Hyperfine, Inc. Reports Third Quarter 2024 Financial Results

November 12, 2024

GUILFORD, Connecticut, Nov. 12, 2024 (GLOBE NEWSWIRE) -- Hyperfine, Inc. (Nasdaq: HYPR), the groundbreaking health technology company that has redefined brain imaging with the first FDA-cleared portable magnetic resonance (MR) brain imaging system—the Swoop® system—today announced third quarter 2024 financial results and provided a business update.

“The Hyperfine team delivered yet another strong quarter of financial performance across revenue growth, gross margin expansion, and disciplined cash management while executing against several important priorities in our plans to expand into new sites of care and internationally,” said Maria Sainz, Chief Executive Officer and President of Hyperfine, Inc. “I am increasingly confident in our growth prospects in 2025 and beyond as we execute on our expansion strategy with advancements in image quality and clinical evidence.”

Third Quarter 2024 Financial Results

- Revenues were a record $3.64 million, up 56%, compared to $2.33 million in the third quarter of 2023.
- Gross margin was $1.91 million, compared to $1.12 million in the third quarter of 2023, translating to a gross margin of 52% compared to 48% in the third quarter of 2023.
- Research and development expenses were $5.98 million, compared to $5.74 million in the third quarter of 2023.
- Sales, marketing, general, and administrative expenses were $6.89 million, compared to $7.14 million in the third quarter of 2023.
- Net loss was $10.33 million, equating to a net loss of $0.14 per share, as compared to a net loss of $10.76 million, or a net loss of $0.15 per share, for the third quarter of 2023.

Recent Achievements and Business Highlights

- Technology Enhancements:
  - Obtained CE approval of 9th generation AI-powered brain imaging software with enhanced speed.
  - Commenced full rollout of 9th generation AI-powered brain imaging software following FDA clearance in July 2024.
- Alzheimer’s Clinical Data:
  - High exposure at three significant Alzheimer’s meetings: Alzheimer’s Association International Conference (AAIC) Philadelphia, AAIC Tokyo, and the Clinical Trials on Alzheimer’s Disease conference with three presentations showcasing the potential value of the Swoop® system in Alzheimer’s patient management.
- Stroke Clinical Data:
  - Subset of ACTION PMR (ACuTe Ischemic strOke detectioN with Portable MR) study data from MGH and Yale, published in the August 2024 issue of Annals of Neurology.
  - Presentation by Keith Muir, MD, of the University of Glasgow, at European Society of Radiology showcasing the Swoop® systems ability to detect stroke was significantly faster than conventional MRI in the Emergency Room setting.

Nine Months Financial Results

- Revenues were $10.57 million, up 27%, compared to $8.35 million in the nine months ended September 30, 2023.
- Gross margin was $5.07 million, compared to $3.72 million in the nine months ended September 30, 2023, translating to a gross margin percentage of 48% in the nine months ended September 30, 2024, compared to a gross margin percentage of 45% in the nine months ended September 30, 2023.
- Research and development expenses were $17.51 million, compared to $16.53 million in the nine months ended September 30, 2023.
- Sales, marketing, general, and administrative expenses were $20.13 million, compared to $23.68 million in the nine months ended September 30, 2023.
- Net loss was $30.33 million, equating to a net loss of $0.42 per share, as compared to a net loss of $33.55 million, or a net loss of $0.47 per share, for the nine months ended September 30, 2023.

2024 Financial Guidance

- Management expects revenue for the full year 2024 to be $14 to $14.5 million, reflecting year over year growth of 27% to 31%.
- Management expects its cash burn for the full year 2024 to be $37 to $40 million.

Conference Call

Hyperfine, Inc. will host a conference call at 1:30 p.m. PT/ 4:30 p.m. ET on Tuesday, November 12, 2024, to discuss its third quarter 2024 financial

results and provide a business update. Those interested in listening should register online by visiting https://investors.hyperfine.io/. and clicking on News & Events. Participants are encouraged to register more than 15 minutes before the start of the call. A live and archived audio webcast will be available through the Investors page of Hyperfine, Inc.'s corporate website at https://investors.hyperfine.io/.

About Hyperfine, Inc. and the Swoop® Portable MR Imaging® System

Hyperfine, Inc. (Nasdaq: HYPR) is the groundbreaking health technology company that has redefined brain imaging with the Swoop® system—the first FDA-cleared, portable, ultra-low-field, magnetic resonance brain imaging system capable of providing imaging at multiple points of care. The Swoop® system received initial U.S. Food and Drug Administration (FDA) clearance in 2020 as a portable magnetic resonance brain imaging device for producing images that display the internal structure of the head where a full diagnostic examination is not clinically practical. When interpreted by a trained physician, these images provide information that can be useful in determining a diagnosis. The Swoop® system has been approved for brain imaging in several countries, including Canada and Australia, has UKCA certification in the United Kingdom, CE certification in the European Union, and is also available in New Zealand.

The mission of Hyperfine, Inc. is to revolutionize patient care globally through transformational, accessible, clinically relevant diagnostic imaging and data solutions. Founded by Dr. Jonathan Rothberg in a technology-based incubator called 4Catalyzer, Hyperfine, Inc. scientists, engineers, and physicists developed the Swoop® system out of a passion for redefining brain imaging methodology and how clinicians can apply accessible diagnostic imaging to patient care. Traditionally, access to costly, stationary, conventional MRI technology can be inconvenient or not available when needed most. With the portable, ultra-low-field Swoop® system, Hyperfine, Inc. is redefining the neuroimaging workflow by bringing brain imaging to the patient's bedside. For more information, visit hyperfine.io.

Hyperfine, Swoop, and Portable MR Imaging are registered trademarks of Hyperfine, Inc.

Forward-Looking Statements

This press release includes "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Actual results of Hyperfine, Inc. (the "Company") may differ from its expectations, estimates and projections and consequently, you should not rely on these forward-looking statements as predictions of future events. Words such as "expect," "estimate," "project," "budget," "forecast," "anticipate," "intend," "plan," "may," "will," "could," "should," "believes," "predicts," "potential," "continue," and similar expressions (or the negative versions of such words or expressions) are intended to identify such forward-looking statements. These forward-looking statements include, without limitation, expectations about the Company's financial and operating results, including, the Company's expected revenue and cash burn for the full year 2024, the Company's goals and commercial plans, including the Company's plans to expand internationally and in new sites of care, the Company's stroke observational clinical study and Alzheimer's feasibility study, the benefits of the Company's products and services, progress on improvements and advancements in the Company's products and services, and the Company's future performance, including its financial performance, and its ability to implement its strategy. These forward-looking statements involve significant risks and uncertainties that could cause the actual results to differ materially from the expected results. Most of these factors are outside of the Company's control and are difficult to predict. Factors that may cause such differences include, but are not limited to: the success, cost and timing of the Company's product development and commercialization activities, including the degree that the Swoop® system is accepted and used by healthcare professionals; the ability to maintain the listing of the Company's Class A common stock on the Nasdaq Stock Market LLC; the Company's ability to grow and manage growth profitably and retain its key employees; changes in applicable laws or regulations; the ability of the Company to raise financing in the future; the ability of the Company to obtain and maintain regulatory clearance or approval for its products, and any related restrictions and limitations of any cleared or approved product; the ability of the Company to identify, in-license or acquire additional technology; the ability of the Company to maintain its existing or future license, manufacturing, supply and distribution agreements and to obtain adequate supply of its products; the ability of the Company to compete with other companies currently marketing or engaged in the development of products and services that the Company is currently marketing or developing; the size and growth potential of the markets for the Company's products and services, and its ability to serve those markets, either alone or in partnership with others; the pricing of the Company's products and services and reimbursement for medical procedures conducted using the Company's products and services; the Company's ability to successfully complete and generate positive data from the ACTION PMR study and the CARE PMR study; the Company's ability to generate clinical evidence of the benefits of the Company's products and services and to progress on product advancements and improvements; the Company's estimates regarding expenses, revenue, capital requirements and needs for additional financing; the Company's financial performance; and other risks and uncertainties indicated from time to time in Company's filings with the Securities and Exchange Commission, including those under "Risk Factors" therein. The Company cautions readers that the foregoing list of factors is not exclusive and that readers should not place undue reliance upon any forward-looking statements which speak only as of the date made. The Company does not undertake or accept any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements to reflect any change in its expectations or any change in events, conditions or circumstances on which any such statement is based.

Investor Contact
Webb Campbell
Gilmartin Group LLC
webb@gilmartinir.com

HYPERFINE, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share amounts)
(Unaudited)

	September 30, 2024	December 31, 2023
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 45,765	$ 75,183
Restricted cash	219	621

Accounts receivable, less allowance of $482 and $321 as of September 30, 2024 and December 31, 2023, respectively	6,800	3,189
Unbilled receivables	2,264	942
Inventory	7,044	6,582
Prepaid expenses and other current assets	2,002	2,391
Total current assets	64,094	88,908
Property and equipment, net	3,125	2,999
Other long term assets	2,167	2,292
Total assets	**$ 69,386**	**$ 94,199**
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 1,404	$ 1,214
Deferred grant funding	219	621
Deferred revenue	1,413	1,453
Due to related parties	53	61
Accrued expenses and other current liabilities	6,870	5,419
Total current liabilities	9,959	8,768
Long term deferred revenue	1,105	968
Other noncurrent liabilities	—	64
Total liabilities	**11,064**	**9,800**
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY		
Class A Common stock, $.0001 par value; 600,000,000 shares authorized; 57,893,458 and 56,840,949 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	5	5
Class B Common stock, $.0001 par value; 27,000,000 shares authorized; 15,055,288 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	2	2
Additional paid-in capital	342,367	338,114
Accumulated deficit	(284,052)	(253,722)
Total stockholders' equity	**58,322**	**84,399**
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 69,386**	**$ 94,199**

HYPERFINE, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(in thousands, except share and per share amounts)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Sales				
Device	$ 3,033	$ 1,728	$ 8,707	$ 6,670
Service	610	602	1,862	1,676
Total sales	3,643	2,330	10,569	8,346
Cost of sales				
Device	1,359	835	4,280	3,321
Service	376	371	1,224	1,302
Total cost of sales	1,735	1,206	5,504	4,623
Gross margin	**1,908**	**1,124**	**5,065**	**3,723**
Operating Expenses:				
Research and development	5,865	5,739	17,394	16,531
General and administrative	4,510	4,615	13,361	16,103
Sales and marketing	2,496	2,529	6,769	7,575
Total operating expenses	**12,871**	**12,883**	**37,524**	**40,209**
Loss from operations	**(10,963)**	**(11,759)**	**(32,459)**	**(36,486)**
Interest income	585	1,021	2,056	2,920
Other income (expense), net	52	(19)	73	12
Loss before provision for income taxes	**(10,326)**	**(10,757)**	**(30,330)**	**(33,554)**
Provision for income taxes	—	—	—	—
Net loss and comprehensive loss	**$ (10,326)**	**$ (10,757)**	**$ (30,330)**	**$ (33,554)**

Net loss per common share attributable to common stockholders, basic and diluted	$ (0.14)	$ (0.15)	$ (0.42)	$ (0.47)
Weighted-average shares used to compute net loss per share attributable to common stockholders, basic and diluted	72,678,622	71,464,315	72,219,681	71,178,769

HYPERFINE, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (30,330)	$ (33,554)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	775	791
Stock-based compensation expense	3,308	3,453
Loss on disposal of property and equipment, net	156	48
Other	6	25
Changes in assets and liabilities:		
Accounts receivable, net	(3,611)	(334)
Unbilled receivables	(1,322)	(228)
Inventory	(579)	(2,494)
Prepaid expenses and other current assets	(324)	1,010
Due from related parties	—	48
Prepaid inventory	693	281
Other long term assets	(9)	142
Accounts payable	193	229
Deferred grant funding	(402)	(196)
Deferred revenue	97	(364)
Due to related parties	(8)	48
Accrued expenses and other current liabilities	949	(776)
Operating lease liabilities, net	(2)	—
Net cash used in operating activities	**(30,410)**	**(31,871)**
Cash flows from investing activities:		
Purchases of property and equipment	(375)	(546)
Net cash used in investing activities	**(375)**	**(546)**
Cash flows from financing activities:		
Proceeds from exercise of stock options	160	146
Proceeds from shares issued under “at-the-market” offering program, net of selling costs	805	—
Net cash provided by financing activities	**965**	**146**
Net decrease in cash and cash equivalents and restricted cash	**(29,820)**	**(32,271)**
Cash, cash equivalents and restricted cash, beginning of period	75,804	118,243
Cash, cash equivalents and restricted cash, end of period	**45,984**	**85,972**
Reconciliation of cash, cash equivalents, and restricted cash reported in the balance sheets		
Cash and cash equivalents	45,765	85,424
Restricted cash	219	548
Total cash, cash equivalents and restricted cash	**$ 45,984**	**$ 85,972**
Supplemental disclosure of noncash information:		
Unpaid purchase of property and equipment	$ 571	$ 54

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Source: Hyperfine, Inc.