
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549**

FORM 10-Q

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

For the quarterly period ended June 30, 2023

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 7, 2023, there were 13,882,060 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, 2023

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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, 2023	December 31, 2022
	<u>(Unaudited)</u>	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 2,140	\$ 1,241
Short-term investments	2,523	—
Prepaid research and development	259	274
Prepaid expenses and other current assets	79	79
Total current assets	<u>5,001</u>	<u>1,594</u>
Property, plant and equipment, net	39	49
Right-of-use assets, net	135	147
Deferred financing costs	544	610
Other long-term assets	62	—
Total assets	<u>\$ 5,781</u>	<u>\$ 2,400</u>
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	\$ 372	\$ 682
Accrued and other current liabilities	1,476	582
Operating lease liability, current	119	99
Total current liabilities	<u>1,967</u>	<u>1,363</u>
Operating lease liability, net of current portion	18	48
Total liabilities	<u>1,985</u>	<u>1,411</u>
Commitments and contingencies (Note 7)		
Series E convertible preferred stock, par value \$0.01 per share, 5,000 shares authorized; 0 and 4,180 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	—	4,180
Stockholders' equity (deficit):		
Common stock, par value \$0.01 per share, 60,000,000 shares authorized; 13,882,060 and 12,174,467 issued and outstanding at June 30, 2023 and December 31, 2022, respectively	139	122
Additional paid-in capital	92,172	79,698
Accumulated deficit	<u>(88,515)</u>	<u>(83,011)</u>
Total stockholders' equity (deficit)	<u>3,796</u>	<u>(3,191)</u>
Total liabilities and stockholders' equity (deficit)	<u>\$ 5,781</u>	<u>\$ 2,400</u>

See accompanying notes to unaudited condensed consolidated financial statements.

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

(In thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	\$ 1,566	\$ 326	\$ 2,075	\$ 629
Selling, general and administrative	1,085	1,049	3,463	2,951
Total operating expenses	<u>2,651</u>	<u>1,375</u>	<u>5,538</u>	<u>3,580</u>
Operating loss	<u>(2,651)</u>	<u>(1,375)</u>	<u>(5,538)</u>	<u>(3,580)</u>
Other income, net:				
Sublease income	—	32	—	61
Other income (expense), net	37	(2)	34	(3)
Total other income, net	<u>37</u>	<u>30</u>	<u>34</u>	<u>58</u>
Net loss	(2,614)	(1,345)	(5,504)	(3,522)
Preferred stock dividends	3	(18)	(77)	(18)
Net loss attributable to common stockholders	<u>\$ (2,611)</u>	<u>\$ (1,363)</u>	<u>\$ (5,581)</u>	<u>\$ (3,540)</u>
Basic and diluted net loss per share	<u>\$ (0.19)</u>	<u>\$ (0.12)</u>	<u>\$ (0.43)</u>	<u>\$ (0.32)</u>
Weighted average common shares, basic and diluted	<u>13,785,657</u>	<u>11,230,525</u>	<u>13,000,211</u>	<u>10,996,996</u>

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	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	Total Stockholders' Deficit
Balance at April 1, 2022	\$ —	10,760,871	\$ 108	\$ 74,036	\$ (79,115)	\$ (4,971)
Issuance of series E convertible preferred stock	4,000	—	—	—	—	—
Preferred stock dividends	18	—	—	(18)	—	(18)
Issuance of common stock, net of offering costs	—	854,771	8	5,052	—	5,060
Share-based compensation expense	—	—	—	277	—	277
Net loss	—	—	—	—	(1,345)	(1,345)
Balance at June 30, 2022	\$ 4,018	11,615,642	\$ 116	\$ 79,347	\$ (80,460)	\$ (997)

	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

	Series E Convertible Preferred Stock	Number of Common Shares Outstanding	Common Stock	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
Balance at January 1, 2022	\$ —	10,760,871	\$ 108	\$ 73,801	\$ (76,938)	\$ (3,029)
Issuance of series E convertible preferred stock	4,000	—	—	—	—	—
Preferred stock dividends	18	—	—	(18)	—	(18)
Issuance of common stock, net of offering costs	—	854,771	8	5,052	—	5,060
Share-based compensation expense	—	—	—	512	—	512
Net loss	—	—	—	—	(3,522)	(3,522)
Balance at June 30, 2022	\$ 4,018	11,615,642	\$ 116	\$ 79,347	\$ (80,460)	\$ (997)

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)
(In thousands)

	Six Months Ended June 30,	
	2023	2022
OPERATING ACTIVITIES		
Net loss	\$ (5,504)	\$ (3,522)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	2,319	512
Depreciation	23	27
Change in fair value of warrant liability	—	(2)
Changes in operating assets and liabilities:		
Prepaid research and development	15	—
Prepaid expenses and other current assets	—	198
Deferred financing costs	66	(173)
Other long-term assets	(62)	—
Accounts payable	(310)	823
Accrued and other current liabilities	894	483
Net cash used in operating activities	<u>(2,559)</u>	<u>(1,654)</u>
INVESTING ACTIVITIES		
Purchases of short-term investments	(2,523)	—
Purchases of property, plant, and equipment	(11)	(8)
Net cash used in investing activities	<u>(2,534)</u>	<u>(8)</u>
FINANCING ACTIVITIES		
Proceeds from issuance of common stock	5,992	5,060
Net cash provided by financing activities	<u>5,992</u>	<u>5,060</u>
Net increase in cash and cash equivalents	899	3,398
Cash and cash equivalents at the beginning of the year	1,241	1,292
Cash and cash equivalents at the end of the period	<u>\$ 2,140</u>	<u>\$ 4,690</u>
Supplemental disclosure of non-cash activities:		
Settlement of contingency matter	<u>\$ —</u>	<u>\$ (3,250)</u>
Settlement of due to Harvard Bioscience included in accrued and other current liabilities	<u>\$ —</u>	<u>\$ (750)</u>
Issuance of Series E convertible preferred stock	<u>\$ —</u>	<u>\$ 4,000</u>
Purchases of property and equipment in accounts payable or accrued expenses	<u>\$ 5</u>	<u>\$ —</u>
Preferred stock dividends	<u>\$ 77</u>	<u>\$ 18</u>
Conversion of preferred stock into common stock	<u>\$ 4,257</u>	<u>\$ —</u>

See accompanying notes to unaudited condensed consolidated financial statements.

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

1. Overview and Basis of Presentation

Overview

Harvard Apparatus Regenerative Technology, Inc., formerly Biostage, Inc., (HRGN or the Company) is 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. The Company's technology is based on our proprietary cell-therapy platform that uses a patient's own stem cells to regenerate and restore function to damaged organs. The Company believes that its 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. 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. The Company has two business segments and does not have significant costs or assets outside the United States.

On October 31, 2013, Harvard Bioscience, Inc., or Harvard Bioscience, contributed its regenerative medicine business assets, plus \$15 million of cash into HRGN, or the Separation. On November 1, 2013, the spin-off of the Company from Harvard Bioscience was completed. On that date, the Company became an independent company that operates the regenerative medicine business previously owned by Harvard Bioscience. The spin-off was completed through the distribution to Harvard Bioscience stockholders of all the shares of common stock of HRGN, or the Distribution.

The Company filed an amendment (the "Certificate of Amendment") to its Amended and Restated Certificate of Incorporation (the "Certificate of Incorporation") with the Secretary of State for the State of Delaware to change its name from Biostage, Inc. to Harvard Apparatus Regenerative Technology, Inc. The Company also amended and restated its Amended and Restated Bylaws, solely to reflect the name change (as amended, the "Third Amended and Restated Bylaws"). The Certificate of Amendment and the Third Amended and Restated Bylaws each became effective on July 20, 2023.

In connection with the name change, the Company will trade on the OTCQB under the new ticker symbol "HRGN". The new ticker symbol was effective at the open of the market on July 20, 2023.

Consumer Health

In the second quarter of 2023, the Company's subsidiary in Hong Kong, Harvard Apparatus Regenerative Technology Limited, or HRGN LTD, started a Consumer Health business.

The Consumer Health business will include a broad range of products focused on anti-aging dietary supplements. The Company plans to start selling anti-aging supplements through HRGN LTD in the third quarter of 2023. These products are 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, 2023 had an accumulated deficit of approximately \$88.5 million and will require additional financing to fund future operations. The Company expects that its operating cash and short-term investments on-hand as of June 30, 2023 of approximately \$4.7 million will enable it to fund its operating expenses and capital expenditure requirements into the first quarter of 2024. Therefore, these conditions present risks about the Company's ability to continue as a going concern.

The Company will need to raise additional funds to fund its operations. In the event the Company is unable to raise additional capital from outside sources before or during the first 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 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 unaudited condensed consolidated financial statements are those set forth in Note 2 to the consolidated financial statements for the year ended December 31, 2022 included in the Company's Annual Report on Form 10-K.

Principles of Consolidation

The condensed consolidated financial statements include the accounts of HRGN and its subsidiaries, Harvard Apparatus Regenerative Technology Limited (Hong Kong), Harvard Apparatus Regenerative Technology (Hangzhou) Limited (China), Harvard Apparatus Regenerative Technology GmbH (Germany) and HRGN Limited (UK). The functional currency for HRGN and these subsidiaries is the U.S. dollar. 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 cash flows in conformity with accounting principles generally accepted in the United States, or U.S. GAAP.

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.

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.

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
<u>Leasehold improvements</u>	
Furniture, machinery and equipment, computer equipment and software	3-7 years

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

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 treasury-stock 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, 2023, condensed consolidated interim statements of operations and stockholders' equity (deficit) for the three and six months ended June 30, 2023 and 2022, and cash flows for the six months ended June 30, 2023 and 2022 are unaudited. The interim unaudited condensed consolidated financial statements have been prepared in accordance with 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, 2023, its condensed consolidated results of operations and stockholders' equity (deficit) for the three and six months ended June 30, 2023 and 2022, and cash flows for the six months ended June 30, 2023 and 2022. The financial data and other information disclosed in these notes related to the three and six months ended June 30, 2023 and 2022 are unaudited. The results for the three and six months ended June 30, 2023 are not necessarily indicative of results to be expected for the year ending December 31, 2023, 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 June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments (ASU 2016-12)*. The new standard requires that expected credit losses relating to financial assets measured on an amortized cost basis and available-for-sale debt securities be recorded through an allowance for credit losses. It also limits the amount of credit losses to be recognized for available-for-sale debt securities to the amount by which carrying value exceeds fair value and also requires the reversal of previously recognized credit losses if fair value increases. The Company adopted this standard on January 1, 2023, and the adoption of ASU 2016-13 did not have a material impact on its consolidated financial statements.

3. Fair Value Measurements and Short-term Investments

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, 2023 and December 31, 2022. The Company's short-term investments consist of a certificate of deposit account held to maturity and is carried at amortized cost. 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. The certificate of deposit matures in October 2023.

The company has investments classified as short term and held-to-maturity on the accompanying condensed consolidated balance sheets. Investment income is included as other income. Investment income for the three months ended June 30, 2023 and June 30, 2022 consists primarily of interest earned of \$41,000 and \$0, respectively. Investment income for the six months ended June 30, 2023 and June 30, 2022 consists of interest earned of \$41,000 and \$0, respectively.

The Company had approximately \$2.1 million in cash equivalents and \$2.5 million in short-term investments that consist of a certificate of deposit held to maturity and is carried at amortized cost on the Company's balance sheet as of June 30, 2023. The Company had \$1.2 million in cash equivalents and \$0 in short-term investments that were measured and recorded at fair value on the Company's balance sheet at December 31, 2022.

<i>(In thousands)</i>	June 30, 2023
	Amortized cost
Held-to-maturity	
Certificate of deposit	\$ 2,523
Total investment securities	<u>\$ 2,523</u>

4. Accrued and Other Current Liabilities

Accrued and other current liabilities consist of the following:

June 30, 2023	December 31, 2022
<u>(in thousands)</u>	

Research and development	\$	923	\$	—
Advisory costs		375		300
Legal costs		—		135
Audit services		70		80
Payroll		82		55
Other liabilities		26		12
Total accrued and other current liabilities	\$	<u>1,476</u>	\$	<u>582</u>

5. Capital Stock

Private Placement

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 Company had 1,113,622 warrants to purchase common stock outstanding as of June 30, 2023 with a weighted-average exercise price of \$4.69.

6. Series E Convertible Preferred Stock

On April 28, 2022, the Company entered into a Preferred Issuance Agreement, or PIA, with Harvard Bioscience, Inc., or HBIO, dated as of April 27, 2022. Pursuant to the PIA, the Company and HBIO agreed that once HBIO had paid at least \$4.0 million in certain settlement and related legal expenses, to satisfy the Company's indemnification obligations with respect thereto, in lieu of paying cash, the Company would issue senior convertible preferred stock to HBIO that will contain terms as described in the PIA.

On June 10, 2022, following the execution of a subscription agreement and HBIO providing evidence of payment of the requisite \$4.0 million amount, the Company issued HBIO 4,000 shares of Series E Convertible Preferred Stock, or Series E Preferred Stock, at a price of \$1,000 per share to satisfy the Company's related indemnification obligations pertaining to the \$4.0 million, in lieu of paying cash.

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

In connection with the private placement, as of April 12, 2023, the Company had received \$6.0 million in aggregate proceeds in such private placement. The 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.

There were no shares of any of the classes of preferred stock outstanding as of June 30, 2023. Authorized shares for each preferred stock class are as follows:

	Authorized
Undesignated preferred stock	<u>979,000</u>
Series B convertible preferred stock	<u>1,000,000</u>
Series C convertible preferred stock	<u>4,000</u>

Series D convertible preferred stock	12,000
Series E convertible preferred stock	5,000

7. Share-Based Compensation

HRGN Amended and Restated Equity Incentive Plan

The Company maintains the Amended and Restated Equity Incentive Plan (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 vesting of the 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.

The Company's Plan has 5,098,000 authorized shares to be issued under the Plan. There were 1,293,379 shares available for issuance as of June 30, 2023.

The following table summarizes information concerning options outstanding and exercisable:

	<u>Amount</u>	<u>Weighted- average exercise price</u>	<u>Weighted- average contractual life (years)</u>	<u>Aggregate intrinsic value (in thousands)</u>
Outstanding at December 31, 2022	2,516,924	\$ 3.95	7.68	\$ 6,917
Granted	1,863,309	6.05		
Canceled / forfeited	(593,333)	6.12		
Outstanding at June 30, 2023	3,786,900	4.64	8.06	2,756
Options exercisable	1,998,552	4.65	7.44	1,971
Options vested and expected to vest	3,687,482	4.69	8.06	2,653

The Company's outstanding stock options include 698,195 performance-based awards that have vesting provisions subject to the achievement of certain business milestones. Total unrecognized compensation expense for the remaining performance-based awards is approximately \$2.6 million. No expense has been recognized for these awards as of June 30, 2023 given that the milestone achievements for these awards have not yet been deemed probable for accounting purposes.

Aggregate intrinsic value for outstanding options and exercisable options as of June 30, 2023, was approximately \$2.8 million and \$2.0 million, respectively, based on the Company's closing stock price of \$3.65 per share as of June 30, 2023. As of June 30, 2023, unrecognized compensation cost related to unvested non-performance-based awards amounted to \$4.4 million, which will be recognized over a weighted-average period of 2.69 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, 2023 and 2022 were as follows:

	<u>Six months ended June 30,</u>	
	<u>2023</u>	<u>2022</u>
Risk-free interest rate	3.76%	2.59%
Expected volatility	126.16%	124.51%
Expected term (in years)	5.9 years	5.5 years
Expected dividend yield	—%	—%

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

	Three months ended		Six months ended	
	June 30,		June 30,	
	2023	2022	2023	2022
	(In thousands)		(In thousands)	
Research and development	\$ 51	\$ 88	\$ 113	\$ 148
Selling, general and administrative	428	189	2,206	364
Total	<u>\$ 479</u>	<u>\$ 277</u>	<u>\$ 2,319</u>	<u>\$ 512</u>

8. Commitments and Contingencies

On April 14, 2017, representatives for the estate of an individual plaintiff filed a wrongful death complaint with the Suffolk Superior Court, in the County of Suffolk, Massachusetts, against the Company and other defendants, including Harvard Bioscience, Inc., or HBIO, the former parent of the Company that spun off the Company in 2013, as well as another third party. The complaint sought payment for an unspecified amount of damages and alleged that the plaintiff sustained terminal injuries allegedly caused by products provided by certain of the named defendants and utilized in connection with surgeries performed by third parties in Europe in 2012 and 2013. This lawsuit related to the Company's first-generation trachea scaffold technology for which the Company discontinued development in 2014, and not to the Company's current HRGN Esophageal Implant.

On April 27, 2022, the Company and HBIO executed a settlement with the plaintiffs (the "Settlement"), which resolves all claims relating to the litigation. The Settlement resulted in the dismissal with prejudice of the wrongful death claim, and neither the Company nor HBIO admit any fault or liability in connection with the claim. The Settlement also resolved any and all claims by and between the parties and the Company's product liability insurance carriers, which resulted in the dismissal with prejudice of all claims asserted by or against those carriers, the Company and HBIO.

In relation to the litigation, the Company paid approximately \$5.9 million of aggregate costs related to the lawsuit, of which 100% has been paid as of December 31, 2022. This aggregate amount included the cost of legal and related costs incurred by the Company, which consisted of attorneys' fees and advisor and specialist costs as part of its defense in this matter. On March 3, 2022, the Company received a cash payment of approximately \$0.1 million from Medmarc, the Company's insurance carrier. This amount represented a reimbursement of previously incurred legal costs and was recorded as a reduction to selling, general and administrative expenses during the six months ended June 30, 2022.

With respect to such \$5.9 million of costs described above, the Company was required to either pay such costs directly or indemnify HBIO as to such amounts it incurs. Of such amounts, the Company anticipated that HBIO would pay an aggregate amount of \$4.0 million by the end of the second quarter of 2022. With respect to the indemnification obligation of the Company to HBIO pertaining to such costs, the Company and HBIO entered into a Preferred Issuance Agreement dated as of April 27, 2022, or the "PIA". In connection with the PIA, the Company and HBIO agreed that once HBIO had paid at least \$4.0 million in such costs, to satisfy the Company's indemnification obligations with respect thereto, in lieu of paying cash, the Company would issue senior 8% convertible preferred stock to HBIO that will contain terms as described in the PIA, including the term sheet attached thereto. On June 10, 2022, following the execution of a subscription agreement and HBIO providing evidence of payment of the requisite \$4.0 million amount, the Company issued HBIO 4,000 shares of Series E 8% Convertible Preferred Stock at a price of \$1,000 per share to satisfy the Company's related indemnification obligations aggregating \$4.0 million, which included the accrual for contingency of \$3.3 million and approximately \$0.8 million of legal and related costs paid on behalf of the Company by HBIO previously included in accrued expenses.

From time to time, the Company may be involved in various claims and legal proceedings arising in the ordinary course of business. Other than the above matter, 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.

9. Leases

The Company leases laboratory and office space and certain equipment with remaining terms ranging from 1 to 2 years.

The laboratory and office space arrangement is under a sublease that was renewed in December of 2022 and currently extends through May 31, 2024. This lease automatically renews annually for one-year periods unless the Company or the counterparty provides a notice of termination within one hundred and eighty days prior to May 31st of each year.

On January 5, 2022, the Company executed a four-month sublease agreement for certain laboratory and office space at its Holliston, Massachusetts facility. The Company further extended the sublease agreement on a month-to-month basis until August 31, 2022 when the other party vacated the premises. For the six months ended June 30, 2022, the Company recorded sublease income of approximately \$61,000 relating to this agreement.

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:

	<u>Balance Sheet Classification</u>	<u>June 30, 2023</u>	<u>December 31, 2022</u>
<i>Assets:</i>			
Operating lease assets	Right-of-use asset, net	<u>\$ 135</u>	<u>\$ 147</u>
<i>Liabilities:</i>			
Current portion of operating lease liabilities	Current portion of operating lease liabilities	119	99
Operating lease liabilities, net of current portion	Operating lease liabilities, net of current portion	<u>18</u>	<u>48</u>
Total operating lease liabilities		<u>\$ 137</u>	<u>\$ 147</u>

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

	<u>Three months ended June 30,</u>		<u>Six months ended June 30,</u>	
	<u>2023</u>	<u>2022</u>	<u>2023</u>	<u>2022</u>
	<u>(In thousands)</u>		<u>(In thousands)</u>	
Research and development	\$ 17	\$ 19	\$ 35	\$ 38
General and administrative	11	11	22	22
Total	<u>\$ 28</u>	<u>\$ 30</u>	<u>\$ 57</u>	<u>\$ 60</u>

Cash paid included in the computation of the operating lease assets and lease liabilities during the three and six months ended June 30, 2023 amounted to approximately \$28,000 and \$57,000, respectively. Cash paid included in the computation of the operating lease assets and lease liabilities during the three and six months ended June 30, 2022 amounted to approximately \$30,000 and \$60,000, 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,	
	2023	2022
Remaining lease term (in years)	0.88	1.16
Discount rate	12.78%	9.25%

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

	As of	
	June 30, 2023	
	(in thousands)	
2023	\$	70
2024		69
2025		5
Total lease payments		144
Less: imputed interest		(7)
Present value of operating lease liabilities	\$	137

10. Net Loss Per Share

	Three months ended June 30,		Six months ended June 30,	
	2023	2022	2023	2022
	(in thousands, except shares and per share data)		(in thousands, except shares and per share data)	
Net loss	\$ (2,614)	\$ (1,345)	\$ (5,504)	\$ (3,522)
Preferred stock dividends	3	(18)	(77)	(18)
Net loss attributable to common stockholders	<u>\$ (2,611)</u>	<u>\$ (1,363)</u>	<u>\$ (5,581)</u>	<u>\$ (3,540)</u>
Basic and diluted weighted average common shares outstanding	<u>13,785,657</u>	<u>11,230,525</u>	<u>13,000,211</u>	<u>10,996,996</u>
Basic and diluted net loss per share attributable to common stockholders	<u>\$ (0.19)</u>	<u>\$ (0.12)</u>	<u>\$ (0.43)</u>	<u>\$ (0.32)</u>

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, 2023 and 2022 because including them would have had an anti-dilutive effect:

	Six months ended June 30,	
	2023	2022
Options to purchase common stock	3,786,900	2,402,603
Warrants to purchase common stock	1,113,622	1,888,622
Series E convertible preferred stock	—	686,680
Total	<u>4,900,522</u>	<u>4,977,905</u>

11. Income Taxes

The Company did not record a federal or state income tax provision or benefit for the six months ended June 30, 2023 and 2022, respectively, due to the expected loss before income taxes to be incurred for the years ended December 31, 2023 and 2022, as well as the Company's continued maintenance of a full valuation allowance against its net deferred tax assets.

12. Subsequent Events

The Company performed a review of events subsequent to the balance sheet through the date the financial statements were issued and determined that there were no such events requiring recognition or disclosure in the financial statements except as disclosed below.

In July 2023, the Company's shareholders approved the Amended and Restated Equity Incentive Plan to increase of the number of shares of the Company's common stock available for issuance pursuant to the 2013 Equity Incentive Plan by 4,000,000 shares, which increased the total shares authorized to be issued under the Plan to 9,098,000.

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," "expects," "plans," "anticipates," "believes," "goals," "sees," "estimates," "projects," "predicts," "intends," "think," "potential," "objectives," "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 funds 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; 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, 2022 filed with the Securities and Exchange Commission (the "SEC") on March 30, 2023 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. Our technology is based on our proprietary cell-therapy platform that uses a patient’s own stem cells to regenerate and restore function to damaged organs. 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.

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We conducted the world’s first successful regeneration of the esophagus in a cancer patient in August 2017. This surgery was performed by Dr. Dennis Wigle, Chair of Thoracic Surgery at the Mayo Clinic in a patient with esophageal cancer. The results were published in the Journal of Thoracic Oncology Clinical and Research Reports in August 2021. The procedure demonstrated that using HRGN’s technology, we were able to successfully regenerate esophageal tissue, including the mucosal lining, to restore the integrity, continuity and functionality of the esophageal tube. This successful first-in-human experience, plus the research we have performed on 45 pigs, led the U.S. Food and Drug Administration (“FDA”) to approve our 10-patient combined phase 1 and phase 2 clinical trial. This combination trial will measure both safety and efficacy in the patient population.

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 HRGN to Harvard Bioscience stockholders.

We have also formed a subsidiary in Hong Kong, Harvard Apparatus Regenerative Technology Limited, as 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.

We filed an amendment (the “Certificate of Amendment”) to our Amended and Restated Certificate of Incorporation with the Secretary of State for the State of Delaware to change our name from Biostage, Inc. to Harvard Apparatus Regenerative Technology, Inc. We also amended and restated our Amended and Restated Bylaws, solely to reflect the name change (as amended, the “Third Amended and Restated Bylaws”). The Certificate of Amendment and the Third Amended and Restated Bylaws each became effective on July 20, 2023.

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. We did not recognize any revenues during the six months ended June 30, 2023 and 2022.

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 are currently screening patients in the third quarter of 2023. Our product candidates are currently in development and have not yet received regulatory approval for sale anywhere in the world.

In the second quarter of 2023, the Company's subsidiary in Hong Kong, Harvard Apparatus Regenerative Technology Limited, or HRGN LTD, started a Consumer Health business.

The Consumer Health business will include a broad range of products focused on personal healthcare including anti-aging dietary supplements. The Company plans to start selling anti-aging supplements through the Hong Kong subsidiary in the third quarter of 2023. These products are marketed to the general public and initially targeted at consumers in the Great China Region through eCommerce (online sales).

Financial Condition and Need for Additional Funds

We expect to continue to incur operating losses and negative cash flows from operations for 2023 and in future years.

Operating Losses and Cash Requirements

We have incurred substantial operating losses since our inception, and as of June 30, 2023 had an accumulated deficit of approximately \$88.5 million and will require additional financing to fund future operations. We expect that our operating cash and short-term investments on-hand as of June 30, 2023 of approximately \$4.7 million will enable us to fund our operating expenses and capital expenditure requirements into the first quarter of 2024. We expect to continue to incur operating losses and negative cash flows from operations for 2023 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 funds to fund our operations. In the event we do not raise additional capital from outside sources before or during the first 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 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

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.

Selling, 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.

Sublease income. On January 5, 2022, we executed a four-month sublease agreement for certain laboratory and office space at its Holliston, Massachusetts facility. We further extended the sublease agreement to a month-to-month basis until August 31, 2022 when the other party vacated the premises. We have no sublease agreements generating sublease income as of June 30, 2023.

Other income, net. Other income, net, consists primarily of interest income and the changes in fair value of our warrant liability from the change in the fair value of common stock warrants classified as liability awards during the six months ended June 30, 2022. We previously used the Black-Scholes pricing model to value the related warrant liability. In February of 2022, the underlying common stock warrants expired unexercised.

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 accounting principles generally accepted in the United States, or 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. 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.

Warrant Liability

Most of the warrants to purchase shares of our common stock have been classified on our condensed consolidated balance sheets as equity. We classify warrants as a liability in our condensed consolidated balance sheets if the warrant is a free-standing financial instrument that may require us to transfer cash consideration upon exercise and that cash transfer event would be out of our control. Such a “liability warrant” is initially recorded at fair value on the date of grant using the Black-Scholes model, net of issuance costs, and it is subsequently re-measured to fair value at each subsequent balance sheet date. Changes in fair value of the warrants is recognized as a component of other expense in the condensed consolidated statements of operations. The warrants classified as a liability expired unexercised during the six months ended June 30, 2022 and the remaining liability on the expiration date of approximately \$2,000 was recognized as other income.

Results of Operations

The following table summarizes the results of our operations for the three and six months ended June 30, 2023 and 2022 (in thousands):

	Three months ended June 30,		Change 2023 vs. 2022		Six months ended June 30,		Change 2023 vs. 2022	
	2023	2022	Change	%	2023	2022	Change	%
Operating expenses								
Research and development	\$ 1,566	\$ 326	\$ 1,240	380%	\$ 2,075	\$ 629	\$ 1,446	230%
Selling, general and administrative	1,085	1,049	36	3%	3,463	2,951	512	17%
Total operating expenses	2,651	1,375	1,276	93%	5,538	3,580	1,958	55%
Other income								
Sublease income	—	32	(32)	nm%	—	61	(61)	nm%
Other income (expense), net	37	(2)	39	nm%	34	(3)	37	nm%
Total other income, net	37	30	7	23%	34	58	(24)	(41)%
Net loss	<u>\$(2,614)</u>	<u>\$(1,345)</u>	<u>\$(1,269)</u>	<u>94%</u>	<u>\$(5,504)</u>	<u>\$(3,522)</u>	<u>\$(1,982)</u>	<u>56%</u>

nm = not meaningful

Comparison of the three months ended June 30, 2023 and June 30, 2022

Research and Development Expense

Research and development expense increased approximately \$1.2 million, or 380%, to approximately \$1.6 million for the three months ended June 30, 2023 as compared to approximately \$0.3 million for the three months ended June 30, 2022. This increase was primarily due to clinical trial activities resulting in our first site activation in the third quarter of 2023.

Selling, General and Administrative Expense

Selling, general and administrative expense increased approximately \$0.1 million, or 3%, to approximately \$1.1 million for the three months ended June 30, 2023 as compared to approximately \$1.0 million for the three months ended June 30, 2022. This increase was primarily due to share-based compensation expense from the vesting of performance based awards in the second quarter of 2023, increased headcount related costs of approximately \$0.1

million offset by the reduced legal and related costs relating to the completion of litigation for a wrongful death complaint and related matters more fully described in Note 8 to our condensed consolidated financial statements.

Sublease income

On January 5, 2022, we executed a four-month sublease agreement for certain laboratory and office space at our Holliston, Massachusetts facility. We further extended the sublease agreement on a month-to-month basis until August 31, 2022 when the other party vacated the premises. For the three months ended June 30, 2022, we recorded sublease income of approximately \$32,000 relating to this agreement. We have no sublease agreements generating sublease income as of June 30, 2023.

Other income, net

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. During the three months ended June 30, 2022, we recorded interest expense of approximately \$2,000 on insurance installment payments.

Comparison of the six months ended June 30, 2023 and June 30, 2022

Research and Development Expense

Research and development expense increased approximately \$1.5 million, or 230%, to approximately \$2.1 million for the six months ended June 30, 2023 as compared to approximately \$0.6 million for the six months ended June 30, 2022. This increase was primarily due to preclinical trial activities and clinical trial activities resulting in our first site activation in the third quarter of 2023.

Selling, General and Administrative Expense

Selling, general and administrative expense increased approximately \$0.5 million, or 17%, to approximately \$3.5 million for the six months ended June 30, 2023 as compared to approximately \$3.0 million for the six months ended June 30, 2022. This increase was primarily due to share-based compensation expense of \$1.8 million from the vesting of performance based awards in the first half of 2023, increased headcount related costs of approximately \$0.2 million and the initial operating costs of \$0.1 million for the Hong Kong subsidiary offset by a decrease of approximately \$0.3 million for supporting our ongoing public company requirements and reduced legal and related costs of approximately \$1.3 million relating to the completion of litigation for a wrongful death complaint and related matters more fully described in Note 8 to our condensed consolidated financial statements.

Sublease income

On January 5, 2022, we executed a four-month sublease agreement for certain laboratory and office space at our Holliston, Massachusetts facility. We further extended the sublease agreement on a month-to-month basis until August 31, 2022 when the other party vacated the premises. For the six months ended June 30, 2022, we recorded sublease income of approximately \$61,000 relating to this agreement. We have no sublease agreements generating sublease income as of June 30, 2023.

Other income, net

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.

During the six months ended June 30, 2022, we recorded a gain on expiration of the common share warrants of approximately \$2,000 in other expense, net as they expired unexercised in February 2022. We also recorded interest expense of approximately \$5,000 on insurance installment payments.

Liquidity and Capital Resources

Sources of liquidity. We have incurred operating losses since inception, and as of June 30, 2023, we had an accumulated deficit of approximately \$88.5 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.

The following table sets forth the primary uses of cash for the three months ended June 30, 2023 and 2022 (in thousands):

	Six Months Ended June 30,	
	2023	2022
Net cash used in operating activities	\$ (2,559)	\$ (1,654)
Net cash used by investing activities	\$ (2,534)	\$ (8)
Net cash provided by financing activities	\$ 5,992	\$ 5,060

Comparison of six months ended June 30, 2023 and 2022

Operating activities. 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.

Net cash used in operating activities of approximately \$1.7 million for the six months ended June 30, 2022 was due primarily to our net loss of approximately \$3.5 million and offset by adjustments for non-cash items of approximately \$0.5 million due to non-cash expenses for share-based compensation and depreciation, and an approximately \$1.3 million increase to cash from changes in working capital due to the timing of payments for accounts payable, accrued expenses, prepaid expenses and deferred financing costs.

Investing activities. Net cash used in investing activities included purchases of property, plant and equipment for the six months ended June 30, 2023 and 2022 representing approximately \$11,000 and \$8,000, 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 matures in October 2023.

Financing activities. 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 a private placement transaction 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.

Net cash generated from financing activities during the six months ended June 30, 2022 of approximately \$5.1 million consisted of net proceeds received from a private placement transaction that resulted in the issuance of 854,771 shares of our common stock at a purchase price of \$5.92 per share and warrants to purchase 427,390 shares of common stock at an exercise price of \$8.88 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, 2023.

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. This Item 4 includes information concerning the controls and control evaluations referred to in those certifications.

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, 2023. 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, 2023. 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. Other than the civil lawsuit described in Item 3 of Part I of our Annual Report on Form 10-K filed with the SEC on March 30, 2023 and in our Form 8-K filed with the SEC on April 27, 2022, 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, 2022, which was filed with the SEC on March 30, 2023.

Item 5. Other Information

In the three months ended June 30, 2023, 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 | <u>Amended and Restated Certificate of Incorporation (previously filed as an exhibit to the Registration Statement on Form 10-12B, filed on July 31, 2012, and incorporated herein by reference).</u> |
| 3.2 | <u>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).</u> |
| 3.3 | <u>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).</u> |
| 3.4 | <u>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).</u> |
| 3.5 | <u>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).</u> |
| 3.6 | <u>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).</u> |
| 3.7 | <u>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).</u> |
| 3.8 | <u>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).</u> |
| 3.9 | <u>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).</u> |
| 3.10 | <u>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).</u> |

- 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 \(previously filed as an exhibit to the Current Report on Form 8-K, filed on April 6, 2023, and incorporated herein by reference\).](#)
- 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.

+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.

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 10, 2023

**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)

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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 10, 2023

/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 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 10, 2023

/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, 2023 (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 10, 2023

/s/ Junli He

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

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, 2023 (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 10, 2023

/s/ Joseph L. Damasio Jr.

Name: Joseph L. Damasio Jr.

Title: Chief Financial Officer
