

**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): November 09, 2023

Hyperfine, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-39949
(Commission File Number)

98-1569027
(IRS Employer
Identification No.)

351 New Whitfield Street
Guilford, Connecticut
(Address of Principal Executive Offices)

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:

Title of each class	Trading 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

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 November 9, 2023, Hyperfine, Inc. issued a press release announcing its results for the third quarter ended September 30, 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 November 9, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: November 9, 2023

By: /s/ Brett Hale

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

Hyperfine, Inc. Reports Third Quarter 2023 Financial Results

GUILFORD, Connecticut, November 9, 2023 (GLOBE NEWSWIRE) – Hyperfine, Inc. (Nasdaq: HYPR), the groundbreaking medical device company that has redefined brain imaging with the world’s first FDA-cleared, portable, ultra-low-field, magnetic resonance brain imaging system—the Swoop® system—today announced third quarter 2023 financial results and provided a business update.

“We remain focused on our three strategic pillars of innovation, clinical evidence, and commercialization, all while actively managing our spending, resulting in meaningful progress in the transformation of the business” said Maria Sainz, Chief Executive Officer and President of Hyperfine, Inc. “The quarter was dominated by U.S. direct deals driving record average selling price and gross margin percentage for our business. We also received FDA clearance for our latest AI-powered software and drove strong progress on all our clinical programs, including our upcoming Alzheimer’s feasibility study.”

Third Quarter 2023 Financial Results

- Revenues for the third quarter of 2023 were \$2.33 million, compared to \$2.35 million in the third quarter of 2022.
- Hyperfine, Inc. sold six commercial Swoop® systems in the third quarter of 2023.
- Gross margin for the third quarter of 2023 was \$1.12 million, resulting in a 48% gross margin, compared to \$0.69 million in the third quarter of 2022.
- Research and development expenses for the third quarter of 2023 were \$5.74 million, compared to \$7.34 million in the third quarter of 2022.
- Sales, marketing, general, and administrative expenses for the third quarter of 2023 were \$7.14 million, compared to \$6.63 million in the third quarter of 2022.
- Net loss for the third quarter of 2023 was \$10.76 million, equating to a net loss of \$0.15 per share, as compared to a net loss of \$13.17 million, or a net loss of \$0.19 per share, for the third quarter of 2022.

Nine Months Financial Results

- Revenues for the nine months ended September 30, 2023 were \$8.35 million, compared to \$5.39 million in the nine months ended September 30, 2022.
- Gross margin for the nine months ended September 30, 2023 was \$3.72 million, resulting in a 45% gross margin, compared to \$0.61 million in the nine months ended September 30, 2022.
- Research and development expenses for the nine months ended September 30, 2023 were \$16.53 million, compared to \$22.94 million in the nine months ended September 30, 2022.
- Sales, marketing, general, and administrative expenses for the nine months ended September 30, 2023 were \$23.68 million, compared to \$37.92 million in the nine months ended September 30, 2022.
- Net loss for the nine months ended September 30, 2023 was \$33.55 million, equating to a net loss of \$0.47 per share, as compared to a net loss of \$60.11 million, or a net loss of \$0.85 per share, for the nine months ended September 30, 2022.

2023 Financial Guidance

- Management expects revenue for the full year 2023 to be \$11 to \$13 million.
- Management expects cash burn for the full year 2023 to be \$41 to \$44 million.

Conference Call

Hyperfine, Inc. will host a conference call at 1:30 p.m. PT/ 4:30 p.m. ET on Thursday, November 9, 2023, to discuss its third quarter 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 medical technology company that has redefined brain imaging with the Swoop® system—the world's 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 and 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, 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 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

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

	September 30, 2023	December 31, 2022
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 85,424	\$ 117,472
Restricted cash	548	771
Accounts receivable, less allowance of \$241 and \$180 as of September 30, 2023 and December 31, 2022, respectively	2,437	2,103
Unbilled receivables	682	454
Inventory	6,940	4,622
Prepaid expenses and other current assets	2,184	3,194
Due from related parties	—	48
Total current assets	98,215	128,664
Property and equipment, net	3,158	3,248
Other long term assets	1,691	2,139
Total assets	\$ 103,064	\$ 134,051
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	\$ 908	\$ 678
Deferred grant funding	548	771
Deferred revenue	1,454	1,378
Due to related parties	48	—
Accrued expenses and other current liabilities	5,253	5,976
Total current liabilities	8,211	8,803
Long term deferred revenue	1,086	1,526
Total liabilities	9,297	10,329
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY		
Class A Common stock, \$.0001 par value; 600,000,000 shares authorized; 56,537,946 and 55,622,488 shares issued and outstanding at September 30, 2023 and December 31, 2022, 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, 2023 and December 31, 2022, respectively	2	2
Additional paid-in capital	336,798	333,199
Accumulated deficit	(243,038)	(209,484)
Total stockholders' equity	93,767	123,722
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 103,064	\$ 134,051

HYPERFINE, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except share and per share amounts)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Sales				
Device	\$ 1,728	\$ 1,945	\$ 6,670	\$ 4,305
Service	602	403	1,676	1,085
Total sales	2,330	2,348	8,346	5,390
Cost of sales				
Device	835	1,215	3,321	3,511
Service	371	445	1,302	1,272
Total cost of sales	1,206	1,660	4,623	4,783
Gross margin	1,124	688	3,723	607
Operating Expenses:				
Research and development	5,739	7,338	16,531	22,937
General and administrative	4,615	3,198	16,103	26,570
Sales and marketing	2,529	3,434	7,575	11,345
Total operating expenses	12,883	13,970	40,209	60,852
Loss from operations	(11,759)	(13,282)	(36,486)	(60,245)
Interest income	1,021	170	2,920	203
Other income (expense), net	(19)	(59)	12	(63)
Loss before provision for income taxes	(10,757)	(13,171)	(33,554)	(60,105)
Provision for income taxes	—	—	—	—
Net loss and comprehensive loss	\$ (10,757)	\$ (13,171)	\$ (33,554)	\$ (60,105)
Net loss per common share attributable to common stockholders, basic and diluted	\$ (0.15)	\$ (0.19)	\$ (0.47)	\$ (0.85)
Weighted-average shares used to compute net loss per share attributable to common stockholders, basic and diluted	71,464,315	70,509,639	71,178,769	70,398,103



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

	Nine Months Ended September 30,	
	2023	2022
Cash flows from operating activities:		
Net loss	\$ (33,554)	\$ (60,105)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	791	754
Stock-based compensation expense	3,453	8,859
Loss on disposal of property and equipment, net	48	—
Payments received on net investment in lease	25	6
Changes in assets and liabilities:		
Accounts receivable, net	(334)	(2,149)
Unbilled receivables	(228)	(1,384)
Inventory	(2,494)	308
Prepaid expenses and other current assets	1,010	(439)
Due from related parties	48	14
Prepaid inventory	281	—
Other long term assets	142	62
Accounts payable	229	(1,522)
Deferred grant funding	(196)	(1,403)
Deferred revenue	(364)	1,098
Due to related parties	48	(1,920)
Accrued expenses and other current liabilities	(776)	827
Net cash used in operating activities	(31,871)	(56,994)
Cash flows from investing activities:		
Purchases of property and equipment	(546)	(427)
Net cash used in investing activities	(546)	(427)
Cash flows from financing activities:		
Proceeds from exercise of stock options	146	2
Net cash provided by financing activities	146	2
Net decrease in cash and cash equivalents and restricted cash	(32,271)	(57,419)
Cash, cash equivalents and restricted cash, beginning of period	118,243	191,160
Cash, cash equivalents and restricted cash, end of period	85,972	133,741
Reconciliation of cash, cash equivalents, and restricted cash reported in the balance sheets		
Cash and cash equivalents	85,424	132,482
Restricted cash	548	1,259
Total cash, cash equivalents and restricted cash	\$ 85,972	\$ 133,741
Supplemental disclosure of noncash information:		
Noncash acquisition of fixed assets	\$ 54	\$ —
Write-off of notes receivable	\$ —	\$ 90

