

**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): May 11, 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 May 11, 2023, Hyperfine, Inc. issued a press release announcing its results for the first quarter ended March 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

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release dated May 11, 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: May 11, 2023

By: /s/ Brett Hale

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

Hyperfine, Inc. Reports First Quarter 2023 Financial Results

GUILFORD, Connecticut, May 11, 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 first quarter 2023 financial results and provided a business update.

“We had strong growth at Hyperfine in the first quarter of 2023 and delivered record revenue of \$2.6 million. We remained focused on executing on our three strategic pillars of innovation, clinical evidence, and commercial expansion, while continuing to exercise financial discipline to extend our cash runway through the end of 2025,” said Maria Sainz, Chief Executive Officer and President of Hyperfine, Inc. “We are excited and committed to deliver on the vision to expand access to MRI for clinicians and their patients globally.”

First Quarter 2023 Financial Results

- Revenues for the first quarter of 2023 were \$2.64 million, compared to \$1.51 million in the first quarter of 2022.
- Hyperfine, Inc. installed 10 commercial Swoop systems in the first quarter of 2023.
- Gross margin for the first quarter of 2023 was \$1.16 million, compared to \$0.08 million in the first quarter of 2022.
- Research and development expenses for the first quarter of 2023 were \$5.46 million, compared to \$8.33 million in the first quarter of 2022.
- Sales, general, and administrative expenses for the first quarter of 2023 were \$8.73 million, compared to \$15.52 million in the first quarter of 2022.
- Net loss for the first quarter of 2023 was \$12.16 million, equating to a net loss of \$0.17 per share, as compared to a net loss of \$23.78 million, or a net loss of \$0.34 per share, for the same period of the prior year.

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 Thursday, May 11, 2023, to discuss its first 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, 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. Hyperfine, Inc. (the "Company")'s actual results 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 commercial plans, 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 impact of COVID-19 on the Company's business; 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 estimates regarding expenses, future 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)

	March 31, 2023	December 31, 2022
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 104,027	\$ 117,472
Restricted cash	713	771
Accounts receivable, less allowance of \$191 and \$180 as of March 31, 2023 and December 31, 2022, respectively	3,018	2,103
Unbilled receivables	713	454
Inventory	5,744	4,622
Prepaid expenses and other current assets	2,923	3,194
Due from related parties	—	48
Total current assets	117,138	128,664
Property and equipment, net	3,091	3,248
Other long term assets	1,873	2,139
Total assets	\$ 122,102	\$ 134,051
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	\$ 1,668	\$ 678
Deferred grant funding	713	771
Deferred revenue	1,415	1,378
Due to related parties	64	—
Accrued expenses and other current liabilities	4,141	5,976
Total current liabilities	8,001	8,803
Long term deferred revenue	1,364	1,526
Total liabilities	9,365	10,329
COMMITMENTS AND CONTINGENCIES (NOTE 12)		
STOCKHOLDERS' EQUITY		
Class A Common stock, \$.0001 par value; 600,000,000 shares authorized; 56,000,995 and 55,622,488 shares issued and outstanding at March 31, 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 March 31, 2023 and December 31, 2022, respectively	2	2
Additional paid-in capital	334,374	333,199
Accumulated deficit	(221,644)	(209,484)
Total stockholders' equity	112,737	123,722
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 122,102	\$ 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 March 31,	
	2023	2022
Sales		
Device	\$ 2,132	\$ 1,192
Service	503	317
Total sales	2,635	1,509
Cost of sales		
Device	1,071	1,037
Service	409	388
Total cost of sales	1,480	1,425
Gross margin	1,155	84
Operating Expenses:		
Research and development	5,461	8,334
General and administrative	6,182	11,360
Sales and marketing	2,547	4,161
Total operating expenses	14,190	23,855
Loss from operations	(13,035)	(23,771)
Interest income	869	1
Other income (expense), net	6	(5)
Loss before provision for income taxes	(12,160)	(23,775)
Provision for income taxes	—	—
Net loss and comprehensive loss	\$ (12,160)	\$ (23,775)
Net loss per common share attributable to common stockholders, basic and diluted	\$ (0.17)	\$ (0.34)
Weighted-average shares used to compute net loss per share attributable to common stockholders, basic and diluted	70,864,226	70,332,349



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

	Three Months Ended	
	March 31,	
	2023	2022
Cash flows from operating activities:		
Net loss	\$ (12,160)	\$ (23,775)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	254	253
Stock-based compensation expense	1,126	4,111
Payments received on net investment in lease	2	2
Changes in assets and liabilities:		
Accounts receivable	(915)	(1,391)
Unbilled receivables	(259)	(387)
Inventory	(1,122)	(228)
Prepaid expenses and other current assets	272	(1,848)
Due from related parties	48	13
Prepaid inventory	281	—
Other long term assets	(18)	11
Accounts payable	954	(565)
Deferred grant funding	(58)	(679)
Deferred revenue	(125)	584
Due to related parties	64	(1,884)
Accrued expenses and other current liabilities	(1,835)	(1,506)
Net cash used in operating activities	(13,491)	(27,289)
Cash flows from investing activities:		
Purchases of property and equipment	(61)	(308)
Net cash used in investing activities	(61)	(308)
Cash flows from financing activities:		
Proceeds from exercise of stock options	49	—
Net cash provided by financing activities	49	—
Net (decrease) increase in cash and cash equivalents and restricted cash	(13,503)	(27,597)
Cash, cash equivalents and restricted cash, beginning of period	118,243	191,160
Cash, cash equivalents and restricted cash, end of period	104,740	163,563
Reconciliation of cash, cash equivalents, and restricted cash reported in the balance sheets		
Cash and cash equivalents	104,027	161,580
Restricted cash	713	1,983
Total cash, cash equivalents and restricted cash	\$ 104,740	\$ 163,563
Supplemental disclosure of noncash information:		
Noncash acquisition of fixed assets	\$ 36	\$ 62
Write-off of notes receivable	\$ —	\$ 90

