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, 2024

☐ 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)

Delaware	**45-5210462**
(State or Other Jurisdiction of Incorporation or Organization)	**(IRS Employer Identification No.)**
84 October Hill Road, Suite 11, Holliston, MA	**01746**
(Address of Principal Executive Offices)	**(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 ☐ Accelerated filer ☐

Non-accelerated filer ☒ Smaller reporting company ☒

Emerging growth company ☐

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

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

As of August 5, 2024, there were 14,530,091 shares of common stock, par value $0.01 per share, outstanding.

Harvard Apparatus Regenerative Technology, Inc.
(formerly Biostage, Inc.)
Form 10-Q
For the Quarter Ended June 30, 2024

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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, 2024	December 31, 2023
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 139	$ 432
Accounts receivable	—	4
Inventory	60	50
Prepaid research and development	343	210
Prepaid expenses and other current assets	114	87
Total current assets	656	783
Property, plant and equipment, net	14	25
Right-of-use assets, net	68	48
Deferred financing costs	—	544
Long-term prepaid contracts	992	1,214
Total assets	$ 1,730	$ 2,614
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
Current liabilities:		
Accounts payable	$ 752	$ 445
Accrued and other current liabilities	700	475
Convertible debt – related party	500	—
Operating lease liability	40	48
Total current liabilities	1,992	968
Operating lease liability, net of current portion	28	—
Total liabilities	2,020	1,411
Commitments and contingencies (Note 7)		
Stockholders' (deficit) equity:		
Common stock, par value $0.01 per share, 60,000,000 shares authorized; 14,315,091 and 13,947,324 issued and outstanding at June 30, 2024 and December 31, 2023, respectively	143	139
Additional paid-in capital	96,073	93,463
Accumulated deficit	(96,484)	(91,956)
Accumulated other comprehensive loss	(22)	—
Total stockholders' (deficit) equity	(290)	1,646
Total liabilities and stockholders' (deficit) equity	$ 1,730	$ 2,614

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 June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Product revenue	$ 56	$ —	$ 113	$ —
Operating expenses:				
Cost of sales	13	—	25	—
Research and development	642	1,566	1,482	2,075
Sales and marketing	197	55	312	55
General and administrative	1,685	1,030	2,796	3,408
Total operating expenses	2,537	2,651	4,615	5,538
Operating loss	(2,481)	(2,651)	(4,502)	(5,538)
Other (expense) income, net:				
Other (expense) income, net	(17)	37	(26)	34
Net loss	(2,498)	(2,614)	(4,528)	(5,504)
Preferred stock dividends	—	3	—	(77)
Net loss attributable to common stockholders	$ (2,498)	$ (2,611)	$ (4,528)	$ (5,581)
Basic and diluted net loss per share attributable to common stockholders	$ (0.18)	$ (0.19)	$ (0.32)	$ (0.43)
Weighted average common shares outstanding, basic and diluted	14,258,511	13,785,657	14,102,918	13,000,211
Comprehensive loss:				
Net loss	$ (2,498)	$ (2,614)	$ (4,528)	$ (5,504)
Foreign currency translation adjustments	(21)	—	(22)	—
Comprehensive loss	(2,519)	(2,614)	(4,550)	(5,504)
Less: Preferred stock dividends	—	3	—	(77)
Comprehensive loss attributable to common stockholders	$ (2,519)	$ (2,611)	$ (4,550)	$ (5,581)

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*)

	Series E Convertible Preferred Stock	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	—	—	—	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)**

	Series E Convertible Preferred Stock	Number of Common Shares Outstanding	Common Stock	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' (Deficit) Equity
Balance at April 1, 2023	**$ 4,051**	**12,716,534**	**$ 127**	**$ 84,712**	**$ (85,901)**	**$ (1,062)**
Preferred stock dividends	(3)	—	—	3	—	3
Conversion of preferred stock for common stock	(4,048)	674,693	7	4,041	—	4,048
Issuance of common stock, net of offering costs	—	490,833	5	2,937	—	2,942
Share-based compensation expense	—	—	—	479	—	479
Net loss	—	—	—	—	(2,614)	(2,614)
Balance at June 30, 2023	**$ —**	**13,882,060**	**$ 139**	**$ 92,172**	**$ (88,515)**	**$ 3,796**

	Series E Convertible Preferred Stock	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	—	—	—	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)**

	Series E Convertible Preferred Stock	Number of Common Shares Outstanding	Common Stock	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' (Deficit) Equity
Balance at January 1, 2023	**$ 4,180**	**12,174,467**	**$ 122**	**$ 79,698**	**$ (83,011)**	**$ (3,191)**
Preferred stock dividends	77	—	—	(77)	—	(77)
Conversion of preferred stock for common stock	(4,257)	706,626	7	4,250	—	4,257
Issuance of common stock, net of offering costs	—	1,000,967	10	5,982	—	5,992
Share-based compensation expense	—	—	—	2,319	—	2,319
Net loss	—	—	—	—	(5,504)	(5,504)
Balance at June 30, 2023	**$ —**	**13,882,060**	**$ 139**	**$ 92,172**	**$ (88,515)**	**$ 3,796**

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,	
	2024	**2023**
OPERATING ACTIVITIES		
Net loss	$ (4,528)	$ (5,504)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	1,132	2,319
Depreciation	11	23
Amortization of operating lease right-of-use assets	55	57
Changes in operating assets and liabilities:		
Accounts receivable	4	—
Inventory	(10)	—
Prepaid research and development	(133)	15
Prepaid expenses and other current assets	(27)	—
Deferred financing costs	544	66
Long-term prepaid contracts	222	(62)
Accounts payable	307	(310)
Operating lease liability	(55)	(57)
Accrued and other current liabilities	225	894
Net cash used in operating activities	(2,253)	(2,559)
INVESTING ACTIVITIES		
Purchases of short-term investments	—	(2,523)
Purchases of property, plant, and equipment	—	(11)
Net cash used in investing activities	—	(2,534)
FINANCING ACTIVITIES		
Proceeds from convertible debt – related party	500	—
Proceeds from issuance of common stock	1,482	5,992
Net cash provided by financing activities	1,982	5,992
Effect of exchange rate changes on cash	(22)	—
Net (decrease) increase in cash and cash equivalents	(293)	899
Cash and cash equivalents at the beginning of the year	432	1,241
Cash and cash equivalents at the end of the period	$ 139	$ 2,140
Supplemental disclosure of non-cash activities:		
Purchases of property and equipment in accounts payable or accrued expenses	$ —	$ 5
Preferred stock dividends	$ —	$ 77
Conversion of preferred stock into common stock	$ —	$ 4,257

See accompanying 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 with a mission to cure patients of cancers, injuries, and birth defects of the gastro-intestinal tract and the airways. The Company believes its technology is likely to be used to treat esophageal cancer, esophageal injuries, and birth defects in the esophagus. The Company believes additional product candidates in our development pipeline may treat intestinal cancer and colon cancer. 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.

Longevity Products

In the second quarter of 2023, the Company's subsidiary in Hong Kong, Harvard Apparatus Regenerative Technology Limited, or Longevity Products, started focusing on sales of longevity products.

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

Going Concern

The Company has incurred substantial operating losses since its inception, and as of June 30, 2024, had an accumulated deficit of approximately $96.5 million and will require additional financing to fund future operations. The Company expects that its operating cash on-hand as of June 30, 2024 of approximately $0.1 million and equity financing of $0.4 million in gross proceeds received subsequent to June 30, 2024 will enable it to fund its operating expenses and capital expenditure requirements into the third quarter of 2024. 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 2024, 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 unaudited condensed consolidated financial statements have been prepared assuming that the Company will continue as a going concern and therefore, the unaudited 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 unaudited condensed consolidated financial statements are those set forth in Note 2 to the consolidated financial statements for the year ended December 31, 2023 included in the Company's Annual Report on Form 10-K.

Prior Period Reclassifications

Certain prior period amounts have been reclassified to conform to the current period presentation. "Selling and marketing" operating expenses was reclassified from "Selling, general and administrative" operating expenses on our unaudited condensed consolidated financial statements.

Principles of Consolidation

The unaudited 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 unaudited 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 unaudited consolidated financial statements should be read in conjunction with the consolidated financial statements and the notes thereto included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023.

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

We recognize revenue in accordance with Financial Accounting Standards Board (FASB) *ASC 606, Revenue from Contracts with Customers*. We offer 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. Revenue also excludes any amounts collected on behalf of third parties, including sales and indirect taxes.

We identify 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 our 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.

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 cure patients of cancers, injuries, and birth defects of the gastro-intestinal tract and the airways. The other operating unit is focused on personal healthcare through longevity dietary supplements. We have determined that our chief executive officer is the chief operating decision maker ("CODM"). The CODM reviews financial information presented by operating unit. Resource allocation decisions are made by the CODM based on operating unit results.

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, 2024 and December 31, 2023, we determined that no allowance for credit losses against accounts receivable was necessary.

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.

We maintain ownership of our inventory at the third-party warehouse, regardless of whether fulfillment is provided by us or the third-party e-commerce seller, and therefore these products are included in our inventory.

Deferred Financing Costs

We capitalized costs relating to a registered offering that we postponed in fiscal year 2023 but expected to resume in the near future. The costs include payments made to attorneys, accountants, regulators and consultants. We have changed our outlook and do not expect to complete the registered offering in fiscal year 2024, therefore, the deferred financing costs were expensed to general and administrative expenses on the unaudited condensed consolidated statements of operations and comprehensive loss for the quarter ended June 30, 2024.

Long-term Prepaid Contracts

We have contracted with partners relating to our clinical trial activities. Upon execution of the contracts, we 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 our clinical trial under these contracts are recognized as expense and payable based on costs incurred. Our clinical trial partner applied $0.2 million of the $1.2 million deposits against outstanding invoices in July 2024 so we reclassified the $0.2 million as current assets as of June 30, 2024.

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:

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

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

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 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.

Unaudited Interim Financial Information

The accompanying interim condensed consolidated balance sheet as of June 30, 2024, condensed consolidated interim statements of operations and comprehensive loss and condensed consolidated statements of stockholders' equity (deficit) for the three and six months ended June 30, 2024 and 2023, and cash flows for the six months ended June 30, 2024 and 2023 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, 2024, its condensed consolidated results of operations and stockholders' equity for the three and six months ended June 30, 2024 and 2023, and cash flows for the six months ended June 30, 2024 and 2023. The financial data and other information disclosed in these notes related to the three and six months ended June 30, 2024 and 2023 are unaudited. The results for the three and six months ended June 30, 2024 are not necessarily indicative of results to be expected for the year ending December 31, 2024, any other interim periods or any future year or period.

Recently Adopted 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 August 2020, the FASB issued Accounting Standards Update (ASU) No. 2020-06, *Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, as part of its overall simplification initiative to reduce costs and complexity of applying accounting standards while maintaining or improving the usefulness of the information provided to users of financial statements. Among other changes, the new guidance removes the beneficial conversion separation model for convertible debt. As a result, after adopting the guidance, entities will no longer account for beneficial conversion features in equity. The guidance is effective for public business entities, other than small reporting company's financial statements starting January 1, 2022, with early adoption permitted. The Company is a small reporting company and adopted the new guidance on January 1, 2024, and the adoption of ASU 2020-06 did not have a material impact on its consolidated financial statements.

3. Fair Value Measurements

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.

The Company utilizes a valuation hierarchy for disclosure of the inputs to the valuations used to measure fair value that prioritizes the inputs into three broad levels. Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities. Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument. Level 3 inputs are unobservable inputs based on the Company's own assumptions used to measure assets and liabilities at fair value. A financial asset or liability's classification within the hierarchy is determined based on the lowest level input that is significant to the fair value measurement.

The Company had no assets or liabilities classified as Level 2 or Level 3 as of June 30, 2024 and December 31, 2023. The carrying value of financial instruments (consisting of cash, accounts payable, accrued compensation and accrued expenses) is considered to be representative of their respective fair values due to the short-term nature of those instruments. For the six months ended June 30, 2023, the Company had short-term investments generating investment income. Investment income is included as other income. Investment income for the three months ended June 30, 2024 and June 30, 2023 consists primarily of interest earned of $0 and $41,000, respectively. Investment income for the six months ended June 30, 2024 and June 30, 2023 consists of interest earned of $0 and $41,000, respectively.

4. Accrued and Other Current Liabilities

Accrued and other current liabilities consist of the following:

	June 30, 2024	December 31, 2023
	(in thousands)	
Advisory costs	$ 402	$ 325
Audit services	77	70
Payroll	156	79
Other liabilities	65	1
Total accrued and other current liabilities	$ 700	$ 475

5. Capital Stock

Preferred Stock

The Company has authorized a total of 2,000,000 shares of preferred stock, par value $0.01 per share, none of which were outstanding at June 30, 2024 and December 31, 2023. The Company's Board of Directors has the authority to issue preferred stock and to determine the rights, preferences, privileges, and restrictions, including voting rights.

Common Stock

On April 15, 2024, the Company entered into securities purchase agreements (each an "April Purchase Agreement," collectively the "April Purchase Agreements") with certain investors each named therein (the "Investor," collectively the "Investors") pursuant to which each of the 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 unit of $4.03 (the "2024 Private Placement").

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.

On April 12, 2023 and on March 31, 2023, the Company entered into Securities Purchase Agreements, each a Purchase Agreement, with new and existing investors, the Investors, pursuant to which the Investors agreed to purchase in a private placement an aggregate of 1,000,967 shares of common stock for the aggregate purchase price of approximately $6 million with a purchase price per unit of $6.00 (the "2023 Private Placement").

On January 18, 2023, Harvard Bioscience converted 200 Series E Preferred Shares with accrued dividends of $9,545 into 31,933 shares of common stock.

In connection with the 2023 Private Placement, as of April 12, 2023, the Company had received $6.0 million in aggregate proceeds in such private placement. The 2023 Private Placement resulted in gross proceeds of at least $4,000,000 which triggered the mandatory conversion of all the Company's outstanding Series E Preferred Stock and related accrued dividends into shares of common stock at a conversion price of $6.00 per share. The conversion resulted in 674,693 shares of common stock being issued to the holder of the Series E Preferred Stock. Following such conversion, there are no shares of Series E Preferred Stock outstanding.

Warrants

The Company had 1,113,622 warrants to purchase common stock outstanding as of June 30, 2024 with a weighted-average exercise price of $4.69.

6. 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 the Company's 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, 2024, the Company's Plan has 9,098,000 authorized shares to be issued under the Plan. There were 4,672,994 shares available for issuance as of June 30, 2024.

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, 2023	3,977,289	$ 4.64	7.7	$ 5,728
Granted	361,766	3.62		
Outstanding at June 30, 2024	4,339,055	4.56	7.4	1,169
Options exercisable	2,489,412	4.69	6.9	948
Options vested and expected to vest	4,239,637	4.59	7.4	1,122

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 $0.04 million and $0.08 million in stock-based compensation during the three and six months ended June 30, 2024 given that some milestone achievements for these awards have been deemed probable for accounting purposes. No expense had been recognized for these awards during the three and six months ended June 30, 2023 given that the milestone achievements for these awards were not probable at the time for accounting purposes.

Aggregate intrinsic value for outstanding options as of June 30, 2024 was approximately $1.2 million and calculated as the difference between the Company's closing stock price of $2.92 per share as of June 28, 2024 and the weighted average exercise price of $4.56. As of June 30, 2024, unrecognized compensation cost related to unvested non-performance-based awards amounted to $3.2 million, which will be recognized over a weighted-average period of 1.7 years.

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, 2024 and 2023 were as follows:

	Six months ended June 30,	
	2024	2023
Risk-free interest rate	4.07%	3.76%
Expected volatility	116.86%	126.16%
Expected term (in years)	5.4 years	5.9 years
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,	
	2024	2023	2024	2023
	(In thousands)		(In thousands)	
Research and development	$ 110	$ 51	$ 219	$ 113
General and administrative	462	428	913	2,206
Total	$ 572	$ 479	$ 1,132	$ 2,319

7. 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 March 25, 2024, the Company entered into an operating lease agreement for office space in Beijing, China for the period from April 1, 2024 through April 10, 2026 (the "Office Lease"). Our total Office Lease obligation is $81,352, consisting of minimum annual rental obligations of $30,507 for fiscal year 2024, $40,676 for fiscal year 2025 and $10,169 for fiscal year 2026.

We currently have a co-development initiative with Yale University and the McGowan Institute for Regenerative Medicine at the University of Pittsburgh. We owe advance payments of approximately $100,000 and $61,000, respectively at June 30, 2024. We plan to make these advance payments in the third quarter of 2024. The universities started preparatory work in 2023 with substantial work being performed in 2024. Either party can terminate the contract with reasonable notice and any incurred costs will be reimbursed by us to the universities.

8. Convertible Debt – Related Party

Convertible Debt

On February 1, 2024, the Company entered into a loan arrangement with Junli He, the Chairman and Chief Executive Officer of the Company (the "Lender"), pursuant to which the Lender loaned the Company an aggregate amount of $500,000 as evidenced by a Bridge Note executed by the Company in favor of, and accepted by, the Lender (the "Bridge Note"). As of June 30, 2024, the Company accrued $16,222 of interest payable on the Bridge Note. The Company evaluated the convertible note for derivative liability treatment and has determined that the components of the Bridge Note did not qualify for derivative accounting treatment as of June 30, 2024.

The Bridge Note accrues interest at an annual fixed rate of 8%, and the principal amount thereof will be due and payable in full, together with all accrued and unpaid interest thereon, on the earlier to occur of a) the closing date (or later date of capital being provided pertaining to such continued offering that the following threshold is tripped) of the Company's next capital raise that includes gross proceeds of at least $5,000,000 or b) February 1, 2025. The Bridge Note provides for optional conversion at the discretion of the Lender, contains covenants, and provides for certain events of default including if the Company fails to pay when due any amount owed thereunder, fails to comply with any agreement, covenant, condition, provision or term contained therein and other customary events of default.

9. Leases

The Company leases laboratory and office space and certain equipment with a remaining term of 1 year.

The laboratory and office space arrangement in Holliston, MA is under a sublease that was renewed in December of 2022. The sublease is currently on a month-to-month basis until August 31, 2024. The Company is currently negotiating with the landlord for a three-year lease starting September 1, 2024.

On March 25, 2024, the Company entered into an operating lease agreement for office space in Beijing, China for the period from April 1, 2024 through April 10, 2026. We recorded approximately $75,000 as a right-of-use asset and a corresponding operating lease liability on the Company's unaudited condensed consolidated balance sheets upon the accounting commencement date in April 1, 2024. The lease liability was measured at the accounting commencement date utilizing a 8% discount rate. The right-of-use asset had a balance of $65,000 at June 30, 2024. The operating lease obligations totaled $65,000 at June 30, 2024 of which $40,000 is included under current liabilities and $25,000 is included under non-current liabilities.

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, 2024	December 31, 2023
Assets:			
Operating lease assets	Right-of-use assets, net	$ 68	$ 48
Liabilities:			
Current portion of operating lease liability	Current portion of operating lease liability	40	48
Operating lease liability, net of current portion	Operating lease liability, net of current portion	28	—
Total operating lease liability		$ 68	$ 48

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,	
	2024	2023	2024	2023
	(in thousands)		(in thousands)	
Research and development	$ 12	$ 17	$ 28	$ 35
Sales and marketing	9	—	9	—
General and administrative	7	11	18	22
Total	$ 28	$ 28	$ 55	$ 57

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. Cash paid included in the computation of the operating lease assets and lease liability during the three and six months ended June 30, 2023 amounted to approximately $28,000 and $57,000, 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,	
	2024	2023
Remaining lease term (in years)	1.70	0.88
Discount rate	8.19%	12.78%

The minimum lease payments for the next year are expected to be as follows:

	As of June 30, 2024
	(in thousands)
2024	$ 23
2025	41
2026	10
Total lease payments	74
Less: imputed interest	(6)
Present value of operating lease liability	$ 68

10. Net Loss Per Share

	Three months ended June 30,		Six months ended June 30,	
	2024	2023	2024	2023
	(in thousands, except shares and per share data)		(in thousands, except shares and per share data)	
Net loss	$ (2,498)	$ (2,614)	$ (4,528)	$ (5,504)
Preferred stock dividends	—	3	—	(77)
Net loss attributable to common stockholders	$ (2,498)	$ (2,611)	$ (4,528)	$ (5,581)
Basic and diluted weighted average common shares outstanding	14,258,511	13,785,657	14,102,918	13,000,211
Basic and diluted net loss per share attributable to common stockholders	$ (0.18)	$ (0.19)	$ (0.32)	$ (0.43)

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, 2024 and 2023 because including them would have had an anti-dilutive effect:

	Six months ended June 30,	
	2024	2023
Options to purchase common stock	4,339,055	3,786,900
Warrants to purchase common stock	1,113,622	1,113,622
Total	5,452,677	4,900,522

11. Income Taxes

The Company did not record a federal or state income tax provision or benefit for the six months ended June 30, 2024 and 2023, respectively, due to the expected loss before income taxes to be incurred for the years ended December 31, 2024 and 2023, as well as the Company's continued maintenance of a full valuation allowance against its net deferred tax assets.

12. 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 revenues and net income (loss).

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) Longevity Products relating to longevity products with operations currently in Asia. The following table presents the Company's reportable segment results for the six months ended June 30, 2024:

	Regenerative Biotech	Longevity Products	Total
2024			
Revenues	$ —	$ 113	$ 113
Net loss	(4,255)	(273)	(4,528)
Total assets	1,456	274	1,730

13. Subsequent Events

On various dates between July 8, 2024 and ending on July 31, 2024, common stock warrants were exercised for an aggregate issuance of 215,000 shares of the Company's Common Stock at an exercise price of $2.00 per share, resulting in gross proceeds to the Company of $430,000.

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

Forward Looking Statements

This Quarterly Report on Form 10-Q contains statements that are not statements of historical fact and are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 (the "Exchange Act"). The forward-looking statements are principally, but not exclusively, contained in "Item 2: Management's Discussion and Analysis of Financial Condition and Results of Operations." Forward-looking statements include, but are not limited to, statements about management's confidence or expectations and our plans, objectives, expectations and intentions that are not historical facts and the potential impact of COVID-19 on our business and operations. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "expect," "plan," "anticipate," "believe," "goal," "see," "estimate," "project," "predict," "intend," "think," "potential," "objective," "optimistic," "strategy," and similar expressions intended to identify 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. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Factors that may cause our actual results to differ materially from those in the forward-looking statements include our ability to access debt and equity markets and raise additional capital when needed; 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 failure to comply with regulations and any changes in regulations; unpredictable difficulties or delays in the development of new technology; our collaborators or other third parties we contract with, including with respect to conducting any clinical trial or pre-clinical development efforts, not devoting sufficient time and resources to successfully carry out their duties or meet expected deadlines; our ability to attract and retain qualified personnel and key employees and retain senior management; potential liability exposure with respect to our products; the availability and price of acceptable raw materials and components from third-party suppliers; difficulties in obtaining or retaining the management and other human resource competencies that we need to achieve our business objectives; increased competition in the field of regenerative medicine and bioengineering, and the financial resources of our competitors; increased competition in the field of longevity products; our ability to obtain and maintain intellectual property protection for our device and product candidates; our inability to implement our growth strategy; the control our principal stockholders can exert based on holding a majority of voting power; plus factors described under the heading "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2023 filed with the Securities and Exchange Commission (the "SEC") on March 28, 2024 or described in our other public filings. Our results may also be affected by factors of which we are not currently aware. We may not update these forward-looking statements, even though our situation may change in the future, unless we have obligations under the federal securities laws to update and disclose material developments related to previously disclosed information.

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 longevity dietary supplements. In the second quarter of 2023, the Company's subsidiary in Hong Kong, Longevity Products started focusing on longevity products. Longevity Products plans to include a broad range of products focused on personal healthcare including longevity dietary supplements. Longevity Products started selling longevity supplements in the third quarter of 2023. These products are commercially marketed to the general public and initially targeted at consumers in the Great China Region 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 and preferred stock. In December 2017, we sold the inventory and rights to manufacture and sell research-only versions of our bioreactors to Harvard Bioscience.

Business Segments

The Company has two separate reportable segments. The Company has one segment, Harvard Apparatus Regenerative Technology, Inc., or Regenerative Biotech, focused on the development and commercialization of therapies to cure patients of cancers, injuries, and birth defects of the gastro-intestinal tract and the airways. The other segment, Longevity Products, is focused on personal healthcare including longevity dietary supplements.

Financial Condition and Need for Additional Funds

We expect to continue to incur operating losses and negative cash flows from operations for 2024 and in future years.

Operating Losses and Cash Requirements

We have incurred substantial operating losses since our inception, and as of June 30, 2024 had an accumulated deficit of approximately $96.5 million and will require additional financing to fund future operations. We expect that our operating cash on-hand as of June 30, 2024 of approximately $0.1 million and equity financing of $0.4 million in gross proceeds received subsequent to June 30, 2024 will enable us to fund our operating expenses and capital expenditure requirements into the third quarter of 2024. We expect to continue to incur operating losses and negative cash flows from operations for 2024 and in future years. Therefore, as disclosed in Note 1 to our unaudited 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 2024, 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 unaudited condensed consolidated financial statements have been prepared assuming that we will continue as a going concern and therefore, the unaudited 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 longevity product sales, launched in the Great China Region in the third quarter of 2023. We had not generated any revenue prior to the launch of our longevity 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 (expense) income, net. Other (expense) income, 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 unaudited 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. Until December 31, 2022, we estimated forfeitures at the time of grant and would revise our estimate, if necessary, in subsequent periods. As of January 1, 2023, 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, 2024 and 2023 (in thousands):

	Three months ended June 30,		Change 2024 vs. 2023		Six months ended June 30,		Change 2024 vs. 2023	
	2024	2023	Change	%	2024	2023	Change	%
Product revenue	$ 56	$ —	$ 56	100%	$ 113	$ —	$ 113	100%
Operating expenses								
Cost of sales	13	—	13	100%	25	—	25	100%
Research and development	642	1,566	(924)	(59)%	1,482	2,075	(593)	(29)%
Sales and marketing	197	55	142	258%	312	55	257	467%
General and administrative	1,685	1,030	655	64%	2,796	3,408	(612)	(18)%
Total operating expenses	2,537	2,651	(114)	(4)%	4,615	5,538	(923)	(17)%
Other (expense) income								
Other (expense) income, net	(17)	37	(54)	(146)%	(26)	34	(60)	(177)%
Net loss	$ (2,498)	$ (2,614)	$ 116	4%	$ (4,528)	$ (5,504)	$ 976	18%

Comparison of the three months ended June 30, 2024 and June 30, 2023

Product Revenue

Product revenue was $56,000 and zero for the three months ended June 30, 2024 and 2023, respectively. Product revenue consists of longevity product sales, launched in the Great China Region in the third quarter of 2023. We had not generated any revenue prior to the launch of our longevity products.

Cost of Sales

Cost of sales was $13,000 and zero for the three months ended June 30, 2024 and 2023, respectively. For the three months ended June 30, 2024, cost of sales consists of the purchase price of consumer products, taxes, inbound and outbound shipping costs.

Research and Development Expense

Research and development expense decreased approximately $0.9 million, or 59%, to approximately $0.6 million for the three months ended June 30, 2024 as compared to approximately $1.5 million for the three months ended June 30, 2023. This decrease was primarily due to significant initial clinical trial activities in the prior period resulting in our first site activation in the third quarter of 2023.

Sales and Marketing Expense

Selling and marketing expense was $0.2 million for the three months ended June 30, 2024 as compared to $0.06 million for the three months ended June 30, 2023. The increase is from increased headcount-related costs.

General and Administrative Expense

General and administrative expense increased approximately $0.7 million, or 64%, to approximately $1.7 million for the three months ended June 30, 2024 as compared to approximately $1.0 million for the three months ended June 30, 2023. This increase was primarily due to the recording of expense in the current period of one-time offering costs of $0.5 million relating to the initial registered offering that did not occur in a prior year.

Other (expense) income, net

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. During the three months ended June 30, 2023, we recorded interest income of approximately $41,000 earned from our money market account and certificate of deposit offset by approximately $4,000 on insurance installment payments.

Comparison of the six months ended June 30, 2024 and June 30, 2023

Product Revenue

Product revenue was $113,000 and zero for the six months ended June 30, 2024 and 2023, respectively. Product revenue consists of longevity product sales, launched in the Asia region in the third quarter of 2023. We had not generated any revenue prior to the launch of our longevity products.

Cost of Sales

Cost of sales was $25,000 and zero for the six months ended June 30, 2024 and 2023, respectively. For the six months ended June 30, 2024, cost of sales consists of the purchase price of consumer products, taxes, inbound and outbound shipping costs.

Research and Development Expense

Research and development expense decreased approximately $0.6 million, or 29%, to approximately $1.5 million for the six months ended June 30, 2024 as compared to approximately $2.1 million for the six months ended June 30, 2023. This decrease was primarily due to significant initial clinical trial activities in the prior period resulting in our first site activation in the third quarter of 2023.

Sales and Marketing Expense

Selling and marketing expense was $0.3 million for the six months ended June 30, 2024 as compared to $0.06 million for the six months ended June 30, 2023.

General and Administrative Expense

General and administrative expense decreased approximately $0.6 million, or 18%, to approximately $2.8 million for the six months ended June 30, 2024 as compared to approximately $3.4 million for the six months ended June 30, 2023. This decrease was primarily due to share-based compensation expense of $1.3 million from the vesting of performance based awards in the first half of 2023 offset by the recording of expense in the current period of one-time offering costs of $0.5 million relating to the initial registered offering that did not occur in a prior year.

Other (expense) income, net

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. During the six months ended June 30, 2023, we recorded interest income of approximately $41,000 earned from our money market account and certificate of deposit offset by approximately $7,000 on insurance installment payments.

Liquidity and Capital Resources

Sources of liquidity. We have incurred operating losses since inception, and as of June 30, 2024, we had an accumulated deficit of approximately $96.5 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 unaudited 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, 2024 and 2023 (in thousands):

	Six Months Ended June 30,	
	2024	2023
Net cash used in operating activities	$ (2,253)	$ (2,559)
Net cash used by investing activities	$ —	$ (2,534)
Net cash provided by financing activities	$ 1,982	$ 5,992

Comparison of the six months ended June 30, 2024 and 2023

Operating activities. 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 and depreciation, 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.

Net cash used in operating activities of approximately $2.6 million for the six months ended June 30, 2023 was due primarily to our net loss of approximately $5.5 million offset by adjustments for non-cash items of approximately $2.3 million due to non-cash expenses for share-based compensation and depreciation, and an approximately $0.6 million increase to cash from changes in working capital due to the timing of payments for accounts payable, accrued expenses, prepaid expenses, deferred financing costs and other long-term assets.

Investing activities. Net cash used in investing activities included purchases of property, plant and equipment for the six months ended June 30, 2024 and 2023 representing approximately zero and $11,000, respectively. During the six months ended June 30, 2023, we invested in a certificate of deposit for $2.5 million that earned $23,000 in interest. The certificate of deposit matured in October 2023.

Financing activities. Net cash generated from financing activities during the six months ended June 30, 2024 of approximately $2.0 million consisted of net proceeds of $0.5 million received from debt financing and $1.5 million from 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. Net cash generated from financing activities during the six months ended June 30, 2023 of approximately $6.0 million consisted of net proceeds received from private placement transactions that resulted in the issuance of 1,000,967 shares of our common stock at a purchase price of $6.00 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, 2024.

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, Director, 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, 2024. 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, 2024. 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, 2023, which was filed with the SEC on March 28, 2024.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 5. Other Information

In the three months ended June 30, 2024, 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 Index	
3.1	Amended and Restated Certificate of Incorporation (previously filed as an exhibit to the Registration Statement on Form 10-12B, filed on July 31, 2013, and incorporated herein by reference).
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation (previously filed as exhibit to the Current Report on Form 8-K, filed on March 31, 2016, and incorporated herein by reference.
3.3	Certificate of Amendment to Amended and Restated Certificate of Incorporation (previously filed as exhibit to the Annual Report on Form 10-K, filed on March 17, 2017, and incorporated herein by reference).
3.4	Certificate of Designations, Preferences and Rights of Series A Preferred Stock classifying and designating the Series A Junior Participating Cumulative Preferred Stock (previously filed as exhibit to the Registration Statement on Form 8-A, filed on October 31, 2013, and incorporated herein by reference).
3.5	Certificate of Designation of Series B Convertible Preferred Stock classifying and designating the Series B Convertible Preferred Stock (previously filed as an exhibit to the Current Report on Form 8-K, filed on February 12, 2015, and incorporated by reference thereto).
3.6	Certificate of Amendment to Amended and Restated Certificate of Incorporation (previously filed as exhibit to the Current Report on Form 8-K, filed on April 27, 2017, and incorporated herein by reference).
3.7	Certificate of Designations, Preferences, Rights and Limitations of Series C Convertible Preferred Stock classifying and designating the Series C Convertible Preferred Stock (previously filed as an exhibit to the Current Report on Form 8-K, filed on August 17, 2017, and incorporated by reference thereto).
3.8	Certificate of Elimination of Series A Junior Participating Cumulative Preferred Stock (previously filed as an exhibit to the Current Report on Form 8-K, filed on August 17, 2017, and incorporated by reference thereto).
3.9	Certificate of Amendment to Amended and Restated Certificate of Incorporation (previously filed as exhibit to the Current Report on Form 8-K, filed on December 22, 2017, and incorporated herein by reference).
3.10	Certificate of Designations, Preferences, Rights and Limitations of Series D Convertible Preferred Stock classifying and designating the Series D Convertible Preferred Stock (previously filed as an exhibit to the Current Report on Form 8-K, filed on January 3, 2018, and incorporated by reference thereto).

3.11	Certificate of Amendment to Amended and Restated Certificate of Incorporation (previously filed as exhibit to the Current Report on Form 8-K, filed on May 28, 2019, and incorporated herein by reference).
3.12	Certificate of Amendment to Amended and Restated Certificate of Incorporation (previously filed as an exhibit to the Current Report on Form 8-K, filed on July 20, 2023, and incorporated herein by reference).
3.13	Third Amended and Restated Bylaws (previously filed as an exhibit to the Current Report on Form 8-K, filed on July 20, 2023, and incorporated herein by reference).
10.1	Form of Securities Purchase Agreement (previously filed as an exhibit to the Current Report on Form 8-K, filed on April 17, 2024, 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.

Management contract or compensatory plan or arrangement.

+ 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 13, 2024

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 officer)

Exhibit 31.1

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 consolidated 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 the consolidated 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 13, 2024

/s/ Junli He
Junli He
Chief Executive Officer, Director, and Chairman

Exhibit 31.2

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 consolidated 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 the consolidated 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 13, 2024

/s/ Joseph L. Damasio Jr.
Joseph L. Damasio Jr.
Chief Financial Officer

Exhibit 32.1

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, 2024 (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 13, 2024

/s/ Junli He
Name: Junli He
Title: Chief Executive Officer, Director, and Chairman

Exhibit 32.2

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, 2024 (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 13, 2024

/s/ Joseph L. Damasio Jr.
Name: Joseph L. Damasio Jr.
Title: Chief Financial Officer