

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Log Off

Washington, DC 20549

FORM 10-Q

X Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the quarterly period ended September 30, 2025

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

(State or other jurisdiction of incorporation or organization)

81-4016391

(I.R.S. Employer Identification No.)

47685 Lakeview Blvd.

Fremont, CA 94538

(Address of principal executive offices including zip code)

(888) 276-6888

(Registrant's telephone number, including area code)

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

<u>Title of Each Class</u>	<u>Trading Symbol(s)</u>	<u>Name of Each Exchange on Which Registered</u>
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 X 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 X 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
- ☒ Non-accelerated Filer
- ☒ Emerging Growth Company
- ☐ Accelerated Filer
- ☒ Smaller reporting 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 X

As of November 12, 2025 there were 1,765,952 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

Item 1. Financial Statements

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

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This Quarterly Report on Form 10-Q (this "Quarterly Report") for the quarter ended September 30, 2025, should be read in conjunction with the Tivic Health Systems, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2024, filed with the Securities and Exchange Commission (the "SEC") on March 21, 2025.

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 September 30, 2025 are not necessarily indicative of the results that can be expected for the full year.

Tivic Health Systems, Inc.
Condensed Balance Sheets
September 30, 2025 and December 31, 2024
(in thousands, except share and per share data)

	September 30, 2025 (Unaudited)	December 31, 2024 (Audited)
ASSETS		
Current assets		
Cash and cash equivalents	\$ 3,450	\$ 2,002
Accounts receivable, net	19	69
Inventory, net	4	319
Prepaid expenses and other current assets	267	249
Total current assets	3,740	2,639
Property and equipment, net	12	119
Deferred offering costs	211	49
Licensed technology	2,243	—
Other assets	23	—
Total assets	<u>\$ 6,229</u>	<u>\$ 2,807</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 465	\$ 125
Other accrued expenses	173	147
Total current liabilities	638	272
Total liabilities	638	272
Commitments and contingencies (Note 8)		
Stockholders' equity		
Preferred stock, \$0.0001 par value, 10,000,000 shares authorized; 3,984 shares issued and outstanding at September 30, 2025 and no shares issued and outstanding at December 31, 2024	—	—
Common stock, \$0.0001 par value, 200,000,000 shares authorized; 1,662,921 and 556,902 shares issued and outstanding at September 30, 2025 and December 31, 2024, respectively	2	1
Additional paid in capital	55,206	46,075
Accumulated deficit	(49,617)	(43,541)
Total stockholders' equity	5,591	2,535
Total liabilities and stockholders' equity	<u>\$ 6,229</u>	<u>\$ 2,807</u>

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

Tivic Health Systems, Inc.
Condensed Statements of Operations (Unaudited)
Three and Nine Months Ended September 30, 2025 and 2024
(in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Revenue	\$ 146	\$ 126	\$ 302	\$ 600
Cost of sales	291	82	343	359
Gross profit (loss)	(145)	44	(41)	241
Operating expenses:				
Research and development	858	422	1,848	980
Sales and marketing	415	234	1,020	946
General and administrative	1,065	819	3,014	2,493
Total operating expenses	2,338	1,475	5,882	4,419
Loss from operations	(2,483)	(1,431)	(5,923)	(4,178)
Other income (expense):				
Interest income	4	—	11	—
Loss on disposal of property and equipment	(117)	—	(117)	—
Total other income (expense)	(113)	—	(106)	—
Net loss	\$ (2,596)	\$ (1,431)	\$ (6,029)	\$ (4,178)
Net loss per share attributed to common stockholders - basic and diluted	\$ (1.97)	\$ (3.93)	\$ (6.49)	\$ (18.22)
Weighted-average number of shares - basic and diluted	1,320,778	364,184	928,971	229,291

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

Tivic Health Systems, Inc.
Condensed Statements of Stockholders' Equity (Unaudited)
Three and Nine Months Ended September 30, 2025 and 2024
(in thousands except share and per share data)

For the Three and Nine Months Ended September 30, 2025

	Preferred Stock		Common Stock			Additional		Total
	Shares	Amount	Shares	Amount		Paid-in	Accumulated	Stockholders'
						Capital	Deficit	Equity
Balances at January 1, 2025	—	\$ —	556,902	\$ —	1	\$ 46,075	\$ (43,541)	\$ 2,535
Issuance of common stock and preferred stock, net of issuance costs	491	—	111,339	—	—	1,700	—	1,700
Issuance of common stock for equity line of credit	—	—	29,800	—	—	94	—	94
Issuance of common stock in lieu of fractional shares for stock split	—	—	76	—	—	—	—	—
Exercise of warrants	—	—	7,524	—	—	109	—	109
Stock-based compensation expense	—	—	—	—	—	100	—	100
Net loss	—	—	—	—	—	—	(1,502)	(1,502)
Balances at March 31, 2025	491	\$ —	705,641	\$ —	1	\$ 48,078	\$ (45,043)	\$ 3,036
Issuance of common stock, net of issuance costs	—	—	260,258	—	—	1,908	—	1,908
Issuance of preferred stock and warrants, net of issuance costs and warrants to placement agents	700	—	—	—	—	549	—	549
Issuance of warrants	—	—	—	—	—	36	—	36
Stock-based compensation expense	—	—	—	—	—	90	—	90
Dividends declared on Series B preferred stock	—	—	—	—	—	—	(1)	(1)
Net loss	—	—	—	—	—	—	(1,931)	(1,931)
Balances at June 30, 2025	1,191	\$ —	965,899	\$ —	1	\$ 50,661	\$ (46,975)	\$ 3,687
Issuance of common stock, net of issuance costs	—	—	148,234	—	—	429	—	429
Settlement of restricted stock units	—	—	32,788	—	—	100	—	100
Issuance of preferred stock and warrants, net of issuance costs and warrants to placement agents	4,200	—	—	—	—	3,753	—	3,753
Issuance of warrants for services	—	\$ —	—	\$ —	—	93	—	93
Conversion of preferred stock into common stock	(1,407)	—	516,000	—	1	(1)	—	—
Dividends declared on Series B preferred stock	—	—	—	—	—	36	(36)	—
Deemed dividends on purchase warrants for common shares	—	—	—	—	—	10	(10)	—
Stock-based compensation expense	—	—	—	—	—	125	—	125
Net loss	—	—	—	—	—	—	(2,596)	(2,596)
Balances at September 30, 2025	<u>3,984</u>	<u>\$ —</u>	<u>1,662,921</u>	<u>\$ —</u>	<u>2</u>	<u>\$ 55,206</u>	<u>\$ (49,617)</u>	<u>\$ 5,591</u>

For the Three and Nine Months Ended September 30, 2024

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount			
Balances at January 1, 2024	—	\$ —	86,241	\$ —	\$ 41,466	\$ (37,886)	\$ 3,580
Issuance of common stock for restricted stock award	—	—	441	—	—	—	—
Stock-based compensation expense	—	—	—	—	54	—	54
Net loss	—	—	—	—	—	(1,481)	(1,481)
Balances at March 31, 2024	—	\$ —	86,682	\$ —	\$ 41,520	\$ (39,367)	\$ 2,153
Issuance of Common stock and warrants, net of issuance costs and warrants to placement agents	—	—	277,059	1	3,180	—	3,181
Issuance of warrants	—	—	—	—	70	—	70
Stock-based compensation expense	—	—	—	—	54	—	54
Net loss	—	—	—	—	—	(1,266)	(1,266)
Balances at June 30, 2024	—	\$ —	363,741	\$ 1	\$ 44,824	\$ (40,633)	\$ 4,192
Issuance of common stock, net of issuance costs	—	—	3,518	—	15	—	15
Issuance of Common stock and warrants, net of issuance costs and warrants to placement agents	—	—	—	—	—	—	—
Issuance of warrants	—	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	58	—	58
Net loss	—	—	—	—	—	(1,431)	(1,431)
Balances at September 30, 2024	—	\$ —	367,259	\$ 1	\$ 44,897	\$ (42,064)	\$ 2,834

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

Tivic Health Systems, Inc.
Condensed Statements of Cash Flows (Unaudited)
Nine Months Ended September 30, 2025 and 2024
(in thousands)

	Nine Months Ended September 30,	
	2025	2024
Cash flows from operating activities		
Net loss	\$ (6,029)	\$ (4,178)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	415	166
Depreciation	2	3
Issuance of warrants for services	93	—
Loss on disposal of property and equipment	117	—
Amortization of right-of-use asset	—	76
Inventory allowances	230	16
Provision for credit losses	—	5
Changes in operating assets and liabilities:		
Accounts receivable	50	160
Inventory	85	9
Prepaid expenses and other current assets	(18)	93
Accounts payable	340	(380)
Accrued expenses	26	(268)
Lease liabilities	—	(96)
Other Assets	(23)	34
Net cash used in operating activities	(4,712)	(4,360)
Cash flows from investing activities		
Acquisition of property and equipment	(13)	—
Acquisition of licensed technology	(543)	—
Net cash used in investing activities	(556)	—
Cash flows from financing activities		
Proceeds from issuance of common stock, net of issuance costs	2,337	—
Proceeds from issuance of common stock and warrants, net of issuance costs	—	3,266
Proceeds from issuance of preferred stock and warrants, net of issuance costs	4,338	—
Proceeds from warrant exercises	109	—
Offering costs in advance of sale of common stock	(68)	(112)
Net cash provided by financing activities	6,716	3,154
Net increase (decrease) in cash and cash equivalents	1,448	(1,206)
Cash and cash equivalents		
Beginning of period	2,002	3,395
End of period	\$ 3,450	\$ 2,189
Supplemental disclosure on noncash investing and financing activities		
Issuance of warrants	\$ 314	70
Issuance of common stock and preferred stock in exchange for license	\$ 1,700	\$ —
Issuance of common stock for equity line of credit commitment fee	\$ 94	\$ —
Dividends declared	\$ 36	\$ —
Deemed dividends	\$ 10	\$ —
Write-off of ROU asset and lease liability	\$ —	\$ 290

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 and, in November 2021, it completed its initial public offering. In 2019, the Company commercially launched ClearUP, a handheld device for treatment of sinus pain and congestion and the Company's first FDA-regulated product, a business it is in the process of exiting. In 2021, the Company also began developing a novel platform directed to vagus nerve stimulation, which has undergone clinical evaluation and optimization studies. In February 2025, the Company acquired a worldwide exclusive license from Statera Biopharma, Inc. ("Statera") to the late-stage toll-like receptor 5 agonist Entolimod™ for the treatment of Acute Radiation Syndrome ("ARS"). At the same time, the Company acquired an exclusive option to license five additional indications and clinical use cases for Entolimod and its immune-optimized derivative, Entolasta™, with buy-out rights to enable use across all indications. In March 2025, the Company exercised its option to license Entolimod and Entolasta for the treatment of neutropenia, one of the indications covered by the Statera license. With its entrance into the biopharmaceutical market in early 2025 and its impending exit from the consumer healthtech business, the Company is a late-stage prescription therapeutics company harnessing the power of the immune system to improve clinical outcomes and save lives. The Company is headquartered in Fremont, California and operates on a decentralized, virtual basis.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying condensed balance sheet as of December 31, 2024, which has been derived from audited financial statements, and the unaudited interim condensed financial statements as of September 30, 2025, and for the three and nine months ended September 30, 2025 and September 30, 2024, 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 GAAP 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 and nine months ended September 30, 2025 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2025.

Going Concern Uncertainty

During the nine months ended September 30, 2025 and 2024, the Company incurred a net loss of \$6.0 million and \$4.2 million, respectively. At September 30, 2025, the Company had an accumulated deficit of \$49.6 million. Cash and cash equivalents at September 30, 2025 were \$3.5 million. During the nine months ended September 30, 2025 and 2024, the Company had negative cash flows from operations of \$4.7 million and \$4.4 million, respectively. 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.

We expect to incur significant expenses and operating losses for the foreseeable future as we continue the development of, and seek regulatory approval for, our product candidates and technologies. Future capital requirements will depend upon many factors, including, without limitation, progress with developing, manufacturing and marketing our product candidates and technologies; the time and costs involved in obtaining regulatory approvals for our product candidates and technologies; the time and costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other proprietary rights; our ability to execute our strategy to expand our business, including through the closing of potential acquisitions or licenses and integrating new business into our own; our ability to establish collaborative arrangements; 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. We will require substantial additional financing to fund our ongoing clinical trials and operations, and to continue to execute our strategy. These activities, including our planned research and development efforts, will require significant uses of working capital. There can be no assurance that we will obtain regulatory approval of our product candidates or generate sufficient revenue and cash to achieve profitability.

The Company recognizes it will need to raise additional capital to continue research and development and to fund its planned operations, including to execute on its strategy to expand its business, complete pre-clinical and clinical trials and, if regulatory approval is obtained, commercialize any future products. The Company may seek additional funds through equity or debt offerings and/or borrowings under notes payable, lines of credit or other sources. The Company does 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, the Company's ability to fund its operations, support the growth of its business or otherwise respond to competitive pressures could be significantly delayed or limited, which could materially adversely affect its business, financial conditions, or results of operations.

Reverse Stock Split

Effective March 7, 2025, the Company implemented a reverse stock split of its issued and outstanding shares of common stock, par value \$0.0001 per share, at a ratio of 1-for-17. As a result of the reverse stock split, the total number of shares of common stock held by each stockholder of the Company were converted automatically into the number of shares of common stock equal to the number of issued and outstanding shares of common stock held by each such stockholder immediately prior to the reverse stock split divided by 17. The Company issued one whole share of the post reverse stock split common stock to any stockholder who otherwise would have been entitled to receive a fractional share as a result of the reverse stock split (for a total of 76 shares). As a result, no fractional shares were issued in connection with the reverse stock split and no cash or other consideration was paid in connection with any fractional shares that would otherwise have resulted from the reverse stock split. Also, all options, warrants, preferred stock and other convertible securities of the Company outstanding immediately prior to the reverse stock split were adjusted by dividing the number of shares of common stock into which such options, warrants, preferred stock and other convertible securities were exercisable or convertible by 17 and multiplying the exercise or conversion price thereof by 17, all in accordance with the terms of the plans, agreements or arrangements governing such options, warrants, preferred stock and other convertible securities and subject to rounding pursuant to such terms. There was no change to the par value or authorized shares, of either the Company's common stock or preferred stock, as a result of the reverse stock split. All share and per share amounts for the Company's common stock, as well as the number of shares of common stock issuable upon conversion of outstanding preferred stock and upon exercise of options and warrants outstanding, and conversion/exercise prices thereof, from dates prior to completion of the reverse stock split that are included in this Quarterly Report, including the financial statements and footnotes thereto included herein, have been retroactively restated to give effect to the reverse stock split.

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 September 30, 2025 and December 31, 2024, cash and cash equivalents totaled \$3.5 million and \$2.0 million, respectively.

Accounts Receivable

Trade accounts receivable are recorded at the invoiced amount, net of allowances for credit losses. The allowance for credit losses is based on our assessment of the collectability of accounts. Management regularly reviews the adequacy of the allowance for credit losses by considering the age of each outstanding invoice, each customer's expected ability to pay, and the collection history with each customer, when applicable, to determine whether a specific allowance is appropriate. Accounts receivable deemed uncollectible are charged against the allowance for credit losses when identified. As of each September 30, 2025 and December 31, 2024, the allowance for credit losses was zero.

Inventory

Inventories are stated at the lower of cost or net realizable value, with cost determined on a first-in, first-out basis. Inventories are reviewed periodically to identify slow-moving inventory based on anticipated sales activity. As of each September 30, 2025 and December 31, 2024, the reserve for obsolescence was \$568 thousand and \$338 thousand, respectively.

Deferred Offering Costs

The Company complies with the requirements of Financial Accounting Standards Board ("FASB") Accounting Standard Codification ("ASC") 340-10-S99-1. The Company capitalizes incremental legal, professional, accounting, and other third-party fees that are directly associated with an equity or debt offering. As of September 30, 2025, the balance of deferred offering costs was \$211 thousand and consisted of legal and accounting fees paid in connection with the Equity Line of Credit and the Tranched Financing, which are discussed further in Notes 11 and 10, respectively, below. 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. The costs relating to the Equity Line of Credit and the Tranched Financing are reclassified to additional paid in capital on a pro-rata basis when the Company completes offerings.

Business Combination

The Company follows the guidance in ASC 805, Business Combinations, for determining the appropriate accounting treatment for asset acquisitions. ASU No. 2017-01, Clarifying the Definition of a Business, provides an initial fair value screen to determine if substantially all of the fair value of the assets acquired is concentrated in a single asset or group of similar assets. If the initial screening test is not met, the set is considered a business based on whether there are inputs and substantive processes in place. The accounting treatment is derived based on the results of this analysis and conclusion on an acquisition's classification of a business combination or an asset acquisition.

If the acquisition is deemed to be a business, the purchase method of accounting is applied. Identifiable assets acquired and liabilities assumed at the acquisition date are recorded at fair value. If the transaction is deemed to be an asset acquisition, the cost accumulation and allocation model is used whereby the assets and liabilities are recorded based on the purchase price and allocated to the individual assets and liabilities based on relative fair values.

Property and Equipment

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

Impairment of Long-Lived Assets

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

Commitments and Contingencies

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

Revenue Recognition

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

Under Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are 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 inception, 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 is 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 September 30, 2025 and December 31, 2024, the contract liability related to the Company's deferred revenues was \$3 thousand and \$2 thousand, respectively, and is included in "Other Accrued Expenses" 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 and nine months ended September 30, 2025 and 2024 (in thousands):

Product Revenue by Sales Channel	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Product Revenue				
Direct-to-consumer	\$ 137	\$ 130	\$ 277	\$ 557
Reseller	24	16	48	110
Returns	(15)	(20)	(23)	(67)
Revenue	<u>\$ 146</u>	<u>\$ 126</u>	<u>\$ 302</u>	<u>\$ 600</u>

Sales Tax

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

Shipping and Handling

Shipping and handling fees paid by customers are recorded in revenue, with the related expenses recorded in cost of sales. Shipping and handling fees paid by customers for the three and nine months ended September 30, 2025 were \$1 thousand and \$2 thousand, respectively. There were no shipping and handling fees paid by customers for the three and nine months ended September 30, 2024.

Shipping costs for delivery of product to customers in the three and nine months ended September 30, 2025 were \$8 thousand and \$16 thousand, respectively. Shipping costs for delivery of product to customers in the three and nine months ended September 30, 2024 were \$5 thousand and \$28 thousand, respectively.

Product Warranty

The Company generally offers a one-year limited warranty on its products. The Company has also offered for sale at times a limited two-year warranty. The limited two-year warranty is occasionally provided to customers in connection with promotional sales. The Company estimates the costs associated with the warranty obligation using historical data of warranty claims and costs incurred to satisfy those claims. Estimated warranty costs are expensed to cost of sales.

Returns

The Company estimates a reserve for future product returns based on several factors, including historical returns as a percentage of revenue, an understanding of the reasons for past returns and any other known factors that indicate a return is imminent. Reserves for sales returns are estimated and recorded in the same period as the underlying revenue recognition as a deduction to arrive at net product sales and as a liability classified as "Other Accrued Expenses" on the balance sheet. As of September 30, 2025 and December 31, 2024, the reserve for sales returns was \$8 thousand and \$10 thousand, respectively.

Research and Development Expenses

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

Sales and Marketing Expenses

Sales and marketing expenses are expensed as incurred and consist primarily of personnel costs, 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. Personnel costs consist of salaries, bonuses, benefits and stock-based compensation expense. Beginning in the second quarter of 2025, sales and marketing expenses also include personnel and consulting expenses incurred to secure customer awareness of Entolimod's development. Advertising and other promotional costs to market the Company's products and services amounted to \$140 thousand and \$271 thousand for the three and nine months ended September 30, 2025, respectively. Advertising and other promotional costs to market the Company's products and services were \$94 thousand and \$415 thousand for the three and nine months ended September 30, 2024, respectively.

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, restricted stock units and warrants. 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 publicly traded companies. The historical volatility is calculated based on a period of time commensurate with the expected term assumption. The group of representative companies have characteristics similar to the Company, including stage of product development and focus on the life science industry. Changes to the group are made on an as needed basis to ensure it remains representative of the Company. The Company uses the simplified method, which is the average of the final vesting tranche date and the contractual term, to calculate the expected term for options granted to employees as it does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. The risk-free interest rate is based on a treasury instrument whose term is consistent with the expected term of the stock options. The Company uses an assumed dividend yield of zero as the Company has never paid dividends and has no current plans to pay any dividends on its common stock. The Company accounts for forfeitures as they occur.

Deemed Dividend

The Investor Warrants issued to the Investor in connection with the Tranche Financing contain a provision for the change in exercise price should the Company issue a new Investor Warrant in a subsequent Tranche Closing with an exercise price lower than the exercise price of the Investor Warrant issued earlier. The provision lowers the exercise price to the new Investor Warrant triggering the repricing feature and creates a deemed dividend. The deemed dividend is added to the net income or loss for the period and used in calculating the earnings per share for the period.

Segment Reporting

Operating segments are identified as components of an enterprise for which separate discrete financial information is available for evaluation by the chief operating decision-maker ("CODM") in deciding how to allocate resources and assess performance. The Company's CODM is the Chief Executive Officer, who reviews the Company's operations and manages its business as a single operating segment.

Net Loss per Share

Basic earnings (loss) per share is computed using the weighted-average number of shares of common stock outstanding during the period adjusted to add back dividends (declared or cumulative undeclared) applicable to the Series B Preferred Stock. Diluted earnings (loss) per share is computed using the weighted-average number of shares of common stock and the dilutive effect of contingent shares outstanding during the period. Potentially dilutive contingent shares, which primarily consist of stock options issued to employees, directors and consultants, restricted stock units ("RSUs"), warrants issued to third parties, all of which are accounted for as equity instruments, would be excluded from the diluted earnings per share calculation because their effect is anti-dilutive.

Basic and diluted net income (loss) per share attributable to common stockholders is presented in conformity with the two-class method required for participating securities such as our preferred stock. Under the two-class method, basic and diluted net income (loss) per share attributable to common stockholders is computed by dividing the basic and diluted net income (loss) attributable to common stockholders by the basic and diluted weighted-average number of shares of common stock outstanding during the period. Diluted net income per share attributable to common stockholders adjusts basic net income per share for the potentially dilutive impact of stock options, RSUs and warrants.

The treasury stock method is used to calculate the potentially dilutive effect of stock options and RSUs. The if-converted method is used to calculate the potentially dilutive effect of shares of the Series A and B Preferred Stock. In both methods, diluted net income (loss) attributable to common stockholders and diluted weighted-average shares outstanding are adjusted to account for the impact of the assumed issuance of potential shares of common stock that are dilutive, subject to dilution sequencing rules.

At September 30, 2025 and 2024, the Company had options to purchase 355,368 and 3,904 shares of common stock outstanding, respectively, 79,415 and zero restricted stock units outstanding, respectively, and warrants to purchase 1,055,809 and 707,234 shares of common stock, respectively, that are excluded from the calculation of diluted earnings per share as their effect is anti-dilutive.

The following table shows the calculation of basic and diluted earnings per share for the effect of dividends on the B Preferred Stock, and deemed dividends on warrants, which were outstanding for the periods presented below.

	Three Months Ended September 30, 2025		Nine Months Ended September 30, 2025	
	2025	2024	2025	2024
(In thousands, except per share amounts)				
Net loss attributed to Tivic Health Systems, Inc.	\$ (2,596)	\$ (1,431)	\$ (6,029)	\$ (4,178)
Dividends on Series B Preferred Stock	(36)	—	(37)	—
Deemed dividends on warrants	(10)	—	(10)	—
Net loss attributed to Tivic Health Systems, Inc.	(2,642)	(1,431)	(6,076)	(4,178)
Basic and diluted weighted average number of shares outstanding	1,320,778	364,184	928,971	229,291
Net loss per share - basic and diluted	<u>\$ (2.00)</u>	<u>\$ (3.93)</u>	<u>\$ (6.54)</u>	<u>\$ (18.22)</u>

Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist of cash and cash equivalents and accounts receivable. Cash and cash equivalents include a checking account and a money market account held at a single national financial institution in the United States. At times, such deposits may be in excess of insured limits. 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 September 30, 2025 and December 31, 2024, the Company had cash and cash equivalents balances exceeding FDIC insured limits by \$2.95 million and \$1.6 million, respectively.

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

During the first nine months of 2025, the majority, or 85%, of the Company's sales were to individual customers. In the first nine months of 2024, the majority, or 82%, of the Company's sales were to individual consumers. As of September 30, 2025, the Company had one customer whose accounts receivable balance totaled 10% or more of the Company's total accounts receivable (37%) compared with one such customer at December 31, 2024 (95%).

For each of the three and nine months ended September 30, 2025, the Company had one customer who individually accounted for 10% or more of the Company's total revenue (16% and 10%, respectively). For each of the three and nine months ended September 30, 2024, the Company had one customer who individually accounted for 10% or more of the Company's total revenue (13% and 10%, respectively).

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

Recently Issued Accounting Pronouncements

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

Management does not believe any other recently issued but not yet effective accounting pronouncement, if adopted, would have a material effect on the Company's present or future consolidated financial statements.

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 September 30, 2025 and December 31, 2024 (in thousands):

	As of September 30, 2025 (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	\$ 2,797	\$ 2,797	\$ 2,797	\$ —	\$ —
Total assets	\$ 2,797	\$ 2,797	\$ 2,797	\$ —	\$ —

	As of December 31, 2024				
	Carrying Amount	Fair Value	Quoted Priced in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets					
Money market funds	\$ 1,819	\$ 1,819	\$ 1,819	\$ —	\$ —
Total assets	\$ 1,819	\$ 1,819	\$ 1,819	\$ —	\$ —

Cash equivalents – Cash equivalents of \$2.8 million as of September 30, 2025 and \$1.8 million as of December 31, 2024, consisted of money market funds. Money market funds are classified as Level 1 of the fair value hierarchy because they are valued using quoted market prices in active markets.

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

There have been no changes to the valuation methodologies utilized by the Company during the nine months ended September 30, 2025 compared to the year ended December 31, 2024. The Company evaluates transfers between levels at the end of each reporting period. There were no transfers of financial instruments between levels during the nine months ended September 30, 2025 and the year ended December 31, 2024.

4. Prepaid Expenses (in thousands)

	September 30, 2025 (unaudited)	December 31, 2024
Prepaid director and officer liability insurance	\$ 44	\$ 27
Refundable Delaware franchise taxes	—	133
Other	223	89
Total prepaid expenses and other current assets	<u>\$ 267</u>	<u>\$ 249</u>

5. Inventory, net (in thousands)

	September 30, 2025 (unaudited)	December 31, 2024
Raw materials	\$ 458	\$ 460
Work in process	5	5
Finished goods	109	192
Inventory at cost	572	657
Less reserve for obsolescence	(568)	(338)
Inventory, net	<u>\$ 4</u>	<u>\$ 319</u>

6. Property and equipment, net (in thousands)

	September 30, 2025	December 31, 2024
Computers and equipment	\$ 24	\$ 11
Manufacturing tools and dies	—	148
Total property and equipment	24	159
Less accumulated depreciation	(12)	(40)
Property and equipment, net	<u>\$ 12</u>	<u>\$ 119</u>

Depreciation expense was zero and \$2 thousand for the three and nine months ended September 30, 2025, respectively. Depreciation expense was \$1 thousand and \$3 thousand for the three and nine months ended September 30, 2024, respectively. During the third quarter of 2025, we wrote off certain manufacturing molds related to the next generation of ClearUP as we no longer plan to manufacture the product in the future. The net book value of the assets written off was \$117 thousand and is included in loss from disposition of property and equipment in the statement of operations.

7. Statera License Agreement

On February 11, 2025, the Company entered into an exclusive license agreement (the "License Agreement") with Statera, pursuant to which the Company acquired (i) an exclusive worldwide license to the patented Toll-like Receptor 5 ("TLR5") agonist lead program of Statera known as Entolimod (the "Licensed Molecules") as it relates to the ARS indication (the "Initial Indication") and (ii) an exclusive option (the "Exclusive Option") to acquire the exclusive worldwide license to additional indications, including lymphocyte exhaustion, immunosenescence, neutropenia and/or for use as a vaccine adjuvant (the "Subsequent Indications") and to the optimized TLR5 agonist follow-on program of Statera known as Entolasta.

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

As consideration for the License Agreement, the Company agreed to pay Statera a license fee of \$1.5 million, consisting of (i) \$300 thousand in cash consideration and (ii) \$1.2 million in stock consideration, as discussed further in Notes 9 and 10 below. As additional consideration for the License Agreement, the Company agreed to pay Statera certain royalty payments on net sales for the ARS indication as a single agent, and, if it exercises the Exclusive Option with respect to any Subsequent Indication, net sales for such Subsequent Indications, within certain royalty periods.

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

In conjunction with the License Agreement, Statera additionally transferred to the Company the title to approximately fifteen kilograms (15kg) of frozen manufactured Entolimod bulk drug substance and bulk/finished drug product lots and associated quality records associated with their production and applicable verification records (the "Materials"). In connection with this acquisition of ownership of the Materials, the Company will be negotiating a \$1 per year lease with an affiliate of Statera for the proper care, storage and handling of the Materials. The Company determined that the fair value associated with the Entolimod lots and associated lease was not material to the transaction.

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

The Company makes certain judgments to determine whether transactions should be accounted for as acquisitions of assets or as business combinations. If it is determined that substantially all of the fair value of gross assets acquired in a transaction is concentrated in a single asset (or a group of similar assets), the transaction is treated as an acquisition of assets. The Company evaluates the inputs, processes, and outputs associated with the acquired set of activities and assets. If the assets in a transaction include an input and a substantive process that together significantly contribute to the ability to create outputs, the transaction is treated as an acquisition of a business. The Company's assessments concluded that the transactions pursuant to the License Agreement constitute an asset acquisition.

The Company determined the acquisition constituted an acquisition of assets instead of a business combination, as substantially all of the fair value of the gross assets acquired was concentrated in a group of similar identifiable assets, and therefore, the acquisition was not considered a business combination. In transactions accounted for as acquisitions of assets, no goodwill is recorded and contingent consideration, such as payments upon achievement of various developmental, regulatory and commercial milestones, generally is not recognized at the acquisition date. In an asset acquisition, up front payments allocated to in-process research and development ("IPRD") projects at the acquisition date are expensed unless there is an alternative future use. In addition, product development milestones are expensed upon achievement. As the Company is recording the transaction as an asset acquisition under ASC 805, the contingent payments will be recognized upon achievement and at that time will be expensed to in-process research and development, or capitalized, depending on the determination if there is alternative future use of the purchase. Transaction costs of approximately \$243 thousand associated with the acquisition were capitalized as part of the acquisition.

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

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

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

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

Pursuant to the License Agreement, in the event that the Company exercises its Exclusive Option with respect to one or more Subsequent Indications, the Company may elect, in its sole discretion, to accelerate any of the Milestone Payments in advance of the milestone achievements.

On March 28, 2025, the Company notified Statera of its election to exercise its Exclusive Option to acquire the exclusive worldwide license to the neutropenia indication for Entolimod under the License Agreement (the "Neutropenia Option") and to accelerate the first milestone payment of \$500 thousand related to the neutropenia indication (the "Neutropenia Milestone Payment"), payable by the Company in connection with the filing of an IND and initiation of a Phase 2 clinical study for neutropenia. The Company paid the \$500 thousand Neutropenia Milestone Payment paid in Company stock, as discussed further in Notes 9 and 10 below, and was capitalized as licensed technology.

As a result of the Company's exercise of the Neutropenia Option, the Company is obligated to develop and commercialize the expanded licensed products related to the neutropenia indication, at its own cost and expense, including to meet those milestones discussed above, and is obligated to pay the milestone payments, other than the Neutropenia Option, upon accomplishing each such milestone.

On June 18, 2025, the Company entered into an Amended and Restated Exclusive License Agreement (the "A&R License Agreement") with Statera, which amended certain terms of the License Agreement to, amongst other things, (i) provide that the payment of royalties pursuant to the A&R License Agreement, if any, may be made by the Company in either cash or securities of the Company, at the discretion of the Company; (ii) increase the approximate amount of the lien held by Avenue Venture Opportunities Fund, L.P. ("Avenue") to up to \$5.6 Million (the "Payoff Amount"); and (iii) provide that, other than the original license fee paid by the Company to Statera in connection with the closing of the license transaction in February 2025 and payment of the Neutropenia Milestone Payment, until such date that the Payoff Amount has been paid in full to Avenue, all subsequent payments due to Statera under the A&R License Agreement shall be paid by the Company as follows: 20% of any such payments shall be paid to Statera and 80% of any such payments shall be paid directly to Avenue on behalf of Statera.

8. Commitments and Contingencies

Lease

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

Exclusive License Agreement – Statera BioPharma

As discussed above in Note 7, the Company is obligated to make certain payments to Statera pursuant to the A&R License Agreement, upon the achievement of certain commercialization milestones.

Scorpius Statement of Work

On May 9, 2025, the Company entered into a Statement of Work (the "Scorpius SOW") with Scorpius BioManufacturing, Inc. ("Scorpius"), pursuant to which Scorpius will serve as the primary U.S. manufacturer for the Company's late-stage TLR5 agonist, Entolimod, for the treatment of ARS. Pursuant to the Scorpius SOW, Scorpius will provide the following services, among others: cell line verification, legacy process verification, GMP scale-up production, drug product fill and finish, analytical development and qualification, and upstream and downstream optimization of the process. The Scorpius SOW shall be governed by the Terms and Conditions attached thereto, unless and until a Master Services Agreement is executed by and between the parties in connection with the services contemplated by the Scorpius SOW.

Pursuant to the Scorpius SOW, the Company has agreed to pay Scorpius service fees estimated to be approximately \$2.4 million, with a total estimated investment by the Company of approximately \$4.1 million, inclusive of additional pass-through costs and expenses, including for consumables and external services. The fees and costs will be payable on a milestone-based invoicing schedule tied to the completion of defined project stages and deliverables, as provided in the Scorpius SOW. Pass-through costs for raw materials, consumables, reagents, shipping, and subcontracted services will be managed by Scorpius on behalf of the Company at cost plus a 15% administrative fee. The Company is required to settle invoices within 30 days, with Scorpius reserving the right to impose monthly interest charges of 1% for undisputed amounts unpaid after 30 days. The Company will also be responsible for payment of any taxes, fees, duties or charges imposed by any governmental authority in connection with the services provided by Scorpius under the Scorpius SOW, other than on Scorpius' net income taxes or franchise taxes. The Company estimates the duration of the Scorpius SOW to be approximately two years, with approximately \$3.9 million of costs to be incurred in the next 12 months. As of September 30, 2025, the Company had paid Scorpius a total of \$209 thousand in connection with the Scorpius SOW.

Contingencies

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of its business activities. The Company accrues a liability for such matters when future expenditures are probable and such expenditures can be reasonably estimated. The Company recorded no liabilities for contingent matters as of September 30, 2025.

9. Other Accrued Expenses (in thousands)

	September 30, 2025	December 31, 2024
Legal and professional fees	\$ 29	\$ 39
Consulting fees	30	—
Delaware franchise tax	73	—
Research study costs	—	90
Other	41	18
Total other accrued expenses	<u>\$ 173</u>	<u>\$ 147</u>

10. 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.

As of September 30, 2025, there were 403 shares of the Company's Series A Non-Voting Convertible Preferred Stock, par value \$ 0.0001 per share ("Series A Preferred Stock"), and 3,581 shares of the Company's Series B Non-Voting Convertible Preferred Stock, par value \$ 0.0001 per share ("Series B Preferred Stock"), issued and outstanding. As of December 31, 2024 there were no series of preferred stock designated and no shares of preferred stock issued or outstanding.

Series A Preferred Stock

On February 10, 2025, in connection with the License Agreement, the Company filed a Certificate of Designation of Preferences, Rights and Limitations of the Series A Non-Voting Convertible Preferred Stock (the "Series A Certificate of Designation") with the Secretary of State of the State of Delaware, pursuant to which 6,000 shares of the Company's authorized shares of preferred stock were designated as Series A Preferred Stock. A summary of the powers, preferences, rights, qualifications, limitations and restrictions applicable to the Series A Preferred Stock is set forth below.

Ranking - the Series A Preferred Stock ranks on parity with the Company's common stock and junior to the Company's Series B Preferred Stock with respect to dividend rights and rights on the distribution of assets on any voluntary or involuntary liquidation, dissolution or winding up of the affairs of the Company.

Dividend Rights - to the extent that dividends are paid to holders of the Company's common stock, holders of Series A Preferred Stock shall be entitled to participate in such dividends on an as-if-converted-to-common-stock basis, without regard to the Series A Beneficial Ownership Limitation (as defined below).

Voting Rights - except as otherwise provided by the Series A Certificate of Designation or required by law, the Series A Preferred Stock has no voting rights. Provided, however, that so long as any shares of Series A Preferred Stock are outstanding, the Company will not, without the affirmative vote of the holders of a majority of the then-outstanding shares of the Series A Preferred Stock, (i) alter or change adversely the powers, preferences or rights given to the Series A Preferred Stock or alter or amend the Series A Preferred Certificate of Designation, amend or repeal any provision of, or add any provision to, the Company's amended and restated articles of incorporation, as amended (the "Charter"), or amended and restated bylaws (the "Bylaws"), or file any articles of amendment, certificate of designations, preferences, limitations and relative rights of any series of preferred stock, in each case if any such action would adversely alter or change the preferences, rights, privileges or powers of, or restrictions provided for the benefit of the Series A Preferred Stock, regardless of whether any of the foregoing actions shall be by means of amendment to the Charter or by merger, consolidation, recapitalization, reclassification, conversion or otherwise, (ii) issue further shares of Series A Preferred Stock, or (iii) enter into any agreement with respect to any of the foregoing.

Conversion - subject to the Series A Beneficial Ownership Limitation, each share of Series A Preferred Stock is convertible into approximately 588 shares of Company common stock (the "Series A Conversion Ratio"), as follows:

- Automatic Conversion - effective as of 5:00 p.m. Eastern time on the third business day after the date that the Company's stockholders approve the conversion of the Series A Preferred Stock into shares of common stock in accordance with the listing rules of the Nasdaq Stock Market ("Stockholder Approval"), each share of Series A Preferred Stock then outstanding shall automatically convert into a number of shares of common stock equal to the Series A Conversion Ratio, subject to the Series A Beneficial Ownership Limitation.

The Company received Stockholder Approval at its 2025 Annual Meeting of Stockholders, held on June 30, 2025. As a result, on July 3, 2025, 88 shares of Series A Preferred Stock automatically converted into 51,504 shares of Company common stock.

- Optional Conversion - subject to the Series A Beneficial Ownership Limitation and the automatic conversion (discussed above), each share of Series A Preferred Stock then outstanding shall be convertible, at any time and from time to time following 5:00 p.m. Eastern time on the third business day after the date that the Stockholder Approval is obtained by the Company, at the option of the holder thereof, into a number of shares of common stock equal to the Series A Conversion Ratio.

Beneficial Ownership Limitation - a holder of Series A Preferred Stock is prohibited from converting shares of Series A Preferred Stock into shares of common stock if, as a result of such conversion, such holder, together with its affiliates, would beneficially own in excess of the applicable beneficial ownership limitation (the "Series A Beneficial Ownership Limitation"). For purposes of the Series A Preferred Stock, the Series A Beneficial Ownership Limitation shall initially be set at 9.9% for each holder and its affiliates and may be adjusted at the discretion of the holder to a percentage between 4.9% and 19.9% (but not to exceed 19.9%) of the number of shares of common stock outstanding immediately after giving effect to the issuance of shares of common stock pursuant to such conversion.

Redemption Rights - shares of Series A Preferred Stock are not redeemable.

Liquidation Rights - in the event of the liquidation, dissolution, or winding up of the affairs of the Company, whether voluntary or involuntary, holders of Series A Preferred Stock shall rank on parity with common stockholders as to the distributions of assets.

On February 11, 2025, in connection with, and as consideration for the License Agreement, the Company entered into a Securities Purchase Agreement with Statera, pursuant to which the Company issued and sold to Statera an aggregate of (i) 55,635 shares of Company common stock and (ii) approximately 360 shares of Series A Preferred Stock for an aggregate price of approximately \$1.2 million.

On March 31, 2025, in connection with the Company's exercise of the Neutropenia Option pursuant to the License Agreement and as consideration for the Neutropenia Milestone Payment, the Company entered into a Securities Purchase Agreement with Statera and Avenue, pursuant to which the Company issued to Statera and Avenue an aggregate of \$500 thousand shares of Company stock, consisting of 55,704 shares of common stock and approximately 131 shares of Series A Preferred Stock.

On July 3, 2025, in connection the Company's receipt of Stockholder Approval at its 2025 annual meeting of stockholders, 88 shares of Series A Preferred Stock automatically converted into 51,504 shares of common stock.

Series B Preferred Stock

On April 29, 2025, the Company filed a Certificate of Designation of Preferences, Rights and Limitations of the Series B Non-Voting Convertible Preferred Stock (the "Series B Certificate of Designation") with the Secretary of State of the State of Delaware in connection with the Tranche Financing. The Series B Certificate of Designation became effective upon filing and designates 8,400 shares of the Company's preferred stock as Series B Preferred Stock.

Ranking - the Series B Preferred Stock ranks senior to the Company's common stock and Series A Preferred Stock with respect to dividend rights and rights on the distribution of assets on any voluntary or involuntary liquidation, dissolution or winding up of the affairs of the Company.

Dividend Rights - the holders of outstanding shares of Series B Preferred Stock shall be entitled to cumulative dividends at an annual rate of 10% of the Stated Value (as defined below) per share. Dividends shall accrue from the date of each such Tranche Closing, and for as long as any shares of Series B Preferred Stock remain issued and outstanding and are payable quarterly in arrears. At the Company's option, dividends on the Series B Preferred Stock may be paid in (i) cash, (ii) by adding the amount of dividends payable on such date to the aggregate Stated Value of such holder's shares of Series B Preferred Stock ("PIK Dividends"), or (iii) any combination of cash and PIK Dividends. The "Stated Value" shall mean \$1,000 per share, subject to adjustment in the event of any stock dividend (including PIK Dividends), stock split, combination, recapitalization, or other similar event affecting such shares.

Voting Rights - except as otherwise provided by the Series B Certificate of Designation or required by law, the Series B Preferred Stock has no voting rights. Provided, however, that so long as any shares of Series B Preferred Stock are outstanding, the Company will not, without the affirmative vote of the holders of a majority of the then-outstanding shares of the Series B Preferred Stock, (i) alter or change adversely the powers, preferences or rights given to the Series B Preferred Stock or alter or amend the Series B Certificate of Designation, amend or repeal any provision of, or add any provision to, the Company's Charter or Bylaws, or file any articles of amendment, certificate of designations, preferences, limitations and relative rights of any series of preferred stock, in each case if any such action would adversely alter or change the preferences, rights, privileges or powers of, or restrictions provided for the benefit of the Series B Preferred Stock, (ii) issue further shares of Series B Preferred Stock, or (iii) enter into any agreement with respect to any of the foregoing.

Conversion - subject to the Series B Beneficial Ownership Limitation, at any time, each holder of Series B Preferred Stock shall have the right, at such holder's option, to convert any or all of the shares of Series B Preferred Stock held by such holder into fully paid and nonassessable shares of Company common stock. The number of shares of common stock issuable upon conversion of each share of Series B Preferred Stock shall be equal to the quotient obtained by dividing (i) the Stated Value of such share of Series B Preferred Stock plus all accrued and unpaid dividends thereon by (ii) the Series B Conversion Price in effect on the date of conversion. The conversion price (the "Series B Conversion Price") in effect on any conversion date shall be equal to 90% of the lowest closing volume-weighted average price of the Company's common stock on the Nasdaq Capital Market for the five trading days immediately preceding the date of the conversion notice delivered by the holder, subject to adjustment, provided, however, that in no event shall the Series B Conversion Price be lower than \$1.294 per share (the "Floor Price"), subject to adjustment.

Beneficial Ownership Limitation - a holder of Series B Preferred Stock is prohibited from converting shares of Series B Preferred Stock into shares of common stock if, as a result of such conversion, such holder, together with its affiliates, would beneficially own in excess of the applicable beneficial ownership limitation (the "Series B Beneficial Ownership Limitation"). For purposes of the Series B Preferred Stock, the Series B Beneficial Ownership Limitation shall initially be set at 4.9% for each holder and its affiliates and may be adjusted at the discretion of the holder to a percentage between 4.9% and 19.9% (but not to exceed 19.9%) of the number of shares of common stock outstanding immediately after giving effect to the issuance of shares of common stock pursuant to such conversion.

Redemption Rights - the Company may, at any time and in its sole discretion, request to redeem all or any portion of the outstanding shares of Series B Preferred Stock at a price equal to 115% of the Stated Value plus all accrued and unpaid dividends thereon by providing the holder at least 10 days prior written notice, during which 10 day period the holder thereof shall have the right to convert such holder's shares of Series B Preferred Stock into shares of Company common stock. Upon the closing of any equity or equity-linked financing by the Company after the issuance date, the holder shall have the right, but not the obligation, to require the Company to redeem, out of the proceeds of such financing, up to 25% of the aggregate amount of net proceeds raised in the financing, outstanding shares of Series B Preferred Stock at a per share price equal to the Stated Value, plus all accrued and unpaid dividends thereon, provided that such right shall expire 5 days after the holder receives notice from the Company of the consummation of a financing.

Liquidation Rights - in the event of the liquidation, dissolution, or winding up of the Company, whether voluntary or involuntary, the holders of Series B Preferred Stock shall be entitled to receive, prior and in preference to any distribution of any of the assets, funds, or proceeds available for distribution of the Company to the holders of common stock or any other class or series of capital stock ranking junior to the Series B Preferred Stock upon liquidation, by reason of their ownership thereof, an amount per share equal to the greater of (i) the Stated Value plus all accrued and unpaid dividends thereon or (ii) the amount that such holder would receive if such holder converted all of its shares of Series B Preferred Stock into common stock immediately prior to such liquidation, dissolution or winding up.

On April 29, 2025, the Company entered into a Securities Purchase Agreement (the "Preferred Purchase Agreement") with an investor (the "Investor"), pursuant to which, subject to the conditions set forth therein, the Company shall sell to the Investor, and the Investor shall purchase from the Company, up to 8,400 shares of the Company's Series B Preferred Stock and warrants ("Investor Warrants") to purchase shares of the Company's common stock for a total purchase price of up to \$8,400,000 (the "Tranched Financing") in several tranche closings (each, a "Tranche Closing").

The Preferred Purchase Agreement provides that the Tranched Financing shall be conducted through six separate Tranche Closings pursuant to which, subject to satisfaction of the applicable closing conditions set forth in the Preferred Purchase Agreement, the Company shall sell and issue the Investor up to an aggregate of 8,400 shares of Series B Preferred Stock as follows: (i) 700 shares of Series B Preferred Stock, for \$700,000, in the initial Tranche Closing, which was consummated on June 25, 2025; (ii) 700 shares of Series B Preferred Stock, for \$700,000, in the second Tranche Closing, which shall be consummated 10 trading days after the initial Tranche Closing; (iii) 1,750 shares of Series B Preferred Stock, for \$1,750,000, in the third Tranche Closing, which shall be consummated 20 trading days after the second Tranche Closing; (iv) 1,750 shares of Series B Preferred Stock, for \$1,750,000, in the fourth Tranche Closing, which shall be consummated 20 trading days after the third Tranche Closing; (v) 1,750 shares of Series B Preferred Stock, for \$1,750,000, in the fifth Tranche Closing, which shall be consummated 20 trading days after the fourth Tranche Closing; and (vi) 1,750 shares of Series B Preferred Stock, for \$1,750,000, in the final Tranche Closing, which shall be consummated 20 trading days after the fifth Tranche Closing.

In addition to the shares of Series B Preferred Stock to be sold and issued to the Investor in the Tranche Financing, at each Tranche Closing the Company shall also issue the Investor an Investor Warrant to purchase that number of shares of Company common stock equal to 30% of shares of common stock issuable upon conversion in full of the shares of Series B Preferred Stock issued at the same Tranche Closing. Each Investor Warrant shall be immediately exercisable (subject to certain beneficial ownership limitations), expire five years from the date of issuance, and have an initial exercise price equal to the average closing price of the Company's common stock during the prior five trading days preceding each Tranche Closing (as may be adjusted for stock dividends, subdivisions, or combinations in the manner described in the Investor Warrant). In the event that Investor Warrants issued to the Investor in a subsequent Tranche Closing have a lower exercise price than the Investor Warrants outstanding as of such later Tranche Closing, immediately after the Tranche Closing the exercise price of all outstanding Investor Warrants held by the Investor shall automatically be reduced to equal such lower exercise price of the Investor Warrants issued in such Tranche Closing.

In the event that the average closing price of the Company's common stock during the prior three trading days preceding a Tranche Closing date shall not be equal to or greater than the Floor Price (as defined below), then the applicable Tranche Closing shall be delayed until such time as the price meets the required threshold for a period of five consecutive trading days. Notwithstanding the foregoing, the Investor has the ability, subject to prior written consent of the Company, to purchase any number of shares of Series B Preferred Stock prior to the dates of the Tranche Closings provided for in the Preferred Purchase Agreement.

The consummation of the transactions contemplated by the Preferred Purchase Agreement is subject to various customary closing conditions. Pursuant to the Preferred Purchase Agreement, subject to certain exceptions, for so long as any shares of Series B Preferred Stock remain outstanding (the "ROFR Period"), the Investor will have a right of first refusal to with respect to any investment proposed to be made by any other person for each and every future variable rate transaction during the ROFR Period. Additionally, subject to certain exceptions, for so long as the Investor holds any shares of Series B Preferred Stock, Warrants, or shares of common stock issued upon conversion of the Series B Preferred Stock or exercise of the Warrants, the Investor shall have the right to participate in any subsequent financing for up to 20% of such financing. Moreover, for so long as any shares of Series B Preferred Stock remain outstanding, subject to certain exceptions, the Investor shall have the right to require the Company to use 25% of the proceeds received by the Company from any future financing to redeem any shares of Series B Preferred Stock held by the Investor in accordance with the terms of the Series B Certificate of Designation.

The Preferred Purchase Agreement contains customary termination provisions for the Investor under certain limited circumstances and the Preferred Purchase Agreement will automatically terminate if any Tranche Closing has not occurred prior to December 31, 2025.

Craft Capital Management LLC ("Craft") acted as placement agent to the Company in connection with the Tranche Financing. As consideration for services rendered by Craft, the Company shall (i) pay Craft a cash fee equal to eight percent (8%) of any such funds received by the Company from the Investor pursuant to the Preferred Purchase Agreement and (ii) issue to Craft that number of warrants to purchase shares of common stock equal in value to six percent (6%) of any such funds received by the Company from the Investor pursuant to the Preferred Purchase Agreement.

Initial Tranche

On June 25, 2025, the Company and the Investor held the initial Tranche Closing, pursuant to which the Company received gross proceeds of \$700 thousand pursuant to the Preferred Purchase Agreement and issued 700 shares of Series B Preferred Stock to the Investor. In addition to the shares of Series B Preferred Stock, the Company issued Investor Warrants to purchase 61,287 shares of Company common stock with an initial exercise price of \$3.85 per share. The Investor Warrants are exercisable immediately and expire on June 25, 2030. On August 21, 2025, in connection with closing of the Third Tranche and pursuant to the Investor Warrants, the exercise price of the Investor Warrants issued to Investor in the Initial Tranche was reduced to \$3.372 per share. On September 26, 2025, in connection with closing of the Fourth Tranche and pursuant to the Investor Warrants, the exercise price of the Investor Warrants issued to the Investor in the Initial Tranche was further reduced to \$3.04 per share. The triggering of the anti-dilution clause created a change in valuation of the Investor Warrants issued to the Investor. The valuation resulted in a deemed dividend from the repricing calculation of the 61,287 warrants of \$1 thousand.

Additionally, as consideration for placement agent services rendered by Craft in connection therewith, the Company paid Craft \$56 thousand at closing of the Initial Tranche and issued warrants to purchase an aggregate of 10,000 shares of Company common stock to the designees of Craft, which warrants have a term of four years from the date of issuance, are exercisable immediately upon issuance, and have an exercise price of \$4.20 per share of common stock (equal to 110% of the closing price per share of the Company's common stock on June 25, 2025). Net proceeds to the Company, after deducting placement agent fees and offering expenses paid by the Company, were \$585 thousand. The net proceeds were allocated between the Series B Preferred Stock and Investor Warrants issued in the offering based on the relative fair values, which were \$455 thousand and \$130 thousand, respectively.

Between July 31, 2025 and August 15, 2025, the Investor converted all 700 Initial Tranche Preferred Shares issued to the Investor in connection with the Initial Tranche Closing into an aggregate of 244,597 shares of common stock.

Second Tranche

On July 31, 2025, the Company and the Investor held the second Tranche Closing, pursuant to which the Company received gross proceeds of \$700 thousand pursuant to the Preferred Purchase Agreement and issued 700 shares of Series B Preferred Stock to the Investor. In addition to the shares of Series B Preferred Stock, the Company issued Investor Warrants to purchase 64,065 shares of Company common stock with an initial exercise price of \$3.966 per share. The Investor Warrants are exercisable immediately and expire on July 31, 2030. On August 21, 2025, in connection with closing of the Third Tranche and pursuant to the Investor Warrants, the exercise price of the Investor Warrants issued to the Investor in the Initial Tranche was reduced to \$3.372 per share. On September 26, 2025, in connection with closing of the Fourth Tranche and pursuant to the Investor Warrants, the exercise price of the Investor Warrants issued to the Investor in the Initial Tranche was further reduced to \$3.04 per share. The triggering of the anti-dilution clause created a change in valuation of the Investor Warrants issued to the Investor. The valuation resulted in a deemed dividend from the repricing calculation of the 64,065 warrants of \$4 thousand.

Additionally, as consideration for placement agent services rendered by Craft in connection therewith, the Company paid Craft \$56 thousand at closing of the Initial Tranche and issued warrants to purchase an aggregate of 11,068 shares of Company common stock to the designees of Craft, which warrants have a term of four years from the date of issuance, are exercisable immediately upon issuance, and have an exercise price of \$3.795 per share of common stock (equal to 110% of the closing price per share of the Company's common stock on July 31, 2025). Net proceeds to the Company, after deducting placement agent fees and offering expenses paid by the Company, were \$625 thousand. The net proceeds were allocated between the Series B Preferred Stock and Investor Warrants issued in the offering based on the relative fair values, which were \$499 thousand and \$126 thousand, respectively.

Between August 15, 2025 and September 30, 2025, the Investor converted 615 Second Tranche Preferred Shares issued to the Investor in connection with the Second Tranche Closing into an aggregate of 219,899 shares of common stock.

Third Tranche

On August 21, 2025, the Company and the Investor held the third Tranche Closing, pursuant to which the Company received gross proceeds of \$1,750,000 pursuant to the Preferred Purchase Agreement and issued 1,750 shares of Series B Preferred Stock to the Investor. In addition to the shares of Series B Preferred Stock, the Company issued Investor Warrants to purchase 188,842 shares of Company common stock with an initial exercise price of \$3.372 per share. On September 26, 2025, in connection with closing of the Fourth Tranche and pursuant to the Investor Warrants, the exercise price of the Investor Warrants issued to the Investor in the Initial Tranche was further reduced to \$3.04 per share. The triggering of the anti-dilution clause created a change in valuation of the Investor Warrants issued to the Investor. The valuation resulted in a deemed dividend from the repricing calculation of the 188,842 warrants of \$5 thousand.

Additionally, as consideration for placement agent services rendered by Craft in connection therewith, the Company paid Craft \$140 thousand at closing of the Third Tranche and issued warrants to purchase an aggregate of 29,830 shares of Company common stock to the designees of Craft, which warrants have a term of four years from the date of issuance, are exercisable immediately upon issuance, and have an exercise price of \$3.52 per share of common stock (equal to 110% of the closing price per share of the Company's common stock on August 21, 2025). Net proceeds to the Company, after deducting placement agent fees and offering expenses paid by the Company, were \$1.6 million. The net proceeds were allocated between the Series B Preferred Stock and Investor Warrants issued in the offering based on the relative fair values, which were \$1.3 million and \$319 thousand, respectively.

As of September 30, 2025, all 1,750 of the Third Tranche Preferred Shares remain outstanding.

Fourth Tranche

On September 26, 2025, the Company and the Investor held the fourth Tranche Closing, pursuant to which the Company received gross proceeds of \$1,750,000 pursuant to the Preferred Purchase Agreement and issued 1,750 shares of Series B Preferred Stock to the Investor. In addition to the shares of Series B Preferred Stock, the Company issued to the Investor Warrants to purchase 195,793 shares of Company common stock with an initial exercise price of \$3.04 per share.

Additionally, as consideration for placement agent services rendered by Craft in connection therewith, the Company paid Craft \$140 thousand at closing of the Third Tranche and issued warrants to purchase an aggregate of 32,249 shares of Company common stock to the designees of Craft, which warrants have a term of four years from the date of issuance, are exercisable immediately upon issuance, and have an exercise price of \$3.256 per share of common stock (equal to 110% of the closing price per share of the Company's common stock on September 26, 2025). Net proceeds to the Company, after deducting placement agent fees and offering expenses paid by the Company, were \$1.6 million. The net proceeds were allocated between the Series B Preferred Stock and Investor Warrants issued in the offering based on the relative fair values, which were \$1.2 million and \$321 thousand, respectively.

As of September 30, 2025, all 1,750 of the Fourth Tranche Preferred Shares remain outstanding.

11. Common Stock

At September 30, 2025 and December 31, 2024, there were 1,662,921 and 556,902 shares of Company common stock issued and outstanding, respectively.

Effective March 7, 2025, the Company implemented a reverse stock split of its issued and outstanding shares of common stock, par value \$0.0001 per share, at a ratio of 1-for-17. As a result of the reverse stock split, the total number of shares of common stock held by each stockholder of the Company were converted automatically into the number of shares of common stock equal to the number of issued and outstanding shares of common stock held by each such stockholder immediately prior to the reverse stock split divided by 17. Refer to Note 2, Summary of Significant Accounting Policies, for details of the reverse stock split.

On May 13, 2024, the Company sold 277,059 shares of its common stock, together with Series A warrants (the "Series A Warrants") to purchase an aggregate of 277,059 shares of common stock and Series B warrants (the "Series B Warrants" and collectively with the Series A Warrants, the "Common Warrants") to purchase an aggregate of 415,589 shares of common stock, to certain investors in a registered public offering. Each share of common stock was sold together with one Series A Warrant and one and a half Series B Warrants at a combined price of \$14.45 per share and Common Warrants, resulting in gross proceeds to the Company of approximately \$4 million. Net proceeds to the Company, after deducting placement agent fees and offering expenses paid by the Company, was approximately \$3.3 million. The net proceeds were allocated between the common stock and Common Warrants issued in the offering based on the relative fair values, which were \$1.4 million and \$1.9 million, respectively. Each of the Common Warrants are exercisable immediately upon issuance and have an exercise price of \$14.45 per share, subject to certain adjustments. The Series A Warrants will expire one year from the date of issuance and the Series B Warrants will expire five years from the date of issuance. As compensation for services rendered by the placement agent, the Company paid the placement agent a cash fee of 7.0% of the gross proceeds of the offering (amounting to approximately \$280 thousand) at closing, as well as \$100 thousand for the reimbursement of certain expenses. Additionally, as partial consideration for services rendered in connection with the offering, the Company issued the placement agent registered warrants to purchase an aggregate of 11,083 shares of Company common stock, equal to 4.0% of the aggregate shares of common stock sold in the offering. The placement agent warrants have an initial exercise price of \$15.90 per share (equal to 110% of the combined offering price per share and Common Warrants), have a term of five years from the commencement of sales in the offering, and are exercisable commencing six months from closing. During the six months ended June 30, 2025, a total of 7,524 Series A Warrants were exercised for total proceeds of \$109 thousand. On May 13, 2025, the remaining 269,535 Series A Warrants outstanding as of such date expired pursuant to their terms.

On September 13, 2024, the Company entered into an Equity Distribution Agreement (the "Distribution Agreement") with Maxim Group LLC ("Maxim"), pursuant to which the Company may offer and sell, from time to time, through or to Maxim, as sales agent or principal, shares of its common stock. The Company will pay Maxim a commission of 3% of the aggregate gross proceeds from each sale of shares pursuant to the Distribution Agreement. The Company also agreed to reimburse Maxim for certain specified fees and expenses of up to \$40 thousand, plus an additional \$5 thousand for each bringdown, as provided in the Distribution Agreement. The agreement will terminate upon the earlier of (i) the sale of all shares of common stock having an aggregate offering price of \$10 million; (ii) twenty-four months from the date of the agreement; (iii) the mutual termination of the agreement upon fifteen days' prior written notice; and (iv) as otherwise permitted therein. During the year ended December 31, 2024, the Company sold a total of 193,161 shares of its common stock pursuant to the Distribution Agreement for gross proceeds of \$1.2 million. The Company paid Maxim \$37 thousand in commissions. Net proceeds to the Company, after deducting commissions and offering expenses paid by the Company, was approximately \$1.1 million. During the nine months ended September 30, 2025, the Company sold an aggregate of 172,700 shares of common stock pursuant to the Distribution Agreement for gross proceeds of \$1.8 million and net proceeds of \$1.6 million after \$53 thousand of commissions paid by the Company to Maxim and \$108 thousand of legal and other fees.

On February 11, 2025, in connection with, and as consideration for, the License Agreement, the Company entered into a Securities Purchase Agreement with Statera, pursuant to which it issued and sold to Statera an aggregate of (i) 55,635 shares of Company common stock and (ii) approximately 360 shares of Series A Preferred Stock for an aggregate price of approximately \$1.2 million.

On March 18, 2025, the Company entered into an Equity Purchase Agreement (the "Purchase Agreement") with Mast Hill Fund, L.P. ("Mast Hill"), pursuant to which the Company will have the right, but not the obligation, to sell to Mast Hill, and Mast Hill will have the obligation to purchase from the Company, up to \$25 million shares of the Company's common stock, at the Company's sole discretion, over the 24 months following the date of execution, subject to the terms of the Purchase Agreement (the "Equity Line of Credit"). As consideration for Mast Hill's commitment to purchase shares of Company common stock under the Purchase Agreement, the Company issued Mast Hill 29,800 restricted shares of common stock following the execution of the Purchase Agreement (the "Commitment Shares"). During the nine months ended September 30, 2025, the Company sold and issued an aggregate of 235,792 shares of common stock to Mast Hill pursuant to the Purchase Agreement for gross proceeds of \$783 thousand and net proceeds of \$741 thousand, after deducting offering costs.

On March 31, 2025, in connection with the Company's exercise of the Neutropenia Option pursuant to the License Agreement and as consideration for the Neutropenia Milestone Payment, the Company entered into a Securities Purchase Agreement with Statera and Avenue, pursuant to which the Company issued to Statera and Avenue an aggregate of \$500 thousand shares of Company stock, consisting of an aggregate of 55,704 shares of common stock and approximately 131 shares of Series A Preferred Stock.

Common stockholders are entitled to dividends if and when declared by the Company's Board of Directors, subject to the rights of the preferred stockholders. As of September 30, 2025, no dividends on common stock had been declared by the Company. At September 30, 2025 and December 31, 2024, the Company had reserved shares of common stock for issuance as follows:

	September 30, 2025	December 31, 2024
Warrants to purchase common stock	1,055,809	707,234
Options issued and outstanding	355,368	8,868
Restricted stock units outstanding	79,415	44,119
Shares available for future incentive plan grants	79,113	5,555
Shares available for the conversion of Series A Preferred Stock	237,200	—
Shares available for the conversion of Series B Preferred Stock	2,770,477	—
Total	4,577,382	765,776

12. Common Stock Warrants

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

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

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

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

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

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In May 2024, in connection with the sale of 277,059 shares of common stock, the Company issued Series A Warrants to purchase an aggregate of 277,059 shares of common stock and Series B Warrants to purchase an aggregate of 415,589 shares of common stock to the purchasers of the stock. The warrants are exercisable upon issuance and have an exercise price of \$14.45 per share. During the six months ended June 30, 2025, a total of 7,524 Series A Warrants were exercised for total proceeds of \$ 109 thousand. All remaining outstanding Series A Warrants expired on May 13, 2025 and the Series B Warrants expire on May 14, 2029. Additionally, the Company issued warrants to purchase 11,083 shares of common stock to Maxim, the placement agent for the public offering of the Company's securities. The placement agent warrants are exercisable at any time beginning six months after the closing date of the equity offering and expire five years from the commencement of sales under the offering.

The Company estimated the value of the warrants issued to the placement agent in May 2024 using the Black-Scholes options valuation model. The fair value of the warrants issued in February 2023 was \$195 thousand and was recognized as issuance costs of the common stock issued in the underwritten public offering and was classified within stockholders' equity. The fair value of the warrants issued in July and August 2023 totaled \$168 thousand and was recognized as issuance costs of the common stock issued in the three offerings during the period and was classified within stockholders' equity. The fair value of the warrants issued in May 2024 was \$70 thousand and was recognized as issuance costs of the common stock issued in the public offering and was classified within stockholders' equity as additional paid in capital.

In June 2025, in connection with the Initial Tranche Closing, the Company issued Investor Warrants to purchase 61,287 shares of common stock. The Investor Warrants are exercisable upon issuance, had an initial exercise price of \$3.85 per share and expire on June 25, 2030. On August 21, 2025, in connection with closing of the Third Tranche and pursuant to the Investor Warrants, the exercise price of the Investor Warrants issued in the Initial Tranche was reduced to \$3.372 per share. On September 26, 2025, in connection with closing of the Fourth Tranche and pursuant to the Investor Warrants, the exercise price of the Investor Warrants issued in the Initial Tranche was further reduced to \$3.04 per share. Additionally, the Company issued warrants to purchase 10,000 shares of common stock to designees of Craft, the placement agent in connection with the Tranche Financing, as partial consideration for services rendered by Craft in connection therewith. The placement agent warrants are exercisable upon issuance, have an exercise price of \$4.20 per share and expire on June 25, 2029.

The Company estimated the value of the placement agent warrants issued to the Craft designees using the Black-Scholes options valuation model. The fair value was \$36 thousand and was recognized as issuance costs of the Series B Preferred Stock issued in the offering and was classified within stockholders' equity as additional paid in capital.

In July 2025, in connection with the Second Tranche Closing, the Company issued Investor Warrants to purchase 64,065 shares of common stock. The Investor Warrants are exercisable upon issuance, had an initial exercise price of \$3.996 per share and expire on July 31, 2030. On August 21, 2025, in connection with closing of the Third Tranche and pursuant to the Investor Warrants, the exercise price of the Investor Warrants issued in the Initial Tranche was reduced to \$3.372 per share. On September 26, 2025, in connection with closing of the Fourth Tranche and pursuant to the Investor Warrants, the exercise price of the Investor Warrants issued in the Initial Tranche was further reduced to \$3.04 per share. Additionally, the Company issued warrants to purchase 11,068 shares of common stock to designees of Craft, the placement agent in connection with the Tranche Financing, as partial consideration for services rendered by Craft in connection therewith. The placement agent warrants are exercisable upon issuance, have an exercise price of \$3.795 per share and expire on July 31, 2029.

The Company estimated the value of the placement agent warrants issued to the Craft designees using the Black-Scholes options valuation model. The fair value was \$31 thousand and was recognized as issuance costs of the Series B Preferred Stock issued in the offering and was classified within stockholders' equity as additional paid in capital.

In August 2025, in connection with the Third Tranche Closing, the Company issued Investor Warrants to purchase 188,842 shares of common stock. The Investor Warrants are exercisable upon issuance, had an initial exercise price of \$3.372 per share and expire on August 21, 2030. On September 26, 2025, in connection with closing of the Fourth Tranche and pursuant to the Investor Warrants, the exercise price of the Investor Warrants issued in the Initial Tranche was further reduced to \$3.04 per share. Additionally, the Company issued warrants to purchase 29,830 shares of common stock to designees of Craft, the placement agent in connection with the Tranche Financing, as partial consideration for services rendered by Craft in connection therewith. The placement agent warrants are exercisable upon issuance, have an exercise price of \$3.52 per share and expire on August 21, 2029.

The Company estimated the value of the placement agent warrants issued to the Craft designees using the Black-Scholes options valuation model. The fair value was \$77 thousand and was recognized as issuance costs of the Series B Preferred Stock issued in the offering and was classified within stockholders' equity as additional paid in capital.

In August 2025, the Company issued warrants to purchase an aggregate of 32,500 shares of common stock to two individuals in exchange for investor relations services provided. The warrants are exercisable upon issuance, have an exercise price of \$3.64 per share and expire on August 11, 2029. The Company estimated the value of the warrants issued to the individuals using the Black-Scholes options valuation model. The fair value was \$94 thousand and was classified within stockholders' equity as additional paid in capital.

In September 2025, in connection with the Fourth Tranche Closing, the Company issued to the Investor warrants to purchase 195,793 shares of common stock. The warrants are exercisable upon issuance, have an initial exercise price of \$3.04 per share and expire on September 26, 2030. Additionally, the Company issued warrants to purchase 32,249 shares of common stock to designees of Craft, the placement agent in connection with the Tranche Financing, as partial consideration for services rendered by Craft in connection therewith. The placement agent warrants are exercisable upon issuance, have an exercise price of \$3.256 per share and expire on September 26, 2029.

The Company estimated the value of the placement agent warrants issued to the Craft designees using the Black-Scholes options valuation model. The fair value was \$78 thousand and was recognized as issuance costs of the Series B Preferred Stock issued in the offering and was classified within stockholders' equity as additional paid in capital.

The fair value of the warrants issued to placement agents in 2025 and 2024 was estimated on the date of grant using the following assumptions:

	2025		2024	
	Minimum	Maximum	Minimum	Maximum
Expected life (in years)	4.0	5.0	5.0	5.0
Expected volatility	126.3%	187.8%	118.6%	118.6%
Risk-free interest rate	3.71%	3.96%	4.50%	4.50%
Dividend yield	0%	0%	0%	0%

A summary of the Company's outstanding warrants as of September 30, 2025 is as follows:

Class of Shares	Number of Warrant Shares	Exercise Price of Warrants	Expiration Date of Warrants
Common Stock	30	\$ 1,768.00	July 1, 2026
Common Stock	30	\$ 1,768.00	November 15, 2026
Common Stock	102	\$ 10,625.00	November 10, 2026
Common Stock	589	\$ 531.25	August 9, 2027
Common Stock	765	\$ 112.20	July 10, 2028
Common Stock	1,206	\$ 81.60	July 14, 2028
Common Stock	781	\$ 83.64	August 4, 2028
Common Stock	11,083	\$ 15.90	May 9, 2029
Common Stock	415,589	\$ 14.45	May 14, 2029
Common Stock	61,287	\$ 3.04	June 25, 2030
Common Stock	10,000	\$ 4.20	June 25, 2029
Common Stock	64,065	\$ 3.04	July 31, 2030

Common Stock	11,068	\$	3.80	July 31, 2029
Common Stock	32,500	\$	3.64	August 11, 2029
Common Stock	188,842	\$	3.04	August 21, 2030
Common Stock	29,830	\$	3.52	August 21, 2029
Common Stock	195,793	\$	3.04	September 26, 2030
Common Stock	32,249	\$	3.26	September 26, 2029
Total	1,055,809			

During the nine months ended September 30, 2025, a total of 7,524 Series A Warrants were exercised for total proceeds of \$ 109 thousand. There were no warrant exercises in the nine months ended September 30, 2024.

13. Equity Incentive Plans

2017 Equity Incentive Plan

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 governed by the 2021 Plan. To the extent that outstanding awards under the 2017 Plan are forfeited or lapse unexercised, the shares of common stock subject to such awards will no longer be available for future issuance.

2021 Equity Incentive Plan

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

Amended and Restated 2021 Equity Incentive Plan, as amended

On August 9, 2024, the Company adopted its Amended and Restated 2021 Equity Incentive Plan (the "A&R 2021 Plan"), which amended and restated the 2021 Plan in full to, amongst other things, increase the number of shares of common stock authorized for issuance thereunder from 5,434 shares to 58,823 shares. The Company's Board of Directors unanimously approved the adoption of the A&R 2021 Plan, subject to stockholder approval, on June 15, 2024, and the Company's stockholders approved the A&R 2021 Plan at the Company's 2024 Annual Meeting of Stockholders held on August 9, 2024. On January 1, 2025, 27,846 shares were automatically added to the number of shares authorized for issuance under A&R 2021 Plan (an increase equal to 5% of the number of the outstanding shares of Company common stock as of December 31, 2024).

On June 30, 2025, following stockholder approval, the Company further amended the A&R 2021 Plan to increase the number of shares of common stock authorized for issuance thereunder from 86,669 to 511,669 shares.

As of September 30, 2025, there were 79,113 shares of common stock available for issuance under the A&R 2021 Plan, as amended.

Stock Options

In the case of an incentive stock option (i) granted to an employee who, at the time of grant of such option, owns stock representing more than 10% of the voting power of all classes of stock of the Company or any parent or subsidiary of the Company, 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 of the Company, 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. 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 nine months ended September 30, 2025:

	Outstanding	Exercisable
January 1, 2025	8,868	1,935
Granted	346,500	—
Vested	—	5,201
Canceled or expired	—	—
Exercised	—	—
September 30, 2025	<u>355,368</u>	<u>7,136</u>

The weighted-average exercise price as of September 30, 2025 for stock options outstanding and stock options exercisable was \$8.63 and \$259.70, respectively. The weighted average remaining contractual life as of September 30, 2025 for stock options outstanding and stock options exercisable was 9.82 and 8.54 years, respectively. Stock-based compensation expense related to stock options was \$91 thousand and \$222 thousand for the three and nine months ended September 30, 2025, respectively. Stock-based compensation expense related to stock options was \$55 thousand and \$160 thousand for the three and nine months ended September 30, 2024, respectively. As of September 30, 2025, there was \$1.0 million of remaining expense, which is expected to be amortized over 3.46 years.

Restricted Stock Awards

The following table summarizes the restricted stock award activity for the nine months ended September 30, 2025:

	Number of Shares	Weighted-Average Grant Date Fair Value Per Share
January 1, 2025	111	\$ 22.78
Issuance of restricted common stock	—	\$ —
Vested	(111)	\$ 22.78
Cancelled	—	\$ —
September 30, 2025	<u>—</u>	<u>\$ —</u>

The fair value of restricted stock awards vested during the three and nine months ended September 30, 2025 was \$0 and \$2 thousand, respectively. The fair value of restricted stock awards vested during the three and nine months ended September 30, 2024 was \$2 thousand and \$5 thousand, respectively. There is no remaining expense to be recognized in connection with restricted stock awards.

Restricted Stock Units

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

	Number of Shares	Weighted-Average Grant-Date Fair Value Per Share
Non-vested as of January 1, 2025	44,119	\$ 3.91
Granted	68,084	\$ 5.96
Vested	(32,788)	\$ 3.05
Cancelled	—	\$ —
Non-vested as of September 30, 2025	<u>79,415</u>	<u>\$ 5.98</u>

The fair value of restricted stock units granted during the three and nine months ended September 30, 2025 was \$100 thousand and \$406 thousand, respectively. There were no restricted stock units granted during the three and nine months ended September 30, 2024. Stock-based compensation expense related to restricted stock units was \$133 thousand and \$190 thousand for the three and nine months ended September 30, 2025, respectively. There was no expense for the three and nine months ended September 30, 2024, as no restricted stock units had been issued. As of September 30, 2025, there was \$383 thousand of remaining expense, which is expected to be amortized over 3.38 years.

In May 2025, the Company's Board of Directors approved the award of certain bonus payments related to performance in 2024, to be paid in the form of restricted stock units once certain milestones have been achieved. The milestones were achieved and the restricted stock units were issued in the third quarter.

Total Stock-Based Compensation

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Research and development	\$ 58	\$ 23	\$ 160	\$ 68
Sales and marketing	3	—	25	1
General and administrative	77	35	230	97
Total stock-based compensation	<u>\$ 138</u>	<u>\$ 58</u>	<u>\$ 415</u>	<u>\$ 166</u>

14. Net Loss per Share

The Company applies the two-class method pursuant to the issuance of our Series B Preferred Stock. Accordingly, the Company's basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period. Net loss attributable to common stockholders is equal to the Company's net loss.

The calculation of basic earnings per share requires an allocation of earnings to all securities that participate in dividends with shares of common stock to the extent that each security may share in the Company's earnings. Basic earnings per share are calculated by dividing undistributed earnings allocated to common stock by the weighted average number of shares of common stock.

Diluted earnings per share are calculated using the more dilutive of the two-class or if-converted methods. The two-class method uses net income available to common stockholders and assumes conversion of all potential shares other than the participating securities. The if-converted method uses net income and assumes conversion of all potential shares including the participating securities. For the periods where a net loss attributable to common stockholders is present, dilutive securities have been excluded from the calculation of diluted net loss per share attributable to common stockholders as including them would have been anti-dilutive.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
(In thousands, except per share amounts)				
Net loss	\$ (2,596)	\$ (1,431)	\$ (6,029)	\$ (4,178)
Less dividends on Series B Preferred Stock	(36)	—	(37)	—
Deemed dividends on warrants	(10)	—	(10)	—
Net loss available to common stockholders	<u>(2,642)</u>	<u>(1,431)</u>	<u>(6,076)</u>	<u>(4,178)</u>
Weighted average number of shares of common stock outstanding	<u>1,320,778</u>	<u>364,184</u>	<u>928,971</u>	<u>229,291</u>
Net loss per share - basic	<u>\$ (2.00)</u>	<u>\$ (3.93)</u>	<u>\$ (6.54)</u>	<u>\$ (18.22)</u>

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:

	Nine Months Ended September 30,	
	2025	2024
Warrants to purchase common stock	1,055,809	707,234
Common stock options issued and outstanding	355,368	3,904
Restricted stock units issued and outstanding	79,415	—
Series A Preferred Stock	237,200	—
Series B Preferred Stock	2,767,387	—
Total	4,495,179	711,138

15. Segment Information

Tivic Health is a late-stage therapeutics company harnessing the power of the immune system to improve clinical outcomes and save lives. Tivic's biopharma program is focused on advancing its first drug product candidate, Entolimod, into manufacturing, conducting process validation utilizing the output of such manufacturing, and filing the associated Biologics License Application with the FDA, with the intent to sell the biologic compounds either inside or outside of the United States. Tivic's bioelectronic program has focused on developing non-invasive medical devices that influence biologic functions associated with various diseases and conditions. Tivic has an FDA-approved over-the-counter device, ClearUP, that treats sinus pain and pressure, which it plans to discontinue before the end of the year. Historically, revenue has been derived from sales of the Company's first commercial product, ClearUP. To date, the Company has managed its business activities as a single operating segment. Tivic's Chief Executive Officer is the CODM. The CODM utilizes the Company's long-term plan, which includes product development roadmaps and long-term financial models, as key input to resource allocation. The CODM makes decisions on resource allocation, assesses performance of the business, and monitors budget versus actual results using factors such as gross margin, operating expenses, loss from operations and net loss.

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

During the three and nine months ended September 30, 2025 and 2024, all revenue was domestic revenue. To date, the Company has not sold its product outside of the United States.

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

16. Subsequent Events

On November 12, 2025, after considering all reasonably available options and a broader strategic reassessment, the Company's board of directors approved the wind down of the Company's ClearUP business, which the Company intends to substantially complete prior to the end of the year. In connection with the wind down of the ClearUP business, the Company incurred approximately \$347 thousand in charges during the quarter ended September 30, 2025 and expects to incur additional related expenditures in the range of approximately \$20 thousand to \$50 thousand through the end of the year. Additionally, as a result of its exit from its consumer health business, the Company expects that it will generate minimal to no revenue until such time that it is able to obtain regulatory approval of, and commercialize, its other product candidates. The estimates of the charges and costs that the Company expects to incur, and the timing thereof, as well as its revenue expectations, are subject to a number of assumptions and actual results may differ materially from those described above. In addition, the Company may incur other charges or cash expenditures not currently contemplated due to unanticipated events that may occur as a result of, or in connection with, the wind down of the ClearUP business.

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 (this "Quarterly Report"), 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, 2024 (our "Annual Report"). 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, as well as those identified in the "Risk Factors" section of our Annual Report, which Risk Factors are incorporated in this Quarterly Report 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."

Business Overview

Tivic Health Systems, Inc. (the "Company" or "Tivic Health") is a late-stage therapeutics company harnessing the power of the immune system to improve clinical outcomes and save lives.

Tivic Health's Toll-like Receptor 5 ("TLR5") program's lead product candidate is the late-stage TLR5 agonist, Entolimod™, to treat acute radiation syndrome ("ARS") and for remediating side effects of medical radiation and chemotherapy. Tivic Health holds investigational new drug ("IND") applications for Entolimod for ARS and advanced cancer applications. The U.S. Federal Drug Administration ("FDA") has granted Fast Track and Orphan Drug designations to Entolimod™ for the treatment of ARS. The Company has licensed the rights to Entolimod and Entolasta as they related to the neutropenia indication and plans, over time, to undertake Phase 2 clinical studies for Entolimod and/or Entolasta for the treatment of neutropenia and other oncology-related indications.

Tivic Health's bioelectronic program has focused on developing non-invasive medical devices that influence biologic functions associated with various diseases and conditions seeking to meaningfully improve treatment options in neurologic, cardiac and autonomic-related diseases. Tivic Health has an FDA-approved over-the-counter device, ClearUP, that treats sinus pain and pressure, which we plan to discontinue before the end of the year. As the Company exits its consumer health business, Tivic Health's bioelectronic portfolio is now primarily focused on non-invasive vagus nerve stimulation ("VNS"). Both a pilot study and an optimization study have been completed at the Feinstein Institute for Bioelectronic Medicine at Northwell Health. While study outcomes have been positive, the Company is currently focusing its resources on the advancement of its lead product candidate, Entolimod, and investments in its bioelectronics program may be significantly reduced or eliminated.

Wind Down of Current Commercial Product

In 2019, Tivic Health commercially launched ClearUP, a handheld device for treatment of sinus pain and congestion and our first FDA-regulated product. As previously disclosed, after our purchase of the Entolimod license, our focus substantially shifted from growing the ClearUP business to advancing our biologic pipeline and we began pursuing monetization strategies for the ClearUP business, including a potential strategic divestiture of the business.

On November 12, 2025, after considering all reasonably available options and a broader strategic reassessment, our board of directors approved the wind down of the ClearUP business, which we intend to substantially complete prior to the end of the year. In connection with the wind down of the ClearUP business, the Company incurred approximately \$347 thousand in charges during the quarter ended September 30, 2025 and expects to incur additional related expenditures in the range of approximately \$20 thousand to \$50 thousand through the end of the year. Additionally, as a result of its exit from its consumer health business, the Company expects that it will generate minimal to no revenue until such time that it is able to obtain regulatory approval of and commercialize its other product candidates.

The estimates of the charges and costs that the Company expects to incur, and the timing thereof, as well as its revenue expectations, are subject to a number of assumptions and actual results may differ materially from those described above. In addition, the Company may incur other charges or cash expenditures not currently contemplated due to unanticipated events that may occur as a result of or in connection with the wind down of the ClearUP business.

Clinical Pipeline

Biologics Program

As announced in February 2025, we acquired worldwide exclusive license rights from Statera Biopharma, Inc. ("Statera") to the late-stage toll-like receptor TLR5 agonist Entolimod for the treatment of ARS. In addition, we acquired an exclusive option to license five additional indications and clinical use cases for Entolimod and immune-optimized second-generation product candidate, Entolasta. In March 2025, we exercised our option to acquire an exclusive worldwide license to the neutropenia indication for Entolimod and Entolasta. Entolimod and Entolasta have been the subject of more than forty animal and human trials and \$140 million of prior investment, including \$35.6 million from the Department of Defense, Defense Threats Reduction Agency, NASA, National Institutes of Health and the Department of Army. The FDA has granted Fast Track and Orphan Drug designations to Entolimod for the prevention and treatment of ARS and to mitigate the likelihood of death following a potential lethal dose of total body ionization during or after a radiation disaster.

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

In addition, we have an active IND application for oncology-related applications and intend to use it to initiate one or more Phase 2 clinical studies for Entolimod and/or Entolasta for the treatment of neutropenia and other oncology-related indications. The TLR5 agonist works through the activation of the NF-kappaB pathway, upstream of G-CSF. Entolimod treatment also led to reduced apoptosis and accelerated crypt regeneration in the gastrointestinal tract (Krivokrysenko, et al, PLOS-One, 2015). Entolimod and Entolasta's mechanisms of action encompass the same active pathway as currently approved Granulocyte colony-stimulating factor (G-CSF) drugs but have additional benefits in reducing apoptosis and preventing cell death. The anti-apoptotic pathway has been tested for its prophylactic benefits and has shown efficacy in mitigating the damaging effects of radiation on both the gastrointestinal and hemopoietic systems and has been demonstrated to provide such benefits both before radiation exposure and within 48 hours after exposure. We believe these properties have the potential to make our TLR5 agonists compelling as adjuvants and/or as alternatives to currently marketed G-CSF.

Bioelectronic Medicine

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

In May 2024, we announced the final results of an initial clinical validation study with The Feinstein Institutes for Medical Research at Northwell Health ("Feinstein"). Through this collaboration, we have confirmed the effectiveness of our patent-pending non-invasive ncVNS approach, which induces responses in the autonomic, cardiac, and central nervous systems and can be expected to have clinical utility in several major disease areas.

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

Based upon initial results, in May 2024, we initiated a second collaborative research study with Feinstein to identify VNS device parameters, including frequency, signal parameters, electrode placement and duration of treatment, that deliver the optimal effect on autonomic nervous system ("ANS") function (elsewhere referred to as our "optimization study"). In September 2024, we announced approval for the contracted clinical work by Northwell Health's Institutional Review Board, required before enrollment of subjects. In October 2024, we announced enrollment of the first subject in this optimization study for our patent pending, non-invasive VNS device. Enrollment was completed in November 2024. In early 2025, following the completion of two rounds of study visits, the Company expanded the protocol to include additional parameters for optimization, leading to additional intellectual property, including those claims covered in various patent filings. In June 2025, the Company announced the completion of the optimization study, noting that findings reinforce the importance of personalization for therapeutic efficacy, and in November 2025, the Company announced the filing of resulting intellectual property and reported study outcomes. While study outcomes have been positive, the company is currently focusing its resources on the advancement of its lead product candidate and investments in its bioelectronics program may be significantly reduced or eliminated.

Business Updates

Equity Line of Credit

On March 18, 2025, we entered into an Equity Purchase Agreement (the "Mast Hill Purchase Agreement") with Mast Hill Fund, L.P. ("Mast Hill"), pursuant to which we will have the right, but not the obligation, to sell to Mast Hill, and Mast Hill will have the obligation to purchase from us, up to \$25 million shares of our common stock, at our sole discretion, over 24 months, subject to certain conditions precedent and other limitations. We began utilizing the equity line of credit in May 2025, and, as of September 30, 2025, we have sold an aggregate of 235,792 shares of our common stock to Mast Hill for gross proceeds of \$783 thousand and net proceeds of \$741 thousand, after deducting offering costs.

Preferred Purchase Agreement

On April 29, 2025, we entered into an Securities Purchase Agreement (the "Preferred Purchase Agreement") with an investor (the "Investor"), pursuant to which, subject to the conditions set forth therein, we shall sell to the Investor, and the Investor shall purchase from us, up to 8,400 shares of our Series B Non-Voting Convertible Preferred Stock ("Series B Preferred Stock") and warrants ("Investor Warrants") to purchase shares of Company common stock for a total purchase price of up to \$8,400,000 (the "Tranched Financing") in a series of six separate tranche closings (each, a "Tranche Closing"). To date, we have completed a total of four of the six Tranche Closings for aggregate gross proceeds of \$4.9 million and aggregate net proceeds of \$4.3 million, after deducting placement agent fees and offering expenses paid by the Company.

On June 25, 2025, we completed the initial Tranche Closing, pursuant to which we sold and issued 700 shares of Series B Preferred Stock and Investor Warrants to purchase 61,287 shares of common stock to the Investor for gross proceeds of \$700 thousand and net proceeds of \$585 thousand, after deducting placement agent fees and offering expenses. In connection with the initial Tranche Closing, as consideration for placement agent services rendered by Craft Capital Management LLC ("Craft"), we paid Craft \$56 thousand and issued warrants to purchase an aggregate of 10,000 shares of common stock to the designees of Craft. Between July 31, 2025 and August 15, 2025, the Investor converted all 700 shares of Series B Preferred Stock issued to the Investor in connection with the initial Tranche Closing into an aggregate of 244,597 shares of common stock.

On July 31, 2025, we completed the second Tranche Closing, pursuant to which we sold and issued 700 shares of Series B Preferred Stock and Investor Warrants to purchase 64,065 shares of common stock to the Investor for gross proceeds of \$700 thousand and net proceeds of \$625 thousand, after deducting placement agent fees and offering expenses. In connection with the second Tranche Closing, as consideration for placement agent services rendered by Craft, we paid Craft \$56 thousand and issued warrants to purchase an aggregate of 11,068 shares of common stock to the designees of Craft. Between August 15, 2025 and October 8, 2025, the Investor converted all 700 shares of Series B Preferred Stock issued to the Investor in connection with the second Tranche Closing into an aggregate of 252,710 shares of common stock.

On August 21, 2025, we completed the third Tranche Closing, pursuant to which we sold and issued 1,750 shares of Series B Preferred Stock and Investor Warrants to purchase 188,842 shares of common stock to the Investor for gross proceeds of \$1.75 million and net proceeds of \$1.6 thousand, after deducting placement agent fees and offering expenses. In connection with the third Tranche Closing, as consideration for placement agent services rendered by Craft, we paid Craft \$140 thousand and issued warrants to purchase an aggregate of 29,830 shares of common stock to the designees of Craft. Between October 27, 2025 and November 5, 2025, the Investor converted an aggregate of 160 shares of Series B Preferred Stock issued to the Investor in connection with the third Tranche Closing into an aggregate of 70,220 shares of common stock.

On September 26, 2025, we completed the fourth Tranche Closing, pursuant to which we sold and issued 1,750 shares of Series B Preferred Stock and Investor Warrants to purchase 195,793 shares of common stock to the Investor for gross proceeds of \$1.75 million and net proceeds of \$1.6 thousand, after deducting placement agent fees and offering expenses. In connection with the fourth Tranche Closing, as consideration for placement agent services rendered by Craft, we paid Craft \$140 thousand and issued warrants to purchase an aggregate of 32,249 shares of common stock to the designees of Craft. All 1,750 of the shares of Series B Preferred Stock issued to the Investor in the fourth Tranche Closing remain outstanding.

For more information about the Preferred Purchase Agreement, see Note 10 to our condensed financial statements included in Part I, Item 1 of this Quarterly Report.

Operational Updates

In February 2025, we hired Michael Handley, the previous Chief Executive Officer, President and Chairman of Statera, as Chief Operating Officer of Tivic and President, Tivic Biopharma, a role in which he will lead the establishment of a biopharmaceutical capability within Tivic. In July 2025, our Board appointed Lisa Wolf as our Chief Financial Officer. Ms. Wolf previously served as our interim Chief Financial Officer since October 2024 and has been supporting Tivic as a consultant since 2022. In July 2025, Blake Gurfein stepped down as our Chief Scientific Officer and transitioned to a consulting role. We also continued to build and invest in developing our intellectual property portfolio.

We have continued to intentionally maintain a small core team at this stage of the Company, including managing our headcount to reduce operating expenses; however, as we progress in the clinical development of our product candidates, we expect that we will increase our headcount to address our needs. We have relied, and continue to rely, heavily on third-party service providers, including consultants, marketing agencies, contract manufacturing organizations, software-as-a-service platforms, clinical research organizations, academic research partnerships, finance and accounting support, quality and regulatory support and legal support to carry out our operations. As we integrate new services associated with the ramp-up in biologic development and commercialization, we may experience unexpected delays and incur additional expenses.

Results of Operations

Comparison of the Three and Nine Months Ended September 30, 2025 and 2024

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2025	2024	Change	2025	2024	Change
	(unaudited)			(unaudited)		
Revenue	\$ 146	\$ 126	\$ 20	\$ 302	\$ 600	\$ (298)
Cost of sales	291	82	209	343	359	(16)
Gross profit (loss)	(145)	44	(189)	(41)	241	(282)
Operating expenses:						
Research and development	858	422	436	1,848	980	868
Sales and marketing	415	234	181	1,020	946	74
General and administrative	1,065	819	246	3,014	2,493	521
Total operating expenses	2,338	1,475	863	5,882	4,419	1,463
Loss from operations	(2,483)	(1,431)	(1,052)	(5,923)	(4,178)	(1,745)
Other income (expense):						
Interest income	4	—	4	11	—	11
Loss on disposal of property and equipment	(117)	—	(117)	(117)	—	(117)
Total other income (expense)	(113)	—	(113)	(106)	—	(106)
Net loss	\$ (2,596)	\$ (1,431)	\$ (1,165)	\$ (6,029)	\$ (4,178)	\$ (1,851)

Revenue

Revenue is currently generated solely by the sale of our ClearUP and ancillary products, including accessories and accelerated shipping charges, and is net of return reserves. We currently sell ClearUP directly to consumers online through our own website and to resellers such as McKesson-affiliate Simply Medical and Cardinal Health. Through our direct and reseller relationships, ClearUP has been available through Amazon, McKesson, Optum Store, Walmart, Target, Best Buy, Cardinal Health and FSA/HSA Store. We are in the process of winding down the consumer business and will no longer be selling ClearUP directly to consumers in 2026. Resellers who continue to hold inventory may continue to sell our product until their inventory is exhausted and we may fulfill orders by resellers until inventory is depleted.

For the three months ended September 30, 2025, revenue increased overall by \$20 thousand, or 16%, compared to the same period in 2024, primarily due to a 40% increase in the number of units sold offset by lower average selling prices as we reduced prices in order to increase unit sales and move through our existing inventory. Additionally, we reduced advertising spend in order to focus our capital resources into accelerating our TLR5 program.

For the nine months ended September 30, 2025, revenue decreased overall by \$298 thousand, or 50%, compared to the same period in 2024, primarily due to a 45% decrease in the number of units sold associated with a 35% decrease in advertising spend as we focused our capital resources into securing the License Agreement with Statera and accelerating our TLR5 program.

We expect revenues to decrease significantly as we plan to exit the consumer business by the end of the year. We are no longer spending the significant advertising and marketing costs required to support sales of ClearUP. Our near-term focus is to advance the development of our biopharmaceutical product candidates and to ultimately obtain regulatory approval of our product candidates and generate revenue through the sale thereof.

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. Cost of sales is expected to vary on an absolute basis as sales volume increases or decreases. Cost of sales also includes inventory adjustments and reserves which may be necessary due to excess or obsolete inventory. Cost of sales is expected to decrease as we wind down and exit the consumer business.

For the three months ended September 30, 2025, cost of sales increased by \$209 thousand, or 255%, compared to the same period in 2024. The increase was primarily due to the \$230 thousand inventory reserve for excess and obsolete inventory. In 2024 we recorded \$21 thousand of disposal costs when we moved to a new logistics provider.

For the nine months ended September 30, 2025, cost of sales decreased by \$16 thousand, or 4%, compared to the same period in 2024. The decrease was due to a 45% decrease in unit sales and a \$64 thousand reduction in product support and fulfillment costs, offset by \$230 thousand of inventory reserves for excess and obsolete inventory.

Gross Margin

Gross margin has been affected by a variety of factors, including sales volumes, product and channel mix, pricing strategies, costs of finished goods, and product return rates, and new manufacturing partners and suppliers.

During the three months ended September 30, 2025, our gross margin, without the \$230 thousand of inventory reserves recorded, was 42%, compared to 35% for the same period in 2024. During the nine months ended September 30, 2025, our gross margin, without the \$230 thousand of inventory reserves recorded, was 37% compared to 40% for the same period in 2024.

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 cell line verification of Entolimod, development and testing of drug product, drug substance, and 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 as product candidates are advanced towards commercialization and with the discovery and validation of new product candidates.

For the three months ended September 30, 2025, research and development expenses increased by \$436 thousand compared to the same period in 2024. For the nine months ended September 30, 2025, research and development expenses increased by \$868 thousand compared to the same period in 2024. The increases for both periods were primarily due to the addition of our biopharma program that was formed when we acquired the exclusive worldwide license to the patented TLR5 agonist, Entolimod, from Statera. The increased costs are comprised primarily of employment related expenses, consulting expenses and manufacturing and validation services.

Sales and Marketing Expenses

Sales and marketing expenses include personnel costs, consulting expenses and expenses for advertising and other marketing services. Personnel costs consist of salaries, bonuses, benefits and stock-based compensation expense. Commencing in the second quarter of 2025, sales and marketing expenses include the costs associated with business development and government relations efforts related to Entolimod, in addition to advertising and other marketing costs related to our ClearUP product. We expect sales and marketing expenses to vary as we have eliminated sales and marketing costs related to our ClearUP product and have expanded our business development efforts related to Entolimod.

Sales and marketing expenses increased to \$415 thousand for the three months ended September 30, 2025, compared to \$234 thousand for the three months ended September 30, 2024. The increase was primarily related to the addition of business development headcount and consultants related to Entolimod as well as a modest increase in advertising expenses as we pushed to reduce inventory prior to our exit of the consumer business before year-end.

Sales and marketing expenses increased to \$1.0 million for the nine months ended September 30, 2025, compared to \$0.9 million for the nine months ended September 30, 2024. The increase was due primarily to the addition of business development headcount and consultants related to Entolimod. The increase was offset by a \$193 thousand reduction in advertising and other marketing costs related to ClearUP. The decrease in advertising and other marketing costs was driven by our decision to focus our capital resources into advancing our TLR5 program.

General and Administrative Expenses

General and administrative expenses include D&O insurance, personnel costs, expenses for outside professional services and other expenses. Personnel costs consist of salaries, bonuses, benefits and stock-based compensation expense. Outside professional services consist of legal, finance, accounting and audit services, and other consulting fees. We expect general and administrative expenses to increase moderately as we implement compliance programs related to potential government customers.

For the three months ended September 30, 2025, general and administrative expenses increased by \$246 thousand compared to the same period in 2024. The overall increase was the result of increases in employee related costs of \$60 thousand, increased investor relations expenses of \$128 thousand, which included \$93 thousand of non-cash expenses for warrants issued for services, and increased legal fees of \$90 thousand.

For the nine months ended September 30, 2025, general and administrative expenses increased by \$521 thousand compared to the same period in 2024. The overall increase was the result of increases in employee related costs of \$179 thousand, including stock-based compensation increases of \$134 thousand, increased legal and professional fees of \$228 thousand, and increased corporate expenses of \$304 thousand which included increased investor relations expenses of \$159 thousand, of which \$93 thousand was non-cash expenses for warrants issued for services, and \$109 thousand of expenses related to the Nasdaq hearing and additional shareholder meeting held in 2025. The increases were offset by a decrease of \$145 thousand in lease expenses due to the change in our headquarters in the second quarter of 2024.

Liquidity and Capital Resources

Sources of Liquidity

Since our formation in September 2016, we have devoted substantially all of our efforts to research and development, to regulatory clearance and to early market development and testing for our first product, released September 2019 in the United States, investments in product candidates deriving from our work in vagus nerve stimulation, entry into biologic therapeutics with our TLR5 program, and evaluation and conducting diligence on inorganic growth opportunities. Our focus has substantively shifted from growing the ClearUP business to advancing our biologic and bioelectronic pipeline towards commercial outcomes as we wind down the ClearUP business by the end of the year. We are not profitable and have incurred net losses and negative cash flows from our operations in each year since our inception. As of September 30, 2025, we had cash and cash equivalents of \$3.5 million, working capital of \$3.1 million and an accumulated deficit of \$49.6 million.

We have financed our operations to date primarily through the sale of our securities and, prior to our IPO, convertible notes payable, the full balance of which converted into shares of our common stock in connection with our IPO.

On September 13, 2024, we entered into an Equity Distribution Agreement with Maxim Group LLC ("Maxim"), pursuant to which we may offer and sell, from time to time, through or to Maxim, as sales agent or principal, up to \$10 million in shares of our common stock, subject to our then current "baby shelf" limitation under General Instruction I.B.6. of Form S-3. As of June 30, 2025, we had sold an aggregate of 3,456,435 shares of common stock pursuant to the Distribution Agreement, for gross proceeds of \$3.0 million. We paid Maxim \$90 thousand in commissions in connection with such sales. Net proceeds after deducting all offering costs were \$2.8 million. No shares were sold pursuant to the Equity Distribution Agreement in the quarter ended September 30, 2025.

On March 18, 2025, we entered into the Mast Hill Purchase Agreement with Mast Hill, pursuant to which we will have the right, but not the obligation, to sell to Mast Hill up to \$25 million in shares of our common stock from time to time over a two-year period, subject to certain conditions precedent and other limitations (including without limitation beneficial ownership limitations). As a condition to our ability to effect sales under the Mast Hill Purchase Agreement, the shares must be registered for resale by Mast Hill pursuant to an effective registration statement. As of September 30, 2025, we had sold an aggregate of 235,792 shares of our common stock to Mast Hill pursuant to the Mast Hill Purchase Agreement for gross proceeds of \$783 thousand and net proceeds of \$741 thousand after deducting placement agent fees and offering costs.

On April 29, 2025, we entered into the Preferred Purchase Agreement with the Investor, pursuant to which, subject to the conditions set forth therein, we shall sell to the Investor, and the Investor shall purchase from us, up to 8,400 shares of Series B Preferred Stock and Investor Warrants for a total purchase price of up to \$8.4 million in six separate Tranche Closings. The Investor's obligation to purchase shares of Series B Preferred Stock and Warrants and to complete a Tranche Closing is subject to satisfaction of certain conditions precedent and other limitations. On June 25, 2025, we closed the initial Tranche of funding, which included the sale and issuance to the Investor of 700 shares of Series B Preferred Stock and Investor Warrants to purchase 61,287 shares of our common stock at an initial exercise price of \$3.85 per share. Gross proceeds were \$700 thousand and net proceeds were \$585 thousand, after deducting placement agent fees and offering expenses. On July 31, 2025, we closed the second Tranche of funding, which included the sale and issuance to the Investor of 700 shares of Series B Preferred Stock and Investor Warrants to purchase 64,065 shares of our common stock at an initial exercise price of \$3.97 per share. Gross proceeds were \$700 thousand and net proceeds were \$635 thousand, after deducting placement agent fees and offering expenses. On August 21, 2025, we closed the third Tranche of funding, which included the sale and issuance to the Investor of 1,750 shares of Series B Preferred Stock and Investor Warrants to purchase 188,842 shares of our common stock at an initial exercise price of \$3.372 per share. Gross proceeds were \$1.75 million and net proceeds were \$1.6 million, after deducting placement agent fees and offering expenses. On September 26, 2025, we closed the fourth Tranche of funding, which included the sale and issuance to the Investor of 1,750 shares of Series B Preferred Stock and Warrants to purchase 195,793 shares of our common stock at an initial exercise price of \$3.04 per share. Gross proceeds were \$1.75 million and net proceeds were \$1.6 million, after deducting placement agent fees and offering expenses. Due to certain repricing protections in the Investor Warrants, the exercise price of the Investor Warrants issued in the initial, second and third tranche closings were adjusted down each time such warrants were subsequently issued to the investor at a lower price. Therefore, as of September 26, 2025, with the closing of the fourth Tranche, all warrants issued in connection with the Preferred Purchase Agreement had an exercise price of \$3.04 per share.

Although we continuously monitor operating expenses, we expect that our operating expenses may increase significantly as we discover, acquire, validate and develop our current product candidates and new product candidates; seek regulatory approval and, if approved, proceed to commercialization of new products, including near-term investments in validation of our biologic manufacturing process, preparation of regulatory submissions to domestic and international bodies, and further activities supporting sales and commercialization of Entolimod and, in the future, Entolasta; 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. Management expects to incur substantial additional operating losses for the foreseeable future to conduct pre-clinical and clinical trials, complete development or acquisition of new product lines, obtain regulatory approvals, launch and commercialize our products and continue research and development programs. Based on the Company's current cash levels and burn rate, amongst other things, the Company believes its cash and financial resources may be insufficient to meet the Company's anticipated needs for the twelve months following the date of issuance of the financial statements for the nine months ended September 30, 2025, included elsewhere in this Quarterly Report, which raises substantial doubt about the Company's ability to continue as a going concern within one year from the issuance date of the financial statements.

Plan of Operation and Future Funding Requirements

We have used our capital resources primarily, to date, to fund marketing and advertising for ClearUP, development of both our trigeminal and our vagus nerve platforms and product candidates, our entry into biologic therapeutics through our License Agreement with Statera, evaluating and conducting diligence on potential licensing and acquisition candidates, and the establishment of public company operating infrastructure and general operations. Although we have taken measures to manage our operating expenses, we expect that our operating expenses may increase as we advance product candidates, as well as, over time, discover, acquire, validate or develop additional product candidates; seek regulatory approval and, if approved, proceed to commercialization of new products; obtain, maintain, protect and enforce our intellectual property portfolio; hire additional personnel; and maintain compliance with material government (in addition to environmental) regulations. We may increase our research and development investments in clinical studies to advance additional indications for our licensed TLR5 agonists, Entolimod and Entolasta, during the remainder of 2025 and 2026. We also plan to increase investments in manufacturing and regulatory processes for these product candidates as we prepare to seek a Biologics License, via a BLA, from the FDA.

Furthermore, we have incurred, and will continue to incur, significant costs associated with operating as a public company. We expect to continue to incur losses for the foreseeable future. At this time, due to the inherently unpredictable nature of research and new product adoption, the regulatory approval process, 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. We expect to reduce our costs for advertising and marketing of ClearUP as we wind down our consumer health business and shift our capital resources to the advancement of our TLR5 agonist programs. As a result, we expect revenue to decline and eventually cease altogether until such time, if ever, that we obtain regulatory approval and are able to commercialize and derive revenue from the sale of our product candidates. Although we have explored alternative monetization strategies for ClearUP, our efforts have been unsuccessful and we have determined to move forward with the wind down of our consumer health business.

Manufacturing of biologics is inherently unpredictable, and costs and timelines associated with development of the manufacturing processes may vary materially from our expectations, particularly as we rely on collaboration with outside suppliers. Additionally, clinical and preclinical development timelines, the probability of success, and costs can differ materially from expectations. We cannot forecast which product candidates may be best developed and/or monetized through future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

As previously disclosed, we encountered disruptions in our supply of various materials and components in 2022 due to the well-documented shortages and constraints in the global supply chain. The contract manufacturer that we engaged to manufacture Entolimod has experienced financial stress in the wake of government actions earlier this year, which impacted several of its customers' programs and negatively impacted its business and operating results. This has resulted in delays to our clinical development timeline, and may continue to result in further delays and/or additional costs in the event that they cease operations and/or if determine to engage an alternative contract manufacturer or manufacturers to replace them. We are continuing to monitor their situation and are considering our options. Foreseen or unforeseen supply chain shortages, including as a result of delays in the manufacturing of our product candidates, tariffs and/or trade wars, may continue to pose a material risk for the Company in the near term or future. Additionally, high levels of safety stock can (and did in Q4 2024) result in the Company holding significant reserves against future obsolescence. We continue to maintain significant amounts of inventory on hand relative to the ClearUP unit sales to-date in 2025. As discussed elsewhere in this Quarterly Report, we do not intend to manufacture additional products related to ClearUP and we plan to wind down the consumer business before the end of year. During the third quarter of 2025, we recorded inventory reserves of \$230 thousand for excess and obsolete inventory, which brings our total inventory balance to our expected net realizable value. Additionally, in the third quarter of 2025, we disposed of certain property and equipment related to ClearUP and recorded a net loss on the disposal of \$117 thousand. We may incur additional costs related to the exit from the consumer business.

Our entry into biologic therapeutics requires us to develop relationships with new suppliers, which may adversely impact our ability to accurately forecast lead times and manufacturing costs for our TLR5 Program. We have recently experienced disruptions in our manufacturing program for Entolimod due to our contract manufacturer's financial dependencies on government-funded programs, which were significantly impacted by government actions earlier this year.

We intend to regularly evaluate alternative and secondary manufacturing partners and source suppliers in order to ensure that we are able to support the manufacturing of our product candidates, including the development of processes, analytical methods and validation testing for the manufacturing process itself. Global supply chain concerns (including tariffs, inflation, trade policies, material lead times and other economic factors) could result in an increase in the cost of materials needed for our product candidates. Additionally, in the event that we are unable to develop relationships with suppliers or source sufficient materials from suppliers to manufacture enough of our product candidates to satisfy demand, we may have to cease or slow down production, and our business operations and financial condition may be materially harmed, and we may need to alter our plan of operation.

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

We have generated operating losses in each period since inception. We have incurred an accumulated deficit of \$49.6 million through September 30, 2025. We expect to incur additional losses in the future as we expand both our research and development activities. Based on our current cash levels and burn rate, amongst other things, we believe our cash and financial resources may be insufficient to meet our anticipated needs for the next twelve months. As a result, we expect that we will need to raise additional capital to continue operating our business and fund our planned operations, including research and development, clinical trials and, if regulatory approval is obtained, commercialization of future product candidates.

Longer term, our ability to grow revenue will be dependent on our ability to successfully manufacture, secure regulatory approval for, and commercialize product candidates in our pipeline, including Entolimod, Entolasta and the product candidates stemming from our bioelectronic program.

Until we can generate significant revenue from product sales, if ever, we expect to finance our operations through private or public equity or debt financings, collaborative or other arrangements with corporate, foundation or government funding sources, or through other sources of financing. We do not know whether additional financing will be available on commercially acceptable terms, or at all, when needed. If adequate funds are not available or are not available on commercially acceptable terms, our ability to fund our operations, support the growth of our business or otherwise respond to competitive pressures could be significantly delayed or limited, which could materially adversely affect our business, financial conditions or results of operations, and we may have to significantly delay, scale back or discontinue the development and commercialization of our products and/or future product candidates.

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

- our ability to raise additional capital if and when necessary and on terms favorable to the Company;
- our progress in winding down the ClearUP business, including expected and unexpected costs that we have incurred or may incur related thereto;
- the availability of materials for our product candidates, as well as our ability to source such materials at favorable prices;
- the timing and progress of preclinical and clinical development activities;

- the timing and progress of regulatory activities governing our product candidates;
- the ability to sell our product candidates under an emergency use authorization or similar regulatory measure, domestically and internationally;
- payment terms and timing of commercial contracts entered into for emergency use of our product candidates prior to regulatory approval to and through governments, military and other emergency channels;
- the number and scope of preclinical and clinical programs we decide to pursue;
- the timing and amount of milestone payments we may receive or be required to pay under any current or future collaboration agreements;
- whether we close potential future strategic opportunities, including without limitation pursuant to our exclusive option to license other indications for Entolimod pursuant to the A&R License Agreement with Statera or our buyout option pursuant thereto, 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, domestically and internationally and to establish compliance with new requirements should we secure sales or contracts with government entities.

Until such time, if ever, as we can generate substantial revenue from product sales or licensing, 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, reprioritize investments, 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):

	Nine Months Ended September 30,	
	2025	2024
	(unaudited)	(unaudited)
Cash used in operating activities	\$ (4,712)	\$ (4,360)
Cash used in investing activities	(556)	—
Cash provided by financing activities	6,716	3,154
Net increase (decrease) in cash and cash equivalents	\$ 1,448	\$ (1,206)

Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2025 was \$4.7 million, which consisted primarily of a net loss of \$6.0 million, decreased by non-cash charges of \$857 thousand and a net increase of \$460 thousand in our net operating assets and liabilities. The non-cash charges primarily consisted of \$415 thousand of stock-based compensation, \$230 thousand of inventory reserves for excess and obsolete ClearUP inventory, a \$117 thousand loss recorded on the disposal of property and equipment related to ClearUP, and \$93 thousand of warrants issued to consultants for services. The change in our net operating assets and liabilities was primarily due to an increase in accounts payable and accrued expenses of \$366 thousand.

Net cash used in operating activities for the nine months ended September 30, 2024 was \$4.4 million, which consisted primarily of a net loss of \$4.2 million, decreased by non-cash charges of \$266 thousand and increased by a net decrease of \$448 thousand in our net operating assets and liabilities. The non-cash charges primarily consisted of stock-based compensation of \$166 thousand and amortization of right-of-use assets of \$76 thousand. The change in our net operating assets and liabilities was primarily due to a decrease in accounts payable and accrued expenses of \$648 thousand, a decrease in accounts receivable of \$160 thousand, a decrease in prepaid and other current assets of \$93 thousand, and a decrease of \$96 thousand in lease liabilities.

Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2025 was \$556 thousand, which consisted primarily of \$300 thousand of cash paid for the Statera License Agreement and transactions costs of \$243 thousand. There were no investing activities for the nine months ended September 30, 2024.

Financing Activities

Our financing activities provided \$6.7 million of cash during the nine months ended September 30, 2025. In February 2025, Series A Warrants to purchase 7,524 shares of common stock were exercised for proceeds of \$109 thousand. In April 2025, we sold an aggregate of 172,700 shares of common stock pursuant to our Equity Distribution Agreement with Maxim for gross proceeds of \$1.8 million and net proceeds of \$1.6 million after deducting commissions and offering expenses. In 2025, we sold an aggregate of 235,792 shares of our common stock to Mast Hill pursuant to the equity line of credit for gross proceeds of \$783 thousand and net proceeds of \$741 thousand after deducting offering costs. In the nine months ended September 30, 2025, we sold and issued to the Investor a total of 4,900 shares of Series B Preferred Stock and Investor Warrants to purchase an aggregate of 509,987 shares of our common stock, for gross proceeds of \$4.9 million and net proceeds of \$4.3 million after deducting placement agent fees and offering costs.

For the nine months ended September 30, 2024, our financing activities provided \$3.2 million of cash, which consisted primarily of proceeds from the sale of 4,710,000 shares of our common stock and Common Warrants to purchase an aggregate of 11,775,000 shares of common stock in May 2024, net of offering discounts and other costs.

Known Trends or Uncertainties

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

We encountered disruptions in our supply of various materials and components in 2022 due to the well-documented shortages and constraints in the global supply chain. We experienced increased pricing, longer lead-times, unavailability of product and limited supplies, protracted delivery dates, and shortages of certain parts and supplies that were necessary components for our products. As a result, we have carried increased inventory balances since 2023 to ensure availability of necessary products and to secure pricing. The carried inventory resulted in material reserves in 2024 and 2025. More recently, the contract manufacturer that we engaged to manufacturer Entolimod has experienced financial stress, which has resulted in delays to our clinical development timeline, and may continue to result in further delays and/or additional costs in the event that they cease operations and/or if determine to engage an alternative contract manufacturer or manufacturers to replace them. We are continuing to monitor their situation and are considering our options.

As a result of the foregoing, it is possible that we may face a supply shortage with respect to Entolimod in the near term. We are in close communication with our contract manufacturer and certain of their stakeholders to establish stability and are also considering our options with respect to alternative contract manufacturers in an effort to mitigate the risk of delays in our clinical development timeline and any additional costs that we may incur in connection therewith. As a matter of business, we evaluate alternative manufacturers and secondary source suppliers in order to ensure that we are able to source sufficient materials to manufacture our product candidates. Global supply chain shortages (especially when coupled with inflation, tariffs, and other economic factors) could result in an increase in the cost of the materials used in our product candidates. Additionally, if we are unable to develop relationships with suppliers or source sufficient materials needed to develop and manufacture our product candidates, we may experience delays in production and will seek to develop relationships with alternative suppliers. If we are unable to manufacture enough of our product candidates 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.

On July 4, 2025, the One Big Beautiful Bill Act ("OBBBA") was enacted in the U.S. The OBBBA includes significant provisions, such as the permanent extension of certain expiring provisions of the Tax Cuts and Jobs Act, modifications to the international tax framework and the restoration of favorable tax treatment for certain business provisions. The legislation has multiple effective dates, with certain provisions effective in 2025 and others implemented through 2027. The Company is currently assessing its impact on its consolidated financial statements.

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

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

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

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

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

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

Inflation

Inflation increased significantly in 2024; although it has decreased recently. 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 begin to rise again) due to supply chain constraints, consequences associated with the ongoing conflicts between Russia and Ukraine, employee availability and wage increases, trade tariffs imposed on certain products from China and other countries and increased component and services pricing.

Off-Balance Sheet Arrangements

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

Contractual Obligations and Commitments

Office Lease

The Company previously entered into a noncancelable operating lease for approximately 9,091 square feet of office space in Hayward, California as its headquarters. The lease was set to expire in October 2025 and there was no option to renew for an additional term. The Company was obligated to pay, on a pro-rata basis, real estate taxes and operating costs related to the premises. The lease was terminated on May 31, 2024 and the Company has no further obligations with regard to the lease.

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

Lease costs recorded during the nine months ended September 30, 2024 were \$84 thousand. There were no lease costs recorded for the nine months ended September 30, 2025 as the lease was terminated in 2024.

Statera A&R License Agreement

On February 11, 2025, we entered into the License Agreement with Statera, as amended and restated in June 2025 (the "A&R License Agreement"), pursuant to which we acquired (i) an exclusive worldwide license to the Licensed Molecules as it relates to the Initial Indication and (ii) the Exclusive Option to acquire the exclusive worldwide license to the Subsequent Indications and to the TLR5 agonist follow-on program of Statera known as Entolasta. Additionally, on March 28, 2025, we notified Statera of our election to exercise the Neutropenia Option. As partial consideration for the license, we made certain cash payments and issued certain shares of common stock and Series A Preferred Stock to Statera and Avenue.

Pursuant to the A&R License Agreement, we will be liable to Statera for certain royalty payments on net sales for the ARS indication as a single agent and the neutropenia indication, and, if we exercise the Exclusive Option with respect to other indications, net sales for all Subsequent Indications, within certain royalty period. Additionally, the A&R License Agreement obligates us to develop and commercialize the licensed products, at our own cost and expense, inclusive of licensed products with respect to any Subsequent Indications obtained upon exercise of an Exclusive Option. In the development and commercialization process, we are obligated to meet certain milestones, and must provide Statera and Avenue certain milestone payments, payable in either the form of cash or Company stock (at our sole discretion), upon accomplishing each milestone, as discussed in additional detail in Note 7 to the unaudited condensed financial statements filed with this Quarterly Report.

Scorpius Statement of Work

On May 9, 2025, we entered into a Statement of Work (the "Scorpius SOW") with Scorpius BioManufacturing, Inc. ("Scorpius"), pursuant to which Scorpius agreed to serve as the primary U.S. manufacturer for our late-stage TLR5 agonist, Entolimod, for the treatment of ARS. Pursuant to the Scorpius SOW, Scorpius will provide the following services, among others: cell line verification, legacy process verification, GMP scale-up production, drug product fill and finish, analytical development and qualification, and upstream and downstream optimization of the process.

Pursuant to the Scorpius SOW, we have agreed to pay Scorpius service fees estimated to be approximately \$2.4 million, with a total estimated investment by the Company of approximately \$4.1 million, inclusive of additional pass-through costs and expenses, including for consumables and external services. The fees and costs will be payable on a milestone-based invoicing schedule tied to the completion of defined project stages and deliverables, as provided in the Scorpius SOW. Pass-through costs for raw materials, consumables, reagents, shipping, and subcontracted services will be managed by Scorpius on behalf of the Company at cost plus a 15% administrative fee. We are required to settle invoices within 30 days, with Scorpius reserving the right to impose monthly interest charges of 1% for undisputed amounts unpaid after 30 days. We will also be responsible for payment of any taxes, fees, duties or charges imposed by any governmental authority in connection with the services provided by Scorpius under the Scorpius SOW, other than on Scorpius' net income taxes or franchise taxes. The Company estimates the duration of the Scorpius SOW to be approximately two years, with approximately \$3.9 million of costs to be incurred in the next 12 months. As of September 30, 2025 we have paid Scorpius a total of \$209 thousand in connection with the Scorpius SOW. Scorpius has experienced financial distress, in part due to cessation of government contracts, and has experienced and may reasonably be expected to continue to experience, delays in delivery of the contracted services.

Either party may terminate the Scorpius SOW for at any time for any reason by providing the other party with 60 days written notice of termination. In addition, either party shall be permitted to terminate the Scorpius SOW in the event that the other party breaches a material provision thereunder and fails to cure such breach within 30 days from the date of the written notice sent by the nonbreaching party detailing the specifics of such breach. In the event of any termination, the Company shall pay (i) any open invoices and pay the greater of (a) all of its costs due for completed milestones per Table 4 of the Scorpius SOW; and (ii) the documented reasonable expense incurred or irrevocably obligated related to the Scorpius SOW and Scorpius to wind down activities, plus as liquidated damages and not as a penalty, an amount equal to the greater of a 50% of the cost of the Scorpius SOW not yet performed or (b) 75% of the prices of the services for the applicable manufacturing run(s) set to be performed within sixty (60) days of termination under the Scorpius SOW. Given the recent financial instability of Scorpius, we are currently considering our options, including the potential engagement of alternative contract manufacturers to perform the services to be provided by Scorpius pursuant to the Scorpius SOW.

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. Except as set discussed elsewhere in this Quarterly Report, 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 our Annual Report.

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 inventory reserves, sales return 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, filed with the SEC on March 21, 2025.

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.

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.

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 Chief Financial Officer, after evaluating our "disclosure controls and procedures" (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this Quarterly Report (the "Evaluation Date"), have concluded that as of the Evaluation Date, our disclosure controls and procedures are effective to ensure that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in 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 Chief Financial Officer, where appropriate, to allow timely decisions regarding required disclosure.

Management Report on Internal Control over Financial Reporting

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

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

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

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 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 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 and the risk factors discussed in Part I, "Item 1A. Risk Factors" in our 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.

Except as set forth below, 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.

The wind down of our ClearUP business may adversely impact our business, results of operations, financial performance, and reputation.

On November 12, 2025, after considering all reasonably available options and a broader strategic reassessment, our board of directors approved the wind down of our ClearUP business, which we intend to substantially complete prior to the end of the year. In connection with the wind down of the ClearUP business, we incurred approximately \$347 thousand in charges during the quarter ended September 30, 2025 and expect to incur additional related expenditures in the range of approximately \$20 thousand to \$50 thousand through the end of the year. Additionally, as a result of our exit from the consumer health business, we expect to generate minimal to no revenue until such time that we are able to obtain regulatory approval of and commercialize our other product candidates.

The estimates of the charges and costs that we expect to incur, and the timing thereof, are subject to a number of assumptions and actual results may differ materially from those described above due to various factors, many of which are outside of our control. In addition, we may incur other charges or cash expenditures not currently contemplated due to unanticipated events that may occur as a result of or in connection with the wind down of our commercial health business.

In addition, because of uncertainties with respect to our wind down plan (including those described above), we may not be able to realize the anticipated benefits of the wind down, or any benefits at all, or complete the wind down in the timeframe, on the terms or in the manner we expect, and the costs incurred in connection with such wind down activities may exceed our estimates. If the time to complete the wind down takes longer than expected, if we effect the wind down on terms or in a manner less favorable to us than currently anticipated, or if the actual costs or other non-cash charges exceed our estimates, then our business, operational results, financial position, and cash flows could be adversely affected.

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

We rely on, and currently expect to continue to rely on, third-party providers for the supply and manufacturing of our product candidates, including materials for our licensed biopharmaceutical products. Lead times for materials and our product candidates may vary significantly, and some materials to manufacture our product candidates are provided by a limited number of sources.

We encountered disruptions in our supply of various materials and components during 2022 due to the well-documented shortages and constraints in the global supply chain. Additionally, we have recently experienced delays in our clinical development timeline as a result of the financial stress of Scorpius, the contract manufacturer that we engaged to manufacture Entolimod. Although we are in close communication with Scorpius and certain of its stakeholders to establish stability and are also considering our options with respect to alternative contract manufacturers, there can be no guarantee that Scorpius will be able to continue to manufacture our product candidates or that we will be able to identify and retain an alternative manufacturer to provide the services in a timely fashion or at all. If we are unable to continue to use Scorpius as our contract manufacturer or engage an alternative manufacturer, the supply or manufacture of our product candidates could be stopped, delayed or made less profitable.

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

A prolonged U.S. federal government shutdown could materially and adversely affect our business and operations.

Any disruption in the operations of the U.S. government, including as a result of the recent or future temporary or prolonged shutdowns resulting from the failure of Congress to enact appropriations bills or raise the federal debt ceiling, could materially and adversely affect our business, operations and financial condition. Recently, beginning on October 1, 2025, the U.S. federal government shut down and remained shut down through November 12, 2025, during which time certain regulatory agencies, such as the FDA and the SEC, furloughed critical employees and stopped critical activities. Additionally, on October 10, 2025, the U.S. government implemented substantial layoffs and workforce reductions in connection with the federal government shutdown, which resulted in the suspension or delay of various government-funded programs. While we continue to monitor developments, no assurance can be provided as to if or when affected government employees or contractors will be reinstated and that government-funded programs will resume as normal. Furthermore, the recent federal government shutdown has resulted, and may continue for a prolonged period of time to result, in reduced availability of government services, and suspension or delay of activities by key agencies that regulate, fund, or interact with our business, including the SEC, the FDA, the Department of Health and Human Services, and the U.S. Patent and Trademark Office. As a result, the review and approval of our filings, applications, and submissions could be delayed, and we may be unable to access or rely upon certain government data or systems. In particular, it may lead to disruptions and delays in FDA's review and oversight of our product candidates and impact the FDA's ability to provide timely feedback on our development program or pending applications.

Additionally, a prolonged or future shutdown of the U.S. federal government could materially impact the operations of the SEC. For example, the SEC announced that during the recent U.S. federal government shutdown, it would not review or declare registration statements effective, which resulted in the delays of the effectiveness of the registration statement on Form S-3 that we filed to register the securities issued to Helena and the designees of Craft in connection with the fourth Tranche Closing, which in turn has resulted in delays in the funding of the fifth and sixth Tranche Closings under the Preferred Purchase Agreement. In the event of an extended shutdown, the SEC may operate with limited staff or suspend certain functions altogether, which could delay the review or effectiveness of our filings, including registration statements or other financing-related disclosures. Such delays could adversely affect our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue to fund our operations.

Government shutdowns, if prolonged, can significantly impact the ability of government agencies upon which rely, such as the FDA and SEC, to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Even the threat of a government shutdown or prolonged budget negotiation uncertainty may adversely affect the broader U.S. economy, investor confidence, and capital markets. Such conditions could negatively impact our access to financing, timing of capital-raising transactions, and the liquidity or trading volume of our securities. Accordingly, the current or future federal government shutdowns, or uncertainty regarding the continuity of government operations, could have a material adverse effect on our business, results of operations, and stock price.

Federal budget and debt-ceiling disputes may adversely affect capital markets and our financing activities.

Moreover, the uncertainty surrounding government funding debates and debt-ceiling negotiations can negatively affect market conditions, investor sentiment, and the liquidity of small-cap and microcap issuers such as ours. If market volatility or trading disruptions were to occur during the current or future government shutdowns, our ability to execute at-the-market offerings or other financing transactions under our effective shelf registration statement or through private equity offerings could be materially impaired.

Accordingly, any federal government shutdown or protracted budget impasse could materially and adversely affect our regulatory compliance, financing options and capabilities, and overall financial condition.

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

Recent Sales of Unregistered Securities

During the quarter ended September 30, 2025, except as set forth below, there were no unregistered sales of our securities that were not disclosed in a Current Report on Form 8-K.

In August 2025, the Company issued warrants to purchase an aggregate of 32,500 shares of common stock to two individuals in exchange for investor relations services provided. The warrants are exercisable upon issuance, have an exercise price of \$3.64 per share and expire on August 11, 2029.

The warrants and the shares of common stock issuable upon exercise thereof have not been registered under the Securities Act of 1933, as amended (the "Securities Act"), or any state securities laws, and were issued to the respective recipients in transactions exempt from registration under the Securities Act in reliance upon the exemption from registration provided by Section 4(a)(2) under the Securities Act and/or Regulation D promulgated thereunder. Accordingly, the securities constitute "restricted securities" within the meaning of Rule 144 under the Securities Act.

Repurchases

The Company did not repurchase any of the Company's outstanding equity securities during the nine months ended September 30, 2025.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Rule 10b5-1 Trading Plans

During the nine months ended September 30, 2025, none of our directors or officers entered into, modified or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," that were intended to satisfy the affirmative defense conditions of Rule 10b5-1, in each case as defined in Item 408 of Regulation S-K.

Item 6. Exhibits

Exhibit Number	Exhibit description	Incorporated by Reference (Form Type)	Filing Date	Filed herewith
4.1	Form of Warrant (Helena Global Investment Opportunities 1 Ltd.)	8-K	5/2/2025	
4.2	Form of Placement Agent Warrant (Craft Capital Management LLC)	S-1/A	7/25/2025	
10.1	Securities Purchase Agreement, by and between Tivic Health Systems, Inc. and Helena Global Investment Opportunities 1 Ltd., dated April 29, 2025	8-K	5/2/2025	
10.2	Registration Rights Agreement, by and between Tivic Health Systems, Inc. and Helena Global Investment Opportunities 1 Ltd., dated April 29, 2025	8-K	5/2/2025	
10.3†	Statement of Work, by and between Tivic Health Systems, Inc. and Scorpius BioManufacturing, Inc., dated May 9, 2025	10-Q	5/15/2025	
10.4†	Amended and Restated Exclusive License Agreement, effective as of June 18, 2025, by and between the Tivic Health Systems, Inc. and Statera Biopharma, Inc.	8-K/A	6/25/2025	
10.5#	First Amendment to Tivic Health Systems, Inc. Amended and Restated 2021 Equity Incentive Plan, dated June 30, 2025	8-K	7/7/2025	
10.6#	Executive Employment Agreement, by and between Tivic Health Systems, Inc. and Lisa Wolf, effective July 7, 2025	8-K	7/7/2025	
10.7#	Executive Employment Agreement, by and between Tivic Health Systems, Inc. and Jennifer Ernst, dated October 8, 2025	8-K	10/15/2025	
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			X
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 With Embedded Linkbase Documents.			**
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.

Indicates management contract or compensatory plan.

† Pursuant to Item 601(b)(10) of Regulation S-K, certain confidential portions of this exhibit have been omitted by means of marking such portions with asterisks as the identified confidential portions are both not material and are the type of information that the registrant treats as private or confidential. The registrant agrees to supplementally furnish an unredacted copy of this exhibit to the SEC upon its request.

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 city of Fremont, State of California, on November 14, 2025.

Date: November 14, 2025

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

Date: November 14, 2025

By: /s/ Lisa Wolf
Lisa Wolf
Title: Chief Financial Officer
(Principal Financial and Accounting Officer)

**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: November 14, 2025

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

**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, Lisa Wolf, 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: November 14, 2025

By: /s/ Lisa Wolf

Lisa Wolf
Chief Financial Officer
(Principal Financial and Accounting Officer)

**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 September 30, 2025, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Jennifer Ernst, Chief Executive Officer of the Company, and Lisa Wolf, 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: November 14, 2025

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

Date: November 14, 2025

By: /s/ Lisa Wolf
Lisa Wolf
Chief Financial Officer
(Principal Financial and Accounting Officer)