

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
WASHINGTON, D.C. 20549

FORM 10-Q

☒ Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the quarterly period ended June 30, 2025

☐ Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the transition period from to

Commission file number 001-35853

Harvard Apparatus Regenerative Technology, Inc.
(Exact Name of Registrant as Specified in Its Charter)

<u>Delaware</u> (State or Other Jurisdiction of Incorporation or Organization)	<u>45-5210462</u> (IRS Employer Identification No.)
<u>84 October Hill Road, Suite 11, Holliston, MA</u> (Address of Principal Executive Offices)	<u>01746</u> (Zip Code)

(774) 233-7300
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act: None

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
N/A	N/A	N/A

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

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

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

Large accelerated filer <input type="checkbox"/>	Accelerated filer <input type="checkbox"/>
Non-accelerated filer <input checked="" type="checkbox"/>	Smaller reporting company <input checked="" type="checkbox"/>
	Emerging growth company <input type="checkbox"/>

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

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

As of August 4, 2025, there were 17,168,979 shares of common stock, par value \$0.01 per share, outstanding.

Harvard Apparatus Regenerative Technology, Inc.
Form 10-Q
For the Quarter Ended June 30, 2025

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), that relate to future events, our future operations or financial performance, or our plans, strategies and prospects. These statements are based on the beliefs and assumptions of our management team. Although we believe that our plans, intentions and expectations reflected in or suggested by these forward-looking statements are reasonable, we cannot assure that we will achieve or realize these plans, intentions or expectations. Forward-looking statements are inherently subject to risks, uncertainties and assumptions. Generally, statements that are not historical facts, including statements concerning possible or assumed future actions, business strategies, events or performance, are forward-looking statements. These statements may be preceded by, followed by or include the words “believes,” “estimates,” “expects,” “projects,” “forecasts,” “may,” “will,” “should,” “seeks,” “plans,” “scheduled,” “anticipates” or “intends” or the negative of these terms, or other comparable terminology intended to identify statements about the future, although not all forward-looking statements contain these identifying words. The forward-looking statements are based on projections prepared by, and are the responsibility of, our management team. Forward-looking statements contained in this Quarterly Report on Form 10-Q include, but are not limited to, statements about:

- our ability to access debt and equity markets and raise additional capital when needed;
- plans and expectations that depend on our ability to continue as a going concern;
- the success of our collaborations, clinical trials and pre-clinical development efforts and programs, which success may not be achieved on a timely basis or at all;
- our ability to obtain and maintain regulatory approval for our implant products, bioreactors, scaffolds and other devices we pursue, including for the esophagus or airway, which approvals may not be obtained on a timely basis or at all;
- the number of patients who can be treated with our products;
- the amount and timing of costs associated with our development of implant products, bioreactors, scaffolds and other devices;
- our ability to comply with regulations and any changes in regulations;
- our ability to avoid or minimize unpredictable difficulties or delays in the development of new technology;
- the ability of our collaborators or other third parties we contract with, including with respect to conducting any clinical trial or pre-clinical development efforts, to devote sufficient time and resources to successfully carry out their duties or meet expected deadlines;
- our ability to implement our growth strategy;
- our ability to attract and retain qualified personnel and key employees and retain senior management;
- the availability and price of acceptable raw materials and components from third-party suppliers;
- the potential for liability exposure with respect to our products;
- our estimates regarding expenses, future revenue, capital requirements, cash runway and needs for additional financing;
- our ability to compete in the fields of regenerative medicine and bioengineering and in consumer health products, and the financial resources of our competitors;
- our financial performance;
- the effects of the control our principal stockholders can exert based on holding a majority of voting power;
- our intellectual property rights and our ability to protect or enforce these rights, and the impact on our business, results and financial condition if we are unsuccessful in doing so; and
- our ability to address economic downturns and political and market conditions beyond our control and their potential to adversely affect our business, financial condition and results of operations, including, but not limited to, increasing our expenses and cost of capital and adversely impacting our supply chain.

These forward-looking statements are based on information available as of the date of this report, and current expectations, forecasts and assumptions, and involve a number of judgments, risks and uncertainties. Important factors could cause actual results, performance or achievements to differ materially from those indicated or implied by forward-looking statements such as those described under the caption “Risk Factors” in Part I, Item 1A of our Annual Report on Form 10-K, in Part II, Item 1A of this Quarterly Report on Form 10-Q, elsewhere herein and in other filings that we make from time to time with the U.S. Securities and Exchange Commission (the “SEC”). The risks described in such filings are not exhaustive. New risk factors emerge from time to time, and it is not possible to predict all such risk factors, nor can we assess the impact of all such risk factors on our business or the extent to which any factor or combination of factors may cause actual results to differ materially from those contained in any forward-looking statements. Forward-looking statements are not guarantees of performance. You should not put undue reliance on these statements, which speak only as of the date hereof. All forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by the foregoing cautionary statements. We undertake no obligations to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

PART I. FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements.

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except share and par value data)

	June 30, 2025	December 31, 2024
	<i>(Unaudited)</i>	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 786	\$ 2,486
Accounts receivable	5	231
Inventory	27	80
Prepaid research and development	53	90
Prepaid expenses and other current assets	246	347
Total current assets	1,117	3,234
Property, plant and equipment, net	8	11
Right-of-use assets, net	245	293
Long-term prepaid contracts	767	904
Total assets	\$ 2,137	\$ 4,442
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 352	\$ 452
Accrued and other current liabilities	563	221
Deferred revenue	149	—
Insurance premium financing payable	63	253
Operating lease liability	104	95
Total current liabilities	1,231	1,021
Operating lease liability, net of current portion	145	199
Total liabilities	1,376	1,220
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Common stock, par value \$0.01 per share, 60,000,000 shares authorized; 15,918,979 shares issued and outstanding at each of June 30, 2025 and December 31, 2024	159	159
Additional paid-in capital	103,779	102,757
Accumulated deficit	(103,170)	(99,688)
Accumulated other comprehensive loss	(7)	(6)
Total stockholders' equity	761	3,222
Total liabilities and stockholders' equity	\$ 2,137	\$ 4,442

See accompanying notes to unaudited condensed consolidated financial statements.

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited)
(in thousands, except share and per share data)

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2025	2024	2025	2024
Product revenue	\$ 317	\$ 56	\$ 362	\$ 113
Operating expenses:				
Cost of sales	302	13	335	25
Research and development	697	642	1,298	1,482
Sales and marketing	—	197	10	312
General and administrative	1,151	1,685	2,222	2,796
Total operating expenses	2,150	2,537	3,865	4,615
Operating loss	(1,833)	(2,481)	(3,503)	(4,502)
Other income (expense), net:				
Interest income	7	—	20	—
Interest expense	(3)	(17)	(5)	(26)
Other income	6	—	6	—
Other income (expense), net	10	(17)	21	(26)
Net loss	\$ (1,823)	\$ (2,498)	\$ (3,482)	\$ (4,528)
Basic and diluted net loss per share	\$ (0.11)	\$ (0.18)	\$ (0.22)	\$ (0.32)
Weighted average common shares outstanding, basic and diluted	15,918,979	14,258,511	15,918,979	14,102,918
Comprehensive loss:				
Net loss	\$ (1,823)	\$ (2,498)	\$ (3,482)	\$ (4,528)
Foreign currency translation adjustments	(1)	(21)	(1)	(22)
Comprehensive loss	\$ (1,824)	\$ (2,519)	\$ (3,483)	\$ (4,550)

See accompanying notes to unaudited condensed consolidated financial statements.

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

(Unaudited)

(in thousands, except share data)

	Number of Common Shares Outstanding	Common Stock	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
Balance at April 1, 2025	15,918,979	\$ 159	\$ 103,242	\$ (101,347)	\$ (6)	\$ 2,048
Share-based compensation	—	—	537	—	—	537
Net loss	—	—	—	(1,823)	—	(1,823)
Other comprehensive loss	—	—	—	—	(1)	(1)
Balance at June 30, 2025	15,918,979	\$ 159	\$ 103,779	\$ (103,170)	\$ (7)	\$ 761

	Number of Common Shares Outstanding	Common Stock	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity (Deficit)
Balance at April 1, 2024	13,947,324	\$ 139	\$ 94,023	\$ (93,986)	\$ (1)	\$ 175
Share-based compensation expense	—	—	572	—	—	572
Issuance of common stock	367,767	4	1,478	—	—	1,482
Net loss	—	—	—	(2,498)	—	(2,498)
Other comprehensive loss	—	—	—	—	(21)	(21)
Balance at June 30, 2024	14,315,091	\$ 143	\$ 96,073	\$ (96,484)	\$ (22)	\$ (290)

	Number of Common Shares Outstanding	Common Stock	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
Balance at January 1, 2025	15,918,979	\$ 159	\$ 102,757	\$ (99,688)	\$ (6)	\$ 3,222
Share-based compensation	—	—	1,022	—	—	1,022
Net loss	—	—	—	(3,482)	—	(3,482)
Other comprehensive loss	—	—	—	—	(1)	(1)
Balance at June 30, 2025	15,918,979	\$ 159	\$ 103,779	\$ (103,170)	\$ (7)	\$ 761

	Number of Common Shares Outstanding	Common Stock	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity (Deficit)
Balance at January 1, 2024	13,947,324	\$ 139	\$ 93,463	\$ (91,956)	\$ —	\$ 1,646
Share-based compensation expense	—	—	1,132	—	—	1,132
Issuance of common stock	367,767	4	1,478	—	—	1,482
Net loss	—	—	—	(4,528)	—	(4,528)
Other comprehensive loss	—	—	—	—	(22)	(22)
Balance at June 30, 2024	14,315,091	\$ 143	\$ 96,073	\$ (96,484)	\$ (22)	\$ (290)

See accompanying notes to unaudited condensed consolidated financial statements

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)
(in thousands)

	Six Months Ended	
	June 30,	
	2025	2024
OPERATING ACTIVITIES		
Net loss	\$ (3,482)	\$ (4,528)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	1,022	1,132
Depreciation	3	11
Amortization of operating lease right-of-use assets	48	55
Changes in operating assets and liabilities:		
Accounts receivable	226	4
Inventory	53	(10)
Prepaid research and development	37	(133)
Prepaid expenses and other current assets	101	(27)
Deferred financing costs	—	544
Long-term prepaid contracts	137	222
Accounts payable	(100)	307
Operating lease liability	(45)	(55)
Accrued and other current liabilities	342	225
Deferred revenue	149	—
Insurance premium financing payable	(190)	—
Net cash used in operating activities	(1,699)	(2,253)
FINANCING ACTIVITIES		
Proceeds from convertible debt – related party	—	500
Proceeds from issuance of common stock	—	1,482
Net cash provided by financing activities	—	1,982
Effect of exchange rate changes on cash	(1)	(22)
Net decrease in cash and cash equivalents	(1,700)	(293)
Cash and cash equivalents at the beginning of the year	2,486	432
Cash and cash equivalents at the end of the period	\$ 786	\$ 139
SUPPLEMENTAL INFORMATION		
Interest paid in cash	\$ 5	\$ 26

See accompanying notes to unaudited condensed consolidated financial statements.

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. Organization

Overview

Harvard Apparatus Regenerative Technology, Inc. (“Harvard Apparatus Regenerative Technology” or the “Company”) is a biotechnology company focused on the development of regenerative medicine treatments for disorders of the gastro-intestinal system and other organs that result from cancer, trauma or birth defects. The Company believes its technology is likely to be used to repair wounds or other damage or defects resulting from esophageal cancer, esophageal injuries, and birth defects in the esophagus. The Company believes additional product candidates in its development pipeline may repair wounds or other damage or defects resulting from intestinal cancer and uterus wounds. Since inception, the Company has devoted substantially all of its efforts to business planning, research and development, recruiting management and technical staff, and acquiring operating assets.

Consumer Health Products

In the second quarter of 2023, the Company’s subsidiary in Hong Kong, Harvard Apparatus Regenerative Technology Limited, or Consumer Health Products, started focusing on sales of consumer health products.

Consumer Health Products plans to include a broad range of products focused on personal healthcare including dietary supplements. The Company currently sells dietary supplements through Consumer Health Products. These products are commercially marketed to the general public and initially targeted at consumers in Asia through eCommerce (online sales).

Going Concern

The Company has incurred substantial operating losses since its inception, and as of June 30, 2025, had an accumulated deficit of approximately \$103.2 million and will require additional financing to fund future operations. The Company expects that its operating cash on-hand as of June 30, 2025 of approximately \$0.8 million and equity financing of \$2 million in gross proceeds received subsequent to June 30, 2025 will enable it to fund its operating expenses and capital expenditure requirements into the fourth quarter of 2025. Therefore, these conditions raise substantial doubt about the Company’s ability to continue as a going concern.

The Company will need to raise additional capital to fund its current operations. In the event the Company is unable to raise additional capital from outside sources during the third quarter of 2025, it may be forced to curtail or cease its operations.

Cash requirements and cash resource needs will vary significantly depending upon the timing of the financial and other resource needs that will be required to complete ongoing development, pre-clinical and clinical testing of product candidates, as well as regulatory efforts and collaborative arrangements necessary for the Company’s product candidates that are currently under development. The Company is currently seeking and will continue to seek financing from other existing and/or new investors to raise necessary funds through a combination of public or private equity offerings. The Company may also pursue debt financings, other financing mechanisms, research grants, or strategic collaborations and licensing arrangements. The Company may not be able to obtain additional financing on favorable terms, if at all.

The Company’s operations will be adversely affected if it is unable to raise or obtain needed funding and may materially affect the Company’s ability to continue as a going concern. The accompanying condensed consolidated financial statements have been prepared assuming that the Company will continue as a going concern and therefore, the condensed consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amount and classifications of liabilities that may result from the outcome of this uncertainty.

2. Summary of Significant Accounting Policies and Recently Issued Accounting Pronouncements

Summary of Significant Accounting Policies

The accounting policies underlying the accompanying condensed consolidated financial statements are those set forth in Note 2 to the condensed consolidated financial statements for the year ended December 31, 2024 included in the Company's Annual Report on Form 10-K filed with the SEC on March 31, 2025 (the "Form 10-K").

Principles of Consolidation

The condensed consolidated financial statements include the accounts of Harvard Apparatus Regenerative Technology and its subsidiaries; Harvard Apparatus Regenerative Technology Limited (Hong Kong), Harvard Apparatus Regenerative Technology (Hangzhou) Limited (China), and Harvard Apparatus Regenerative Technology GmbH (Germany). All intercompany balances and transactions have been eliminated in consolidation.

Basis of Presentation

The condensed consolidated financial statements reflect the Company's financial position, results of operations and comprehensive loss and cash flows in conformity with accounting principles generally accepted in the United States, or U.S. GAAP. These condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and the notes thereto included in the Company's Form 10-K for the fiscal year ended December 31, 2024.

Use of Estimates

The process of preparing condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. Such estimates include, but are not limited to, share-based compensation, valuation of warrant liability, accrued expenses and the valuation allowance for deferred income taxes. Actual results could differ from those estimates.

Revenue

The Company recognizes revenue in accordance with Financial Accounting Standards Board ("FASB") ASC 606, *Revenue from Contracts with Customers*. The Company offers consumer products primarily through a third-party online store. Revenue is recognized at a point in time when control of the goods is transferred to the customer, which generally occurs upon the delivery to the customer. For any company direct sales to customers, revenue is recognized at a point in time upon shipment of product or hand-delivery to customer. In October 2024, the Company entered into an exclusive distribution agreement (the "Distribution Agreement") with Health Regen, Inc., of Pittsfield, MA ("Health Regen"). Pursuant to the Distribution Agreement, the Company granted Health Regen exclusive distribution rights to all of its Consumer Health Products globally. For any sales to distributors, revenue is recognized when control of the goods is transferred to the distributor, which is either upon shipment or upon receipt of finished goods by the distributor, depending on the contract terms. Revenue also excludes any amounts collected on behalf of third parties, including sales and indirect taxes.

The Company identifies a performance obligation as distinct if both the following criteria are true: the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer and the entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract. Determining the standalone selling price ("SSP") and allocation of consideration from a contract to the individual performance obligations, and the appropriate timing of revenue recognition, is the result of significant qualitative and quantitative judgments. Management considers a variety of factors such as historical sales, usage rates, costs, and expected margin, which may vary over time depending upon the unique facts and circumstances related to each performance obligation in making these estimates. While changes in the allocation of the SSP between performance obligations will not affect the amount of total revenue recognized for a particular contract, any material changes could impact the timing of revenue recognition, which would have a material effect on the Company's financial position and result of operations. This is because the contract consideration is allocated to each performance obligation, delivered or undelivered, at the inception of the contract based on the SSP of each distinct performance obligation.

Cost of Sales

Cost of sales primarily consists of the purchase price of consumer products, taxes, inbound and outbound shipping costs. Shipping costs to receive products from our suppliers are recognized as cost of sales when incurred. E-commerce processing and related transaction costs, including those associated with seller transactions, are classified in sales and marketing on our condensed consolidated statements of operations and comprehensive loss.

Research and Development

Research and development costs are expensed as incurred.

Sales and Marketing

Sales and marketing costs include advertising and payroll and related expenses for personnel engaged in marketing and selling activities. In October 2024, the Company entered into the Distribution Agreement with Health Regen, pursuant to which the Company granted Health Regen exclusive distribution rights to all of its Consumer Health Products globally. The initial term of the Distribution Agreement is from November 1, 2024 through December 31, 2030.

General and Administrative

General and administrative expenses primarily consist of costs for corporate functions, including payroll and related expenses; facilities and equipment expenses, such as depreciation and amortization expense and rent; and professional fees.

Segment Information

The Company manages its operations as two separate operating segments for the purposes of assessing performance and making operating decisions. The Company has one operating unit focused on the development and commercialization of therapies to treat cancers, injuries, and birth defects of the gastro-intestinal tract and the airways. The other operating unit is focused on personal healthcare through dietary supplements. The Company has determined that its chief executive officer is the chief operating decision maker (the “CODM”). The CODM reviews separate discrete financial information presented by operating segment. Resource allocation decisions are made by the CODM based on operating segment cash used in operations, revenues and net income (loss).

Cash Concentrations

The Company maintains its cash balances with a financial institution in federally insured accounts and may periodically have cash balances in excess of insurance limits. The Company maintains its accounts with financial institutions with a high credit rating. The Company has not experienced any losses to date and believes that it is not exposed to any significant credit risk on cash.

Cash and Cash Equivalents

The Company considers all highly liquid investments with a maturity of three months or less at the date of purchase to be cash equivalents. The Company currently invests available cash in money market funds.

Accounts Receivable

Allowances for credit losses are provided for estimated amounts of accounts receivable which may not be collected. At June 30, 2025 and December 31, 2024, we determined that no allowance for credit losses against accounts receivable was necessary. Standard, but not all, payment terms are either due in advance or within 30 days.

Inventory

Inventory, consisting of products available for sale, are primarily accounted for using the first-in, first-out method, and are valued at the lower of cost and net realizable value. This valuation requires us to make judgments, based on currently available information, about the likely method of disposition, such as through sales to individual customers, returns to product vendors, or liquidations, and expected recoverable values of each disposition category.

The Company maintains ownership of its inventory at the third-party warehouse, regardless of whether fulfillment is provided by the Company or the third-party e-commerce seller, and therefore these products are included in the Company’s inventory.

Long-term Prepaid Contracts

The Company has contracted with partners relating to its clinical trial activities. Upon execution of the contracts, the Company made initial payments of \$1.2 million as deposits recorded as long-term assets and will be applied against final invoices which are more than a year away. The deposits will be recorded as expense when the clinical trial is substantially completed. Costs for the clinical trial activities throughout the Company's clinical trial under these contracts are recognized as expense and payable based on costs incurred. As of June 30, 2025, the Company's clinical trial partner applied \$0.5 million of the \$1.2 million deposits against outstanding invoices, resulting in \$0.7 million of remaining deposits relating to its clinical trial activities. In addition to the clinical trial deposits, the company has \$0.1 million in other deposits paid to its landlord and to a university for future esophageal implant production. The deposits are not expected to be expensed within the next twelve months and are therefore classified as long term.

Property, Plant and Equipment

Property, plant and equipment are recorded at cost and depreciated using the straight-line method over the estimated useful lives of the assets as follows:

	Shorter of expected useful life or lease term (years)
Leasehold improvements	
Computer equipment and software	3
Furniture, machinery and equipment	5 - 7

Maintenance and repairs are charged to expense as incurred, while any additions or improvements are capitalized.

Deferred Revenue

Deferred revenue represents advance payments received from customers for goods or services to be delivered in future periods. These payments are initially recorded as liabilities and recognized as revenue when the related goods or services are provided. As of June 30, 2025, the Company had deferred revenue of \$149,000, which primarily consists of advance payments for consumer health products. The Company expects to recognize this revenue within the next fiscal quarter, as the performance obligations are satisfied.

Management regularly reviews the deferred revenue balance to ensure that revenue is recognized in accordance with the Company's revenue recognition policy and applicable accounting standards.

Foreign Currency

Assets and liabilities of non-U.S. operations where the functional currency is other than the U.S. dollar are translated from the functional currency into U.S. dollars at year end exchange rates, and revenues and expenses are translated at average rates prevailing during the year. Resulting translation adjustments are accumulated as part of accumulated other comprehensive loss. Transaction gains or losses are recognized in income or loss in the period in which they occur.

Net Loss Per Share

Basic net loss per share is calculated by dividing net loss applicable to common stockholders by the weighted-average number of shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by adjusting the weighted-average number of shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the if-converted method. For purposes of the diluted net loss per share calculation, warrants to purchase the Company's common stock, par value \$0.01 per share (the "Common Stock") and stock options are considered to be common stock equivalents, but have been excluded from the calculation of diluted net loss per share, as their effect would be anti-dilutive for all periods presented. Therefore, basic and diluted net loss per share applicable to common stockholders were the same for all periods presented.

Concentration of Credit Risk

Financial investments that potentially subject the Company to credit risk consist of cash. The Company has all cash deposited at accredited financial institutions. Bank accounts in the United States are insured by the Federal Deposit Insurance Corporation up to \$250,000. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

For the three and six months ended June 30, 2025, Health Regen accounted for approximately 98% and 97% of total product revenue, respectively. Health Regen was the only customer to account for more than 10% of total accounts receivable as of both June 30, 2025 and December 31, 2024. There were no customers that accounted for more than 10% in product revenue during the three and six months ended June 30, 2024.

Unaudited Interim Financial Information

The accompanying interim condensed consolidated balance sheet as of June 30, 2025, condensed consolidated interim statements of operations and comprehensive loss and condensed consolidated statements of stockholders' equity for the three and six months ended June 30, 2025 and 2024, and cash flows for the six months ended June 30, 2025 and 2024 are unaudited. The interim unaudited condensed consolidated financial statements have been prepared in accordance with U.S. GAAP on the same basis as the annual audited consolidated financial statements and, in the opinion of management, reflect all adjustments necessary for a fair statement of the Company's financial position as of June 30, 2025, its condensed consolidated results of operations and stockholders' equity for the three and six months ended June 30, 2025 and 2024, and cash flows for the six months ended June 30, 2025 and 2024. The financial data and other information disclosed in these notes related to the three and six months ended June 30, 2025 and 2024 are unaudited. The results for the three and six months ended June 30, 2025 are not necessarily indicative of results to be expected for the year ending December 31, 2025, any other interim periods or any future year or period.

Recent Accounting Pronouncements

Accounting standards that have been issued or proposed by the FASB or other standards-setting bodies that do not require adoption until a future date are not expected to have a material impact on the Company's condensed consolidated financial statements upon adoption.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*. The objective of ASU 2023-09 is to enhance disclosures related to income taxes, including specific thresholds for inclusion within the tabular disclosure of income tax rate reconciliation and specified information about income taxes paid. ASU 2023-09 is effective for public companies starting in annual periods beginning after December 15, 2024. The Company is currently evaluating the impact that ASU 2023-09 will have on its condensed consolidated financial statements.

In November 2024, the FASB issued ASU No. 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*. ASU 2024-03 improves disclosures about a public business entity's expenses by requiring disaggregated disclosures of certain types of expenses, including purchases of inventory, employee compensation, depreciation, intangible amortization and depletion, as applicable, for each income statement caption that includes those expenses. In addition, the standard will require entities to define and disclose total selling expenses. The standard is effective for public business entities for annual periods beginning after December 15, 2026, and interim periods beginning after December 15, 2027. Early adoption is permitted, and entities may apply the standard prospectively or retrospectively. The Company is currently evaluating the impact of adopting this standard on its condensed consolidated financial statements and related disclosures.

3. Accrued and Other Current Liabilities

Accrued and other current liabilities consist of the following:

	June 30, 2025	December 31, 2024
	(in thousands)	
Advisory costs	\$ 133	\$ 82
Audit services	81	69
Payroll	349	70
Total accrued and other current liabilities	<u>\$ 563</u>	<u>\$ 221</u>

4. Capital Stock

Preferred Stock

The Company has authorized a total of 2,000,000 shares of preferred stock, par value \$0.01 per share (the “Preferred Stock”), none of which were outstanding at June 30, 2025 and December 31, 2024. The Company’s Board of Directors (the “Board”) has the authority to issue Preferred Stock and to determine the rights, preferences, privileges, and restrictions, including voting rights.

Common Stock

On August 19, 2024, the Company entered into a securities purchase agreement with an investor (the “August Investor”) pursuant to which the August Investor agreed to purchase in a private placement an aggregate of 1,388,888 shares of Common Stock for the aggregate purchase price of approximately \$5.0 million at a purchase price per share of \$3.60.

The August Purchase Agreement required the Company to increase the size of the Board by one member, to appoint a designee selected by the August Investor to the Board, and to take certain actions to ensure that the designee remains on the Board. The Company also agreed to use its reasonable best efforts to obtain approval from its stockholders at the next annual meeting of stockholders to amend the Company’s Amended and Restated Certificate of Incorporation (the “Charter”) to eliminate classification of directors and to amend the Charter and the Company’s Third Amended and Restated Bylaws to permit special stockholder meetings to be called by holders of at least 35% of the Company’s voting power. The Company held its annual shareholder meeting on June 20, 2025, during which shareholders approved the actions outlined in the August Purchase Agreement.

On April 15, 2024, the Company entered into securities purchase agreements with certain investors each named therein (each, an “April Investor,” and collectively the “April Investors”) pursuant to which each of the April Investors agreed to purchase in a private placement an aggregate of 367,767 shares of Common Stock for the aggregate gross proceeds of approximately \$1.5 million at a purchase price per share of \$4.03.

Pursuant to the April Purchase Agreements, if the Company closes an equity financing in a registered public offering of its securities on or before six (6) months from the date of the April Purchase Agreements, and the public offering price per share was less than the per share purchase price of the 2024 Private Placement, then the Company shall promptly following such closing issue to each Investor additional shares of Common Stock in an amount equal to the difference between (i) the shares issued in the 2024 Private Placement, and (ii) result of dividing (a) the subscription amount for each April Purchase Agreement, by (b) the public offering per share. As of October 15, 2024—six months following the April Purchase Agreements—the Company had not completed an equity financing through a registered public offering of its securities since April 15, 2024.

Warrants

The Company had 898,622 warrants to purchase Common Stock outstanding as of June 30, 2025 and December 31, 2024 with a weighted-average exercise price of \$5.33.

5. Share-Based Compensation

Harvard Apparatus Regenerative Technology Amended and Restated Equity Incentive Plan

The Company maintains the Amended and Restated Equity Incentive Plan, or the Plan, for the benefit of certain officers, employees, non-employee directors, and other key persons (including consultants and advisory board members). All options and awards granted under the Plan consist of shares of Common Stock. The Company's policy is to issue stock available from its registered but unissued stock pool through its transfer agent to satisfy stock option exercises and the vesting of restricted stock units. The vesting period for awards is generally four years and the contractual life is ten years. Canceled and forfeited options and awards are available to be reissued under the Plan.

As of June 30, 2025, the Company's Plan has 9,098,000 authorized shares to be issued under the Plan. There were 4,370,364 shares available for issuance as of June 30, 2025.

The following table summarizes information concerning options outstanding and exercisable:

	Amount	Weighted-average exercise price	Weighted-average contractual life (years)	Aggregate intrinsic value (in thousands)
Outstanding at December 31, 2024	4,385,477	\$ 4.54	6.9	\$ 1,307
Granted	292,489	1.60		
Canceled / forfeited	(36,281)	85.80		
Outstanding at June 30, 2025	4,641,685	3.72	6.7	121
Options exercisable	3,128,686	3.61	6.4	97
Options vested and expected to vest	4,618,336	3.71	6.7	121

The Company's outstanding stock options include 993,835 performance-based awards that have vesting provisions subject to the achievement of certain business milestones. Total unrecognized compensation expense for the performance-based awards is approximately \$3.4 million. The Company recognized approximately \$0.02 million and \$0.04 million in stock-based compensation during the three and six months ended June 30, 2025, respectively, and \$0.04 million and \$0.08 million in stock-based compensation during the three and six months ended June 30, 2024, respectively, as a result of certain milestone achievements for these awards have been deemed probable for accounting purposes.

Aggregate intrinsic value for outstanding options as of June 30, 2025 was approximately \$0.1 million and calculated as the difference between the Company's closing stock price of \$1.70 per share as of June 30, 2025 and the weighted average exercise price of \$3.72. As of June 30, 2025, unrecognized compensation cost related to unvested non-performance-based awards amounted to \$1.6 million, which will be recognized over a weighted-average period of one (1.0) year.

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The Company uses the Black-Scholes option pricing model to value its stock options. The weighted average assumptions for valuing options granted during the six months ended June 30, 2025 and 2024 were as follows:

	Six Months Ended June 30,	
	2025	2024
Risk-free interest rate	3.85%	4.07%
Expected volatility	116.11%	116.86%
Expected term (in years)	5.2	5.4
Expected dividend yield	—%	—%

The Company recorded share-based compensation expense in the following expense categories of its condensed consolidated statements of operations and comprehensive loss:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
	(In thousands)		(In thousands)	
Research and development	\$ 58	\$ 110	\$ 117	\$ 219
General and administrative	479	462	905	913
Total	\$ 537	\$ 572	\$ 1,022	\$ 1,132

6. Commitments and Contingencies

From time to time, the Company may be involved in various claims and legal proceedings arising in the ordinary course of business. There are no such matters pending that the Company expects to be material in relation to its business, financial condition, results of operations, or cash flows.

On August 12, 2024, the Company entered into an operating lease agreement for approximately 10,629 square feet of office, research and development and light manufacturing space located in Holliston, MA (the "HQ Lease"). The space will continue to serve as the Company's corporate headquarters and manufacturing facility. The term of the HQ lease ends on August 31, 2027.

The Company currently has a co-development initiative with Yale University and the McGowan Institute for Regenerative Medicine at the University of Pittsburgh. As of June 30, 2025, the Company had outstanding final billings of approximately \$130,000 and \$30,000, respectively. The \$30,000 payment to the University of Pittsburgh was made in July 2025, and the Company expects to settle the remaining balance by year-end. Both universities have substantially completed their respective studies.

In November 2024, the Company entered into an insurance premium financing and security agreement (the "Financing and Security Agreement"). Under the Financing and Security Agreement, the Company financed \$315,008 of certain premiums at an 7.85% annual interest rate. As of June 30, 2025, the outstanding balance on the Financing and Security Agreement was approximately \$63,000 and is included on the balance sheet in insurance premium financing payable. The final payment is due in August 2025.

As of June 30, 2025 and December, 31, 2024, the Company had an outstanding amount of approximately \$37,000 and \$133,000, respectively, owed to former employees of the Company, which is included in accounts payable.

7. Leases

The Company leases laboratory and office space and certain equipment with a remaining term of one year.

On August 12, 2024, the Company entered into the HQ Lease, an operating lease agreement for laboratory and office space in Holliston, MA, with an initial three-year term from September 1, 2024 through August 31, 2027. The Company accounts for the HQ Lease in accordance with ASC Topic 842, Leases. The Company recorded approximately \$323,000 as a right-of-use asset and a corresponding operating lease liability on the Company's condensed consolidated balance sheets upon the accounting commencement date on September 1, 2024. The lease liability was measured at the accounting commencement date utilizing a 13.3% discount rate.

The HQ Lease contains escalating payments during the lease term. Upon execution of the HQ Lease, the Company paid a security deposit, which will be held in escrow and credited at the termination of the lease. As of June 30, 2025, a security deposit of approximately \$14,000 was included in long-term prepaid contracts on the Company's condensed consolidated balance sheet related to the HQ Lease.

All of the Company's leases qualify as operating leases. The following table summarizes the presentation of the Company's operating leases in its condensed consolidated balance sheets:

	Balance Sheet Classification	June 30, 2025	December 31, 2024
<i>Assets:</i>			
Operating lease assets	Right-of-use assets, net	\$ 245	\$ 293
<i>Liabilities:</i>			
Current portion of operating lease liability	Current portion of operating lease liability	104	95
Operating lease liability, net of current portion	Operating lease liability, net of current portion	145	199
Total operating lease liability		\$ 249	\$ 294

The Company recorded operating lease expense in the following categories in its condensed consolidated statements of operations and comprehensive loss:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
	(in thousands)		(in thousands)	
Research and development	\$ 11	\$ 12	\$ 22	\$ 28
Sales and marketing	—	9	—	9
General and administrative	22	7	44	18
Total	\$ 33	\$ 28	\$ 66	\$ 55

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Cash paid included in the computation of the operating lease assets and lease liability during the three and six months ended June 30, 2025 amounted to approximately \$32,000 and \$64,000, respectively. Cash paid included in the computation of the operating lease assets and lease liability during the three and six months ended June 30, 2024 amounted to approximately \$28,000 and \$55,000, respectively.

The weighted average remaining lease term and weighted average discount rate of the Company's operating leases are as follows:

	As of June 30,	
	2025	2024
Remaining lease term (in years)	2.17	1.70
Discount rate	13.29%	8.19%

The minimum lease payments for future years are as follows:

	As of June 30, 2025
	(in thousands)
2025	\$ 65
2026	133
2027	90
Total lease payments	288
Less: imputed interest	(39)
Present value of operating lease liability	<u>\$ 249</u>

8. Net Loss Per Share

The following potential common shares were excluded from the calculation of diluted net loss per share attributable to common stockholders for the six months ended June 30, 2025 and 2024 because including them would have had an anti-dilutive effect:

	Six Months Ended June 30,	
	2025	2024
Options to purchase Common Stock	4,641,685	4,339,055
Warrants to purchase Common Stock	898,622	1,113,622
Total	<u>5,540,307</u>	<u>5,452,677</u>

9. Income Taxes

The Company did not record a federal or state income tax provision or benefit for the six months ended June 30, 2025 and 2024, respectively, due to the expected loss before income taxes to be incurred for the years ended December 31, 2025 and 2024, as well as the Company's continued maintenance of a full valuation allowance against its net deferred tax assets.

10. Segments

The Company's CODM is its Chief Executive Officer. The Company's CODM evaluates the operating results of the Company's reportable segments based on cash used in operations, revenues and net income (loss).

The Company follows the accounting guidance of ASC 280, Segment Reporting ("ASC 280"). Reportable operating segments are determined based on the management approach. The management approach, as defined by ASC 280, is based on the way that the CODM organizes the segments within an enterprise for making operating decisions and assessing performance. While the Company's results of operations are primarily reviewed on a consolidated basis, the CODM manages the enterprise in two reportable segments, each with different operating and potential revenue generating characteristics.

The Company has two operating and reportable segments: (i) Regenerative Biotech focused on the development of regenerative medicine treatments with operations currently in the United States and (ii) Consumer Health Products relating to consumer health products with operations currently in Asia. All of the Company's revenue was generated in Asia for the three and six months ended June 30, 2025 and 2024. The following tables represent selected financial information for our segments:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Product revenue:				
Regenerative Biotech	\$ —	\$ —	\$ —	\$ —
Consumer Health Products	317	56	362	113
Total	<u>\$ 317</u>	<u>\$ 56</u>	<u>\$ 362</u>	<u>\$ 113</u>
Net loss:				
Regenerative Biotech	\$ (1,842)	\$ (2,320)	\$ (3,511)	\$ (4,255)
Consumer Health Products	19	(178)	29	(273)
Total	<u>\$ (1,823)</u>	<u>\$ (2,498)</u>	<u>\$ (3,482)</u>	<u>\$ (4,528)</u>
			June 30, 2025	December 31, 2024
Cash and cash equivalents:				
Regenerative Biotech			\$ 591	\$ 2,405
Consumer Health Products			195	81
Total			<u>\$ 786</u>	<u>\$ 2,486</u>

Total assets:		
Regenerative Biotech	\$ 1,786	\$ 3,978
Consumer Health Products	351	464
Total	\$ 2,137	\$ 4,442

11. Subsequent Events

On July 11, 2025, the Company entered into securities purchase agreements with certain investors each named therein (the “Investor,” and collectively the “Investors”) pursuant to which each of the Investors agreed to purchase in a private placement an aggregate of 1,250,000 shares of common stock for the aggregate gross proceeds of approximately \$2.0 million at a purchase price per share of \$1.60.

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

Forward Looking Statements

The following section of this Quarterly Report on Form 10-Q entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" contains statements that are not statements of historical fact and are forward-looking statements within the meaning of federal securities laws. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties.

In some cases, you can identify forward-looking statements by terms such as "believe," "may," "estimate," "continue," "anticipate," "intend," "should," "could," "would," "target," "seek," "aim," "believe," "predicts," "think," "objectives," "optimistic," "new," "goal," "strategy," "potential," "likely," "will," "expect," "plan" "project," "permit" and similar expressions intended to identify forward-looking statements. These statements reflect our current views with respect to future events, are based on assumptions and are subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We discuss many of these risks in greater detail under the heading "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2024 filed with the Securities and Exchange Commission (the "SEC") on March 31, 2025. You should carefully review all of these factors, as well as the comprehensive discussion of forward-looking statements on page 3 of this Quarterly Report on Form 10-Q.

Harvard Apparatus Regenerative Technology, Inc. is referred to herein as "we," "our," "us", and "the Company".

Business Overview

We are a clinical-stage biotechnology company focused on the development of regenerative medicine treatments for disorders of the gastro-intestinal system and other organs that result from cancer, trauma or birth defects.

We believe that our technology represents a next generation solution for restoring organ function because it allows the patient to regenerate their own organ, thus eliminating the need for human donor or animal transplants, the sacrificing of another of the patient's own organs or permanent artificial implants.

Our first esophageal product candidate, our esophageal implant was used in the first successful regeneration of the esophagus in a patient with esophageal cancer. This successful first-in-human experience, plus the research we have performed on over 50 pigs, led the FDA to approve our 10-patient phase 1 clinical trial. This combination trial will measure both safety and efficacy in the patient population.

We have contracted with IQVIA, a leading global provider of advanced analytics, technology solutions and clinical research services to the life sciences industry, as the contract research organization ("CRO") to manage our first clinical trial. We activated the first clinical trial site and started screening patients in the third quarter of 2023.

We have encountered delays in patient recruitment for our ongoing clinical trial, driven by several factors, including the existing comorbid conditions for clinical trial participants, the stringent eligibility criteria required by FDA for our studies, and logistical difficulties in enrolling participants across various sites.

Although we are actively implementing strategies to mitigate these challenges, such as increasing the number of trial sites and enhancing patient outreach efforts, there is a risk that these measures may not completely resolve the recruitment issues. Our product candidates are currently in development and have not yet received regulatory approval for sale anywhere in the world.

In addition to our development of regenerative medicine treatments, we also sell dietary supplements. In the second quarter of 2023, the Company's subsidiary in Hong Kong, Consumer Health Products started focusing on consumer health products. Consumer Health Products plans to include a broad range of products focused on personal healthcare including dietary supplements. Consumer Health Products started selling consumer health supplements in the third quarter of 2023. These products are commercially marketed to the general public and currently targeted at consumers in Asia through eCommerce (online sales).

We were incorporated and commenced operations on November 1, 2013 as a result of a spin-off from Harvard Bioscience, Inc., or Harvard Bioscience. On that date, we became an independent company that operates the regenerative medicine business previously owned by Harvard Bioscience. The spin-off was completed through the distribution of all the shares of common stock of Harvard Apparatus Regenerative Technology to Harvard Bioscience stockholders.

We continue to assess the market and regulatory approval pathway in China as to our implant products. We are not certain at this time as to which market, including U.S. or China for example, may provide the most viable initial pathway for regulatory approval to a commercial product. This will depend on a number of factors, including the approval and development processes, related costs, ability to raise capital and the terms and conditions thereof, among other factors. Any development and capital raising efforts in China may include a joint venture in relation to our Hong Kong subsidiary, and would also involve a number of commercial variables, including rights and obligations pertaining to licensing, development, and financing, among others. Our failure to receive or obtain such clearances or approvals on a timely basis or at all, whether that be in the U.S., China or otherwise, would have an adverse effect on our results of operations.

Since our incorporation, we have devoted substantially all of our resources to developing our programs, building our intellectual property portfolio, business planning, raising capital and providing selling, general and administrative support for these operations. To date, we have financed our operations with proceeds from the sales of Common Stock, Preferred Stock and warrants. In December 2017, we sold the inventory and rights to manufacture and sell research-only versions of our bioreactors to Harvard Bioscience.

Business Segments

We have two separate reportable segments. One segment, Harvard Apparatus Regenerative Technology, Inc., or Regenerative Biotech, is focused on the development and commercialization of therapies to treat cancers, injuries, and birth defects of the gastro-intestinal tract and the airways. The other segment, Consumer Health Products, is focused on personal healthcare, including dietary supplements.

Financial Condition and Need for Additional Funds

We expect to continue to incur operating losses and negative cash flows from operations during 2025 and in future years.

Operating Losses and Cash Requirements

We have incurred substantial operating losses since our inception, and as of June 30, 2025, had an accumulated deficit of approximately \$103.2 million and will require additional financing to fund future operations. We expect that our operating cash on-hand as of June 30, 2025 of approximately \$0.8 million and equity financing of \$2 million in gross proceeds received subsequent to June 30, 2025 will enable us to fund our operating expenses and capital expenditure requirements into the fourth quarter of 2025. We expect to continue to incur operating losses and negative cash flows from operations for 2025 and in future years. Therefore, as disclosed in Note 1 to our Condensed Consolidated Financial Statements appearing elsewhere in this Quarterly Report on Form 10-Q, these conditions raise substantial doubt about our ability to continue as a going concern.

We will need to raise additional capital to fund our current operations. In the event we do not raise additional capital from outside sources during the third quarter of 2025, we may be forced to curtail or cease our operations.

Cash requirements and cash resource needs will vary significantly depending upon the timing of the financial and other resource needs that will be required to complete ongoing development, pre-clinical and clinical testing of product candidates, as well as regulatory efforts and collaborative arrangements necessary for our product candidates that are currently under development. We are currently seeking and will continue to seek financings from other existing and/or new investors to raise necessary funds through a combination of public or private equity offerings. We may also pursue debt financings, other financing mechanisms, research grants, or strategic collaborations and licensing arrangements. We may not be able to obtain additional financing on favorable terms, if at all.

Our operations will be adversely affected if we are unable to raise or obtain needed funding and may materially affect our ability to continue as a going concern. Our condensed consolidated financial statements have been prepared assuming that we will continue as a going concern and therefore, the condensed consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amount and classifications of liabilities that may result from the outcome of this uncertainty.

Components of Operating Loss

Product revenue. Product revenue consists of consumer health product sales, launched in Asia in the third quarter of 2023. We had not generated any revenue prior to the launch of our consumer health products.

Research and development expense. Research and development expense consists of salaries and related expenses, including share-based compensation, for personnel and contracted consultants and various materials and other costs to develop our new products, primarily: synthetic scaffolds, including investigation and development of materials and investigation and optimization of cellularization, as well as studies of cells and cell behavior. Other research and development expenses include the costs of outside service providers and material costs for prototype and test units and outside laboratories and testing facilities performing cell growth and materials experiments, as well as the costs of all other preclinical research and testing including animal studies and expenses related to potential patents. We expense research and development costs as incurred.

Sales and marketing expense. Sales and marketing costs include advertising and payroll and related expenses for personnel engaged in marketing and selling activities.

General and administrative expense. Selling, general and administrative expense consists primarily of salaries and other related expenses, including share-based compensation. Other costs include professional fees for legal and accounting services, insurance, investor relations and facility costs.

Other income (expense), net. Other income (expense), net, consists primarily of interest expense on convertible debt and finance charges on insurance installment payments offset by interest income.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the expenses during the reporting periods. We evaluate these estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are 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. Our actual results may differ materially from these estimates under different assumptions or conditions.

While our significant accounting policies are discussed in more detail in Note 2 to our Condensed Consolidated Financial Statements appearing elsewhere in this Quarterly Report on Form 10-Q, we believe that the following accounting policies are the most critical for fully understanding and evaluating our financial condition and results of operations.

Share-based Compensation

We account for our share-based compensation in accordance with the fair value recognition provisions of current authoritative guidance. Share-based awards, including stock options, are measured at fair value as of the grant date and recognized as expense over the requisite service period (generally the vesting period), which we have elected to amortize on a straight-line basis. Expense on share-based awards for which vesting is performance or milestone based is recognized on a straight-line basis from the date when we determine the achievement of the milestone is probable to the vesting/milestone achievement date. Since share-based compensation expense is based on awards ultimately expected to vest, it has been reduced by an estimate for future forfeitures. We account for forfeitures as they occur. We estimate the fair value of options granted using the Black-Scholes option valuation model. Significant judgment is required in determining the proper assumptions used in this model. The assumptions used include the risk-free interest rate, expected term, expected volatility, and expected dividend yield. We base our assumptions on historical data when available or, when not available, on a peer group of companies. However, these assumptions consist of estimates of future market conditions, which are inherently uncertain and subject to our judgment, and therefore any changes in assumptions could significantly impact the future grant date fair value of share-based awards.

Results of Operations

The following table summarizes the results of our operations for the three and six months ended June 30, 2025 and 2024 (in thousands):

	Three Months Ended June 30,		Change 2025 vs. 2024		Six Months Ended June 30,		Change 2025 vs. 2024	
	2025	2024	Change	%	2025	2024	Change	%
Product revenue	\$ 317	\$ 56	\$ 261	466%	\$ 362	\$ 113	\$ 249	220%
Operating expenses								
Cost of sales	302	13	289	2,223%	335	25	310	1,240%
Research and development	697	642	55	9%	1,298	1,482	(184)	(12%)
Sales and marketing	—	197	(197)	(100%)	10	312	(302)	(97%)
General and administrative	1,151	1,685	(534)	(32%)	2,222	2,796	(574)	(21%)
Total operating expenses	2,150	2,537	(387)	(15%)	3,865	4,615	(750)	(16%)
Other income (expense), net:								
Interest income	7	—	7	100%	20	—	20	100%
Interest expense	(3)	(17)	14	(82%)	(5)	(26)	21	(81%)
Other income	6	—	6	100%	6	—	6	100%
Total other income (expense), net	10	(17)	27	(159%)	21	(26)	47	(181%)
Net loss	\$ (1,823)	\$ (2,498)	\$ 675	27%	\$ (3,482)	\$ (4,528)	\$ 1,046	23%

Comparison of the three months ended June 30, 2025 and June 30, 2024

Product Revenue

Product revenue was \$317,000 and \$56,000 for the three months ended June 30, 2025 and 2024, respectively. The \$261,000 increase, representing a 466% growth, was driven by expanded distribution and new product launches within our Health Regen segment, including CoQ-10 and sleep aid gummies, alongside continued strong performance from our existing offerings such as Liver Guard.

Cost of Sales

Cost of sales was \$302,000 and \$13,000 for the three months ended June 30, 2025 and 2024, respectively. The gross profit margin on our products decreased primarily due to wholesale pricing to our distributor compared to retail pricing to consumers in the comparable prior quarter.

Research and Development Expense

Research and development expense increased approximately \$0.06 million, or 9%, to approximately \$0.7 million for the three months ended June 30, 2025 as compared to approximately \$0.6 million for the three months ended June 30, 2024. This increase was primarily due to increased clinical trial and preclinical trial activities.

Sales and Marketing Expense

Selling and marketing expense decreased approximately \$0.2 million, or 101%, for the three months ended June 30, 2025 as compared to approximately \$0.2 million for the three months ended June 30, 2024. The reduction primarily stems from a change in our sales strategy, moving from direct sales to distribution partnerships.

General and Administrative Expense

General and administrative expense decreased approximately \$0.5 million, or 32%, to approximately \$1.2 million for the three months ended June 30, 2025 as compared to approximately \$1.7 million for the three months ended June 30, 2024. This decrease is attributable to the prior period's recognition of \$0.5 million in non-recurring offering expenses associated with an anticipated offering that was not completed.

Interest income

During the three months ended June 30, 2025, we recorded interest income of approximately \$7,000 earned from our money market account. During the three months ended June 30, 2024, we generated no interest income.

Interest expense

During the three months ended June 30, 2025, we recorded interest expense of approximately \$3,000 on insurance installment payments. During the three months ended June 30, 2024, we recorded interest expense of approximately \$10,000 on convertible debt and approximately \$7,000 on insurance installment payments.

Other income

For the three months ended June 30, 2025, we recognized total other income of approximately \$6,000. This amount includes \$2,000 in sublease income and \$4,000 generated from hosting site visits. These activities are part of our ongoing efforts to optimize the use of its facilities and engage with stakeholders.

Comparison of the six months ended June 30, 2025 and June 30, 2024

Product Revenue

Product revenue was \$362,000 and \$113,000 for the six months ended June 30, 2025 and 2024, respectively. The \$249,000, representing a 220% growth, was driven by launching new offerings and extending our market reach within our Health Regen segment, including CoQ-10 and sleep aid gummies, alongside continued strong performance from our existing offerings such as Liver Guard..

Cost of Sales

Cost of sales was \$335,000 and \$25,000 for the six months ended June 30, 2025 and 2024, respectively. The increase reflects scaling of operations to match higher sales.

Research and Development Expense

Research and development expense decreased approximately \$0.2 million, or 12%, to approximately \$1.3 million for the six months ended June 30, 2025 as compared to approximately \$1.5 million for the six months ended June 30, 2024. This decrease was primarily due to reduced share-based compensation expense during the current period.

Sales and Marketing Expense

Selling and marketing expense decreased approximately \$0.3 million, or 97% for the six months ended June 30, 2025 as compared to approximately \$0.3 million for the six months ended June 30, 2024. The decrease was primarily driven by a strategic shift from direct in-house sales to a distributor-based model.

General and Administrative Expense

General and administrative expense decreased approximately \$0.6 million, or 20%, to approximately \$2.2 million for the six months ended June 30, 2025 as compared to approximately \$2.8 million for the six months ended June 30, 2024. This decrease was primarily due to the recognition in the prior period of one-time offering costs totaling \$0.5 million related to an anticipated offering that was not completed.

Interest income

During the six months ended June 30, 2025, we recorded interest income of approximately \$20,000 earned from our money market account. During the six months ended June 30, 2024, we generated no interest income.

Interest expense

During the six months ended June 30, 2025, we recorded interest expense of approximately \$5,000 on insurance installment payments. During the six months ended June 30, 2024, we recorded interest expense of approximately \$16,000 on convertible debt and approximately \$10,000 on insurance installment payments.

Other income

For the six months ended June 30, 2025, we recognized total other income of approximately \$6,000. This amount includes \$2,000 in sublease income and \$4,000 generated from hosting site visits. These activities are part of our ongoing efforts to optimize the use of its facilities and engage with stakeholders. During the six months ended June 30, 2024, we generated no other income.

Liquidity and Capital Resources

Sources of liquidity. We have incurred operating losses since inception, and as of June 30, 2025, we had an accumulated deficit of approximately \$103.2 million. We are currently investing significant resources in the development and commercialization of our product candidates for use by clinicians and researchers in the fields of regenerative medicine and bioengineering. As a result, we expect to incur operating losses and negative operating cash flows for the foreseeable future. Therefore, as disclosed in Note 1 to our Condensed Consolidated Financial Statements, these conditions raise substantial doubt about our ability to continue as a going concern.

The following table sets forth the primary uses of cash for the six months ended June 30, 2025 and 2024 (in thousands):

	Six Months Ended June 30,	
	2025	2024
Net cash used in operating activities	\$ (1,699)	\$ (2,253)
Net cash provided by financing activities	\$ —	\$ 1,982

Comparison of the six months ended June 30, 2025 and 2024

Operating activities. Net cash used in operating activities of approximately \$1.7 million for the six months ended June 30, 2025 was due primarily to our net loss of approximately \$3.5 million offset by adjustments for non-cash items of approximately \$1.1 million due to non-cash expenses for share-based compensation, depreciation and amortization, and an approximately \$0.7 million increase to cash from changes in working capital due to the timing of payments for accounts receivable, inventory, prepaid expenses, long-term prepaid contracts, accounts payable, deferred revenue and accrued expenses.

Net cash used in operating activities of approximately \$2.3 million for the six months ended June 30, 2024 was due primarily to our net loss of approximately \$4.5 million offset by adjustments for non-cash items of approximately \$1.1 million due to non-cash expenses for share-based compensation, depreciation and amortization, and an approximately \$1.1 million increase to cash from changes in working capital due to the timing of payments for accounts receivable, inventory, prepaid expenses, deferred financing costs, long-term prepaid contracts, accounts payable and accrued expenses.

Financing activities. During the six months ended June 30, 2025, we did not generate cash from financing activities. In comparison, net cash provided by financing activities during the six months ended June 30, 2024 totaled approximately \$2.0 million. This amount consisted of \$0.5 million in net proceeds from debt financing and \$1.5 million from a private placement transaction that resulted in the issuance of 367,767 shares of our common stock at a purchase price of \$4.03 per share to a group of investors.

Off-Balance Sheet Arrangements

We do not have any material off-balance sheet arrangements as of June 30, 2025.

Other Information

None.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

The Company is a smaller reporting company and is not required to provide this information pursuant to Item 305(e), Regulation S-K.

Item 4. Controls and Procedures.

This Report includes the certifications of our principal executive officer and our principal financial and accounting officer required by Rule 13a-14 of the Exchange Act. See Exhibits 31.1 and 31.2.

Evaluation of Disclosure Controls and Procedures

Disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) are designed to ensure that information required to be disclosed in reports filed or submitted under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms and that such information is accumulated and communicated to management, including the Chief Executive Officer, and Chairman, who is our principal executive officer, and our Chief Financial Officer, who is our principal financial and accounting officer, to allow timely decisions regarding required disclosures.

In connection with the preparation of this Quarterly Report on Form 10-Q, our management, under the supervision and with the participation of our principal executive officer and our principal financial and accounting officer, conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of June 30, 2025. Based upon the evaluation described above, our principal executive officer and our principal financial and accounting officer have concluded that they believe our disclosure controls and procedures were effective as of the end of the period covered by this report, in providing reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and our principal financial and accounting officer, to allow timely decisions regarding required disclosures, and is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms.

Changes in Internal Control over Financial Reporting

Our management, with the participation of our principal executive officer and our principal financial and accounting officer, has evaluated whether any change in our internal control over financial accounting and reporting occurred during the quarter ended June 30, 2025. During the period covered by this report, we have concluded that there were no changes during the fiscal quarter in our internal control over financial reporting, as defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act, which have materially affected, or are reasonably likely to materially affect, our internal control over financial accounting and reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may be involved in various claims and legal proceedings arising in the ordinary course of business. There are no such matters pending that we expect to be material in relation to our business, financial condition, and results of operations or cash flows.

Item 1A. Risk Factors

To our knowledge and except to the extent additional factual information disclosed in this Quarterly Report on Form 10-Q relates to such risk factors, there have been no material changes in the risk factors described in Item 1A. Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2024, which was filed with the SEC on March 31, 2025.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 5. Other Information

During the three months ended June 30, 2025, no directors or officers adopted or terminated a “Rule 10b5-1 trading arrangement” or a “non-Rule 10b5-1 trading arrangement,” as each term is defined in Item 408(a) of Regulation S-K.

Item 6. Exhibits

Exhibit

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10.1+	Form of Securities Purchase Agreement dated July 11, 2025 (previously filed as an exhibit to the Company’s Current Report on Form 8-K filed on July 14, 2025 and incorporated herein by reference).
31.1*	Certification of Chief Executive Officer, Director, and Chairman of Harvard Apparatus Regenerative Technology, Inc., pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer of Harvard Apparatus Regenerative Technology, Inc., pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Chief Executive Officer, Director, and Chairman of Harvard Apparatus Regenerative Technology, Inc., pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Chief Financial Officer of Harvard Apparatus Regenerative Technology, Inc., 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 - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
Exhibit 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.

+ Schedules and exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The registrant hereby undertakes to furnish copies of any of the omitted schedules and exhibits upon request by the U.S. Securities and Exchange Commission.

* Filed herewith.

** This certification shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liability of that section, nor shall it be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by undersigned thereunto duly authorized.

Date: August 11, 2025

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.

By: /s/ Junli He
Name: Junli He
Title: Chief Executive Officer, Director, and Chairman
(principal executive officer)

By: /s/ Joseph L.Damasio Jr.
Name: Joseph L. Damasio Jr.
Title: Chief Financial Officer
(principal financial and accounting officer)

Certification

I, Junli He, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Harvard Apparatus Regenerative Technology, 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: August 11, 2025

/s/ Junli He

Junli He

Chief Executive Officer, and Chairman
(principal executive officer)

Certification

I, Joseph L. Damasio Jr., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Harvard Apparatus Regenerative Technology, 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: August 11, 2025

/s/ Joseph L. Damasio Jr.

Joseph L. Damasio Jr.

Chief Financial Officer

(principal financial and accounting officer)

CERTIFICATION OF PERIODIC FINANCIAL REPORT
PURSUANT TO 18 U.S.C. SECTION 1350

The undersigned officer of Harvard Apparatus Regenerative Technology, Inc. (the “Company”) hereby certifies to his knowledge that the Company’s Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2025 (the “Report”) to which this certification is being furnished as an exhibit, as filed with the Securities and Exchange Commission on the date hereof, fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company. This certification is provided solely pursuant to 18 U.S.C. Section 1350 and Item 601(b)(32) of Regulation S-K (Item 601(b)(32)) promulgated under the Securities Act of 1933, as amended (the “Securities Act”), and the Exchange Act. In accordance with clause (ii) of Item 601(b) (32), this certification (A) shall not be deemed “filed” for purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of that section, and (B) shall not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act, except to the extent that the Company specifically incorporates it by reference.

Date: August 11, 2025

/s/ Junli He

Name: Junli He
Title: Chief Executive Officer, and Chairman
(principal executive officer)

CERTIFICATION OF PERIODIC FINANCIAL REPORT
PURSUANT TO 18 U.S.C. SECTION 1350

The undersigned officer of Harvard Apparatus Regenerative Technology, Inc. (the “Company”) hereby certifies to his knowledge that the Company’s Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2025 (the “Report”) to which this certification is being furnished as an exhibit, as filed with the Securities and Exchange Commission on the date hereof, fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company. This certification is provided solely pursuant to 18 U.S.C. Section 1350 and Item 601(b)(32) of Regulation S-K (Item 601(b)(32)) promulgated under the Securities Act of 1933, as amended (the “Securities Act”), and the Exchange Act. In accordance with clause (ii) of Item 601(b) (32), this certification (A) shall not be deemed “filed” for purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of that section, and (B) shall not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act, except to the extent that the Company specifically incorporates it by reference.

Date: August 11, 2025

/s/ Joseph L. Damasio Jr.

Name: Joseph L. Damasio Jr.
Title: Chief Financial Officer
(principal financial and accounting officer)