

Harvard Apparatus Regenerative Technology Reports Fourth Quarter and Full Year 2023 Financial Results and Recent Business Highlights

- *Established a Research Collaboration with the McGowan Institute for Regenerative Medicine at the University of Pittsburgh to Study the Repair and Regeneration of the Colon following Colectomy*
- *Established a Collaboration with Hugh Taylor, MD, chair of Obstetrics, Gynecology & Reproductive Sciences at Yale School of Medicine to Repair and Regenerate the Uterus*
- *Activated the second clinical trial site with the University of Michigan in August 2023 to expand the screening of patients.*
- *Received approval of an Orphan Disease Application for our lead product, the Cellspan Esophageal Implant by the European Medicines Agency (EMA for Esophageal Atresia). The EMA is the centralized regulatory agency for the review and approval of new medicines in the European Union.*
- *Activated Mayo Clinic as The First Site for Clinical Trial in Severe Esophageal Disease*
- *Company's subsidiary in Hong Kong launched its longevity product business in Asia, generating more than \$100,000 in 2023 sales.*
- *Entered into securities purchase agreements with accredited investors for a \$6 million private investment in public equity (PIPE) financing. The transaction closed on April 6, 2023.*

Holliston, MA, April 02, 2024 (GLOBE NEWSWIRE) -- [Harvard Apparatus Regenerative Technology, Inc.](#) (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 reported fourth quarter and full year 2023 financial results.

Fourth Quarter 2023 Financial Results

For the three months ended December 31, 2023, the Company reported a net loss of \$1.8 million, (\$0.13) per share, compared to a net loss of \$1.6 million, (\$0.14) per share, for the three months ended December 31, 2022. The \$0.2 million year-over-year net loss increase was due primarily to share-based compensation expense of \$0.3 million from the vesting of time-based awards in the fourth quarter of 2023 and increased headcount related costs of approximately \$0.1 million offset by reduced pre-clinical activities.

Full Year 2023 Financial Results

For the year ended December 31, 2023, the Company reported a net loss of \$9.0 million, (\$0.67) per share, compared to a net loss of \$6.3 million, (\$0.55) per share, for the year ended December 31, 2022. The \$2.8 million year-over-year net loss increase was due to clinical trial activities resulting in our activation of two sites, increased headcount costs and an increase in share-based compensation expense from the vesting of performance-based awards in 2023.

Balance Sheet and Cash and Cash Equivalents

At December 31, 2023, the Company had operating cash on-hand as of \$0.4 million. The Company received \$0.5 million in debt financing from a related party in February 2024.

During the year ended December 31, 2023, the Company used net cash in operations of \$6.9 million and received \$6.1 million from financing activities and consisted of net proceeds received from a private placement transaction for the issuance of common stock and stock option exercises.

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. Dennis 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 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, 2023 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

Joseph Damasio
Chief Financial Officer
774-233-7330
jdamasio@hregen.com

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC. CONSOLIDATED BALANCE SHEETS

(In thousands, except par value and share data)

	December 31, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 432	\$ 1,241
Accounts receivable	4	-
Inventory	50	-
Prepaid research and development	210	274
Prepaid expenses and other current assets	87	79
Total current assets	783	1,594
Property, plant and equipment, net	25	49
Right-of-use assets, net	48	147
Deferred financing costs	544	610
Long-term prepaid contracts	1,214	-
Total assets	\$ 2,614	\$ 2,400
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	\$ 445	\$ 682
Accrued and other current liabilities	475	582
Operating lease liability, current	48	99
Total current liabilities	968	1,363
Operating lease liability, net of current portion	-	48
Total liabilities	968	1,411
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 December 31, 2023 and 2022, respectively	-	4,180
Stockholders' equity (deficit):		
Common stock, par value \$0.01 per share, 60,000,000 shares authorized; 13,947,324 and 12,174,467 issued and outstanding at December 31, 2023 and 2022, respectively	139	122
Additional paid-in capital	93,463	79,698
Accumulated deficit	(91,956)	(83,011)
Total stockholders' equity (deficit)	1,646	(3,191)
Total liabilities and stockholders' equity (deficit)	\$ 2,614	\$ 2,400

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

	Three Months Ended		Year Ended	
	December 31,		December 31,	
	2023	2022	2023	2022
Product revenue	\$ 63	\$ -	\$ 103	\$ -
Operating expenses:				
Cost of sales	11	-	24	-
Research and development	648	744	3,062	1,742
Sales and marketing	96	-	294	-
General and administrative	1,136	749	5,713	4,411
Total operating expenses	1,891	1,493	9,093	6,153
Operating loss	(1,828)	(1,493)	(8,990)	(6,153)
Other income (expense), net:				
Sublease income	-	-	-	87
Change in fair value of warrant liability	-	2	-	2
Interest income	5	-	64	-
Interest expense	(3)	(9)	(14)	(9)
Other expense	-	5	(5)	-
Total other income, net	2	(2)	45	80
Net loss	(1,826)	(1,495)	(8,945)	(6,073)
Preferred stock dividends	-	(85)	(77)	(180)
Net loss attributable to common stockholders	\$ (1,826)	\$ (1,580)	\$ (9,022)	\$ (6,253)
Basic and diluted net loss per share	\$ (0.13)	\$ (0.14)	\$ (0.67)	\$ (0.55)
Weighted average common shares, basic and diluted	13,925,333	11,615,642	13,455,666	11,349,610

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

Year ended December 31,

2023 2022

OPERATING ACTIVITIES

Net loss	\$ (8,945)	\$ (6,073)
Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities:		
Share-based compensation expense	3,461	1,031
Depreciation	35	52
Amortization of operating right-of-use assets	99	22
Change in fair value of warrant liability	-	(2)
Changes in operating assets and liabilities:		
Accounts receivable	(4)	-
Inventory	(50)	-
Prepaid research and development	64	(274)
Prepaid expenses and other current assets	(8)	216
Deferred financing costs	66	(610)
Long-term prepaid contracts	(1,214)	-
Accounts payable	(237)	6
Operating lease liability	(99)	(22)
Accrued and other current liabilities	(107)	548
Net cash used in operating activities	(6,939)	(5,106)

INVESTING ACTIVITIES

Purchases of short-term investments	(2,523)	-
Redemption of short-term investments	2,523	-
Purchases of property, plant and equipment	(11)	(5)
Net cash used in investing activities	(11)	(5)

FINANCING ACTIVITIES

Proceeds from issuance of common stock	5,992	5,060
Proceeds from exercise of stock options	149	-
Net cash provided by financing activities	6,141	5,060
Net decrease in cash and cash equivalents	(809)	(51)
Cash and cash equivalents at the beginning of the year	1,241	1,292
Cash and cash equivalents at the end of the year	\$ 432	\$ 1,241

SUPPLEMENTAL INFORMATION

Interest paid in cash	\$ 14	\$ 9
Supplemental disclosure of non-cash activities:		
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
Preferred stock dividends	\$ 77	\$ 180
Increase of right-of-use asset and liability due to lease extension	\$ -	\$ 63

