

**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 10, 2022

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 10, 2022, Hyperfine, Inc. (the “Company”) issued a press release announcing its results for the second quarter ended June 30, 2022. 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 10, 2022
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: August 10, 2022

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

GUILFORD, Connecticut, August 10, 2022 (GLOBE NEWSWIRE) – Hyperfine, Inc. (Nasdaq: HYPR), the creator of Swoop®, the world's first FDA-cleared portable MRI system™, today reported financial results for the quarter ended June 30, 2022. Management will host a corresponding conference call today at 1:30 p.m. Pacific Time / 4:30 p.m. Eastern Time.

“We continue to build awareness of Swoop’s immense value proposition, deepen our customer relationships, and drive adoption in new hospitals,” said Scott Huennekens, Interim President and CEO of Hyperfine. “We placed 9 commercial systems in the second quarter, including through our recent expansion to Australia and New Zealand – a new geography for Hyperfine – and we continue to build our pipeline for the second half of the year and beyond.”

Second Quarter 2022 Financial Results

- Revenues for the second quarter of 2022 were \$1.533 million, compared to \$0.358 million in the second quarter of 2021.
- Gross margin for the second quarter of 2022 was \$(0.165) million, compared to \$(0.099) million in the second quarter of 2021.
- Research and development expenses for the second quarter of 2022 were \$7.265 million, compared to \$6.037 million in the second quarter of 2021.
- Sales, marketing, general, and administrative expenses for the second quarter of 2022 were \$15.762 million, compared to \$8.450 million in the second quarter of 2021.
- Net loss for the second quarter was \$23.159 million, equating to a net loss of \$0.33 per share, as compared to a net loss of \$14.580 million, or a net loss of \$8.80 per share, for the second quarter of 2021.

Six Months Financial Results

- Revenues for the six months ended June 30, 2022 were \$3.042 million, compared to \$0.689 million in the six months ended June 30, 2021.
 - Gross margin for the six months ended June 30, 2022 was \$(0.081) million, compared to \$(0.376) million in the six months ended June 30, 2021.
 - Research and development expenses for the six months ended June 30, 2022 were \$15.599 million, compared to \$10.511 million in the six months ended June 30, 2021.
 - Sales, marketing, general, and administrative expenses for the six months ended June 30, 2022 were \$31.283 million, compared to \$11.504 million in the six months ended June 30, 2021.
 - Net loss for the six months ended June 30, 2022 was \$46.934 million, equating to a net loss of \$0.67 per share, as compared to a net loss of \$22.374 million, or a net loss of \$13.72 per share, for the six months ended June 30, 2021.
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Commercial System Installations

- Hyperfine installed 9 commercial Swoop systems in the second quarter, bringing total year-to-date commercial installations* to 20 systems.
- Hyperfine has now installed 47 commercial systems launch-to-date and maintains a total installed base* of 92 systems globally.

** The Swoop total installed base consists of three components: Commercial system installations (which make up total revenue), grant fulfillment installations, and research unit installations. The Swoop total installed base (or total installed units) is the number of Swoop devices deployed to hospitals, other healthcare providers, and research institutions. We view the total installed base as a key metric of the growth of our business and is measured from period over period.*

Recent Strategic Highlights

- Received FDA 510(k) clearances for multiple Swoop system enhancements including two new imaging sequences which expand system capabilities using deep learning (DL) and allow shorter brain scan times for patients, as well as improved patient positioning based on customer feedback.
- Launched a partnership with Viz.ai, a leading AI-powered disease detection and intelligent care coordination platform, to bring MRI to the patient's bedside and deliver valuable insights to the clinician's fingertips for timely decision making. Hyperfine and Viz.ai intend to focus on patient care in neuro ICUs to further decrease the time from admission to treatment by expediting clinician access to MRI imaging and increasing access to time-critical diagnostics in the acute and post-acute care phase.

2022 Financial Guidance

- Management expects revenue for the full year 2022 to be \$7 million to \$8 million.
- Management expects 35 to 45 commercial units installed in 2022.

Conference Call

Hyperfine will host a conference call at 1:30 p.m. PST / 4:30 p.m. ET today to discuss its second quarter 2022 financial results. 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's corporate website at <https://investors.hyperfine.io/>.

About Hyperfine

Hyperfine, Inc. is the groundbreaking medical device company that created Swoop®, the world's first FDA-cleared portable MRI system™. Hyperfine designed Swoop to enable rapid diagnoses and treatment for every patient regardless of income, resources, or location, pushing the boundaries of conventional imaging technology and expanding patient access to life-saving care. The Swoop Portable MR Imaging System™ produces high-quality images at a lower magnetic field strength, allowing clinicians to quickly scan, diagnose, and treat patients in various clinical settings. Swoop can be wheeled directly to the patient's bedside, plugged into a standard electrical wall outlet, and controlled by an iPad®. Designed as a complementary system to conventional MRIs at a fraction of the cost, Swoop captures images in minutes, providing critical decision-making capabilities in emergency departments, operating rooms outside the sterile field, and intensive care units, among others.

Investor Contact

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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’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 Hyperfine’s financial and operating results, the benefits of Hyperfine’s products and services, and Hyperfine’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 Hyperfine’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 Hyperfine product development and commercialization activities, including the degree that Swoop is accepted and used by healthcare professionals; the impact of COVID-19 on Hyperfine’s business; the inability to maintain the listing of Hyperfine’s Class A common stock on the Nasdaq following the recently completed business combination; the inability to recognize the anticipated benefits of the business combination, which may be affected by, among other things, competition and Hyperfine’s ability to grow and manage growth profitably and retain its key employees; changes in applicable laws or regulations; the inability of Hyperfine to raise financing in the future; the inability of Hyperfine 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 Hyperfine to identify, in-license or acquire additional technology; the inability of Hyperfine to maintain its existing or future license, manufacturing, supply and distribution agreements and to obtain adequate supply of its products; the inability of Hyperfine to compete with other companies currently marketing or engaged in the development of products and services that Hyperfine is currently marketing or developing; the size and growth potential of the markets for Hyperfine’s products and services, and its ability to serve those markets, either alone or in partnership with others; the pricing of Hyperfine’s products and services and reimbursement for medical procedures conducted using Hyperfine’s products and services; Hyperfine’s estimates regarding expenses, future revenue, capital requirements and needs for additional financing; Hyperfine’s financial performance; and other risks and uncertainties indicated from time to time in Hyperfine’s filings with the Securities and Exchange Commission, including those under “Risk Factors” therein. Hyperfine 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. Hyperfine 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.



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

	June 30, 2022	December 31, 2021
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 145,104	\$ 188,498
Restricted cash	1,604	2,662
Accounts receivable, net	1,987	553
Unbilled receivables	1,118	91
Inventory	4,646	4,310
Prepaid expenses and other current assets	2,570	1,357
Due from related parties	2	14
Total current assets	\$ 157,031	\$ 197,485
Property and equipment, net	3,498	3,753
Other long term assets	1,179	1,235
Total assets	\$ 161,708	\$ 202,473
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	\$ 1,697	\$ 2,248
Deferred grant funding	1,604	2,662
Deferred revenue	964	730
Due to related parties	81	1,981
Accrued expenses and other current liabilities	6,109	8,115
Total current liabilities	\$ 10,455	\$ 15,736
Long term deferred revenue	745	510
Total liabilities	\$ 11,200	\$ 16,246
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY		
Class A Common stock, \$.0001 par value; 600,000,000 shares authorized; 55,312,656 and 55,277,061 shares issued and outstanding at June 30, 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 June 30, 2022 and December 31, 2021, respectively	2	2
Additional paid-in capital	333,755	322,540
Accumulated deficit	(183,254)	(136,320)
Total stockholders' equity	\$ 150,508	\$ 186,227
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 161,708	\$ 202,473



HYPERFINE, INC. AND SUBSIDIARIES
CONDENSED COMBINED AND 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,	
	2022	2021	2022	2021
Sales				
Device	\$ 1,168	\$ 152	\$ 2,360	\$ 321
Service	365	206	682	368
Total sales	<u>\$ 1,533</u>	<u>\$ 358</u>	<u>\$ 3,042</u>	<u>\$ 689</u>
Cost of sales				
Device	\$ 1,259	\$ 364	\$ 2,296	\$ 912
Service	439	93	827	153
Total cost of sales	<u>\$ 1,698</u>	<u>\$ 457</u>	<u>\$ 3,123</u>	<u>\$ 1,065</u>
Gross margin	(165)	(99)	(81)	(376)
Operating Expenses:				
Research and development	\$ 7,265	\$ 6,037	\$ 15,599	\$ 10,511
General and administrative	12,012	6,663	23,372	8,521
Sales and marketing	3,750	1,787	7,911	2,983
Total operating expenses	23,027	14,487	46,882	22,015
Loss from operations	\$ (23,192)	\$ (14,586)	\$ (46,963)	\$ (22,391)
Interest income	\$ 32	\$ 5	\$ 33	\$ 10
Other income (expense), net	1	1	(4)	7
Loss before provision for income taxes	\$ (23,159)	\$ (14,580)	\$ (46,934)	\$ (22,374)
Provision for income taxes	—	—	—	—
Net loss and comprehensive loss	\$ (23,159)	\$ (14,580)	\$ (46,934)	\$ (22,374)
Net loss per common share attributable to common stockholders, basic and diluted	\$ (0.33)	\$ (8.80)	\$ (0.67)	\$ (13.72)
Weighted-average shares used to compute net loss per share attributable to common stockholders, basic and diluted	70,350,178	1,657,345	70,341,411	1,630,190



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

	Six months ended June 30,	
	2022	2021
Cash flows from operating activities:		
Net loss	\$ (46,934)	\$ (22,374)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	516	218
Stock-based compensation expense	11,213	1,756
Write-down of inventory	—	33
Payments received on net investment in lease	4	5
Changes in assets and liabilities:		
Accounts receivable	(1,434)	(263)
Unbilled receivables	(1,027)	(39)
Inventory	(336)	(449)
Prepaid expenses and other current assets	(1,213)	(357)
Due from related parties	12	1,279
Other assets - related party	—	193
Other long term assets	52	(20)
Accounts payable	(551)	196
Deferred grant funding	(1,058)	(322)
Deferred revenue	469	554
Due to related parties	(1,900)	(50)
Accrued expenses and other current liabilities	(2,013)	536
Net cash used in operating activities	\$ (44,200)	\$ (19,104)
Cash flows from investing activities:		
Purchases of fixed assets	(254)	(675)
Net cash used in investing activities	\$ (254)	\$ (675)
Cash flows from financing activities:		
Proceeds from exercise of stock options	2	198
Proceeds from issuance of Series D convertible preferred stock	—	30,468
Stock issuance costs related to Series D convertible preferred stock	—	(7)
Investment from 4Bionics, LLC	—	3,516
Net cash provided by financing activities	\$ 2	\$ 34,175
Net (decrease) increase in cash and cash equivalents and restricted cash	(44,452)	14,396
Cash, cash equivalents and restricted cash, beginning of period	191,160	64,286
Cash, cash equivalents and restricted cash, end of period	\$ 146,708	\$ 78,682
Reconciliation of cash, cash equivalents, and restricted cash reported in the statement of financial position		
Cash and cash equivalents	\$ 145,104	\$ 77,394
Restricted cash	1,604	1,288
Total cash, cash equivalents and restricted cash	\$ 146,708	\$ 78,682
Supplemental disclosure of cash flow information:		
Cash received from exchange of research and development tax credits	\$ —	\$ 324
Supplemental disclosure of noncash information:		
Write-off of notes receivable	\$ 90	\$ —

