



## **Harvard Apparatus Regenerative Technology Reports Second Quarter 2023 Financial Results**

**Holliston, MA** – August 14, 2023 – [Harvard Apparatus Regenerative Technology, Inc.](https://www.harvardapparatus.com) (OTCQB: HRGN) (“Harvard Apparatus Regenerative Technology” or the “Company”), a clinical-stage biotechnology company developing the technology to regenerate organs inside the body to treat severe diseases, today announced its financial results for the three and six months ended June 30, 2023.

### **Operating Highlights**

We officially activated the first clinical trial site with Mayo Clinic and are currently screening patients in the third quarter of 2023. 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.

“The initiation of our first clinical study for Cellspan Esophageal Implant (CEI) marked an important milestone for HRGN,” said Jerry He, Chairman and CEO of HRGN. “Our numerous preclinical studies and first-in-human E-IND study have demonstrated our technology as an effective platform for tubular organ regeneration. We look forward to testing CEI in the trial as we further our understanding of its potential benefits for patients.”

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 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 Greater China region through eCommerce (online sales).

“The Consumer Health business is a great way to generate additional revenue and operating cash flow from China without distracting our R&D and clinical trial efforts in the US.” Commented Mr. He.

### **Summary of Financial Results**

For the three months ended June 30, 2023, the Company reported a net loss of \$2.6 million, (\$0.19) per share, compared to a net loss of \$1.4 million, (\$0.12) per share, for the three months ended June 30, 2022. The \$1.2 million year-over-year net loss increase was due

primarily to clinical trial activities resulting in our first site activation.

For the six months ended June 30, 2023, the Company reported a net loss of \$5.6 million, (\$0.43) per share, compared to a net loss of \$3.5 million, (\$0.32) per share, for the six months ended June 30, 2022. The \$2.1 million year-over-year net loss increase was due to clinical trial activities resulting in our first site activation and an increase in share-based compensation expense from the vesting of performance-based awards in the second quarter of 2023.

## **Balance Sheet and Cash and Cash Equivalents**

At June 30, 2023, the Company had operating cash and short-term investments on-hand as of \$4.7 million.

During the six-month period ended June 30, 2023, the Company used net cash in operations of \$2.6 million and received \$6.0 million from financing activities representing proceeds from private placement transactions that resulted in the issuance of 1,000,967 shares of our common stock to investors.

## **About Harvard Apparatus Regenerative Technology, Inc.**

We are a clinical-stage biotechnology company developing regenerative-medicine treatments for disorders of the gastro-intestinal system and other organs resulting 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 sacrifice of another of the patient's own organs or permanent artificial implants.

We conducted the world's first successful regeneration of the esophagus in a patient with esophageal cancer in August 2017. This surgery was performed by Dr. Denis Wigle, Chair of Thoracic Surgery at the Mayo Clinic. The results were published in the Journal of Thoracic Oncology Clinical and Research Reports in August 2021. The procedure demonstrated that our technology was able to successfully regenerate esophageal tissue, including the mucosal lining, to restore the integrity, continuity and functionality of the esophageal tube.

HRGN has 13 issued U.S. patents, 2 issued in China, 1 issued in Japan, 2 issued in Europe and 2 orphan-drug designations which can provide seven years of market exclusivity once we won the market approval.

For more information, please visit [www.hregen.com](http://www.hregen.com) and connect with the Company on [LinkedIn](#).

## **Forward-Looking Statements**

Some of the statements in this press release are “forward-looking” and are made pursuant to the safe harbor provision of the Private Securities Litigation Reform Act of 1995. These “forward-looking” statements in this press release include, but are not limited to, statements relating to the capabilities and performance of our products and product candidates; development expectations and regulatory approval of any of the Company’s products, by the U.S. Food and Drug Administration, the European Medicines Agency or otherwise, which expectations or approvals may not be achieved or obtained on a timely basis or at all; and success with respect to any collaborations, clinical trials and other development and commercialization efforts of the Company’s products, which such success may not be achieved or obtained on a timely basis or at all. These statements involve risks and uncertainties that may cause results to differ materially from the statements set forth in this press release, including, among other things, the Company’s inability to obtain needed funds in the immediate future; the Company’s ability to obtain and maintain regulatory approval for its products; plus other factors described under the heading “Item 1A. Risk Factors” in the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2022 or described in the Company’s other public filings. The Company’s results may also be affected by factors of which the Company is not currently aware. The forward-looking statements in this press release speak only as of the date of this press release. The Company expressly disclaims any obligation or undertaking to release publicly any updates or revisions to such statements to reflect any change in its expectations with regard thereto or any changes in the events, conditions or circumstances on which any such statement is based.

## **Investor Relations Contacts**

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**HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.**  
**CONSOLIDATED BALANCE SHEETS**  
*(In thousands, except par value and share data)*

	<b>June 30, 2023</b>	<b>December 31, 2022</b>
	<i>(Unaudited)</i>	
<b>ASSETS</b>		
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	5,001	1,594
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>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</b>		
Current liabilities:		
Accounts payable	\$ 372	\$ 682
Accrued and other current liabilities	1,476	582
Operating lease liability, current	119	99
Total current liabilities	1,967	1,363
Operating lease liability, net of current portion	18	48
Total liabilities	<u>1,985</u>	<u>1,411</u>
Commitments and contingencies		
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	(88,515)	(83,011)
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>

**HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**

*(Unaudited)*

*(In thousands, except per share amounts)*

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2023</b>	<b>2022</b>	<b>2023</b>	<b>2022</b>
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	<u>3</u>	<u>(18)</u>	<u>(77)</u>	<u>(18)</u>
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>

**HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
*(Unaudited)*  
*(In thousands)*

	<b>Six Months Ended June 30,</b>	
	<b>2023</b>	<b>2022</b>
<b>OPERATING ACTIVITIES</b>		
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>
<b>INVESTING ACTIVITIES</b>		
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>
<b>FINANCING ACTIVITIES</b>		
Proceeds from issuance of common stock	5,992	5,060
Net cash provided by financing activities	5,992	5,060
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>
<b>Supplemental disclosure of non-cash activities:</b>		
Settlement of contingency matter	\$ —	\$ (3,250)
Settlement of due to Harvard Bioscience included in accrued and other current liabilities	\$ —	\$ (750)
Issuance of Series E convertible preferred stock	\$ —	\$ 4,000
Purchases of property and equipment in accounts payable or accrued expenses	\$ 5	\$ —
Preferred stock dividends	\$ 77	\$ 18
Conversion of preferred stock into common stock	\$ 4,257	\$ —