UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

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 14, 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)

(
ck 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 owing 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
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. \Box

Item 2.02 Results of Operations and Financial Condition.

On August 14, 2023, Hyperfine, Inc. issued a press release announcing its results for the second quarter ended June 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 August 14, 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.

Date:

August 14, 2023

HYPERFINE, INC.

By: /s/ Brett Hale

Brett Hale

Chief Administrative Officer, Chief Financial Officer, Treasurer and

Corporate Secretary



Hyperfine, Inc. Reports Second Quarter 2023 Financial Results

GUILFORD, Connecticut, August 14, 2023 (GLOBE NEWSWIRE) – Hyperfine, Inc. (Nasdaq: HYPR), the groundbreaking medical device company that created the Swoop® system, the world's first FDA-cleared portable, point-of-care MRI system, today announced second quarter 2023 financial results and provided a business update.

"We made solid progress at Hyperfine in the second quarter of 2023 and delivered record revenue of over \$3.3 million. We remained focused on our three strategic pillars of innovation, clinical evidence, and commercial expansion, including the initiation of our ACTION PMR observational study to examine the integration of the Swoop® system into stroke diagnosis and treatment workflow, while continuing to execute with strong spending discipline," said Maria Sainz, Chief Executive Officer and President of Hyperfine, Inc. "We are excited and committed to expanding access to timely, clinically-relevant brain imaging for clinicians and their patients across multiple care settings globally."

Second Quarter 2023 Financial Results

- Revenues for the second quarter of 2023 were \$3.38 million, compared to \$1.53 million in the second quarter of 2022.
- Hyperfine, Inc. sold 14 commercial Swoop® systems in the second quarter of 2023.
- Gross margin for the second quarter of 2023 was \$1.44 million, compared to \$(0.17) million in the second quarter of 2022.
- Research and development expenses for the second quarter of 2023 were \$5.33 million, compared to \$7.27 million in the second quarter of 2022
- Sales, general, and administrative expenses for the second quarter of 2023 were \$7.81 million, compared to \$15.76 million in the second quarter of 2022.
- Net loss for the second quarter of 2023 was \$10.64 million, equating to a net loss of \$0.15 per share, as compared to a net loss of \$23.16 million, or a net loss of \$0.33 per share, for the second quarter of 2022.

Six Months Financial Results

- Revenues for the six months ended June 30, 2023 were \$6.02 million, compared to \$3.04 million in the six months ended June 30, 2022.
- Gross margin for the six months ended June 30, 2023 was \$2.60 million, compared to \$(0.08) million in the six months ended June 30, 2022.
- Research and development expenses for the six months ended June 30, 2023 were \$10.79 million, compared to \$15.60 million in the six months ended June 30, 2022.
- Sales, marketing, general, and administrative expenses for the six months ended June 30, 2023 were \$16.53 million, compared to \$31.28 million in the six months ended June 30, 2022.
- Net loss for the six months ended June 30, 2023 was \$22.80 million, equating to a net loss of \$0.32 per share, as compared to a net loss of \$46.93 million, or a net loss of \$0.67 per share, for the six months ended June 30, 2022.

2023 Financial Guidance

- Management expects revenue for the full year 2023 to be \$10 to \$14 million.
- Management expects cash burn for the full year 2023 to be \$40 to \$45 million.

Conference Call

Hyperfine, Inc. will host a conference call at 1:30 p.m. PT/ 4:30 p.m. ET on Monday, August 14, 2023, to discuss its second 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 created the Swoop® system, the world's first FDA-cleared portable magnetic resonance imaging (MRI) system capable of providing neuroimaging at the point of care. The Swoop® system received initial U.S. Food and Drug Administration (FDA) clearance in 2020 as a bedside magnetic resonance imaging device for producing images that display the internal structure of the head where 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, has 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 ACTION PMR observational 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 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, 2023		December 31, 2022		
ASSETS					
CURRENT ASSETS:					
Cash and cash equivalents	\$	93,948	\$	117,472	
Restricted cash		969		771	
Accounts receivable, less allowance of \$175 and \$180 as of June 30, 2023 and December 31, 2022,					
respectively		3,948		2,103	
Unbilled receivables		663		454	
Inventory		5,983		4,622	
Prepaid expenses and other current assets		2,312		3,194	
Due from related parties		_		48	
Total current assets		107,823		128,664	
Property and equipment, net		3,058		3,248	
Other long term assets		1,725		2,139	
Total assets	\$	112,606	\$	134,051	
LIABILITIES AND STOCKHOLDERS' EQUITY					
CURRENT LIABILITIES:					
Accounts payable	\$	1,372	\$	678	
Deferred grant funding		969		771	
Deferred revenue		1,490		1,378	
Due to related parties		45		_	
Accrued expenses and other current liabilities		4,159		5,976	
Total current liabilities		8,035		8,803	
Long term deferred revenue		1,280		1,526	
Total liabilities		9,315		10,329	
COMMITMENTS AND CONTINGENCIES (NOTE 12)					
STOCKHOLDERS' EQUITY					
Class A Common stock, \$.0001 par value; 600,000,000 shares authorized; 56,284,538 and 55,622,488					
shares issued and outstanding at June 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 June 30, 2023 and December 31, 2022, respectively		2		2	
Additional paid-in capital		335,565		333,199	
Accumulated deficit		(232,281)		(209,484)	
Total stockholders' equity		103,291		123,722	
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$	112,606	\$	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 June 30,		Six Months Ended June 30,				
		2023	2022		2023		2022
Sales		_					
Device	\$	2,810	\$ 1,168	\$	4,942	\$	2,360
Service		571	365		1,074		682
Total sales		3,381	1,533	\$	6,016	\$	3,042
Cost of sales							
Device		1,549	1,259		2,620		2,296
Service		388	439		797		827
Total cost of sales		1,937	 1,698	\$	3,417	\$	3,123
Gross margin		1,444	(165)		2,599		(81)
Operating Expenses:							
Research and development		5,331	7,265	\$	10,792	\$	15,599
General and administrative		5,306	12,012		11,488		23,372
Sales and marketing		2,499	3,750		5,046		7,911
Total operating expenses		13,136	23,027		27,326		46,882
Loss from operations		(11,692)	(23,192)	\$	(24,727)	\$	(46,963)
Interest income		1,030	 32	\$	1,899	\$	33
Other income (expense), net		25	1		31		(4)
Loss before provision for income taxes		(10,637)	(23,159)	\$	(22,797)	\$	(46,934)
Provision for income taxes		_	_		_		_
Net loss and comprehensive loss		(10,637)	\$ (23,159)	\$	(22,797)	\$	(46,934)
Net loss per common share attributable to common stockholders, basic and diluted	\$	(0.15)	\$ (0.33)	\$	(0.32)	\$	(0.67)
Weighted-average shares used to compute net loss per share attributable to common stockholders, basic and diluted		71,201,170	70,350,178		71,033,629		70,341,411



HYPERFINE, INC. AND SUBSIDIARIES CONDENSED CONSOLIDATED STATEMENT OF CASH FLOWS

(in thousands) (Unaudited)

Six Months Ended

	 June 30,		
	 2023		2022
Cash flows from operating activities:			
Net loss	\$ (22,797)	\$	(46,934)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	513		516
Stock-based compensation expense	2,259		11,213
Loss on disposal of property and equipment	100		_
Payments received on net investment in lease	4		4
Changes in assets and liabilities:			
Accounts receivable	(1,845)		(1,434)
Unbilled receivables	(209)		(1,027)
Inventory	(1,537)		(336)
Prepaid expenses and other current assets	946		(1,213)
Due from related parties	48		12
Prepaid inventory	281		_
Other long term assets	129		52
Accounts payable	666		(551)
Deferred grant funding	198		(1,058)
Deferred revenue	(134)		469
Due to related parties	45		(1,900)
Accrued expenses and other current liabilities	 (1,817)		(2,013)
Net cash used in operating activities	(23,150)		(44,200)
Cash flows from investing activities:			
Purchases of property and equipment	(283)		(254)
Net cash used in investing activities	(283)		(254)
Cash flows from financing activities:			
Proceeds from exercise of stock options	107		2
Net cash provided by financing activities	 107		2
Net decrease in cash and cash equivalents and restricted cash	(23,326)		(44,452)
Cash, cash equivalents and restricted cash, beginning of period	118,243		191,160
Cash, cash equivalents and restricted cash, end of period	 94,917		146,708
Reconciliation of cash, cash equivalents, and restricted cash reported in the balance sheets			
Cash and cash equivalents	93,948		145,104
Restricted cash	969		1,604
Total cash, cash equivalents and restricted cash	\$ 94,917	\$	146,708
Supplemental disclosure of noncash information:	 		
11	\$ 28	\$	_
Write-off of notes receivable	\$ _	\$	90
Cash, cash equivalents and restricted cash, end of period Reconciliation of cash, cash equivalents, and restricted cash reported in the balance sheets Cash and cash equivalents Restricted cash Total cash, cash equivalents and restricted cash Supplemental disclosure of noncash information: Noncash acquisition of fixed assets	\$ 94,917 93,948 969 94,917	\$	146,70 145,10 1,60 146,70