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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q

☒ Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the quarterly period ended March 31, 2023

OR

☐ Transmission Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the transition period from _____ to _____

Commission file number: 001-41052

Tivic Health Systems, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**81-4016391**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
25821 Industrial Blvd., Suite 100 Hayward, CA 94545	**(888) 276-6888**
(Address of principal executive offices including zip code)	(Registrant's telephone number, including area code)

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

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

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

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

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

☐ 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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of May 10, 2023,

29,677,734
shares of the registrant's common stock, par value $0.0001 per share, were issued and outstanding.

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PART I - FINANCIAL INFORMATION

PART II - OTHER INFORMATION

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

Our condensed financial statements included in this Quarterly Report on Form 10-Q are as follows:

This Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, should be read in conjunction with the Company's Annual Report on Form 10-K for the year ended December 31, 2022, filed with the Securities and Exchange Commission ("SEC") on March 31, 2023.

The accompanying condensed financial statements and footnotes have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information and the SEC instructions to Form 10-Q. In the opinion of management, all adjustments considered necessary for a fair presentation have been included. Operating results for the interim period ended March 31, 2023 are not necessarily indicative of the results that can be expected for the full year.

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Tivic Health Systems, Inc.
Condensed Balance Sheets (Unaudited)
March 31, 2023 and December 31, 2022
(in thousands, except share and per share data)

	March 31, 2023	December 31, 2022
ASSETS		
Current assets		
Cash and cash equivalents	$ 5,167	$ 3,517
Accounts receivable, net	57	88
Inventory, net	943	863
Deferred offering costs	21	584
Prepaid expenses and other current assets	294	235
Total current assets	6,482	5,287
Property and equipment, net	104	12
Right-of-use assets, operating lease	481	523
Other assets	34	34
Total assets	$ 7,101	$ 5,856
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 1,094	$ 1,323
Other accrued expenses	297	373
Operating lease liability, current	182	163
Total current liabilities	1,573	1,859
Operating lease liability	323	367
Total liabilities	1,896	2,226
Commitments and contingencies		
Stockholders' equity		

Preferred stock, $ 0.0001 par value, 10,000,000 shares authorized; no shares issued and outstanding at March 31, 2023 and December 31, 2022	—	—
Common stock, $ 0.0001 par value, 200,000,000 shares authorized; 29,677,734 and 9,677,734 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	3	1
Additional paid in capital	36,960	33,271
Accumulated deficit	(31,758)	(29,642)
Total stockholders' equity	5,205	3,630
Total liabilities and stockholders' equity	$ 7,101	$ 5,856

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

Tivic Health Systems, Inc.
Condensed Statements of Operations (Unaudited)
Three Months Ended March 31, 2023 and 2022
(in thousands, except share and per share data)

	Three Months Ended March 31,	
	2023	2022
Revenue	$ 376	$ 428
Cost of sales	263	358
Gross profit	113	70
Operating expenses:		
Research and development	490	401
Sales and marketing	458	684
General and administrative	1,281	1,226
Total operating expenses	2,229	2,311
Loss from operations	(2,116)	(2,241)
Other income:		
Interest income	—	1
Total other income	—	1
Net loss	$ (2,116)	$ (2,240)
Net loss per share - basic and diluted	$ (0.11)	$ (0.23)
Weighted-average number of shares - basic and diluted	20,122,178	9,715,234

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

Tivic Health Systems, Inc.
Condensed Statements of Stockholders' Equity (Unaudited)
Three Months Ended March 31, 2023 and 2022
(in thousands except share and per share data)

For the Three Months Ended March 31, 2022

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount			
Balances at January 1, 2022	—	$ —	9,715,234	$ 1	$ 32,817	$ (19,546)	$ 13,272
Stock-based compensation expense	—	—	—	—	61	—	61
Net loss	—	—	—	—	—	(2,240)	(2,240)
Balances at March 31, 2022	—	$ —	9,715,234	$ 1	$ 32,878	$ (21,786)	$ 11,093

For the Three Months Ended March 31, 2023

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount			
Balances at January 1, 2023	—	$ —	9,677,734	$ 1	$ 33,271	$ (29,642)	$ 3,630
Issuance of common stock, net of issuance costs			20,000,000	2	3,410	—	3,412
Issuance of warrants	—	—	—	—	195	—	195
Stock-based compensation expense	—	—	—	—	84	—	84
Net loss	—	—	—	—	—	(2,116)	(2,116)
Balances at March 31, 2023	—	$ —	29,677,734	$ 3	$ 36,960	$ (31,758)	$ 5,205

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

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Tivic Health Systems, Inc.
Condensed Statements of Cash Flows (Unaudited)
Three Months Ended March 31, 2023 and 2022
(in thousands)

	Three Months Ended March 31,	
	2023	2022
Cash flows from operating activities		
Net loss	$ (2,116)	$ (2,240)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock based compensation	84	61
Depreciation	2	2
Amortization of right-of-use asset	42	40
Accounts receivable allowances	—	5
Changes is operating assets and liabilities:		
Accounts receivable	31	(30)
Inventory	(80)	(18)
Prepaid expenses and other current assets	(59)	175
Accounts payable	(229)	(163)
Accrued expenses	(76)	36
Lease liabilities	(25)	(36)
Net cash used in operating activities	(2,426)	(2,168)
Cash flows from investing activities		
Acquisition of property and equipment	(94)	(6)
Net cash used in investing activities	(94)	(6)
Cash flows from financing activities		
Proceeds from issuance of common stock, net of issuance costs	4,191	—
Offering costs in advance of sale of common stock	(21)	—

Net cash provided by financing activities	4,170	—
Net increase (decrease) in cash and cash equivalents	1,650	(2,174)
Cash and cash equivalents		
Beginning of period	3,517	12,975
End of period	$ 5,167	$ 10,801
Supplemental disclosure on noncash financing activities		
Issuance of common stock warrant	$ 195	$ —
Deferred offering costs charged to additional paid-in-capital	$ 584	$ —

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

Tivic Health Systems, Inc.
Notes to Unaudited Condensed Financial Statements
(amounts are as indicated)

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. Tivic is a commercial-stage health tech company advancing the field of bioelectronic medicine. Tivic's patented technology platform leverages stimulation on the trigeminal, sympathetic, and vagus nerve structures. Tivic's non-invasive and targeted approach to the treatment of inflammatory chronic health conditions is intended to give consumers and providers drug-free therapeutic solutions with high safety profiles, low risk, and broad applications. Tivic's first commercial product, ClearUP, is an FDA approved, award-winning, handheld bioelectronic sinus device. ClearUP is clinically proven, doctor-recommended, and is available through online retailers and commercial distributors. The Company is headquartered in Hayward, California.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying condensed balance sheet as of December 31, 2022, which has been derived from audited financial statements, and the unaudited interim condensed financial statements as of March 31, 2023, and for the three months ended March 31, 2023 and March 31, 2022 have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP") for interim financial information. Certain information and note disclosures normally included in annual financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted pursuant to those rules and regulations. In the opinion of management, all accounting entries and adjustments (including normal, recurring adjustments) considered necessary for a fair presentation of the financial position and the results of operations for the interim periods have been made. Operating results for the three months ended March 31, 2023 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2023. Certain reclassifications have been made to the prior year's condensed statement of operations to conform to the current year presentation.

Going Concern Uncertainty

During the three months ended March 31, 2023 and 2022, the Company incurred a net loss of $

2.1
million and $

2.2
million, respectively. At March 31, 2023, the Company had an accumulated deficit of $

31.8
million. Cash and cash equivalents at March 31, 2023 were $

5.2
million. During the three months ended March 31, 2023 and 2022, the Company had negative cash flows from operations of $

2.4
million and $

2.2
million, respectively. Management expects to incur substantial additional operating losses for the foreseeable future in order to continue its research and development programs and potentially launch new commercial products or product extensions of ClearUP. Based on the Company's current cash levels and burn rate, amongst other things, the Company believes its cash and financial resources may be insufficient to meet the Company's anticipated needs for the twelve months following the date of issuance of these financial statements.

The accompanying unaudited interim condensed financial statements have been prepared as if the Company will continue as a going concern. As noted above, the Company has experienced losses and negative cash flows from operations. The Company's working capital as of March 31, 2023 was approximately $

4.9
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 equipment 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, 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.

Use of Estimates

The preparation of financial statements in conformity with 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.

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 March 31, 2023 and December 31, 2022, cash equivalents were $

5.0
million and $

3.1
million, respectively.

Accounts Receivable

Trade accounts receivable are recorded at the invoiced amount, net of allowances for credit losses and returns reserves. 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 March 31, 2023 and December 31, 2022, the allowance for credit losses balance was $

0

. Bad debt expense was not material in the three months ended March 31, 2023 and March 31, 2022. As of March 31, 2023 and December 31, 2022, the reserve for sales returns was $

15
thousand and $

19
thousand, respectively.

Inventory

Inventories are stated at the lower of cost or net realizable value, with cost determined on a first-in, first-out ("FIFO") basis. Inventories are reviewed periodically to identify slow-moving inventory based on anticipated sales activity. As of both March 31, 2023 and December 31, 2022, the reserve for obsolescence was $

0

.

Deferred Financing 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. If the Company consummates an equity offering, the deferred financing 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.

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, 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 revenue after the revenue criteria are met. As of each March 31, 2023 and December 31, 2022, the contract liability related to the Company's deferred revenues approximated $

2

thousand and is included in "Other Accrued Liabilities" on the accompanying balance sheets.

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.

The table below presents revenue by channel for the three months ended March 31, 2023 and 2022 (in thousands):

	Three Months Ended March 31,	
Product Revenue by Sales Channel	**2023**	**2022**
Product Revenue		
Direct-to-consumer	$ 303	$ 370
Reseller	98	106
Return Reserves	(25)	(48)
Revenue	$ 376	$ 428

Shipping and Handling

Shipping and handling fees paid by customers are recorded in revenue, with the related expenses recorded in cost of sales. Shipping and handling fees paid by customers in the three months ended March 31, 2023 and 2022 were $

0
and $

1
thousand, respectively.

Shipping costs for delivery of product to customers in the three months ended March 31, 2023 and 2022 were $

15
thousand and $

30
thousand, respectively.

Product Warranty

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

Sales and Marketing Expenses

Sales and marketing expenses are expensed as incurred and consist primarily of merchandising, customer service and targeted online marketing costs, such as display advertising, keyword search campaigns, search engine optimization and social media and offline marketing costs such as television,

radio and print advertising. Sales and marketing expenses also include payroll costs and stock-based

compensation expense for employees involved in marketing activities. Sales and marketing expenses are primarily related to growing and retaining the customer base.

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. Additionally, the Company incurs costs related to periodic design changes to existing products. Such costs are not considered research and development expenses and are capitalized and amortized over the newly designed product's estimated life.

Stock-Based Compensation

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

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

Determining the appropriate fair value model and related assumptions requires judgment, including estimating stock price volatility, expected dividend yield, expected term, risk-free rate of return, and the estimated fair value of the underlying common stock. Due to the lack of company-specific historical and implied volatility data, the Company has based its estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. The historical volatility is calculated based on a period of time commensurate with the expected term assumption. The group of representative companies have characteristics similar to the Company, including stage of product development and focus on the life science industry. The Company uses the simplified method, which is the average of the final vesting tranche date and the contractual term, to calculate the expected term for options granted to employees as it does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. The risk-free interest rate is based on a treasury instrument whose term is consistent with the expected term of the stock options. The Company uses an assumed dividend yield of

zero

as the Company has never paid dividends and has no current plans to pay any dividends on its common stock. The Company accounts for forfeitures as they occur.

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.

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 money market account, both 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 March 31, 2023 and December 31, 2022, the Company had cash and cash equivalents balances exceeding FDIC insured limits by $

4.7

million and $

3.0

million, respectively.

During 2023, the majority, or

75

%, of the Company’s sales have been to individual consumers. As of March 31, 2023, the Company had

three

reseller customers whose accounts receivable balances each totaled more than 10% or more of the Company’s total accounts receivable (

28

%,

27

% and

13

%) compared with

two

such customers at December 31, 2022 (

43

% and

18
%).

For the three months ended March 31, 2023, the Company had

one
customer who individually accounted for 10% or more of the Company's total revenue (

20
%) compared to

one
customer for the three months ended March 31, 2022 (

20
%).

During 2023, we outsourced

100
% of our contract manufacturing to vendors with locations in California and Canada.

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

Recently Issued Accounting Pronouncements — Adopted

In June 2016, the FASB issued ASU No. 2016-13*, Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, and issued subsequent amendments to the initial guidance within ASU 2018-19, ASU 2019-04, ASU 2019-05, ASU 2019-11, and ASU 2020-02, (collectively, "Topic 326"). Topic 326 introduces an approach, based on expected losses, to estimate credit losses for certain types of financial instruments, including accounts receivable, among other changes. This guidance became effective for us on January 1, 2023. We determined the applicable assets impacted by the guidance to be our accounts receivable. We reviewed the acceptable methods for determining the expected credit losses and utilized the roll-rate method whereby expected credit losses are determined using historical trends in credit quality indicators such as delinquency risk ratings. The majority of our sales are to individual customers where payment is made at the time of purchase, thus no credit loss has been estimated. Our accounts receivable balances represent amounts due primarily from our resellers, which are large, well established companies. We have not experienced any credit losses from our current accounts receivable base in the past and estimate that we will have no credit losses based on the current account attributes. As of March 31, 2023, there have been no estimated credit losses recorded.

Recently Issued Accounting Pronouncements — Not Yet Adopted

There have been no recently issued accounting pronouncements that are applicable to the Company.

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 equivalents carrying value and fair value at March 31, 2023 and December 31, 2022 (in thousands):

	As of March 31, 2023 (unaudited)				
	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	$ 4,993	$ 4,993	$ 4,993	$ —	$ —
Total assets	$ 4,993	$ 4,993	$ 4,993	$ —	$ —

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

Total assets	$ 3,074	$ 3,074	$ 3,074	$ —	$ —

Cash equivalents – Cash equivalents of $

5.0
million and $

3.1
million as of March 31, 2023 and December 31, 2022, 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.

Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

Level 1 - Quoted prices in active markets for identical assets or liabilities.

Level 2 - Observable inputs (other than Level 1 quoted prices) such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.

Level 3 - Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

There have been no changes to the valuation methodologies utilized by the Company during the three months ended March 31, 2023 compared to the year ended December 31, 2022. The Company evaluates transfers between levels at the end of each reporting period. There were

no

transfers of financial instruments between levels during the three months ended March 31, 2

0

23 and the year ended December 31, 2022.

4. Inventory, net (in thousands)

	March 31, 2023 (unaudited)	December 31, 2022
Raw materials	$ 817	$ 724
Work in process	7	23
Finished goods	119	116
Inventory at cost	943	863
Less reserve for obsolescence	—	—
Inventory, net	$ 943	$ 863

5. Commitments and Contingencies

Lease

In November 2021, the Company executed a noncancelable operating lease for approximately

9,091

square feet of office space in Hayward, California to serve as its headquarters. The lease will expire in October 2025 and there is no option to renew for an additional term. The Company is obligated to pay, on a pro-rata basis, real estate taxes and operating costs related to the premises.

The lease costs for each of the three months ended March 31, 2023 and 2022 were $

50

thousand.

The Company's weighted average remaining lease term and weighted average discount rate as of March 31, 2023 is shown below:

Remaining lease term (in years)	2.50
Discount rate	6.0 %

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

51
thousand and $

46
thousand for the three months ended March 31, 2023 and 2022, respectively, which is included in operating activities in the statement of operations.

Future minimum maturities of lease liabilities recognized on the condensed balance sheets as of March 31, 2023 are as follows (in thousands):

Fiscal Year	
Remainder of 2023	$ 155
2024	210
2025	178
Total minimum lease payments	543
Less imputed interest	(38)
Present value of lease payments	$ 505

Fulfillment Service Agreement

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

25

thousand minimum monthly purchase requirement. The ALOM Agreement has a three-year initial term, with automatic annual renewals, and may be terminated for convenience by either party upon sixty days written notice to the other party.

Contingencies

From time to time, the Company may become involved in litigation. Management is not currently aware of any litigation matters or other contingencies that could have a material adverse effect on the financial position, results of operations, or cash flows of the Company.

6. Preferred Stock

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. There were no series of preferred stock designated and

no

shares of preferred stock issued or outstanding at March 31, 2023 and December 31, 2022.

7. Common Stock

On April 1, 2022, the Company exercised its right and repurchased

93,750

shares of unvested restricted common stock from an employee upon the employee’s termination of employment.

On February 13, 2023, the Company sold

20,000,000

shares of its common stock in an underwritten public offering at $

0.25

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, the Company granted the underwriter a 45 -day option to purchase up to an additional

3,000,000

shares of common stock, solely to cover over-allotments. This option expired in March 2023, and the underwriter did not exercise its option to purchase any additional shares prior to such expiration.

As of March 31, 2023,

no

dividends on common stock had been declared by the Company. At March 31, 2023 and December 31, 2022, the Company had reserved shares of common stock for issuance as follows:

	March 31, 2023	December 31, 2022
Warrants to purchase common stock	1,272,680	272,680
Options issued and outstanding	1,223,850	1,268,850
Shares available for future stock option grants	960,268	456,381
Total	3,456,798	1,997,911

8. Common Stock Warrants

In July 2021, the Company entered into a consulting agreement, pursuant to which

50,000

warrants to purchase common stock were granted and an additional

50,000

warrants to purchase commvaon stock were granted in November 2021. The warrants are exercisable upon issuance, have an exercise price of $

1.04

per share and have a term of five years . The consulting agreement 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 stock and were classified within stockholders' equity.

In November 2021, the Company issued warrants to purchase

172,680

shares of common stock to designees of 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 $

6.25

per share and have a term of five years . The warrant issuances are indexed to and settled in the Company's own stock and were classified within stockholders' equity.

In February 2023, the Company issued warrants to purchase

1,000,000

shares of common stock to designees of ThinkEquity, the underwriter of the underwritten public offering of

20,000,000

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 $

0.3125

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.

The Company estimated the value of the warrants in February 2023 using the Black-Scholes options valuation model . The fair value of the warrants of $

195

thousand 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 2023 was estimated on the date of grant using the following assumptions:

Expected life (in years)	4.0
Expected volatility	123.9 %
Risk-free interest rate	4.075 %
Dividend yield	0 %

A summary of the Company's outstanding warrants as of March 31, 2023 is as follows:

Class of Shares	Number of Warrants	Exercise Price	Expiration Date
Common Stock	50,000	$ 1.04	July 1, 2026
Common Stock	50,000	$ 1.04	November 15, 2026
Common Stock	172,680	$ 6.25	November 10, 2026
Common Stock	1,000,000	$ 0.3125	August 9, 2027

9. Equity Incentive Plans

In 2017, the Company adopted its 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 made under and 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.

In 2021, the Company adopted its 2021 Equity Incentive Plan ("2021 Plan"). Options granted under the 2021 Plan may be Incentive Stock Options or Non-statutory Stock Options, as determined at the time of grant by the Compensation Committee of the Company's board of directors, who is responsible for administering the 2021 Plan. Stock Purchase Rights and Restricted Stock Units ("RSUs") may also be granted under the 2021 Plan. The term shall be no more than ten years from the date of grant thereof. In the case of an Incentive Stock Option granted to an optionee who, at the time the option is granted, owns stock representing more than

10
% of the voting power of all classes of stock of the Company or any Parent or Subsidiary, the term of the option shall be five years from the date of grant or such shorter term as may be provided in the relevant 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, 2023,

483,887
shares were automatically added to the number of shares authorized for issuance under 2021 Plan (an increase equal to

5
% of the number of the outstanding shares of Company common stock as of December 31, 2022).

In the case of an Incentive Stock Option (i) granted to an employee who, at the time of grant of such option, owns stock representing more than

10
% of the voting power of all classes of stock of the Company or any Parent or Subsidiary, the exercise price shall be no less than

110
% of the Fair Market Value per Share on the date of grant; (ii) granted to any other employee, the per share exercise price shall be no less than

100
% of the Fair Market Value per Share on the date of grant. In the case of a Non-statutory Stock Option (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 service provider, 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.

As of March 31, 2023, there were

960,268
shares of common stock available for issuance under the 2021 Plan.

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 stock option award activity for the three months ended March 31, 2023:

	Outstanding	Exercisable
January 1, 2023	1,268,850	357,215
Granted	—	—
Vested	—	129,320
Canceled or expired	(45,000)	(25,000)
Exercised	—	—
March 31, 2023	1,223,850	461,535

The weighted-average exercise price as of March 31, 2023 for stock options outstanding and stock options exercisable was $ 2.05 and $ 1.87, respectively. The weighted average remaining contractual life as of March 31, 2023 for stock options outstanding and stock options exercisable was 7.55 and 6.93 years, respectively.

Stock-Based Compensation

Total stock-based compensation recorded in the condensed statements of operations is allocated as follows (in thousands):

	Three Months Ended March 31,	
	2023	2022
Research and development	$ 31	$ 20
Sales and marketing	2	1
General and administrative	51	40
Total stock-based compensation	$ 84	$ 61

10. 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:

	Three Months Ended March 31,	
	2023	2022
Warrants to purchase common stock	1,272,680	272,680
Common stock options issued and outstanding	1,223,850	1,050,969
Total	2,496,530	1,323,649

11. Subsequent Events

We have evaluated subsequent events through the date of this filing.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read together with the interim condensed financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q, as well as our audited financial statements and related notes as disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022. This discussion contains forward-looking statements based upon current expectations that involve risks and uncertainties. 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 Part II, Item 1A "Risk Factors" or in other parts of this Quarterly Report on Form 10-Q, as well as those identified in the "Risk Factors" section of our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, each of which Risk Factors are incorporated in this Quarterly Report on Form 10-Q by reference. Our historical results are not necessarily indicative of the results that may be expected for any period in the future. See "Forward-Looking Statements."

Overview

Tivic is a bioelectronic medicine company developing and commercializing drug-free treatments for various diseases and conditions. Bioelectronic medicine, also referred to as electroceuticals or neuromodulation, is the treatment of disease and conditions by preferentially activating electrical functions of the body to modify central or peripheral nerve activity. ClearUP is our first commercial product, and is FDA-approved for the treatment of sinus pain and congestion. It has also been granted a CE-Mark as a medical device for the treatment of sinus pain, pressure and congestion. ClearUP is currently sold in the U.S. directly to consumers on various platforms and through reseller channels. The Company has also recently announced the expansion of its intellectual property ("IP") portfolio and research programs related to vagus nerve stimulation to expand its applications in non-invasive bioelectronic medicine.

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

Business Updates

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

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

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

On February 13, 2023, the Company sold 20,000,000 shares of its common stock in firm commitment underwritten public offering at $0.25 per share, resulting in gross proceeds to the Company of $5.0 million. Net proceeds to the Company, after deducting the underwriting discount and commissions and expenses paid by the Company, was approximately $3.6 million. Additionally, as partial consideration for services rendered in connection with the offering, the Company issued designees of the underwriter warrants to purchase an aggregate of 1,000,000 shares of common stock (the "Representative's Warrants"), representing 5.0% of the aggregate shares sold in the offering. The Representative's Warrants have an initial exercise price of $0.3125 per share, will be exercisable for a four-year period commencing 180 days following the commencement of sales in the offering, and provide the holders thereof with

certain piggyback and demand registration rights. The securities sold were registered pursuant to the registration statement on Form S-1 (File No. 333-268010), which was declared effective by the SEC on February 8, 2023.

In Q1 2023, we advanced our commercial roadmap as follows:

- We completed cost of manufacturing improvements to increase gross margins, enabling us to sell profitably through a broader range of channels.
- We initiated implementation of a B2B portal, which was subsequently launched in Q2 2023, and began building the sales pipeline for wholesale distribution.
- We invested in product improvements to enhance customer experience and support cost-effective product line expansion.
- We completed a significant market study identifying unmet needs across a range of inflammatory conditions related to sleep, headaches, migraine, and allergies, among other symptoms that afflict over 85 million consumers in the U.S.
- Based on that market study, we completed a product versioning plan to target additive market segments with greater willingness to pay (higher price tolerance) and greater likelihood to purchase.
- We completed brand marketing improvements to increase perceived customer value, in preparation for price increases implemented in Q2 2023.
- We obtained a successful recertification of ISO 13485 Quality Management System and the European Medical Device CE-Mark.

We invested in research and development (“R&D”) programs as follows:

- We continued expanding our IP portfolio, receiving one new issuance and filing application, as well as four additional Patent Cooperation Treaty (“PCT”) applications covering new indications.
- We continued our collaboration with a renowned international hospital that leads in scientific training, biomedical research, and patient care on a sham-controlled clinical trial to evaluate a new bioelectronic approach to treating postoperative pain after sinus surgery. This 60-person randomized sham-controlled clinical trial is currently on-going and the post-operative pain clinical study has now been expanded to include Otolaryngology and Facial Plastic Surgery patients. This study aims to investigate the potential benefits of a drug-free alternative to traditional post-operative pain management methods, with an opportunity to reduce dependence on opioids.
- As part of expanding our bioelectronic portfolio to fight disease and increase vibrancy of life, we announced a partnership with The Feinstein Institute for Medical Research to complete a pilot study to test the novel non-invasive bioelectronic approach to vagus nerve stimulation. Preceding the start of the program, we filed a patent application for a novel approach to non-invasive vagus nerve stimulation.

In recognition of our role advancing bioelectronic medicine, Tivic was named to Fast Company’s annual list of the World’s Most Innovative Companies 2023 in the Medical Device Category, and the company was named the Most Pioneering Bioelectronic Medicine Company by Global Health & Pharma Magazine.

In 2023, we are focused on targeting higher value market segments with stronger return on investment ("ROI") while continuing our R&D push targeting life-threatening or irreversibly debilitating human diseases or conditions that have high costs and could benefit from more effective, patient-centric therapeutic solutions.

We intend to more selectively invest in our clinical work, marketing, e-commerce distribution infrastructure as follows:

- Targeting the identified incremental market segments with unmet needs and high willingness to pay.
- Increasing retail price to drive increased gross margins.
- Optimizing our marketing investment to focus on higher return on ad spending ("ROAS") and ROI.
- Broadening our distribution with large commercial contracts to penetrate pharmacies and medical practices.
- Strategically broadening our intellectual property portfolio, which currently consists of five issued U.S. patents, 96 claims, and 20 pending patents in the U.S. and abroad.

Tivic has proven its ability to innovate by combining science and technology with its expertise in neuroimmunology, medical device product development, and regulatory affairs. As shared in our recent announcements about our provisional patent targeting the vagus nerve and our partnership with The Feinstein Institute, we are beginning to focus our internal research and external evaluation of licensing, partnerships and strategic transactions into life-threatening or irreversibly debilitating human diseases or conditions that have high costs and could benefit from more effective, patient-centric therapeutic solutions.

Operational Updates

On October 21, 2022, the Company entered into a Manufacturing Agreement (the "Microart Agreement") with Microart Services Inc. ("Microart"). Pursuant to the Microart Agreement, Microart will manufacture, on a non-exclusive basis, certain components and sub-assemblies (collectively, "Products") of the Company's current and future products. On November 25, 2022, we entered into a Fulfillment Services Agreement (the "ALOM Agreement") with ALOM Technologies Corporation ("ALOM"). Pursuant to the ALOM Agreement, commencing on November 28, 2022, 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.

As a result of both the Microart and ALOM Agreements signed within the fourth quarter of 2022, we have significantly reduced the cost per unit for the existing ClearUP product in the first quarter of 2023. We expect that the remainder of the ClearUp products previously built under the higher cost structure should sell through in early second quarter 2023, resulting in continued reduction of cost of goods sold as a percentage of revenue.

Team Updates

On April 28, 2023, Veronica Cai resigned from her role as Chief Financial Officer of the Company, and Kimberly Bambach was appointed as interim Chief Financial Officer. Additionally, during the first quarter of 2022, we engaged Christina Valauri as a strategic advisor to our board of directors.

We have continued to strengthen our management team with key new additions. However, we intentionally maintain a small core team at this stage of the Company. We have relied, and continue to rely, heavily on third-party service providers, including marketing agencies, clinical research organizations and academic research partnerships, finance and accounting support, legal support, and contract manufacturing organizations to carry out our operations.

Results of Operations

Comparison of the Three Months Ended March 31, 2023 and 2022

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

	Three Months Ended March 31,		
	2023	2022 (unaudited)	Change
Revenue	$ 376	$ 428	$ (52)
Cost of sales	263	358	(95)
Gross profit	113	70	43
Operating expenses:			
Research and development	490	401	89
Sales and marketing	458	684	(226)
General and administrative	1,281	1,226	55
Total operating expenses	2,229	2,311	(82)
Loss from operations	(2,116)	(2,241)	125
Other income:			
Interest income	—	1	(1)
Total other income	—	1	(1)
Net loss	$ (2,116)	$ (2,240)	$ 124

Revenue

Revenue is currently generated through the sale of our ClearUP device and ancillary products, including accessories and accelerated shipping charges, and is net of return reserves. Sales are currently made directly to consumers online through our own website, Amazon and Walmart. We also sell to major and specialty retailers, such as BestBuy, SharperImage and FSAStore. Noninvasive bioelectronic medicine is an emerging market space that provides consumers with non-drug treatments for various diseases and ClearUP is the first FDA-approved bioelectronic treatment for sinus pain and congestion.

For the three months ended March 31, 2023, revenue decreased by $52 thousand, or 12%, compared to the same period in 2022, primarily due to a 27% decrease in unit sales, offset by a 17% increase in the per unit average sales price. Unit sales in our direct-to-consumer channels decreased 34%, while unit sales in our retail channels decreased by 9%. Average sales price in our direct-to-consumer and reseller channels increased by 23.6% and 4.8%, respectively.

We expect some variability in sales due to reduction in marketing spend and price point positioning for target markets, with the net impact resulting in a higher gross profit and lower loss from operations.

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. However, cost of sales is expected to continue to decrease as a proportion of revenue with (i) the optimization of our supply chain, including the new Microart and ALOM partnerships, and (ii) the allocation of fixed and semi-fixed expenses over increasing unit sales volume over time.

For the three months ended March 31, 2023, cost of sales decreased by $95 thousand, or 27%, compared to the same period in 2022, primarily driven by lower cost per unit and the decrease in sales volume. Variable cost was $192 thousand, or $69.81 per unit, for the three months ended March 31, 2023, compared to $310 thousand, or $81.93 per unit, for the same period in 2022. The decrease in variable cost was primarily driven by lower manufacturing and fulfillment costs. Fixed costs were $71 thousand, or $25.61 per unit, for the three months ended March 31, 2023, compared to $48 thousand, or $12.57 per unit, for the same period in 2022. The increase in the fixed cost was primarily due to lower sales volume to absorb the costs.

Gross Margin

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

Although we currently do not anticipate a supply shortage in the near term, we continue to maintain relationships with and monitor alternative and secondary source suppliers in order to ensure that we are able to source sufficient components and materials to manufacture our products. Global supply chain shortages (especially when coupled with the increase in inflation and other economic factors) could result in an increase in the cost of the components used in our products, which could result in a decrease of our gross margins or in us having to increase the price at which we sell our products until supply chain constraints are resolved.

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, development and validation of new product candidates.

For the three months ended March 31, 2023, research and development expenses increased by $89 thousand compared to the same period in 2022. The increase was primarily due to increased headcount and related costs. The emphasis of research and development activities in 2023 has been primarily related to a large segmentation study to identify additional incremental market segments with high willingness to pay, product design in our next generation device, as well as enhancement of our intellectual property protection. Activities in 2022 were primarily focused on product research and design in the migraine therapeutic area, initiation of a double-blind randomized controlled trial for post-operative pain relief following sinus surgery, and enhancement of our intellectual property protection.

Sales and Marketing Expenses

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

For the three months ended March 31, 2023, sales and marketing expenses decreased by $226 thousand compared to the same period in 2022. The decrease was due primarily to more targeted sales and marketing efforts while bringing new distribution partners online and managing seasonal variability.

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 to continue to look for ways to reduce our general and administrative expenses incurred as a result of our public company status.

For the three months ended March 31, 2023, general and administrative expenses increased by $55 thousand compared to the same period in 2022. The overall increase was primarily attributable to an increase of $72 thousand in personnel costs associated with increased headcount, offset by decreases in other overhead costs.

Other Income, Net

Other income, net consists of interests income on money market funds.

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 in September 2019 in the United States. We are not profitable and have incurred net losses and negative cash flows from our operations in each year since our inception. As of March 31, 2023, we had cash and cash equivalents of $5.2 million, working capital of $4.9 million and an accumulated deficit of $31.8 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 public 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 20,000,000 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.

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

Recent Developments

On February 1, 2023, we filed a Form S-3 universal shelf registration statement (the "Shelf Registration Statement") with the SEC, which was declared effective on February 8, 2023. The Shelf Registration Statement permits us to sell, in one or more public offerings, shares of our common stock, shares of preferred stock, debt securities, warrants, subscription rights, or any combination of such securities, for proceeds in an aggregate amount of up to $100 million, subject to limitations on the amount of securities we may sell in any twelve-month period. We have not yet raised any proceeds from the sale of securities under the Shelf Registration Statement. The Shelf Registration Statement will expire on February 1, 2026.

On February 8, 2023, we entered into an underwriting agreement (the "Underwriting Agreement") with ThinkEquity LLC ("ThinkEquity"), as representative of the underwriters, pursuant to which, on February 13, 2023, we issued and sold to ThinkEquity in a firm commitment underwritten public offering, 20,000,000 shares of our common stock at a public offering price of $0.25 per share, less underwriting discounts and commissions, resulting in gross proceeds to the Company of $5.0 million and net proceeds to the Company of $3.6 million.

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

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

After completion of the first quarter of 2023, on April 28, 2023, Ms. Cai resigned from her role as Chief Financial Officer of the Company. As a result of Ms. Cai's resignation, the employment agreement between the Company and Ms. Cai, dated April 1, 2022 (the "Cai Employment Agreement"), terminated, effective April 28, 2023 (the "Separation Date"). In connection with her resignation, subject

to her execution and non-revocation of a waiver and release of claims agreement, Ms. Cai will be entitled to receive a lump sum cash payment of $125,000, less applicable withholdings, following the Separation Date.

On April 28, 2023, Ms. Bambach was appointed as interim Chief Financial Officer of the Company. Ms. Bambach 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 expects that it will enter into an indemnification agreement as well as a consulting agreement with Ms. Bambach that will set forth the terms and conditions of her engagement. The Company will pay Ms. Bambach $200 per hour for services provided in her capacity as interim Chief Financial Officer.

Plan of Operation and Future Funding Requirements

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

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

We have generated operating losses in each period since inception. We have incurred an accumulated deficit of $31.8 million through March 31, 2023. We expect to incur additional losses in the future as we expand our sales, marketing, and research and development activities. Based on our current cash levels and burn rate, amongst other things, we believe our cash and financial resources may be insufficient to meet our anticipated needs for the next twelve months. As a result, we expect that we will need to raise additional capital to continue operating our business and fund our planned operations, including research and development, clinical trials and, if regulatory approval is obtained, commercialization of future product candidates.

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

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

- our ability to raise additional capital if and when necessary and on terms favorable to the Company;
- the timing and progress of sales initiatives driving top-line revenue;

- the availability of electronic parts and other components for our products, as well as our ability to source such parts and components at favorable prices;
- the timing and adoption rate of ClearUP line extensions at lower cost of goods;
- the payment terms and timing of commercial contracts entered into for manufacturing and sales of our products to and through online third-party retailers;
- the timing and progress of preclinical and clinical development activities;
- the number and scope of preclinical and clinical programs we decide to pursue;
- the timing and amount of milestone payments we may receive under any future collaboration agreements;
- whether we close potential future strategic acquisition opportunities, and if we do, our ability to successfully integrate acquired assets and/or businesses with our own;
- our ability to source new business opportunities through licenses and research and development programs and to establish new collaboration arrangements;
- the costs involved in prosecuting and enforcing patent and other intellectual property claims;
- the cost and timing of additional regulatory approvals beyond those currently held by us;
- our efforts to enhance operational systems and hire additional personnel, including personnel to support finance, sales, marketing, operations and development of our product candidates and satisfy our obligations as a public company; and
- our efforts to maintain compliance with material government (including environmental) regulations.

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

Cash Flows

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

	Three Months Ended March 31,	
	2023 (unaudited)	**2022 (unaudited)**
Cash used in operating activities	$ (2,426)	$ (2,168)
Cash used in investing activities	(94)	(6)
Cash provided by financing activities	4,170	—
Net increase (decrease) in cash and cash equivalents	$ 1,650	$ (2,174)

Operating Activities

Net cash used in operating activities for the three months ended March 31, 2023 was $2.4 million, which consisted primarily of a net loss of $2.1 million, decreased by non-cash charges of $128 thousand and a net decrease of $438 thousand in our net operating assets and liabilities. The non-cash charges primarily consisted of stock-based compensation of $84 thousand and amortization of right-of-use assets of $42 thousand. The change in our net operating assets and liabilities was primarily due to an decrease in accounts payable and accrued expenses of $305 thousand, offset by an increase of $80 thousand in inventory and $59 thousand in prepaids and other current assets.

Investing Activities

Net cash used in investing activities during the three months ended March 31, 2023 and 2022 was related to the purchases of property and equipment.

Financing Activities

Our financing activities provided $4.2 million of cash during the three months ended March 31, 2023, which consisted primarily of proceeds from the sale of 20,000,000 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 been affected by the COVID-19 pandemic, the ongoing conflict between Russia and Ukraine, economic uncertainty in human capital management (“HCM”) and certain other macroeconomic factors. Inflation has risen, Federal Reserve interest rates have increased recently, and the general consensus among economists continues to suggest that we should expect a higher recession risk to continue for the near term. Additionally, there has been significant concern regarding the stability of the banking systems in the United States, in particular with respect to regional banks. Further, climate change continues to be an intense topic of public discussion and is adding additional challenges and financial burden due to impending preparations and changes in the customer mindset. These factors, amongst other things, could result in further economic uncertainty and volatility in the capital markets in the near term, and could negatively affect our operations. The pandemic and recent economic volatility have negatively impacted our business in various ways over the last two years. We will continue to monitor material impacts on our HCM strategies, including potential of employee attrition, amongst other things.

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

U.S. and global markets are experiencing volatility and disruption following the escalation of geopolitical tensions and the ongoing military conflict between Russia and Ukraine. Although the length and impact of the ongoing military conflict is highly unpredictable, the conflict in Ukraine could lead to market disruptions, including significant volatility in commodity prices, credit and capital markets, as well as further supply chain interruptions. Russian military actions and the resulting sanctions that have been imposed by the United States and other countries could adversely affect the global economy and financial markets and lead to instability and lack of liquidity in capital markets, potentially making it more difficult for us to obtain additional funds Although our business has not been materially impacted by the ongoing military conflict between Russian and Ukraine to date, it is impossible to predict the extent to which our operations, or those of our suppliers and manufacturers, will be impacted in the short and long term, or the ways in which the conflict may impact our business. The extent and duration of the military action, sanctions and resulting market disruptions are impossible to predict, but could be substantial. We are continuing to monitor the situation and assessing its potential impact on our business.

Additionally, in March 2023, Silicon Valley Bank and Signature Bank, and most recently on May 1, 2023, First Republic Bank, were closed and taken over by the FDIC, which has created significant market disruption and uncertainty for those who bank with those institutions, and which raised significant concern regarding the stability of the banking system in the United States, and in particular with respect to regional banks. If other banks and financial institutions enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, our ability to access our cash and cash equivalents may be threatened and such events could have a material adverse effect on our business and financial condition.

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

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

Inflation

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

Off-Balance Sheet Arrangements

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

Contractual Obligations and Commitments

Office Lease

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

Lease cost recorded during the each of the three month periods ended March 31, 2023 and 2022 was $50 thousand.

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. There have been no material changes to our previously disclosed business strategy with respect to our contractual obligations as disclosed under Management's Discussion and Analysis of Financial Condition and Results of Operations - Contractual Obligations in the Company's Annual Report on Form 10-K for the year ended December 31, 2022.

Critical Accounting Policies and Significant Judgments and Estimates

Our condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of the condensed financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements, and the reported amounts of expenses during the reporting period. On an ongoing basis, management evaluates its estimates and judgments, including those related to sales return reserves, warranty reserves, stock-based compensation, and going concern. Management bases its estimates and judgments on historical experience and on various other factors, including the macro-economic factors, that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. The methods, estimates, and judgments used by us in applying these critical accounting policies have a significant impact on the results we report in our condensed consolidated financial statements. Our significant accounting policies and estimates are included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, filed with the SEC on March 31, 2023.

Information regarding our significant accounting policies and estimates can also be found in Note 2 to our condensed financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Recent Accounting Pronouncements

For a description of recent accounting pronouncements, see Note 2 to our condensed financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Not applicable.

Item 4. Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our periodic and current reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms; and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

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 Securities Exchange Act of 1934 (the "Exchange Act") Rules 13a 15(e) and 15d 15(e) as of the end of the period covered by this Quarterly Report on Form 10-Q (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 SEC 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 interim Chief Financial Officer, where appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Controls over Financial Reporting

There were no changes in our internal control over financial reporting identified in management's evaluation pursuant to Rules 13a-15(d) or 15d-15(d) of the Exchange Act during the period covered by this Quarterly Report on Form 10-Q that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

We are not currently a party to any legal proceedings, litigation or claims, nor are aware of any pending, threatened, or unasserted claims, which, if determined adversely to us, would have a material adverse effect on our business, financial condition, results of operations or cash flows. We may from time to time, be a party to litigation and subject to claims incident to the ordinary course of business. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources, and other factors.

Item 1A. Risk Factors

Please carefully consider the information set forth in this Quarterly Report on Form 10-Q and the risk factors discussed in Part I, “Item 1A. Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2022 (the “Annual Report”). The risks described in our Annual Report, as well as other risks and uncertainties, could materially and adversely affect our business, results of operations, and financial condition, which in turn could materially and adversely affect the trading price of shares of our common stock. The occurrence of any of the risks discussed in such filings, or other events that we do not currently anticipate or that we currently deem immaterial, could harm our business, prospects, financial condition and results of operations. In that case, the trading price of our common stock could decline, and you may lose all or part of your investment. There have been no material updates or changes to the risk factors previously disclosed in our Annual Report; provided, however, additional risks not currently known or currently material to us may also harm our business.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Recent Sales of Unregistered Securities

The Company did not sell any unregistered equity securities during the three months ended March 31, 2023.

Use of Proceeds

On November 10, 2021, our registration statement on Form S-1 (File No. 333-258411) was declared effective by the Commission for our initial public offering (“IPO”). The proceeds raised in the IPO have been exhausted, and there were no material changes in the planned use of proceeds from our IPO as described in our final prospectus filed with the Commission on November 12, 2021, pursuant to Rule 424(b)(4).

Repurchases

The Company did not repurchase any of the Company's outstanding equity securities during the three months ended March 31, 2023.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit Number	Exhibit description	Incorporated by Reference (Form Type)	Filing Date	Filed herewith
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	
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	Form of Representative's Warrant (February 2023 Offering).	8-K	2/13/2023	
10.1	Underwriting Agreement, dated February 8, 2023.	8-K	10/25/2022	
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	8-K	2/13/2023	
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.			X
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.			*
101.INS	Inline XBRL Instance Document.			**
101.SCH	Inline XBRL Taxonomy Extension Schema Document.			**
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.			**
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.			**
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.			**
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.			**
104	Cover Page Interactive Data File – the cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.			**

* 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.

SIGNATURE

In accordance with Section 13 or 15 (d) of the Securities Exchange Act of 1934, the Registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the Hayward, State of California, on May 15, 2023.

Date: May 15, 2023

By: /s/ Jennifer Ernst
Jennifer Ernst

Title: Chief Executive Officer
(Principal Executive Officer)

Date: May 15, 2023

By: /s/ Kimberly Bambach

Title: Interim Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

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

I, Jennifer Ernst, certify that:

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

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

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

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

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

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 15, 2023

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

Exhibit 31.2

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

I, Kimberly Bambach certify that:

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

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

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

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

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

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 15, 2023

By: /s/ Kimberly Bambach
Kimberly Bambach
Interim Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE AND FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Tivic Health Systems, Inc. (the "Company") for the quarter ended March 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Jennifer Ernst, Chief Executive Officer of the Company, and Kimberly Bambach, Interim Chief Financial Officer of the Company, do each hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to her knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: May 15, 2023

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

Date: May 15, 2023

By: /s/ Kimberly Bambach
Kimberly Bambach
Interim Chief Financial Officer
(Principal Financial and Accounting Officer)