

**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, 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 March 21, 2023, Hyperfine, Inc. (the “Company”) issued a press release announcing its results for the fourth quarter and year ended December 31, 2022 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 March 21, 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: March 21, 2023

By: /s/ Alok Gupta
Alok Gupta
Chief Financial Officer

Hyperfine, Inc. Reports Fourth Quarter and Full Year 2022 Financial Results

GUILFORD, Connecticut, March 21, 2023 (GLOBE NEWSWIRE) – Hyperfine, Inc. (Nasdaq: HYPR), the groundbreaking medical device company that created the Swoop® system, the world's first FDA-cleared portable MRI system™ today announced fourth quarter and full year 2022 financial results and provided a business update.

“We made measurable progress at Hyperfine over the past year. We delivered \$6.8 million in revenue in 2022, received multiple FDA clearances and international approvals, including CE Marking, in recent months, and saw a large number of publications and presentations on the clinical value of Swoop published and presented via major journals and meetings. We also implemented important measures to right size our business and extend our cash runway through the end of 2025, ending the year with a healthy balance sheet. These achievements lay the foundation for strong forward growth,” said Maria Sainz, Chief Executive Officer and President of Hyperfine, Inc. “We believe the opportunity for Hyperfine to transform access to MRI scans across clinical uses and sites of service is incredibly compelling. Our team is dedicated to expanding commercial placements while focusing on additional innovation and clinical evidence. We look forward to growing our impact in the field of medical imaging and diagnostics.”

Recent Achievements

- Installed 35 commercial systems for the full year 2022.
- Multiple FDA clearances for AI-powered software upgrades to support improved image quality.
- 15 clinical publications, including Scientific Reports, Science Advances, and Radiology, and 50 peer-reviewed presentations at key neuro and imaging meetings.
- Strengthened partnership with the Bill & Melinda Gates Foundation with a purchase order through Kings College London for 20 additional Swoop systems.
- Restructured and right-sized organization to extend Hyperfine, Inc.'s cash runway through the end of 2025.

Fourth Quarter 2022 Financial Results

- Revenues for the fourth quarter of 2022 were \$1.424 million, compared to \$0.436 million in the fourth quarter of 2021.
- Gross margin for the fourth quarter of 2022 was \$0.300 million, compared to \$(0.453) million in the fourth quarter of 2021.
- Research and development expenses for the fourth quarter of 2022 were \$5.219 million, compared to \$8.893 million in the fourth quarter of 2021.
- Sales, general, and administrative expenses for the fourth quarter of 2022 were \$8.710 million, compared to \$16.741 million in the fourth quarter of 2021.
- Net loss for the fourth quarter was \$13.059 million, equating to a net loss of \$0.19 per share, as compared to a net loss of \$26.085 million, or a net loss of \$13.79 per share, for the same period of the prior year.

Full Year 2022 Financial Results

- Revenues for the full year 2022 were \$6.814 million, compared to \$1.496 million in 2021.
- Gross margin for the full year 2022 was \$0.907 million, compared to \$(1.167) million in 2021.
- Research and development expenses for the full year 2022 were \$28.156 million, compared to \$25.842 million in 2021.
- Sales, general, and administrative expenses for full year 2022 were \$46.625 million, compared to \$37.859 million in 2021.
- Net loss for the full year was \$73.164 million, equating to a net loss of \$1.04 per share, as compared to a net loss of \$64.851 million, or a net loss of \$17.57 per share, for the prior year.
- Cash and cash equivalents totaled \$117.472 million as of December 31, 2022.

2023 Financial Guidance

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

Hyperfine, Inc. will host a conference call at 1:30 p.m. PT/ 4:30 p.m. ET on Tuesday, March 21, 2023, to discuss its fourth quarter and full year 2022 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 and Pakistan.

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; the inability to recognize the anticipated benefits of the business combination, which may be affected by, among other things, competition and the Company's ability 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

HYPERFINE

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
COMBINED AND CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share amounts)
(Unaudited)

	December 31, 2022	December 31, 2021
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 117,472	\$ 188,498
Restricted cash	771	2,662
Accounts receivable, net	2,103	553
Unbilled receivables	454	91
Inventory	4,622	4,310
Prepaid expenses and other current assets	3,194	1,357
Due from related parties	48	14
Total current assets	\$ 128,664	\$ 197,485
Property and equipment, net	3,248	3,753
Other long term assets	2,139	1,235
Total assets	\$ 134,051	\$ 202,473
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	\$ 678	\$ 2,248
Deferred grant funding	771	2,662
Deferred revenue	1,378	730
Due to related parties	—	1,981
Accrued expenses and other current liabilities	5,976	8,115
Total current liabilities	\$ 8,803	\$ 15,736
Long term deferred revenue	1,526	510
Total liabilities	\$ 10,329	\$ 16,246
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY		
Class A Common stock, \$.0001 par value; 600,000,000 shares authorized; 55,622,488 and 55,277,061 shares issued and outstanding at December 31, 2022 and December 31, 2021, 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, 2022 and December 31, 2021, respectively	2	2
Additional paid-in capital	333,199	322,540
Accumulated deficit	(209,484)	(136,320)
Total stockholders' equity	\$ 123,722	\$ 186,227
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 134,051	\$ 202,473



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

	Three months ended December 31,		Year ended December 31,	
	2022	2021	2022	2021
Sales				
Device	\$ 941	\$ 194	\$ 5,246	\$ 715
Service	483	242	1,568	781
Total sales	\$ 1,424	\$ 436	\$ 6,814	\$ 1,496
Cost of sales				
Device	\$ 720	\$ 638	\$ 4,231	\$ 2,058
Service	404	251	1,676	605
Total cost of sales	\$ 1,124	\$ 889	\$ 5,907	\$ 2,663
Gross margin	300	(453)	907	(1,167)
Operating Expenses:				
Research and development	\$ 5,219	\$ 8,893	\$ 28,156	\$ 25,842
General and administrative	5,836	12,149	32,406	27,497
Sales and marketing	2,874	4,592	14,219	10,362
Total operating expenses	13,929	25,634	74,781	63,701
Loss from operations	\$ (13,629)	\$ (26,087)	\$ (73,874)	\$ (64,868)
Interest income	\$ 558	\$ 5	\$ 761	\$ 18
Other income (expense), net	12	(3)	(51)	(1)
Loss before provision for income taxes	\$ (13,059)	\$ (26,085)	\$ (73,164)	\$ (64,851)
Provision for income taxes	—	—	—	—
Net loss and comprehensive loss	\$ (13,059)	\$ (26,085)	\$ (73,164)	\$ (64,851)
Net loss per common share attributable to common stockholders, basic and diluted	\$ (0.19)	\$ (13.79)	\$ (1.04)	\$ (17.57)
Weighted-average shares used to compute net loss per share attributable to common stockholders, basic and diluted	70,588,368	1,892,208	70,449,191	3,690,523



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

	Three months ended December 31,		Year ended December 31,	
	2022	2021	2022	2021
Cash flows from operating activities:				
Net loss	\$ (13,059)	\$ (26,085)	\$ (73,164)	\$ (64,851)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	261	337	1,015	726
Stock-based compensation expense	1,793	3,770	10,652	6,901
Write-off of other assets - related party	—	984	—	984
Other	85	59	91	85
Changes in assets and liabilities				
Accounts receivable	599	387	(1,550)	(379)
Unbilled receivables	1,021	(43)	(363)	(91)
Inventory	(620)	(1,603)	(312)	(2,667)
Prepaid expenses and other current assets	(1,398)	2,243	(1,837)	(666)
Due from related parties	(48)	(1)	(34)	1,451
Other assets - related party	—	102	—	260
Prepaid inventory	(281)	—	(281)	—
Other long term assets	(694)	(587)	(632)	(1,201)
Accounts payable	(48)	(2,487)	(1,570)	1,436
Deferred grant funding	(488)	(805)	(1,891)	1,052
Deferred revenue	566	126	1,664	1,082
Due to related parties	(61)	647	(1,981)	1,845
Accrued expenses and other current liabilities	(2,973)	4,821	(2,146)	6,851
Net cash used in operating activities	\$ (15,345)	\$ (18,135)	\$ (72,339)	\$ (47,182)
Cash flows from investing activities:				
Purchases of property and equipment	(158)	(975)	(585)	(2,711)
Net cash used in investing activities	\$ (158)	\$ (975)	\$ (585)	\$ (2,711)
Cash flows from financing activities:				
Proceeds from exercise of stock options	5	35	7	1,497
Proceeds from issuance of Series D convertible preferred stock	—	—	—	30,468
Stock issuance costs related to Series D convertible preferred stock	—	—	—	(7)
Repayment of notes payable	—	(178)	—	(178)
Investment from 4Bionics, LLC	—	—	—	3,516
Net proceeds from equity infusion from the Business Combination	—	141,471	—	141,471
Net cash provided by financing activities	\$ 5	\$ 141,328	\$ 7	\$ 176,767
Net (decrease) increase in cash and cash equivalents and restricted cash	(15,498)	122,218	(72,917)	126,874
Cash, cash equivalents and restricted cash, beginning of period	133,741	68,942	191,160	64,286
Cash, cash equivalents and restricted cash, end of period	\$ 118,243	\$ 191,160	\$ 118,243	\$ 191,160
Reconciliation of cash, cash equivalents, and restricted cash reported in the statement of financial position				
Cash and cash equivalents	\$ 117,472	\$ 188,498	\$ 117,472	\$ 188,498
Restricted cash	771	2,662	771	2,662
Total cash, cash equivalents and restricted cash	\$ 118,243	\$ 191,160	\$ 118,243	\$ 191,160
Supplemental disclosure of cash flow information:				
Cash received from exchange of research and development tax credits	\$ —	\$ 50	\$ 131	\$ 374
Supplemental disclosure of noncash information:				
Write-off of notes receivable	\$ —	\$ —	\$ 90	\$ —
Issuance of Class A Common Stock to a service provider in exchange for the service provided in connection with the Business Combination	\$ —	\$ 3,000	\$ —	\$ 3,000

