UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 21, 2024

Hyperfine, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware (State or Other Jurisdiction of Incorporation)

351 New Whitfield Street Guilford, Connecticut (Address of Principal Executive Offices) 001-39949 (Commission File Number) 98-1569027 (IRS Employer Identification No.)

> 06437 (Zip Code)

Registrant's Telephone Number, Including Area Code: (866) 796-6767

N/A (Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

□ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

□ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

□ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

	Trading	
Title of each class	Symbol(s)	Name of each exchange on which registered
Class A common stock, \$0.0001 par value per share	HYPR	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company \boxtimes

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.

Item 2.02 Results of Operations and Financial Condition.

On March 21, 2024, Hyperfine, Inc. issued a press release announcing its results for the fourth quarter and year ended December 31, 2023 and providing a business update. A copy of the press release is furnished as Exhibit 99.1 hereto.

The information in this Current Report on Form 8-K (including Exhibit 99.1) shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release dated March 21, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

The press release may contain hypertext links to information on our website. The information on our website is not incorporated by reference into this Current Report on Form 8-K and does not constitute a part of this Form 8-K.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

HYPERFINE, INC.

Date: March 21, 2024

By: /s/ Brett Hale

Brett Hale Chief Administrative Officer, Chief Financial Officer, Treasurer and Corporate Secretary

Hyperfine, Inc. Reports Fourth Quarter and Full Year 2023 Financial Results

GUILFORD, Connecticut, March 21, 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 fourth quarter and full year 2023 financial results and provided a business update.

"I am pleased with our strong growth in 2023. We continued to drive adoption in our beachhead markets of critical care and pediatrics, and we made significant progress to expand our use cases through clinical evidence and innovation," said Maria Sainz, Chief Executive Officer and President of Hyperfine, Inc. "We remain focused on our 3 strategic pillars in 2024; our technology has been highlighted at several medical conferences, we are selling systems into new flagship institutions, and we have mobilized to build a robust program supporting Swoop's utility in Alzheimer's disease."

2023 Achievements

- Successfully launched two AI-powered software upgrades to improve Swoop® system image quality, both following FDA clearance.
- Received multiple CE and UK Conformity Assessment (UKCA) certifications under European medical device reporting (MDR), including certifications to use Hyperfine, Inc.'s latest AI-powered software.
- Launched acute ischemic stroke program with the initiation of the ACTION PMR observational clinical study and appointment of a worldclass stroke advisory board.
- Developed Alzheimer's disease program, including a utility study using the Swoop® system to scan patients on LEQEMBI.
- Achieved significant clinical evidence milestones, including the completion of enrollment in HOPE PMR, a multi-center study imaging 150 pediatric hydrocephalus patients, the presentation of SAFE MRI, a study evaluating the benefits of portable MR brain imaging to monitor ECMO patients, and the presentation or publication of 27 clinical conference presentations, peer reviewed journal articles, perspectives, case studies and editorials on the Swoop® system.
- Received an additional 3-year grant from the Bill and Melinda Gates Foundation to expand clinical research studying the neurological effects of early childhood malnutrition with the Swoop® system in low- and middle-income countries.
- Completed reorganization in early 2023 and established a lean and seasoned executive management team, including the addition of Brett Hale, Chief Administrative Officer & Chief Financial Officer, and the promotion of Tom Teisseyre, Ph.D. to Chief Operating Officer.
- Drove spending discipline and substantially reduced cash burn from \$71 million in 2022 to \$42 million in 2023 allowing Hyperfine to extend its cash runway into early 2026.

Fourth Quarter 2023 Financial Results

- Revenues for the fourth quarter of 2023 were \$2.69 million, up 89%, compared to \$1.42 million in the fourth quarter of 2022.
- Hyperfine, Inc. sold seven commercial Swoop® systems in the fourth quarter of 2023.
- Gross margin for the fourth quarter of 2023 was \$1.03 million, compared to \$0.30 million in the fourth quarter of 2022.
- Research and development expenses for the fourth quarter of 2023 were \$5.96 million, compared to \$5.22 million in the fourth quarter of 2022.
- Sales, marketing, general, and administrative expenses for the fourth quarter of 2023 were \$6.70 million, compared to \$8.71 million in the fourth quarter of 2022.
- Net loss for the fourth quarter of 2023 was \$10.68 million, equating to a net loss of \$0.15 per share, as compared to a net loss of \$13.06 million, or a net loss of \$0.19 per share, for the fourth quarter of 2022.

Full Year 2023 Financial Results

• Revenues for the full year 2023 were \$11.03 million, up 62%, compared to \$6.81 million in 2022.

- Hyperfine, Inc. sold 37 commercial Swoop® systems in 2023.
- Gross margin for the full year 2023 was \$4.76 million, compared to \$0.91 million in 2022.
- Research and development expenses for the full year 2023 were \$22.49 million, compared to \$28.16 million in 2022.
- Sales, marketing, general, and administrative expenses for the full year 2023 were \$30.38 million, compared to \$46.63 million in 2022.
- Net loss for the full year 2023 was \$44.24 million, equating to a net loss of \$0.62 per share, as compared to a net loss of \$73.16 million, or a net loss of \$1.04 per share, for the prior year.
- Cash and cash equivalents totaled \$75.18 million as of December 31, 2023.

2024 Financial Guidance

- Management expects revenue for the full year 2024 to be \$12 to \$15 million. Management expects revenue for the first quarter 2024 to be over \$3 million.
- Management expects cash burn for the full year 2024 to be approximately \$40 million.

Conference Call

Hyperfine, Inc. will host a conference call at 1:30 p.m. PT/4:30 p.m. ET on Thursday, March 21, 2024, to discuss its fourth quarter and full year 2023 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 for the first quarter of 2024, the Company's goals and commercial plans, the Company's Alzheimer's feasibility study, the benefits of the Company's products and services, and the Company's future 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 inability to maintain the listing of the Company's Class A common stock on the Nasdaq Stock Market LLC; the Company's inability to grow and manage growth profitably and retain its key employees; changes in applicable laws or regulations; the inability of the Company to raise financing in the future; the inability 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 inability of the Company to identify, in-license or acquire additional technology; the inability of the Company to maintain its existing or future license, manufacturing, supply and distribution agreements and to obtain adequate supply of its products; the inability 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 inability to successfully complete and generate positive data from the ACTION PMR study, the HOPE PMR study, and the Alzheimer's feasibility study; 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 Marissa Bych Gilmartin Group LLC marissa@gilmartinir

HYPERFINE, INC. AND SUBSIDIARIES CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share amounts)

(Unaudited)

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	December 31,			
		2023		2022
ASSETS				
CURRENT ASSETS:				
Cash and cash equivalents	\$	75,183	\$	117,472
Restricted cash		621		771
Accounts receivable, less allowance of \$321 and \$180 in 2023 and 2022, respectively		3,189		2,103
Unbilled receivables		942		454
Inventory		6,582		4,622
Prepaid expenses and other current assets		2,391		3,194
Due from related parties		_		48
Total current assets	\$	88,908	\$	128,664
Property and equipment, net		2,999		3,248
Other long term assets		2,292		2,139
Total assets	\$	94,199	\$	134,051
LIABILITIES AND STOCKHOLDERS' EQUITY				
CURRENT LIABILITIES:				
Accounts payable	\$	1,214	\$	678
Deferred grant funding		621		771
Deferred revenue		1,453		1,378
Due to related parties		61		—
Accrued expenses and other current liabilities		5,419		5,976
Total current liabilities	\$	8,768	\$	8,803
Long term deferred revenue		968		1,526
Other noncurrent liabilities		64		—
Total liabilities	\$	9,800	\$	10,329
STOCKHOLDERS' EQUITY:				
Class A Common stock, \$.0001 par value; 600,000,000 shares authorized; 56,840,949 and 55,622,488 shares issued and outstanding at December 31, 2023 and 2022, respectively		5		5
Class B Common stock, \$.0001 par value; 27,000,000 shares authorized; 15,055,288 shares issued and outstanding at December 31, 2023 and 2022		2		2
Additional paid-in capital		338,114		333,199
Accumulated deficit		(253,722)		(209,484)
Total stockholders' equity	\$	84,399	\$	123,722
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$	94,199	\$	134,051



HYPERFINE, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENT OF OPERATIONS AND COMPREHENSIVE LOSS

(in thousands, except share and per share amounts)

(Unaudited)

(Unat	Three months ended December 31.					Year ended December 31.			
		2023		2022		2023		2022	
Sales									
Device	\$	2,076	\$	941	\$	8,746	\$	5,246	
Service		610		483		2,286		1,568	
Total sales	\$	2,686	\$	1,424	\$	11,032	\$	6,814	
Cost of sales									
Device	\$	1,142	\$	720	\$	4,463	\$	4,231	
Service		510		404		1,812		1,676	
Total cost of sales	\$	1,652	\$	1,124	\$	6,275	\$	5,907	
Gross margin		1,034		300		4,757		907	
Operating Expenses:									
Research and development	\$	5,962	\$	5,219	\$	22,493	\$	28,156	
General and administrative		4,173		5,836		20,276		32,406	
Sales and marketing		2,528		2,874		10,103		14,219	
Total operating expenses	_	12,663		13,929		52,872		74,781	
Loss from operations	\$	(11,629)	\$	(13,629)	\$	(48,115)	\$	(73,874)	
Interest income	\$	922	\$	558	\$	3,842	\$	761	
Other income (expense), net		23		12		35		(51)	
Loss before provision for income taxes	\$	(10,684)	\$	(13,059)	\$	(44,238)	\$	(73,164)	
Provision for income taxes		—		—		—		—	
Net loss and comprehensive loss	\$	(10,684)	\$	(13,059)	\$	(44,238)	\$	(73,164)	
Net loss per common share attributable to common stockholders, basic and diluted	\$	(0.15)	\$	(0.19)	\$	(0.62)	\$	(1.04)	
Weighted-average shares used to compute net loss per share attributable to common stockholders, basic and diluted		71,724,900		70,588,368		71,316,424		70,449,191	

HYPERFINE, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENT OF CASH FLOWS

(in thousands) (Unaudited)

		Three mon Decem		led	Year ended December 31,					
		2023		2022		2023		2022		
Cash flows from operating activities:			-							
Net loss	\$	(10,684)	\$	(13,059)	\$	(44,238)	\$	(73,164)		
Adjustments to reconcile net loss to net cash used in operating										
activities:										
Depreciation		263		261		1,054		1,015		
Stock-based compensation expense		1,288		1,793		4,741		10,652		
Write-off of equipment		176		_		224		_		
Other		_		85		25		91		
Changes in assets and liabilities		—								
Accounts receivable		(752)		599		(1,086)		(1,550)		
Unbilled receivables		(260)		1,021		(488)		(363)		
Inventory		285		(620)		(2,209)		(312)		
Prepaid expenses and other current assets		486		(1,398)		1,496		(1,837)		
Due from related parties		—		(48)		48		(34)		
Prepaid inventory		(693)		(281)		(412)		(281)		
Other long term assets		(362)		(694)		(220)		(632)		
Accounts payable		304		(48)		533		(1,570)		
Deferred grant funding		73		(488)		(123)		(1,891)		
Deferred revenue		(119)		566		(483)		1,664		
Due to related parties		13		(61)		61		(1,981)		
Accrued expenses and other current liabilities		34		(2,973)		(742)		(2,146)		
Operating lease liabilities, net		10				10				
Net cash used in operating activities	\$	(9,938)	\$	(15,345)	\$	(41,809)	\$	(72,339)		
Cash flows from investing activities:										
Purchases of property and equipment		(258)		(158)		(804)		(585)		
Net cash used in investing activities	\$	(258)	\$	(158)	\$	(804)	\$	(585)		
Cash flows from financing activities:										
Proceeds from exercise of stock options		28		5		174		7		
Net cash provided by financing activities	\$	28	\$	5	\$	174	\$	7		
Net decrease in cash and cash equivalents and restricted cash		(10,168)		(15,498)		(42,439)		(72,917)		
Cash, cash equivalents and restricted cash, beginning of period		85,972		133,741		118,243		191,160		
Cash, cash equivalents and restricted cash, end of period	\$	75,804	\$	118,243	\$	75,804	\$	118,243		
Reconciliation of cash, cash equivalents, and restricted cash		10,001		110,210	÷	75,001	ф —	110,210		
reported in the balance sheets										
Cash and cash equivalents	\$	75,183	\$	117,472	\$	75,183	\$	117,472		
Restricted cash		621		771		621		771		
Total cash, cash equivalents and restricted cash	\$	75,804	\$	118,243	\$	75,804	\$	118,243		
Supplemental disclosure of cash flow information:										
Cash received from exchange of research and development tax										
credits	\$	519	\$	—	\$	519	\$	131		
Supplemental disclosure of noncash information:										
Write-off of notes receivable	\$	_	\$		\$	_	\$	90		
Noncash acquisition of fixed assets	\$	(51)	\$		\$	3	\$			
Toneash acquisition of fixed assets	Φ	(31)	Φ		Φ	5	φ			