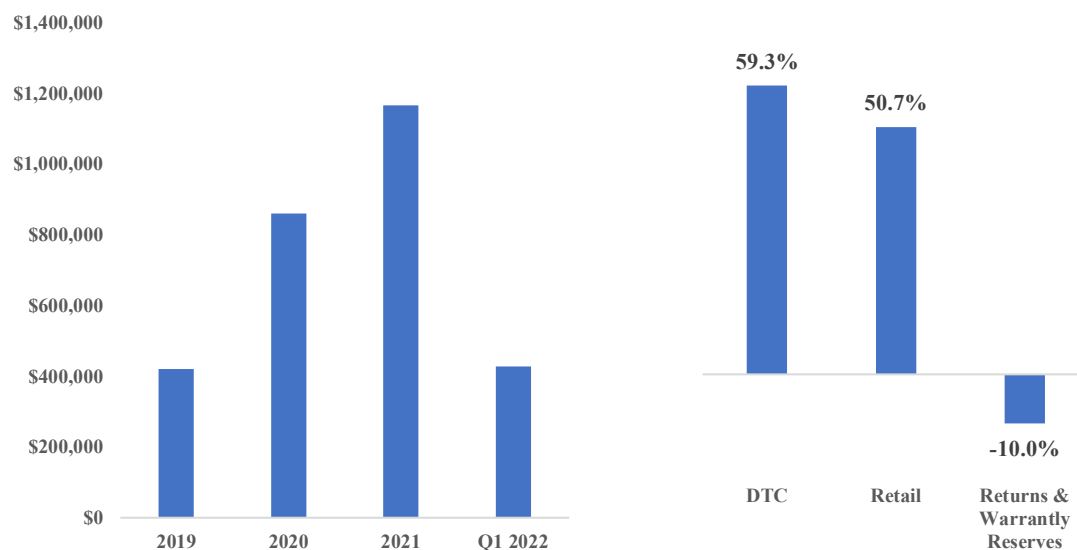


Exhibit 9: Revenue and Revenue Breakdown (2021). Source: Company Filings, Diamond Equity Research

**Improving Margin Profile** - Tivic generates 50.7% of its revenue through retail channels, which has inherently lower gross margins compared to DTC sales. The gross margins have drastically improved from (68.8%) in 2019 to (11.1%) in 2021. Additionally, Tivic reported gross margins at 16.4% in Q1 2022 compared to 6.8% in Q1 2021. This has majorly been achieved with the refinement of the production management process and the incremental benefit of operating leverage. The company is currently developing upgraded versions of ClearUP<sup>®</sup>, which according to the management, will enhance user experience and lower manufacturing, fulfilment, and shipping cost providing a boost to gross margins.

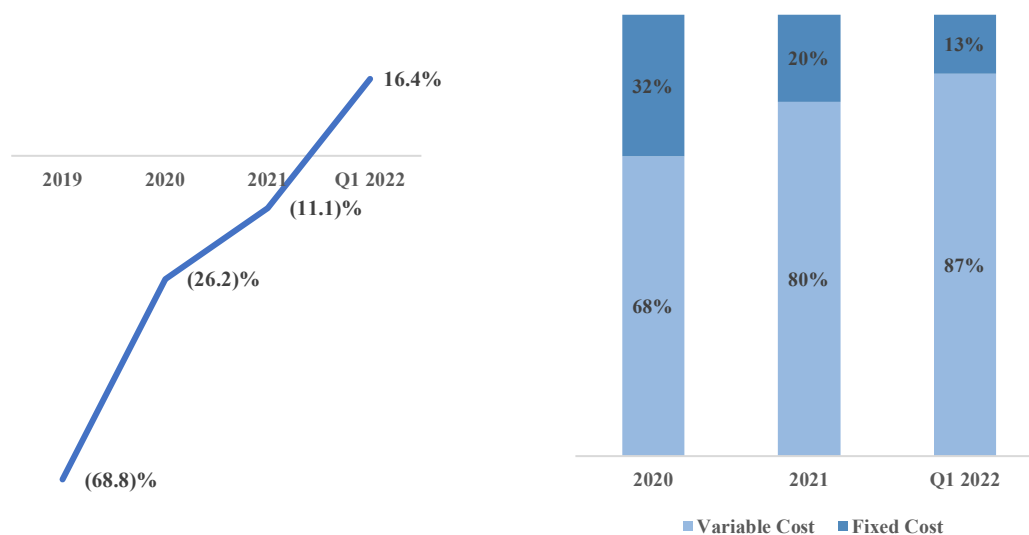


Exhibit 10: Gross Margins (left) and Direct Cost Break-up (right) Source: Company filings, Diamond Equity Research

**Strong Financial Position** - Tivic reported a cash balance of \$10.80 million and zero debt as of March 2022. The company is currently in a comfortable financial position. Based on our estimates for cash burn rate (\$8.83 million and \$8.50 million for 2022 and 2023, respectively), the current cash position would support the company's operations for the next 4-6 quarters. We expect further cash raise and potential dilution, by the end of Q2 2023. We believe the incremental revenue from ClearUP<sup>®</sup> will likely offset the increasing R&D and marketing spending, restricting the cash burn to \$7 - \$9 million.

Year-end 31 December	2020	2021	2022e	2023e	2024e
<b>INCOME STATEMENT</b>					
Revenue	\$860	\$1,166	\$1,984	\$3,663	\$5,793
Gross Profit	(\$225)	(\$129)	\$397	\$2,015	\$3,766
EBITDA	(\$3,196)	(\$5,608)	(\$9,423)	(\$8,791)	(\$7,821)
Depreciation & Amortization	(\$8)	(\$24)	(\$29)	(\$43)	(\$74)
Profit Before Tax (PBT)	(\$3,639)	(\$6,857)	(\$9,452)	(\$8,834)	(\$7,895)
Profit After Tax (PAT)	(\$3,639)	(\$8,494)	(\$9,452)	(\$8,834)	(\$7,895)
Basic Shares Outstanding	2,303,237	3,493,267	9,621,484	9,621,484	9,621,484
EPS - basic	(\$1.58)	(\$2.43)	(\$0.98)	(\$0.92)	(\$0.82)
EPS - diluted	(\$1.58)	(\$2.43)	(\$0.96)	(\$0.90)	(\$0.80)
<b>BALANCE SHEET</b>					
Cash and cash equivalents	\$1,044	\$12,975	\$4,099	\$10,517	\$3,000
Other current assets	\$453	\$1,314	\$1,245	\$1,374	\$1,593
Total current assets	\$1,497	\$14,289	\$5,344	\$11,891	\$4,593
Non-current assets	\$34	\$747	\$758	\$788	\$888
<b>Total Assets</b>	<b>\$1,531</b>	<b>\$15,036</b>	<b>\$6,102</b>	<b>\$12,679</b>	<b>\$5,481</b>
Short-term borrowing	\$36	\$0	\$0	\$0	\$0
Other current liabilities	\$1,239	\$1,219	\$1,231	\$1,112	\$1,258
Total current liabilities	\$1,275	\$1,219	\$1,231	\$1,112	\$1,258
Long-term borrowing	\$1,433	\$0	\$0	\$0	\$0
Other non-current liabilities	\$0	\$545	\$545	\$545	\$545
Total liabilities	\$2,708	\$1,764	\$1,776	\$1,657	\$1,803
Total Equity	(\$1,177)	\$13,272	\$4,326	\$11,023	\$3,678
<b>Total Liabilities &amp; Equity</b>	<b>\$1,531</b>	<b>\$15,036</b>	<b>\$6,102</b>	<b>\$12,679</b>	<b>\$5,481</b>

Values in thousands except no of shares and per-share value

## Valuation Outlook

We have valued Tivic Health Systems, Inc. using DCF as our preferred methodology. Our financial model incorporates the company's commercial product ClearUP<sup>®</sup> Sinus Relief and other devices currently under the research phase (npdPP and npdMI). Even though the company's pipeline provides a long-term growth trajectory, mergers and acquisitions might play a crucial role in the company's future growth strategies. Healthcare has been one of the most active sectors for mergers and acquisitions, with many healthcare companies acquiring innovative technologies and harvesting synergies. This allows the company to expand their pipeline, therapeutic focus and cater to geographical expansion needs.

Additionally, we have accounted for the additive value of the company's platform technology accounting for other potential use cases. We have assumed a 25% probability of success for the company's post-operative pain indication and migraine indication. Utilizing a discount rate of 12.49%, we have valued Tivic Health Systems Inc. at \$41.52 million or \$4.22 per share contingent on successful execution by the company.

Device	Indication	Probability of Success	Status	Commercialization Year
ClearUP Sinus Relief	Sinus Pain & Congestion	-	Commerical	2019
npdPP	Post operative sinus pain	25%	Clinical feasibility	2024e
npdMI	Migraine	25%	Discovery	2025e

	Approaches (in \$ mm)	Value (USD)	Weight	Wtd. Value (USD)
<b>Calculated Equity Value (\$mm)</b>	DCF	\$45.48	90%	\$40.93
Enterprise Value	\$34.68 GPCM	\$5.91	10%	\$0.59
- Debt and Preferrred Stock	\$0.00 GTM	-	0%	\$0.00
+ Cash	\$10.80			
		<b>Wtd Avg. Equity Value (USD)</b>		<b>\$41.52</b>
Net Debt	\$10.80	<b>No of Shares (Diluted)</b>		<b>9.83</b>
Equity Value	\$45.48	<b>Intrinsic Value Per Share</b>		<b>\$4.22</b>

Company Name	Ticker	Price	Currency	Exchange	Market Cap.	LTM P/S	LTM P/R&D
electroCore, Inc.	ECOR	0.40	USD	NASDAQ	28.53	4.64x	6.95x
Brainsway	BWAY	6.30	USD	NASDAQ	104.79	3.33x	20.97x
Heliuss Medical Technologies Inc.	HSDT	1.15	USD	NASDAQ	4.37	6.95x	1.51x
NeuroMetrix Inc.	NURO	4.06	USD	NASDAQ	28.44	3.39x	6.94x
Myomo Inc.	MYO	2.04	USD	NYSEAM	14.04	0.91x	7.55x
Viveve Medical Inc.	VIVE	0.72	USD	NASDAQ	7.66	1.16x	0.90x
NanoVibronix Inc.	NAOV	0.70	USD	NASDAQ	19.62	10.52x	66.07x
<b>Median</b>						<b>3.39x</b>	<b>6.95x</b>
<b>Mean</b>						<b>4.41x</b>	<b>15.84x</b>

Exhibit 11: Valuation Snapshot and Comparable Companies. Source: Diamond Equity Research



## Risk Factors

- **Supply Chain Disruption** - The company relies on third parties for manufacturing, marketing, and distribution. The company sources its electric components in China and packaging components from both China and North America. This exposes the company to numerous supply chain issues.
- **Capital Risk & Dilution of Equity** - Even though the company is generating revenue, the cash flow remains negative and is expected to stay negative for at least the next three years. This might require the company to raise money, either through debt or equity, leading to further dilution.
- **Short Operating History** - Tivic was incorporated in 2016 and launched its first product in 2019. Limited operating history makes the evaluation of the company's future prospects difficult. With the company's revenue and income-generating ability unproven, it may not be able to execute its business strategy.
- **Technology Obsolescence** - The Bioelectronic industry is still evolving, with new technologies being developed and researched. Approval of new and better technology with a greater cost-benefit trade-off could render the company's technology obsolete, negatively affecting its revenue-generating ability.
- **Regulatory Risks** - The company expects to market its product in multiple geographies with different regulatory requirements. The company's future clearances, might get affected due to changing regulatory policies, thus affecting the company's future revenue-generating ability.
- **Competitive Risks** – The company experiences competition from large, well-established, and well-financed companies in the market that can develop a more robust technology or create an effective drug-free alternative to the company's device.

*These risk factors are not comprehensive. For a full list of risk factors, please read Tivic Health System Inc.'s latest prospectus and/or annual SEC filings*

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