

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): August 08, 2024

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 August 8, 2024, Hyperfine, Inc. issued a press release announcing its results for the second quarter ended June 30, 2024 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 August 8, 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: August 8, 2024

By: /s/ Brett Hale

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

Hyperfine, Inc. Reports Record Quarterly Revenue and Raises FY 2024 Revenue Guidance

— Reports \$3.6M in Q2 2024 Revenue; 50% Gross Margin

— Raises FY 2024 Revenue Guidance to \$13-16M

GUILFORD, Connecticut, August 8, 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 second quarter 2024 financial results and provided a business update.

“I am proud of the Hyperfine team, achieving record revenue and delivering meaningful progress across innovation and clinical initiatives in the quarter,” said Maria Sainz, Chief Executive Officer and President of Hyperfine, Inc. “The opportunities ahead in emergency departments, clinics, and offices to support stroke and Alzheimer’s care are incredibly exciting and I believe our efforts to expand into these opportunities will position us well for significant business acceleration in 2025 and beyond.”

Second Quarter 2024 Financial Results

- Revenues for the second quarter of 2024 were a record \$3.63 million, up 7.4%, compared to \$3.38 million in the second quarter of 2023.
- Hyperfine, Inc. sold 13 commercial Swoop® systems in the second quarter of 2024.
- Gross margin for the second quarter of 2024 was a record \$1.80 million, compared to \$1.44 million in the second quarter of 2023, translating to a gross margin percentage of 49.6% compared to 42.7% in the second quarter of 2023.
- Research and development expenses for the second quarter of 2024 were \$5.96 million, compared to \$5.33 million in the second quarter of 2023.
- Sales, marketing, general, and administrative expenses for the second quarter of 2024 were \$6.69 million, compared to \$7.81 million in the second quarter of 2023.
- Net loss for the second quarter of 2024 was \$10.16 million, equating to a net loss of \$0.14 per share, as compared to a net loss of \$10.64 million, or a net loss of \$0.15 per share, for the second quarter of 2023.

Recent Achievements and Business Highlights

- FDA clearance of 9th generation AI-powered brain imaging software for enhanced speed.
- Initiated enrollment of CARE PMR (Capturing ARIA Risk Equitably with Portable MR) study assessing the clinical utility of the Swoop® System to scan Alzheimer’s patients receiving amyloid-targeting therapy to detect ARIA.
- Initial experience on the clinical utility of portable ultra-low-field MRI for Alzheimer’s disease monitoring featured in two posters at the 2024 Alzheimer’s Association International Conference.
- Subset of ACTION PMR (ACuTe Ischemic strOke detectioN with Portable MR), study data published in the August 2024 issue of the Annals of Neurology.
- Appointed distributors in 12 key EU markets and India to support expansion of commercial activity to international markets.

Six Months Financial Results

- Revenues for the six months ended June 30, 2024 were \$6.93 million, up 15.1%, compared to \$6.02 million in the six months ended June 30, 2023.
 - Gross margin for the six months ended June 30, 2024 was \$3.16 million, compared to \$2.60 million in the six months ended June 30, 2023, translating to a gross margin percentage of 45.6% in the six months ended June 30, 2024, compared to a gross margin percentage of 43.2% in the six months ended June 30, 2023.
 - Research and development expenses for the six months ended June 30, 2024 were \$11.53 million, compared to \$10.79 million in the six months ended June 30, 2023.
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- Sales, marketing, general, and administrative expenses for the six months ended June 30, 2024 were \$13.12 million, compared to \$16.53 million in the second quarter of 2023.
- Net loss for the six months ended June 30, 2024 was \$20.00 million, equating to a net loss of \$0.28 per share, as compared to a net loss of \$22.80 million, or a net loss of \$0.32 per share, for the six months ended June 30, 2023.

2024 Financial Guidance

- Management raises its revenue expectations for the full year 2024 to be \$13 to \$16 million from \$12 to \$15 million previously, reflecting year over year growth of 31% at the midpoint compared to 22% previously.
- Management continues to expect its 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, August 8, 2024, to discuss its second 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 international expansion plans, the Company's stroke observational clinical study and 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;

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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 CARE PMR 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)

	June 30, 2024	December 31, 2023
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 53,809	\$ 75,183
Restricted cash	—	621
Accounts receivable, less allowance of \$308 and \$321 as of June 30, 2024 and December 31, 2023, respectively	5,368	3,189
Unbilled receivables	2,121	942
Inventory	7,465	6,582
Prepaid expenses and other current assets	2,262	2,391
Total current assets	71,025	88,908
Property and equipment, net	3,429	2,999
Other long term assets	2,156	2,292
Total assets	\$ 76,610	\$ 94,199
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	\$ 2,238	\$ 1,214
Deferred grant funding	—	621
Deferred revenue	1,425	1,453
Due to related parties	66	61
Accrued expenses and other current liabilities	5,056	5,419
Total current liabilities	8,785	8,768
Long term deferred revenue	1,064	968
Other noncurrent liabilities	—	64
Total liabilities	9,849	9,800
STOCKHOLDERS' EQUITY		
Class A Common stock, \$.0001 par value; 600,000,000 shares authorized; 57,131,702 and 56,840,949 shares issued and outstanding at June 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 June 30, 2024 and December 31, 2023, respectively	2	2
Additional paid-in capital	340,480	338,114
Accumulated deficit	(273,726)	(253,722)
Total stockholders' equity	66,761	84,399
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 76,610	\$ 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 June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Sales				
Device	\$ 2,970	\$ 2,810	\$ 5,674	\$ 4,942
Service	661	571	1,252	1,074
Total sales	3,631	3,381	6,926	6,016
Cost of sales				
Device	1,422	1,549	2,921	2,620
Service	406	388	848	797
Total cost of sales	1,828	1,937	3,769	3,417
Gross margin	1,803	1,444	3,157	2,599
Operating Expenses:				
Research and development	5,959	5,331	11,529	10,792
General and administrative	4,421	5,306	8,851	11,488
Sales and marketing	2,269	2,499	4,273	5,046
Total operating expenses	12,649	13,136	24,653	27,326
Loss from operations	(10,846)	(11,692)	(21,496)	(24,727)
Interest income	675	1,030	1,471	1,899
Other income, net	15	25	21	31
Loss before provision for income taxes	(10,156)	(10,637)	(20,004)	(22,797)
Provision for income taxes	—	—	—	—
Net loss and comprehensive loss	\$ (10,156)	\$ (10,637)	\$ (20,004)	\$ (22,797)
Net loss per common share attributable to common stockholders, basic and diluted	\$ (0.14)	\$ (0.15)	\$ (0.28)	\$ (0.32)
Weighted-average shares used to compute net loss per share attributable to common stockholders, basic and diluted	72,041,332	71,201,170	71,987,688	71,033,629



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

	Six Months Ended	
	June 30,	
	2024	2023
Cash flows from operating activities:		
Net loss	\$ (20,004)	\$ (22,797)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	516	513
Stock-based compensation expense	2,206	2,259
Loss on disposal of property and equipment, net	100	100
Payments received on net investment in lease	18	4
Changes in assets and liabilities:		
Accounts receivable, net	(2,179)	(1,845)
Unbilled receivables	(1,179)	(209)
Inventory	(1,000)	(1,537)
Prepaid expenses and other current assets	(518)	946
Due from related parties	—	48
Prepaid inventory	693	281
Other long term assets	46	129
Accounts payable	867	666
Deferred grant funding	(621)	198
Deferred revenue	68	(134)
Due to related parties	5	45
Accrued expenses and other current liabilities	(912)	(1,817)
Operating lease liabilities, net	1	—
Net cash used in operating activities	(21,893)	(23,150)
Cash flows from investing activities:		
Purchases of property and equipment	(216)	(283)
Net cash used in investing activities	(216)	(283)
Cash flows from financing activities:		
Proceeds from exercise of stock options	114	107
Net cash provided by financing activities	114	107
Net decrease in cash and cash equivalents and restricted cash	(21,995)	(23,326)
Cash, cash equivalents and restricted cash, beginning of period	75,804	118,243
Cash, cash equivalents and restricted cash, end of period	53,809	94,917
Reconciliation of cash, cash equivalents, and restricted cash reported in the balance sheets		
Cash and cash equivalents	53,809	93,948
Restricted cash	—	969
Total cash, cash equivalents and restricted cash	\$ 53,809	\$ 94,917
Supplemental disclosure of noncash information:		
Unpaid purchase of property and equipment	\$ 735	\$ 28

